Professional Development:
External Grants Application Policy

Policy/Procedure

This policy applies to institutionally-sponsored grant proposals as well as individual fellowship grant applications.

Normal procedures

Preparation

Consult with the Director of Corporate and Foundation Relations (C&FR Office in Development) regarding possible funding sources, and Dickinson’s current active grants or proposal activity with that source. The College reserves the right to delay your proposal if it might conflict with other institutional proposals or projects in preparation or under review by the funding source.

Approvals

A completed draft and/or abstract of your proposal and budget must be submitted, reviewed, and approved by the appropriate persons or groups indicated below. The “External Grants Notification/Clearance Form” and more information on the approval process are available through the Director of Corporate and Foundation Relations, and on the Corporate and Foundation Relations web site.

In the case of institutionally-sponsored proposals, any of those officers listed below may veto College support for the proposal or approve it with specific caveats. In such cases every effort will be made to work with you to remove the obstacles to College approval.

In the case of individual fellowship applications to external sources, senior officers of the College need to be notified of the faculty’s scholarly work and research and have an opportunity to learn of its depth and breadth. This information is highly useful for pre-tenure and tenure reviews, promotions, salary increases, awards, and conferral of named chairs, and assists in the preparation of College and community-wide publicity.

- **President**: Any grant proposal involving over $50,000 of Dickinson matching money; any grant having an all-College purpose.
- **Provost and Dean of the College, in consultation with the Academic Program and Standards Committee**: Any grant proposal for curricular purposes, for individual academic research or study, or for individual fellowships.
- **Vice President and Treasurer, in consultation with the Planning and Budget Committee**: Any grant proposal other than one seeking only salary income for the applicant.
- **Vice President for Development**: Any grant proposal to a foundation, corporate or
Faculty Responsibilities, Resources, and Policies: Professional Development: External Grants Application Policy

business entity, or governmental funding source.

- **Vice President for Campus Operations:** Proposals involving construction, renovation or removal of campus facilities.
- **Vice President for Enrollment, Student Life and College Relations:** Grant proposals involving admissions, recruiting, student life, or public relations issues.

**Documentation**

A copy of all grant proposals and award documents must be forwarded to the Corporate and Foundation Relations Office so they may become part of the College’s permanent records. Such documents include (but are not limited to):

- a copy of the signed “External Grants Notification/Clearance Form”
- a complete copy of the final proposal (including narrative, budget, appendices and all other submitted materials)
- copies of any additional documents, e.g., award letters, sub award and/or contract documents, cooperative agreements, project implementation or budgetary amendments, pertinent correspondence with foundation or government program officers
- copies of annual and/or final narrative reports, including budget reports.

**Normal arrangements**

**Principal Investigator/Project Director**

Someone is the PI/PD for the grant. Where the length or complexity of the grant warrants it, the PI/PD should receive released time. This can vary from a single course to 2/3rds time for the duration of the grant. Be sure the grant seeks money for the released time, both salary and (if permitted) fringe benefits at prorated amounts. The full-time salaries and fringe for two summer months should also be sought where the grant period permits. All PI/PD salary figures are to be based on that person’s regular Dickinson salary.

**Project Manager**

Larger grants may require additional help in the form of an assistant who handles details created by the existence of the grant. This could range from typing to planning meetings to involvement in the substance of the project, and might even involve helping apply for further grants. Thus the position, if needed, could range from a lower-level clerical position to a lower-level professional position. Be realistic about such needs and then be sure to include them in the grant, both salary and fringe benefits. All PM salary figures are to be based on the salary ranges at Dickinson for comparable responsibilities. If the grant is funded, appointment letters for such persons must come from a senior administrative officer.

**Indirect Cost Recovery**

The College’s Strategic Plan requires that all grant proposals include maximum feasible provision for the financial relief of existing operations. Many private foundations do not allow the College to bill their grants for (or recover) indirect costs; some external funding sources
External Grants Application Policy

(governmental) specify the figure or the mode of its determination. Unless such restrictions are indicated, Dickinson has a negotiated overhead formula ("indirect cost recovery rate") that must be used in any application to a federal governmental source. Funds garnered through indirect cost recovery go towards College income as appropriate compensation for the general institutional costs of supporting grant projects. Information on Dickinson’s negotiated indirect rate is available from the Director of Corporate and Foundation Relations, Financial Operations, or the Corporate and Foundation Relations web site.

Matching/Cost Sharing

Some grants require matching funds from Dickinson. In other cases, it may be thought that the grant can only be implemented if the College provides additional support (this might be thought of as an informal matching requirement). There must be a written agreement by the College guaranteeing the match should the grant be received. For individual academic grants and for curricular ones, a special Grants Matching Fund has been created. Matching requests compete for this finite resource, except where a request for more significant matching money has been made well in advance and has been approved by the College. All grants involving matching/cost sharing must be discussed and approved by the Provost and Dean.

Subawards/"Subcontracts"

The scope of work in some grant projects may require that the Dickinson PI/PD retain non-Dickinson personnel, consultants, vendors, or institutions (those sponsoring a colleague) to participate in and/or complete portions of the project. The PI/PD must acquire from the proposed subcontractor prior to submission of the grant proposal an "Intention to Enter into a Subaward/Subcontract Agreement" document, signed by an authorized institutional representative. When the grant is awarded and before any work may proceed, a "Subaward/Subcontract Agreement" must be negotiated and signed by institutional representatives of both Dickinson (awardee) and the contractor (subawardee). These documents shall be prepared by College representatives in Corporate and Foundation Relations, and Financial Operations, with input from the College’s legal counsel.

Responsibilities and coordination

A number of campus offices/officials are involved in the grant pre- and post-award process.

- The Provost and Dean serves as the College’s official organizational representative authorized to submit institutionally-sponsored proposals. The Provost and Dean’s signature binds the College to the proposed scope of work and budget, and verifies official information and certifications about institutional policies and practices.
- The Office of Corporate and Foundation Relations functions as the College’s sponsored research office and may be authorized on a case-by-case basis by the Provost and Dean to submit institutionally-sponsored proposals on his/her behalf.
- The Financial Operations office provides information on cost rates, reviews and approves budgets prior to submission, and coordinates financial reports. Financial Operations holds authority to sign grant contracts, subcontracts and cooperative agreements on behalf of the College.
Faculty Responsibilities, Resources, and Policies: Professional Development:
External Grants Application Policy

- The Principal Investigator/Project Director is responsible for implementation and oversight of all aspects of the project (unless otherwise directed by the Provost and Dean), including the preparation and timely submission of reports as may be required by the funding source.

**Variances**

*Partial Funding*

A grant proposal may be accepted but on the condition that the budget be reduced. Before this reduced grant is accepted, the revised budget and any revisions in personnel, overhead, and matching/cost sharing must be approved by the College.

*Supplemental Funding*

It is possible to ask for additional funds during the implementation period of the grant. Original budgets may prove inadequate or unanticipated changes in the situation may require or invite further funds. These should be applied for by a request to the Provost and Dean, and Vice President and Treasurer, detailing and justifying the additional needs. If funds are available and the request persuasive, support will be provided from the Grants Matching Fund. There is no guarantee that support will be forthcoming; sometimes this may mean that the grant must be terminated.

**Related Information**

**History/Revision Information**

- Responsible Office/Division:
- Effective Date:
- Last Amended Date:
- Next Review Date:
- Also Found In: RDC Web Site (www.dickinson.edu/departments/rdc/)
Professional Development:
External Grants Application Policy

Policy/Procedure

This policy applies to all institutionally-sponsored grant proposals as well as individual fellowship grant applications.

1. Notification
   All faculty, staff and students must consult with the Corporate, Foundation & Government Support Office and Sponsored Projects Office regarding possible funding sources, and Dickinson’s current active grants or proposal activity with that source. The College reserves the right to delay any-proposal if it might conflict with other institutional proposals or projects in preparation or under review by the funding source.

2. Approvals
   a) A completed draft and/or abstract of your proposal and budget must be submitted, reviewed, and approved by the appropriate persons. The “External Grants Notification / Clearance Form” and more information on the approval process are available through the Corporate, Foundation & Government Support Office, and on that office’s web site.
   b) In the case of institutionally-sponsored proposals, senior officers of the College may veto College support for the proposal or approve it with specific caveats. In such cases every effort will be made to work with you to remove the obstacles to College approval.
   c) In the case of individual fellowship applications to external sources, senior officers of the College need to be notified of the faculty’s scholarly work and research and have an opportunity to learn of its depth and breadth. This information is highly useful for pre-tenure and tenure reviews, promotions, salary increases, awards, conferral of named chairs, and assists in the preparation of College and community-wide publicity.

3. Conformance with policies regarding Sponsored Projects
   All institutionally sponsored proposals must be prepared, submitted and administered in accordance with policies described in Sponsored Project Policies and Grants and Financial Grants Administration Policies in the Campus Policies Manual.
   http://www.dickinson.edu/homepage/201/corporate基礎andgovernment_support

Related Information

Corporate, Foundation & Government Support (former CFR) website:
http://www.dickinson.edu/homepage/201/corporate_foundation_andgovernment_support

You will need your Dickinson network login and password to enter this site
A Dickinson Sponsored Projects Group

**Policy/Procedure**

**PURPOSE:**
To describe the establishment and responsibilities of a Sponsored Project Group, comprised of grants management stakeholders from various college offices, which shall convene regularly to help achieve compliance and effective management of active grants and sponsored projects.

**POLICY:**
1. A Sponsored Projects Group (SPG) will be established and shall be comprised of the following institutional stakeholders:
   a. Associate Provost for Academic Resources
   b. Director of Global and Sponsored Projects Accounting plus any subordinate staff who assist with grants financial management
   c. Director of Corporate and Foundation Relations plus any subordinate staff who assist with grant pre-or post-award functions
   d. Director of Sponsored Projects and Research Compliance plus any subordinate staff who assist with grant pre-or post-award functions
   e. The office charged with receipting of grant and gift funds.

2. The Sponsored Projects Group (SPG) is charged with the following duties and will convene to:
   a. conduct intensive top-to bottom reviews of all current grants under administration
   b. ensure proper implementation of administrative policies and procedures
   c. ensure compliance with current policy
   d. evaluate and ensure that policies are up-to-date, effective and in compliance with various and changing regulations
   e. develop and implement best practices for effective grant preparation, and pre- and post-award administration

3. The Sponsored Projects Group (SPG) will convene regularly, preferably on a monthly basis, but has the option to meet more frequently and on an ad-hoc basis, if situations warrant.

4. The Sponsored Projects Group (SPG) will prepare an agenda and keep minutes of each meeting. Agenda items at SPG meetings include, but are not limited to:
   a. Review of prior “open business” and agenda items
   b. Review of financial state of current/active grants activity
   c. Review of grant narrative and financial reports due
   d. Review of Grants Matching Accounts budgets
   e. Review of Faculty salary and release times supported by grants
   f. Upcoming grant proposals where input will be required
g. Decisions or news regarding policy changes and/or revisions, and new policies.

h. Other issues, as necessary/appropriate.

5. The Sponsored Projects Group (SPG) will require attendance of all the stakeholders described in 1. (above) at all convened meetings. A quorum will be considered one member from each office (a.-e.) described above.

6. SPG meetings may request the attendance of other members of the college community as appropriate.

### Related Information

### History/Revision Information

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<tr>
<th>Responsible Division/Office:</th>
<th>Sponsored Projects Group</th>
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Administration of Sponsored Projects

Policy/Procedure

PURPOSE: To ensure that funds provided from external sources to support research and other projects are administered in accordance with College policies as well as those of the sponsor. External sources include both governmental and private organizations.

POLICY:
1. All externally sponsored projects for research or other purposes will be administered through the Sponsored Projects Group (SPG) in accordance with established College policies and procedures.
2. Any project, which meets any of the following criteria, is considered to be a “sponsored project” and will be administered accordingly:
   a. The project commits the College to a specific line of scholarly or scientific inquiry, typically documented by a statement of work;
   b. A specific commitment is made regarding the level of personnel effort, deliverables, or milestones;
   c. Project activities are budgeted, and the award includes conditions for specific formal fiscal reports, and/or invoicing;
   d. The project requires that unexpended funds be returned to the sponsor at the end of the project period;
   e. The agreement provides for the disposition of either tangible property (e.g., equipment, records, technical reports, theses or dissertations) or intangible property (e.g., inventions, copyrights or rights in data) which may result from the project;
   f. The sponsor identifies a period of performance as a term and condition.
3. All externally sponsored research and teaching activities that involve human subjects, laboratory animals, use of radioactive materials, or biohazard activities must be reviewed by the appropriate College committees for compliance with College policies and governmental regulations.

Related Information

Dickinson Institutional Review Board (IRB): website
Dickinson Institutional Animal Care and Use Committee (IACUC): website
Dickinson Institutional Biosafety Committee (IBC): website
Dickinson Environmental Health and Safety: website

History/Revision Information

Responsible Division/Office: Sponsored Projects Group
Approval and Submission of Proposals

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PURPOSE:
To ensure that proposals submitted for external support of research and other sponsored projects comply with College financial and other policies.

POLICY:
All proposal submissions, whether electronic or not, seeking external support for research and other sponsored projects must be submitted to Sponsored Projects Group for review and approval prior to submission. A completed Proposal Clearance and Notification Form, signed/certified by the Principal Investigator/Project Director or other individual responsible for proposal preparation and project administration must accompany the proposal.

1. All proposals must be approved by the responsible department chairperson. When a project involves members of more than one department or office, the approval of all responsible chairpersons and/or directors is required.

2. The department chairperson and the Provost and Dean are responsible for attesting to the academic purposes of the proposed project, its departmental compatibility, and its appropriateness in terms of budget, space and equipment.

3. The Vice President for Campus Operations is responsible for attesting to the appropriateness of proposals involving construction, renovation or removal of campus facilities.

4. The Vice President for Enrollment, Student Life and College Relations is responsible for attesting to the appropriateness of grant proposals involving admissions, recruiting, student life, or public relations issues.

5. The Vice President for Finance, in consultation with the Provost and Dean, is responsible for attesting to (a) the appropriateness and availability of personnel, including salary levels, (b) the adequacy of space and other facilities needed for the project, and (c) the budget (including institutional cost-sharing, if any) and Facilities and Administrative (F&A) cost recovery.

6. The Provost and Dean, and Vice President for Finance may approve less than full recovery of Facilities and Administrative (F&A) costs in accordance with policies.

7. Sponsored Projects Group is responsible for ensuring that proposals comply with College and sponsor policies, that proposals are complete and that all signatures/certifications and approvals, including those of appropriate regulatory offices and/or committees have been obtained.
8. Proposals, which raise policy issues, are to be referred to the Provost and Dean for review and approval prior to submission to the sponsor.

9. Proposed projects which do not appear to conform with these policies are to be referred to the Faculty Personnel Committee (FPC) and Academic Program and Standards Committee (AP&SC) for review and approval prior to making any commitments, either formal or informal.

10. Proposals which raise legal issues are to be referred to the Office of the Provost and Dean and General Counsel for review.

11. Proposals which raise intellectual property issues are to be referred to General Counsel for review.

12. The College reserves the right to withdraw any proposal that does not comply with this policy.

Related Information

Policy: Facilities and Administrative (F&A) Costs

History/Revision Information

Responsible Division/Office: Sponsored Projects Group

Effective Date: 10/13/2011

Last Amended Date:

Next Review Date:

Also Found In:
Authorized Institutional Signatories on Proposal Documents

**Policy/Procedure**

**PURPOSE:**
To ensure that proposals submitted for external support of research and other sponsored projects are duly signed by appropriate authorized institutional officials and in so doing comply with College financial and other policies.

**POLICY:**
1. The **Provost and Dean** in consultation with the Academic Program and Standards Committee serves as the College’s official organizational representative authorized to submit those institutionally sponsored proposals and agreements requiring an original signature. This includes any grant proposal for curricular purposes, for individual academic research or study, or for individual fellowships.
2. In the stead of the Provost and Dean if he/she is unavailable, the following Senior Officers may serve as authorized representatives to sign proposal documents under the following circumstances:
   a. **President of the College:** any grant proposal involving over $50,000 of Dickinson matching money; any grant having an all-College purpose.
   b. **Vice President for Finance** in consultation with the Planning and Budget Committee as necessary or appropriate: any grant proposal other than one seeking only salary income for the applicant.
   c. **Vice President for Development:** any grant proposal to a foundation, corporate or business entity, or governmental funding source.
   d. **Vice President for Campus Operations:** proposals involving construction, renovation or removal of campus facilities.
   e. **Vice President for Enrollment, Student Life and College Relations:** grant proposals involving admissions, recruiting, student life, or public relations issues.
   f. **Sponsored Projects Group:** acting on specific written instruction from the Provost and Dean, may be authorized to sign and submit electronic proposals on behalf of Dickinson College.
3. The College reserves the right to withdraw any proposal that does not comply with this policy.

**Related Information**

Faculty Handbook Chapter 8 Section IV “External Grant Applications Policy”

**History/Revision Information**

**Responsible Division/Office:** Sponsored Projects Group
Effective Date: 10/13/2011

Last Amended Date:

Next Review Date:

Also Found In:
Individual Debarment and Certification

PURPOSE: To ensure that Dickinson Principal Investigators and staff are eligible to receive federal funds.

DEFINITIONS: Federal regulations published in 45 CFR Part 76 implement the government-wide debarment and suspension system for Federal non-procurement transactions. “Non-procurement transactions” include grants, cooperative agreements, scholarships, fellowships, and loans. Accordingly, applicants for Federal grants (“primary covered transactions”), including applicants for NIH Kirschstein-NRSA and other Federally-funded individual fellowships, are required to certify\(^6\) that, to the best of their knowledge and belief, they and their principals (including PIs and other key personnel) have not engaged in or committed certain acts.

Individuals who are suspended, debarred, or voluntarily excluded from eligibility cannot receive Federal grants or be paid from Federal agency grant funds, whether under a primary or lower-tier transaction, during the period of suspension, debarment, or exclusion. Because individuals who have been debarred, suspended, declared ineligible, or voluntarily excluded from covered transactions may not receive Federal funds for a specified period of time, charges made to Federal grants for such individuals (e.g., salary) are unallowable.

POLICY:

All PIs or those considered key personnel on a grant application to whom the above standard is applicable are required to certify (see Debarment Certification form) prior to application submission that he/she:

- is not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any Federal department or agency;
- has not, within the 3-year period preceding the application, been convicted of, or had a civil judgment rendered against them for
  - committing fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State, or local) transaction or contract under a public transaction;
  - violating a Federal or State antitrust statute;
  - embezzlement, theft, forgery, bribery, falsification or destruction of records; or
  - making false statements or receiving stolen property;
- is not presently indicted or otherwise criminally or civilly charged by a governmental entity (Federal, State, or local) with commission of any of the offenses enumerated above; and
• has not, within a 3-year period preceding the application, had any public transaction (Federal, State, or local) terminated for cause or default.

Related Information

History/Revision Information

Responsible Division/Office: Sponsored Projects Group

Effective Date: 2/8/2006

Last Amended Date:

Next Review Date:

Also Found In:
Principal Investigator Eligibility

Policy/Procedure

PURPOSE:
To establish the criteria permitting individuals to fulfill the role of principal investigator or co-principal investigator on a sponsored project.

DEFINITION:
A principal investigator or co-principal investigator is an individual designated by the College and approved by the sponsor to direct a project funded by an external sponsor. S/he is responsible and accountable to the College and sponsor for the proper programmatic, scientific, or technical conduct of the project and its financial management.

POLICY:
1. All proposals submitted to sponsors for external support must carry as principal or co-investigator at least one person in a professorial track holding the academic rank of professor, associate professor, assistant professor.
2. The principal investigator must be an employee of the College or hold an adjunct or emeritus appointment.
3. Individuals who are trainees, whether or not they are also employees (such as postdoctoral fellows/associates, students, interns or residents), may apply for external sponsorship only with the approval of a faculty sponsor or mentor as indicated either on the application or the Grant Clearance and Notification form.
4. All applications for external sponsorship must indicate the approval of the appropriate department chair and dean, indicating the availability of resources necessary to carry out the project.
5. Individuals not meeting the above criteria may, by demonstrating sufficient cause, petition the Provost and Dean for approval to submit an application to an external sponsor. Such approval will usually require the agreement of the Provost.

Related Information

History/Revision Information

Responsible Division/Office: Sponsored Projects Group
Effective Date: 10/13/2011
Last Amended Date:
Next Review Date:
Also Found In:
Faculty Reassigned Time Policy

Policy/Procedure

DEFINITION:
Reassigned time for a faculty member may be budgeted in a grant proposal if the work attributable to the grant will take time away from either class preparation/instruction or research during the academic year or summer.

NEED FOR A REASSIGNED TIME POLICY:
To ensure consistent treatment of costs for faculty effort and compensation, whether costs are for funded or unfunded work.

POLICIES AND PROCEDURES:
1. Cost of Reassigned Time
   a) Reassigned time will be budgeted in proposals at $4,600 per reassigned time. This amount will be used for internal and external cost proposals.
   b) Benefit costs are not charged to reassigned time charges.

2. How Reassigned Time is Charged
   a) Reassigned time costs are charged to the funding source during the semester or summer when the reassigned time occurs.
   b) If budgeted as reassigned time, it must be taken as reassigned time from a course and not taken as a stipend payment unless approved as an exception by the Provost and Dean in accordance with policies regarding Summer Stipend vs. Reassigned Time Policy.

3. Use of Reassigned Time Funding
   Reassigned time funds are credited back to the Provost’s salary pool to be used at the Provost’s discretion. The current reassigned time amount of $4,600 is intended to cover the cost of an adjunct’s salary and benefits for teaching a course, however, the Provost may use the funds in a different way to cover the needs of the department.

Related Information

Policy: Summer Stipend vs. Reassigned Time

History/Revision Information
Responsible Division/Office: Sponsored Projects Group
Effective Date: 10/13/2011
Last Amended Date: 7/16/2015
Next Review Date: 
Also Found In:
Stipends for Retired/Emeritus Faculty

Policy/Procedure

PURPOSE:
To describe the conditions under which retired faculty may participate and be granted status as Principal Investigators on institutionally sponsored proposals, and to determine the amount they may be compensated.

NEED FOR A STIPEND POLICY:
To ensure consistent treatment of costs for effort and compensation.

POLICY:
1. Compensation may be budgeted in grant proposals for retired emeritus/emerita faculty when that former faculty member proposes to serve as PI, Co-PI, consultant or other compensated position in the project under both of the following conditions:
   a. the Provost and Dean has officially designated that retired/emeritus faculty member as “Research Professor” or “Emeritus Professor”, and
   b. if Provost and Dean deems that the College will be able to retain sufficient control over the work proposed
2. Such emeritus/emerita faculty members are subject to all College policies as described herein and elsewhere, i.e. all standard controls and compliance checks, etc.
3. Compensation on grant proposals shall be determined as follows:
   a. The base annual salary to be used shall be that at which the emeritus/emerita faculty member retired, plus an additional 3% per year for each year since retirement.
   b. If the emeritus/emerita faculty is actively consulting, a more appropriate base annual salary rate may be used, however supporting documentation of that rate must be obtained and retained with grant documentation.
   c. For summer projects, under no circumstances will more than 2/9ths (at a rate of 1/9th per month) of the base annual salary be permitted.
4. Standard fringe benefits (to reimburse the fringe benefit pool) and indirect costs shall be included in all such proposals and calculated on the full amount of that compensation.

Related Information

History/Revision Information

Responsible Division/Office: Sponsored Projects Group
Effective Date: 10/13/2011
Faculty Summer Stipend and Reassigned Time

Policy/Procedure

DEFINITION:
Reassigned Time for a faculty member may be budgeted in a grant proposal if the work attributable to the grant will take time away from either class preparation/instruction or research during the academic year or summer. Stipends are budgeted in a grant proposal if the faculty member is working additional hours during the summer or other non-academic year time.

NEED FOR A POLICY FOR REASSIGNED TIME VS STIPENDS:
To provide guidance on the treatment of costs if approval is given for switching from budgeted course reassigned time to stipend payment (or vice versa).

POLICIES AND PROCEDURES:
Changing from approved budgeted Reassigned Time to payment of a Stipend
a) If faculty members feel that reassigned time cannot be taken as budgeted in the grant award, and a stipend is desired, a brief justification must be written by the faculty and submitted to the Provost for review and approval.
b) If a stipend payment is approved, the amount available in the grant ($4,500) must cover both the stipend and the associated benefit payments.

Related Information

History/Revision Information

Responsible Division/Office: Sponsored Projects Group

Effective Date: 10/13/2011

Last Amended Date: 7/16/2015

Next Review Date:

Also Found In:
Faculty Overload Policy

Policy/Procedure

PURPOSE:
To describe the terms and conditions regarding the allowability of “overload salary” for faculty, staff and employees who are conducting sponsored research during the academic year, when such salary would represent an “overload” i.e. in excess of 100% effort during their contracted academic year pay period.

POLICY:
1) Dickinson’s policy is stated in the Faculty Handbook and is reproduced here for the sake of completeness. If there are any variations between the text below and that stated in the current version of the Faculty Handbook, (Chapter 7, Section VI.) the Faculty Handbook shall be the ruling document.

Extra-College Employment
Appointment as a full-time faculty member at the College presumes that employment for remuneration outside of the College, during the academic year, shall not be undertaken without the prior approval of the chair of the person’s department and the Dean of the College. Lectures, consultancies, and other professional activities of limited duration are exempted from this need for approval.

2) Dickinson abides by NSF and other federal policies regarding faculty members consulting on Dickinson projects. Dickinson faculty may not serve as outside subcontracted consultants on federal or other external grants for which Dickinson is the sponsoring agent and/or grantee. Dickinson faculty members of a particular profession or those who possess a special skill necessary for the successful completion of the project e.g. internal evaluators, shall be considered a normal part of the project team, and not external consultants.

Related Information

History/Revision Information

Responsible Division/Office: Sponsored Projects Group

Effective Date: 10/13/2011

Last Amended Date:
Next Review Date:

Also Found In: Faculty Handbook
Faculty Summer Effort & Salary

**Policy/Procedure**

**PURPOSE:**
To define the requirements for faculty having appointments less than 12 (twelve) months who choose to work and receive compensation from a sponsored project during the months of June, July and/or August.

**POLICY:**

1. Effort devoted and corresponding salary received must be in accordance with sponsor and College policy.
2. Faculty receiving summer salary (2/9) from external sponsors for all College uncompensated summer months:
   a. are ineligible for time off during that period for which they are being compensated; and
   b. must submit a letter in advance to the Sponsored Projects Group, and Provost and Dean indicating that they will not take time off during the summer months. Letters shall use or conform to the format of the Summer Sponsored Project Salary Request form. (Certification after the fact on the effort report will be an attestation to that full effort.)
3. Sponsored Projects Group shall maintain copies of the above letter in the faculty member’s personnel file and/or appropriate sponsored projects file. The letter must be readily available for audit purposes.
4. Due to the effort commitment to the sponsored project, payment of summer salary as described in 2. (above) means that the faculty member cannot engage in other activities, i.e., administrative or academic activities not compensated by the College.
5. If a faculty member has formal summer academic or administrative responsibilities, summer compensation and the corresponding effort must be adjusted proportionately.
6. Changes reducing effort for the summer months must be reported immediately to the Provost. A payroll distribution adjustment must be made prior to the month end in which the change in effort occurred since the College is not obligated to pay the faculty member for time not worked on the sponsored project(s).
7. If a sponsor has a salary cap and if the faculty member commits to full effort during a summer month, notwithstanding that the sponsor will not pay a full salary because of the cap limitation, the faulty member must still devote their full effort to the project during the month paid.
8. Faculty having academic year appointments and receiving summer salary from a National Science Foundation grant(s) will be limited to no more than two-ninths of their regular academic-year salary. Other sponsors may have other similar or may have no restrictions on summer salaries or payment of a third ninth.
9. It is expected that faculty receiving summer salary from a sponsored project will perform such work in their normal place of business unless the work being
conducted is off site and is a requirement of the project. Any exception will require the approval of the chair, Provost and Dean, Sponsored Projects Group, and may require approval of the sponsor.

Related Information

History/Revision Information

Responsible Division/Office: Sponsored Projects Group
Effective Date: 10/13/2011
Last Amended Date:
Next Review Date:
Also Found In:
Principal Investigator Responsibilities under Sponsored Projects offering Act 48 Credits

Policy/Procedure

DEFINITION
Beginning July 1, 2000, Act 48 of 1999 (see link below) required persons holding Pennsylvania professional educator certification to complete continuing education requirements every five years in order to maintain their certificates as active. Educators must maintain their certificates as active by earning collegiate credits. Dickinson faculty members occasionally offer programs offering such credit. This policy delineates the types of credits, and who is responsible for assigning and administering such credit.

PURPOSE:
Keeping the Act 48 (non college credit credential) and the graduate-level college credit reporting separated is consistent with how the College has handled such programs in the past. It allows the College to continue to support college credit reporting from the Registrar's Office and to maintain the distinction that the Office should not be certifying non-college credit credentials.

POLICY AND PROCEDURES:
1. Continuing education/non-college credit. For programs offered by Dickinson faculty, any award of Act 48 credits must be handled by the faculty member/department sponsoring the program. Costs associated with administering or processing Act 48 credits must be borne by the project sponsor/funding agent. Any such costs should be built into the project budget, particularly those projects seeking external funding.
2. College credit. For programs offering college credit (at the undergraduate or graduate level), the Registrar's Office will collect and record the information. Participants would request a transcript of college credit from Registrar's office. Should these programs grow and result in a substantial increase in work load, the College will revisit this process.

Helpful URLs:

Related Information
History/Revision Information

Responsible Division/Office: Sponsored Projects Group

Effective Date: The source of this document is Office of Provost and Dean, and Registrar, approved 10/24/2006

Last Amended Date: 

Next Review Date: 

Also Found In: 
Conflict of Interest in Research Policy

Policy/Procedure

PURPOSE:
The purpose of this policy is to protect the credibility and integrity of the College’s faculty and staff and to ensure public trust and confidence in the College’s research and educational activities. These policies and procedures are designed to meet the requirements of Federal regulations covering conflicts of interest (42 CFR Part 50 Subpart F for grants and cooperative agreements and 45 CFR Part 94 for contracts). Dickinson College has a responsibility to manage, reduce, or eliminate any actual or potential conflicts of interest that may arise because of the financial interests of an Investigator.

DEFINITIONS:
- A **conflict of interest exists** when the College determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of the research sponsored by federal sources, or the conduct of the Investigator’s institutional responsibilities. (42 CFR 50.605).
- **Investigator** means the principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded by the federal sources, or proposed for such funding. **Investigator** includes the Investigator’s spouse and dependent children. (42 CFR 50.603).
- **Research** means a systematic investigation designed to develop or contribute to generalizable knowledge. (42 CFR 50.603).
- **Significant financial interest** means anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests in publicly-traded or non-publicly traded entities); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). The term does not include:
  - Salary, royalties, or other remuneration from Dickinson College.
  - Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities.
  - Income from service on advisory committees or review panels for public or nonprofit entities;
  - Payments for services or equity interests received from a publicly traded entity, if the aggregate value received by the Investigator (including the Investigator's spouse and dependent children) in the preceding twelve months does not exceed $5,000 in value as determined through reference to public prices or other reasonable measures of fair market value; or
  - Payments for services received from a non-publicly traded entity, if the aggregate value received by the Investigator (including the Investigator's spouse and dependent children) in the preceding twelve months does not exceed $5,000. **NOTE:** Any equity interest in a non-publicly traded company constitutes a **Significant financial interest**.
Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.

- **Sponsored Travel** means any reimbursed or sponsored travel, (i.e. travel that is paid on behalf of the Investigator, including the Investigator’s spouse and dependent children), and that relates to the Investigator’s Institutional Responsibilities, in the preceding twelve months when aggregated with other significant financial interests, per entity, is greater than or equal to $5,000 in value. This definition does not include travel that is paid for or reimbursed by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

- **Institutional Responsibilities** means teaching, research, research consultation, and institutional committee memberships.

**TRAINING:**

1. Dickinson College Investigators must complete conflict of interest training prior to engaging in research related to any Federally-funded grant or contract and at least every four years, and immediately under the designated circumstances:
   - College conflict of interest policies change in a manner that affects Investigator requirements
   - an Investigator is new to the College, or
   - the College finds an Investigator noncompliant with College’s conflict of interest policy or management plan.

2. To meet the training requirement, Investigators must review this policy and complete successfully the Conflict of Interest mini-course, a web-based curriculum provided by the Collaborative Institutional Training Initiative (CITI).

**DISCLOSURE:**

Disclosure of both perceived and actual conflict of interest protects one’s reputation from embarrassing or harmful allegations of misconduct. A faculty or staff member may choose to disclose any financial or related interest, beyond those required by regulation or this policy that could present an actual or perceived conflict of interest.

1. Each Investigator shall complete a Financial Interests Disclosure Form. The completed disclosure form must be submitted to the Associate Provost for Institutional Resources’ office along with a copy of the proposal.
2. All significant financial interests must be disclosed prior to the time a proposal is submitted as required by Federal regulation. All financial disclosures must be updated by Investigators during the period of the award, annually and within thirty days of when a Significant Financial Interest or Sponsored Travel occurs or is discovered.
3. Each Investigator is required to disclose the following significant (greater than or equal to $5,000, when aggregated per entity) financial interests:
a) Any significant financial interest of the Investigator that would reasonably appear to be affected by the research or educational activities funded, or proposed for funding, by an external sponsor, including provision of Sponsored travel; or

b) Any significant financial interest of the Investigator in an entity whose financial interest would reasonably appear to be affected by the research or educational activities funded, or proposed for funding, by an external sponsor.

4. The College will determine if Sponsored travel requires further investigation.

REVIEW PROCESS:

1. Prior to submitting a proposal that involves a Significant financial interest, including Sponsored travel, the Investigator should discuss with appropriate College officials proposed measures that will be taken to manage, reduce, or eliminate any actual or potential conflict of interest presented by a significant financial interest. Such measures could include:
   a) Public disclosure of significant financial interests;
   b) Review of research protocol by independent reviewers; and
   c) Monitoring of research by independent reviewers.

2. The Associate Provost for Institutional Resources or official designee, with the assistance, if necessary, of appropriate members from Financial Operations, shall review all financial disclosures to determine whether a conflict of interest exists. If the Associate Provost for Institutional Resources determines that there is a potential for conflict of interest covered by this policy, then the Associate Provost may impose additional conditions or restrictions other than those listed in #1 above, including the following:
   a) Modification of the research plan;
   b) Disqualification from participation in all or a portion of the research funded;
   c) Divestiture of significant financial interests; or
   d) Severance of relationships that create actual or potential conflicts.

The Associate Provost may require that a plan for reducing or eliminating conflicts of interest be incorporated into a Memo of Understanding between the College and the Investigator.

3. The Associate Provost will notify the Provost and Dean of the College of the conditions or restrictions to be imposed. If the Provost determines that imposing the conditions or restrictions would be ineffective or inequitable, or that the detrimental effects that may arise from a significant financial interest are outweighed by interests of scientific progress, technology transfer, or the public health and welfare, then the Provost may decide that, to the extent permitted by Federal regulations, the research go forward without imposing such conditions or restrictions. In these cases, the Provost shall make the final decision regarding resolution.

MANAGING CONFLICTS OF INTEREST:
Actual or potential conflicts of interest will be satisfactorily managed, reduced, or eliminated in accordance with these guidelines and all required reports regarding the conflict of interest submitted to the sponsor prior to expenditure of any funds under an award.

Where any conflicts of interest exist with regard to a federally-funded research project, the College will develop and implement a management plan that specifies the actions taken, and/or to be taken to manage the conflict of interest, and the College will make any reports or disclosures of the conflict of interest that are required or that the College deems to be appropriate.

VIOLATIONS OF CONFLICT OF INTEREST POLICY:
Whenever an Investigator has violated this policy or the terms of any resolution plan required by the Associate Provost for Institutional Resources (including failure to file or knowingly filing incomplete, erroneous, or misleading disclosure forms), the Associate Provost shall notify the Provost, who, in consultation with the Faculty Personnel Committee, will impose sanctions or institute disciplinary proceedings against the Investigator.

In addition, the College shall follow Federal regulations regarding the notification of the sponsoring agency in the event an Investigator has failed to comply with this policy. The sponsor may take its own action as it deems appropriate, including the suspension of funding for the Investigator until the matter is resolved.

RECORD MAINTENANCE:
Records of Investigator financial disclosures and of actions taken to manage actual or potential conflicts of interest shall be retained by the Corporate, Foundation and Government Support office until three years after the later of the termination or completion of the award to which they relate, or the resolution of any government action involving those records.

COLLABORATIVE PROJECTS/SUB-AGREEMENTS:
Collaborators/sub-recipients/subcontractors from other organizations must either comply with this policy or provide a certification that their organizations are in compliance with Federal policies regarding Investigator significant financial interest disclosure and that their portion of the project is in compliance with their institutional policies.
Effective Date: February 8, 2006

Last Amended Date: 10/31/2012

Next Review Date:

Also Found In:
Inclusion of Women and Children in Research

Purpose/Procedure

Purpose:

In order to meet the requirements of the National Institutes of Health (NIH) policy to include women, minorities, and children in all NIH-funded clinical research, Dickinson College’s Institutional Review Board requires that project proposals which are or hope to be supported by NIH funding include a plan to include women, members of minority groups, and children in the research project or a scientific and ethical rationale explaining why they should be excluded. A brief description of the NIH policies is provided below. Please follow the links provided for more detail about the NIH policy.

Policy:

1. Inclusion of Women and Minorities as Subjects in Clinical Research
   It is the policy of NIH that women and members of minority groups and their subpopulations must be included in all NIH-funded clinical research, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant Institute/Center Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Exclusion under other circumstances may be made by the Director, NIH, upon the recommendation of an Institute/Center Director based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. This policy applies to research subjects of all ages in all NIH-supported clinical research studies.

   The inclusion of women and members of minority groups and their subpopulations must be addressed in developing a research design or contract proposal appropriate to the scientific objectives of the study/contract. The research plan/proposal should describe the composition of the proposed study population in terms of sex/gender and racial/ethnic group, and provide a rationale for selection of such subjects. Such a plan/proposal should contain a description of the proposed outreach programs for recruiting women and minorities as participants.


2. Inclusion of Children in Human Subjects Research
   It is the policy of NIH that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all NIH conducted or supported research involving human subjects, including research that is otherwise "exempt" in accord with Sections 101(b) and 401(b) of 45 CFR 46 - Federal Policy for the Protection of Human Subjects. The inclusion of children as
subjects in research must be in compliance with all applicable subparts of 45 CFR 46 as well as with other pertinent federal laws and regulations. Therefore, proposals for research involving human subjects must include a description of plans for including children. If children will be excluded from the research, the application or proposal must present an acceptable justification for the exclusion.

In the research plan, the investigator should create a section titled "Participation of Children". This section should provide either a description of the plans to include children and a rationale for selecting or excluding a specific age range of child, or an explanation of the reason(s) for excluding children as participants in the research. When children are included, the plan must also include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study. Scientific review groups at the NIH will assess each application as being "acceptable" or "unacceptable" in regard to the age-appropriate inclusion or exclusion of children in the research project, in addition to evaluating the plans for conducting the research in accord with these provisions.


Related Information

History/Revision Information

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Export Controls

INTRODUCTION

Over the past decade, the Federal government has become increasingly concerned with protecting sensitive technologies and information for reasons of national security. The primary focus of these concerns is set forth in the U.S. Export Control laws which represent a comprehensive set of federal regulations that control and restrict the export of critical technologies, technical data, software code, information and services to foreign nationals and foreign countries. For purposes of these laws, an "export" is defined very broadly, and includes not only physical shipments, but also oral and written communications to persons abroad and to disclosures of information to foreign nationals when in this country.

The principal agencies responsible for the implementation of these laws are the Department of Commerce through its Export Administration Regulations (EAR), the Department of State through its International Traffic in Arms Regulations (ITAR) and the Treasury Department through its Office of Foreign Assets Control (OFAC). These laws and resulting regulations are very complicated and apply to a wide range of activities at academic institutions, including research, international programs, technology transfers, foreign travel, and visits to our facilities in the United States by foreign nationals.

DICKINSON'S POLICY

It is Dickinson College's policy to comply fully and completely with all applicable U.S. Export Control laws and regulations, and to obtain any necessary licenses or waivers. While we will assist faculty and staff in complying with Export Control laws, it is critically important that you identify and bring to our attention activities where export controls may apply. Unlike situations in which the College might accept sole liability, in this case, the College's options are limited. In addition to the College's potential liability, individual faculty and staff members are civilly and criminally liable for personally violating export controls and embargoes.

OVERVIEW OF EXPORT CONTROL LAWS

International Traffic in Arms Regulations (ITAR) and Export Administration Regulations (EAR).

The EAR and the ITAR control the export and re-export of commodities, software, technical data and information. As mentioned above, an export is more than the shipment or transmission of items or technical data out of the United States. It also refers to a release of technology or technical data to a foreign national in the United States (a "deemed" export). This could take the form of visual inspections by foreign
nationals of equipment and facilities in the United States, oral exchanges of information to foreign nationals in the United States, or the dissemination of personal knowledge or experience to a foreign national which was acquired in the United States.

The Department of Commerce, through its Bureau of Industry and Security (BIS) bases its export regulations on what is known as the Commerce Control List. Through a process of identifying the category of item to be exported and the reason for its control, one can cross-reference the item against the Commerce Control List and determine whether a license is required for a particular country. (See references below to Department of Commerce websites.)

ITAR regulations focus on the export of defense articles and defense services. The list of items controlled by the ITAR, known as the Munitions List, is shorter but much more vague than the categories of items applicable to the Commerce Control List. It is often difficult to determine whether an item falls within either of these lists or, indeed, which agency has primary jurisdiction over the item. It is sometimes necessary to pursue a Commodity Jurisdiction Request when the issue is in doubt. (See references below to State Department websites.)

The Research Exclusion to the EAR and the ITAR.

As a practical matter, most of the College's activities are excluded from export controls through the Fundamental Research Exclusion. This is research which is ordinarily published and shared broadly within a research community. This can include the following:

- Publicly available technologies and software;
- Research that has already published or will be published in a journal or presented at an open conference;
- Technology and software arising from the fundamental research (which is defined as basic and applied research that can be distinguished from proprietary research or industrial research); and
- Educational information, which is defined as information released in the course of instruction at an academic institution.

Note, however, that this Fundamental Research Exclusion is lost if the College accepts any contract clause that forbids the participation of foreign persons, gives the sponsor a right to approve publications resulting from the research, or otherwise operates to restrict participation and/or access to and disclosure of research results. Any of the foregoing would make the research proprietary and thus not within the definition of fundamental research. Importantly, the Fundamental Research Exclusion applies only to the dissemination of research data and information. It does not apply to the shipment of material goods. And note also that the Exclusion may not apply where the information is related to sensitive space or missile technologies, certain military technologies or certain military applications.
The Office of Foreign Assets Control (OFAC).

OFAC administers and enforces economic and trade sanctions based on U.S. foreign policy and national security concerns, and involves more than simply exports. OFAC prohibits payments or providing anything of value to embargoed or sanctioned countries or foreign nationals. It also prohibits travel to, and other activities with, embargoed or sanctioned countries and foreign nationals. Where OFAC has jurisdiction, its rules generally override restrictions and regulations promulgated under the ITAR and the EAR. The list of sanctioned countries, persons and entities changes based on U.S. policies and Presidential executive orders. Long-time sanctioned countries include Cuba, Iran, North Korea, Syria and the Sudan. Other countries are also the subject of certain sanction regulations. (See references below to OFAC website.)

Penalties for Non-Compliance

EAR Penalties –
- Criminal: up to $1 million or five times the value of the export, whichever is greater, per violation, and up to ten (10) years in prison.
- Civil: loss of export privileges, fines of $10,000 - $120,000 per violation.

ITAR Penalties –
- Criminal: up to $1 million per violation and up to ten (10) years in prison.
- Civil: seizure and forfeiture of articles, revocation of exporting privileges, fines of up to $500,000 per violation.

OFAC Penalties –
- Criminal: up to $1 million and ten (10) years in prison.
- Civil: up to $55,000 per violation.

Website Links for Further Information

EAR (Export Administration Regulations)/Commerce Department
- Introduction to Export Controls: www.bis.doc.gov/licensing/exporting basics.htm
- EAR Control List: http://www.access.gpo.gov/bis/
- EAR Database: www.access.gpo.gov/bis/index.html

ITAR (International Traffic in Arms Regulations)
- ITAR: http://pmdtc.org/reference.htm
- ITAR, Directorate of Defense Trade Controls: http://pmdtc.state.gov/itar_index.htm

OFAC (Office of Foreign Assets Controls)/Treasury Department
- OFAC, Sanction Programs: http://www.treas.gov/offices/enforcement/ofac
FURTHER ASSISTANCE

As indicated above, the first screen for the possible application of U.S. Export Controls necessarily lies with our faculty and staff. However, we are committed to assist with compliance. In the event that you identify any concerns or have questions about U.S. Export Controls and their applicability to a particular export or research activity, please immediately contact the Director for Sponsored Projects and Research Compliance peterman@dickinson.edu, 245-1165

Related Information

History/Revision Information

Responsible Division/Office: Office of the Provost and Dean, Sponsored Projects Group

Effective Date: 12/3/2009

Last Amended Date:

Next Review Date:

Also Found In:
Training of Undergraduates in Responsible Conduct of Research

PURPOSE:
To describe Dickinson’s policy on the training for undergraduates in responsible conduct of research as required by the National Science Foundation (NSF), 1 NIH, 2 and other federal agencies3, and by the College’s Research and Development (R&D) Committee.

POLICY: Dickinson College Plan for the Responsible Conduct of Research

Dickinson College expects its faculty, students and staff to adhere to the highest ethical and professional standards in the conduct and management of research. Anyone whose research is supported by internal or external funding is responsible for compliance with the College plan for the training and oversight of students supported by such funding in the responsible conduct of research.

1. To meet the requirement for training, Dickinson College expects that student research collaborators of grantees receiving such funding will complete successfully the training courses provided by the Collaborative Institutional Training Initiative (CITI) web-based curriculum appropriate to their discipline. Those students supported by NSF and other federal funding must successfully complete the course provided for “Federal Grantees.” Faculty grantees must engage with their student collaborators during the course of the CITI training, and discuss case studies and other issues presented there, as appropriate.

   a. Grantees are encouraged to supplement the CITI training with other texts, case studies and materials as appropriate to their discipline or research. For example, scientists might wish to make use of "On Being a Scientist4" in training their students and discuss the case studies presented there.

   b. Grantees are encouraged to require their students to take various “optional” CITI courses as appropriate to their discipline or research.

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1 Certification Regarding Responsible Conduct of Research (RCR): The AOR is required to complete a certification that the institution has a plan to provide appropriate training and oversight in the responsible and ethical conduct of research to undergraduates, graduate students, and postdoctoral researchers who will be supported by NSF to conduct research”

2 See NIH policies and requirements on RCR training at:

3 See the Office of Science and Technology Policy (OSTP)“Federal Policy on Research Misconduct” http://ori.hhs.gov/federal-research-misconduct-policy

c. Student research collaborators supported by federal funds for science projects may not exclude any aspect of their CITI training course.

d. Grantees under certain NIH funding mechanisms must include face-to-face training on RCR issues. Faculty may use texts and case studies for this purpose, such as a) "On Being a Scientist" and b) “Moral Reasoning in Scientific Research: Cases for Teaching and Assessment” which includes case studies, checklist/evaluations, and discussion materials for educators.

e. Student research collaborators supported by federal funds for non-science projects (generally Division I and II) may request exclusion from certain training modules, and be approved on a case by case basis by the Associate Provost. In this case, explain the reason for the exclusion on the Dickinson RCR Training Certification Form. For instance, a grantee whose research that does not involve animals or human beings as subjects could argue to exclude the “Human Participants and Animal Subjects in Research” materials.

f. Student research collaborators are expected to complete this requirement before the end of the first week after the start of the grant, and must document that they have done so by submitting the RCR Training Certification signed by both the student and the grantee. The final paycheck for the student will be withheld and students will not be able to complete the final two weeks of the project if forms are not completed in a timely manner.

g. If any training has been excluded, then the grantee must include an explanation for the exclusion.

h. Student research collaborators need to take the CITI-RCR training only one time. For example: if a sophomore completes the RCR training for an R&D funded project, she/he need not repeat the RCR training if she/he is involved in an NSF supported project during the senior year.

i. The completed Dickinson RCR Certification Form should be sent to the Office of the Associate Provost.

2. To meet the requirement for oversight, Dickinson College expects faculty grantees to oversee their student research collaborators by serving as mentors who supervise, guide, and instruct the students supported under their NSF, R&D or other grant.

Related Information

History/Revision Information

Responsible Division/Office: Office of the Provost and Dean, Sponsored Projects Group

5 A copy of the reading is available at National Academies Press web site.
6 Free PDF download copies are available at http://poynter.indiana.edu/mr/mr-main.shtml.
Disclosure of Familial Relationships on Federal Grants

Policy/Procedure

DEFINITION:

Dickinson’s Nepotism Policy (see link below) addresses the admissibility of hiring family members for positions in which they would supervise or be subject to supervision by a relative. Dickinson. Dickinson’s Financial Conflict of Interest in Research Policy (see link below) addresses the need to disclose and prevent financial interests as described in NIH’s Grants Policy Statement. The NIH specifically requires grantee institutions have in place standards of conduct and safeguards to “prevent employees, consultants, members of governing bodies, and others who may be involved in grant-supported activities from using their positions for purposes that are, or give the appearance of being, motivated by a desire for private financial gain for themselves or others, such as those with whom they have family, business, or other ties.”


PURPOSE:

This policy covers the interstices between Nepotism and Financial Conflicts of Interest, in which a) the family member is a co-equal investigator on a federal grant and is not supervising the other, and b) there are no financial conflicts of interest. However, there may be the appearance to federal funding agencies that there are inherent conflicts in such a co-equal investigator/familial relationship. This policy allows a) that relationship to be disclosed to federal agencies at the point of proposal submission and b) a potential mitigation plan be developed in the event that the agency has concerns at the post-award stage.

POLICY:

1. All federal grant proposals must disclose any family relationship between the project director and anyone named in the proposal. No family members may be paid with grant funds unless that relationship was disclosed in the proposal or disclosed to the Sponsored Projects Group after receipt of a grant award.

2. The Principal Investigator (PI) on the project must complete and file the FAMILY RELATIONSHIP DISCLOSURE STATEMENT (page 1) with the Sponsored Projects Office prior to grant submission. This statement should be filed with the proposal to the cognizant federal agency, in the manner acceptable to that agency.

3. The Principal Investigator (PI) on the project must complete and file the FAMILY RELATIONSHIP DISCLOSURE STATEMENT (page 2) with the Sponsored Projects Office prior to grant award. This document will be retained with the Sponsored Projects Group in the event that such plan must be provided and/or otherwise be negotiated with the funding agencies’ grants and contracts office.
Related Information

http://www.dickinson.edu/download/downloads/id/1786/nepotism_policy
http://www.dickinson.edu/download/downloads/id/2237/conflict_of_interest_in_research_policy

History/Revision Information

Responsible Division/Office: Academic Affairs, Sponsored Projects

Effective Date: September 17, 2014

Last Amended Date:

Next Review Date:

Also Found In:
Dickinson College
Statement of Policy and Procedures
for Responding to Allegations
of Research Misconduct

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I. Introduction

A. General Policy

Dickinson College requires its faculty to adhere to the highest ethical and professional standards in the conduct and management of research. It is the College’s expectation that all persons conducting research will avoid fabrication, falsification, plagiarism or other practices that undermine the integrity of the institution. Honest error or differences of opinion in the evaluation or interpretation of research is not misconduct. Any person whose research is supported by funding from PHS sources is responsible for compliance with this policy and with federal regulations where appropriate in the disposition of funds. Dickinson College is committed to protecting the positions and reputations of good faith complainants, witnesses and committee members.

B. Scope

This policy and related procedures are intended to carry out Dickinson College’s
responsibilities under the Public Health Service (PHS) Policies on Research Misconduct as well the corresponding policies on research misconduct of a variety of federal funding agencies.

- This document applies to allegations of **research misconduct** (*fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results—see Section II for definitions.*) involving a person who, at the time of the alleged research misconduct, was employed by, was an agent of, was under the authority of, or was affiliated by contract or agreement with Dickinson College.

This document does not distinguish between funded and unfunded research activities, except where it refers to specific agency requirements.

This document does not distinguish between scholarly disciplines. It is acknowledged, at the very least, that research may take on a different character from discipline to discipline. However, each discipline has its professional standards of conduct, and to the extent that *fabrication, falsification, or plagiarism* are rejected by those professional standards, this document applies to the research activities of those disciplines.

Research Misconduct (as defined in this document) is a specific instance of impropriety within the broader domain of personal and professional conduct. Allegations of misconduct outside the scope of this policy should be directed to the department chair, provost or associate provost.

This statement of policy and procedures does not apply to authorship or collaboration disputes and applies only to allegations of research misconduct that occurred within six (6) years of the date Dickinson College or the relevant federal agency received the allegation, subject to the following exceptions:

- subsequent use of alleged research misconduct;
- Health or safety of the public; and
- Grandfathered exceptions as defined in 42 C.F.R, § 93.105(b).

## II. Definitions

Terms used have the same meaning as given them in the Public Health Service Policies on Research Misconduct, 42 CFR Part 93.

**Advocacy** means the presence of an individual or individuals (“advocate(s)”) to provide support and consultation to the respondent throughout the misconduct proceedings. Advocates include individuals whom the respondent selects to serve in this role. Under Dickinson’s system of governance, it is inappropriate for anyone involved in these internal College proceedings to be represented by legal counsel or advocates.
Agency means a public or private agency or organization providing funds to support research.

Allegation means a disclosure of possible research misconduct through any means of communication. All employees will report observed, suspected, or apparent research misconduct to the Research Integrity Officer (RIO). The disclosure may be by written or oral statement or other communication.

Assessment means the process of evaluating an allegation of research misconduct in order to determine whether the allegation falls within the definition of research misconduct, and is sufficiently credible and specific so that potential evidence of research misconduct may be identified. This initial step is conducted by the RIO in order to determine if an inquiry is required. An inquiry must be conducted if the above stated criteria are met. If this is the case, the RIO will launch the inquiry phase, including the convening of an inquiry committee.

Complainant is a person who in good faith makes an allegation of research misconduct.

Deciding Official (DO) means the institutional official who makes final determinations on allegations of research misconduct and any institutional administrative actions. The Deciding Official will not be the same individual as the Research Integrity Officer and should have no direct prior involvement in the institution’s inquiry, investigation, or allegation assessment. A DO’s appointment of an individual (or individuals) to assess allegations of research misconduct, or to serve on an inquiry or investigation committee, is not considered to be direct prior involvement. The DO at Dickinson College is the Provost and Dean of the College, or his/her designee.

Fabrication is making up data or results and recording or reporting them.

Faculty Personnel Committee (FPC) advises the Provost and Dean of the College and the President of the College on the following personnel matters regarding faculty: authorization for recruitment, term appointments, promotion, tenure, salary, sabbatical and other leaves, reduced teaching loads, continuation of appointments beyond normal retirement, early retirement, and assignment of faculty to administrative duties. Candidates for initial appointment at the Associate Professor and Professor levels shall be interviewed by the committee. The Committee includes five tenured faculty: one each from groups 1-3 and two at-large, from different groups, Provost and Dean of the College, without vote, Associate Provost, without vote.

Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

Good faith as applied to a complainant or witness means having a belief in the truth of one’s allegations or testimony that a reasonable person in the complainant or witness’s
position could have based on the information known to the complainant or witness at the
time. An allegation or cooperation with a research misconduct proceeding is not in good
faith if it is made with knowing or reckless disregard for information that would negate
the allegation or testimony. Good faith as applied to a committee member means
cooperating with the research misconduct proceeding by carrying out the duties assigned
impartially for the purpose of helping the College meet its responsibilities. A committee
member does not act in good faith if his/her acts or omissions on the committee are
dishonest or influenced by personal, professional, or financial conflicts of interest with
those involved in the research misconduct proceeding.

**Inquiry** means gathering information and initial fact-finding to determine whether an
allegation or suspected research misconduct warrants an investigation.

**Institutional Members** - Institutional member or members means a person who is
employed by, is an agent of, or is affiliated by contract or agreement with Dickinson
College. Institutional members at Dickinson College may include, but are not limited to,
officials, tenured and untenured faculty, teaching and support staff, researchers, research
coordinators, students, volunteers, agents, and contractors, subcontractors, and
subawardees, and their employees.

**Investigation** means the formal development of a factual record and the examination of
that record leading to: (1) a decision not to make a finding of research misconduct, or (2)
a recommendation for a finding of research misconduct which may include a
recommendation for other appropriate actions, including administrative and/or personnel
actions.

**ORI** means the Office of Research Integrity of the Public Health Service (PHS). This is
the federal office promoting integrity in biomedical and behavioral research supported by
the PHS by monitoring institutional investigations of scientific misconduct and
facilitating the responsible conduct of research.

**PHS** means the Public Health Service. PHS is the umbrella organization in the U.S.
Federal Government consisting of eight Health and Human Services health Agencies, the
Office of Public Health and Science, and the Commissioned Corps (a uniformed service
of more than 6,000 health professionals). The NIH is the largest Agency within the PHS.

**Plagiarism** is the use of, without proper citation or acknowledgment, the words, ideas, or
work of another.

**Preponderance of the evidence** means proof by information that, compared with that
opposing it, leads to the conclusion that the fact at issue is more probably true than not.

**Regulation** means any regulation applicable to an externally funded grant or contract or
to the handling of research misconduct allegations related to such grant, contract, or
research performed under it.
Research Integrity Officer (RIO) means the institutional official responsible for: (1) assessing allegations of research misconduct to determine if they fall within the definition of research misconduct and warrant an inquiry on the basis that the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified; (2) overseeing inquiries and investigations; and (3) the other responsibilities described in this policy. The RIO at Dickinson College is the Associate Provost or his/her designee assigned by the Provost.

Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. It does not include honest error or differences of opinion. A finding of research misconduct requires that there be a significant departure from accepted practices of the relevant research community; that the misconduct be committed intentionally, knowingly, or recklessly; and that the allegation be proven by a preponderance of the evidence.

Research record means the record of data or results that embody the facts resulting from research inquiry, including, but not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, and any documents and materials provided to a government agency or an institutional official by a respondent in the course of the research misconduct proceeding.

Respondent means the person against whom an allegation of research misconduct is directed or the person whose actions are the subject of the inquiry or investigation. There can be more than one respondent in any inquiry or investigation.

Retaliation means an adverse action taken against a complainant, witness, or committee member by an institution or one of its members in response to a good faith allegation of research misconduct; or good faith cooperation with a research misconduct proceeding.

III. Rights and Responsibilities

A. Research Integrity Officer

The RIO at Dickinson College is Associate Provost Robert Winston, or his/her designee assigned by the Provost. A detailed listing of the responsibilities of the RIO is set forth in Appendix A. RIO responsibilities include the following duties related to research misconduct proceedings:

- Consult confidentially with persons uncertain about whether to submit an allegation of research misconduct;
• Receive allegations of research misconduct;

• Assess each allegation of research misconduct in accordance with Section V.A. of this policy to determine whether it falls within the definition of research misconduct and warrants an inquiry;

• As necessary, take interim action and notify relevant external funding agencies of special circumstances;

• Sequester research data and evidence pertinent to the allegation of research misconduct in accordance with Section V.C. of this policy and maintain it securely in accordance with this policy, including but not limited to the College’s Records Management and Information Security policies, and applicable law and regulations;

• Make all reasonable and practical efforts to provide confidentiality to those involved in the research misconduct proceeding as to the extent allowed;

• Notify the respondent and provide opportunities for him/her to review/comment/respond to allegations, evidence, and committee reports in accordance with Section III.C. of this policy;

• Inform respondents, complainants, and witnesses of the procedural steps in the research misconduct proceeding;

• Appoint the chair and members of the inquiry and investigation committees, ensure that those committees are properly staffed and that there is expertise appropriate to carry out a thorough and authoritative evaluation of the evidence;

• Determine whether each person involved in handling an allegation of research misconduct has an unresolved personal, professional, or financial conflict of interest and take appropriate action, including recusal, to ensure that no person with such conflict is involved in the research misconduct proceeding;

• In cooperation with other institutional officials, take all reasonable and practical steps to protect or restore the positions and reputations of good faith complainants, witnesses, and committee members and counter potential or actual retaliation against them by respondents or other institutional members;

• Keep the Deciding Official and others who need to know apprised of the progress of the review of the allegation of research misconduct;
• Notify and make reports to external funding agencies as required by federal regulations or sponsor terms and conditions;

• Ensure that administrative actions taken by the institution and external funding agencies are enforced and take appropriate action to notify other involved parties, such as sponsors, law enforcement agencies, professional societies, and licensing boards of those actions; and

• Maintain records of the research misconduct proceeding and make them available to external funding agencies in accordance with Section VIII.F of this policy.

B. Complainant

The complainant is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with the inquiry and investigation. As a matter of good practice, the complainant should be interviewed at the inquiry stage and given the transcript or recording of the interview for correction. The complainant must be interviewed during an investigation, and be given the transcript or recording of the interview for correction.

C. Respondent

The respondent is responsible for maintaining confidentiality and cooperating with the conduct of an inquiry and investigation. The respondent is entitled to:

• A good faith effort from the RIO to notify the respondent in writing at the time of or before beginning an inquiry;

• An opportunity to comment on the inquiry report and have his/her comments attached to the report;

• Be notified of the outcome of the inquiry, and receive a copy of the inquiry report that includes a copy of the institution’s policies and procedures on research misconduct, as well as applicable external agency misconduct policies (in the case of externally sponsored projects)

• Be notified in writing of the allegations to be investigated within a reasonable time after the determination that an investigation is warranted, but before the investigation begins (within 30 days after the institution decides to begin an investigation), and be notified in writing of any new allegations, not addressed in the inquiry or in the initial notice of investigation, within a reasonable time after the determination to pursue
those allegations;

- Be interviewed during the investigation, have the opportunity to correct the recording or transcript, and have the corrected recording or transcript included in the record of the investigation;

- Have interviewed during the investigation any witness who has been reasonably identified by the respondent as having information on relevant aspects of the investigation, have the recording or transcript provided to the witness for correction, and have the corrected recording or transcript included in the record of investigation; and

- Receive a copy of the draft investigation report and, concurrently, a copy of, or supervised access to the evidence on which the report is based, and be notified that any comments must be submitted within 30 days of the date on which the copy was received and that the comments will be considered by the institution and addressed in the final report.

- File a written appeal of the decision of the Deciding Official (DO), if he/she so chooses, within 30 days of the committee’s completion of the investigation report. All appeals are reviewed and acted upon by the President of the College.

The respondent should be given the opportunity to admit that research misconduct occurred and that he/she committed the research misconduct. With the advice of the RIO and/or other institutional officials, the Deciding Official may terminate the institution’s review of an allegation that has been admitted, provided the institution has received from any relevant agency any required approval of institutional acceptance of the admission and any proposed settlement.

D. Deciding Official

The Deciding Official (“DO”) of Dickinson College is the Provost and Dean of the College, or his/her designee.

The DO will receive the inquiry report and after consulting with the RIO and/or other institutional officials, decide whether an investigation is warranted under the criteria. Any finding that an investigation is warranted must be made in writing by the DO and must be provided to pertinent external agencies as required by regulation, together with a copy of the inquiry report, within 30 days of the finding. If it is found that an investigation is not warranted, the DO and the RIO will ensure that detailed documentation of the inquiry is retained for at least 7 years after termination of the inquiry, so that ORI may assess the reasons why the institution decided not to conduct an investigation.
The DO will receive the investigation report and, after consulting with the RIO and/or other institutional officials including, but not limited to the Faculty Personnel Committee, decide the extent to which this institution accepts the findings of the investigation and, if research misconduct is found, decide what, if any, institutional administrative or personnel actions are appropriate. The DO shall ensure that the final investigation report, the findings of the DO and a description of any pending or completed administrative actions are provided to the pertinent agencies as required by regulation.

IV. General Policies and Principles

A. Responsibility to Report Misconduct

All institutional members will report observed, suspected, or apparent research misconduct to the RIO. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he or she may meet with or contact the RIO to discuss the suspected research misconduct informally, which may include discussing it anonymously and/or hypothetically. If the circumstances described by the individual do not meet the definition of research misconduct, the RIO will refer the individual or allegation to other offices or officials with responsibility for resolving the problem.

At any time, an institutional member may have confidential discussions and consultations about concerns of possible misconduct with the RIO and will be counseled about appropriate procedures for reporting allegations.

B. Cooperation with Research Misconduct Proceedings

Institutional members will cooperate with the RIO and other institutional officials in the review of allegations and the conduct of inquiries and investigations. Institutional members, including respondents, have an obligation to provide evidence relevant to research misconduct allegations to the RIO or other institutional officials.

C. Confidentiality

The RIO shall, make all reasonable and practical efforts to maintain confidentiality, consistent with federal regulations and Dickinson College policy to: (1) limit disclosure of the identity of respondents and complainants to those who need to know in order to carry out a thorough, competent, objective and fair research misconduct proceeding; and (2) except as otherwise prescribed by law, limit the disclosure of any records or evidence from which research subjects might be identified to those who need to know in order to carry out a research misconduct proceeding. The RIO should use written confidentiality agreements
or other mechanisms to ensure that the recipient does not make any further disclosure of identifying information.

D. Protecting complainants, witnesses, and committee members

Institutional members may not retaliate in any way against complainants, witnesses, or committee members. Institutional members should immediately report any alleged or apparent retaliation against complainants, witnesses or committee members to the RIO, who shall review the matter and, as necessary, make all reasonable and practical efforts to counter any potential or actual retaliation and protect and restore the position and reputation of the person against whom the retaliation is directed.

E. Protecting the Respondent

As requested and as appropriate, the RIO and other institutional officials shall make all reasonable and practical efforts to protect or restore the reputation of persons alleged to have engaged in research misconduct, but against whom no finding of research misconduct is made.

During the research misconduct proceeding, the RIO is responsible for ensuring that respondents receive all the notices and opportunities provided for in 42 C.F.R. §93 and the policies and procedures of the institution including, but not limited to assuring that:

- All allegations are proved by a preponderance of the evidence;
- Procedures are kept confidential and in line with the requirements of 42 C.F.R. § 93.108;
- Respondent receives written notice of his/her misconduct;
- Respondent is provided opportunity to submit written comments on the institution's inquiry report;
- Respondent is provided opportunity to submit written comments on the draft report of the investigation, and provisions for the institutional investigation committee to consider and address the comments before issuing the final report; and
- The investigation ends 120 days after it begins.

F. Interim Administrative Actions and Notifying ORI of Special Circumstances

Throughout the research misconduct proceeding, the RIO will review the situation to determine if there is any threat of harm to public health, federal funds and equipment, or the integrity of the externally supported research process. In the event of such a threat, the RIO will, in consultation with the Provost and ORI, take appropriate interim action to protect against any such threat. Interim action
might include additional monitoring of the research process and the handling of federal funds and equipment, reassignment of personnel or of the responsibility for the handling of federal funds and equipment, additional review of research data and results or delaying publication. The RIO shall, at any time during a research misconduct proceeding, notify ORI immediately if he/she has reason to believe that any of the following conditions exist:

- Health or safety of the public is at risk, including an immediate need to protect human or animal subjects;
- Sponsor resources or interests are threatened;
- Research activities should be suspended;
- There is a reasonable indication of possible violations of civil or criminal law;
- Federal action is required to protect the interests of those involved in the research misconduct proceeding;
- The research misconduct proceeding may be made public prematurely and HHS action may be necessary to safeguard evidence and protect the rights of those involved; or
- The research community or public should be informed.

V. Conducting the Assessment and Inquiry

A. Assessment of Allegations

Upon receiving an allegation of research misconduct, the RIO will immediately assess the allegation to determine whether it is sufficiently credible and specific so that potential evidence of research misconduct may be identified. An inquiry must be conducted if these criteria are met.

The assessment period should be brief, preferably concluded within a week. In conducting the assessment, the RIO need not interview the complainant, respondent, or other witnesses, or gather data beyond any that may have been submitted with the allegation, except as necessary to determine whether the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified. The RIO shall, on or before the date on which the respondent is notified or the inquiry begins, whichever is earlier, obtain custody of, inventory, and sequester all research records and evidence needed to
conduct the research misconduct proceeding, as described more fully in paragraph C. of this section.

B. Initiation and Purpose of the Inquiry

If the RIO determines that the criteria for an inquiry are met, he or she will immediately initiate the inquiry process. The purpose of the inquiry is to conduct an initial review of the available evidence to determine whether to conduct an investigation. An inquiry does not require a full review of all the evidence related to the allegation.

C. Notice to Respondent; Sequestration of Research Records

At the time of or before beginning an inquiry, the RIO must make a good faith effort to notify the respondent in writing, if the respondent is known. If the inquiry subsequently identifies additional respondents, they must be notified in writing. On or before the date on which the respondent is notified, or the inquiry begins, whichever is earlier, the RIO must take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence and sequester them in a secure manner, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments. The RIO may consult with ORI or other pertinent federal agencies for advice and assistance in this regard.

D. Appointment of the Inquiry Committee

The RIO, in consultation with other institutional officials as appropriate, will appoint an inquiry committee and committee chair as soon after the initiation of the inquiry as is practical. The inquiry committee must consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the inquiry and should include individuals with the appropriate scientific expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry.

The committee will include two faculty members from departments other than that of the individual against whom the allegation has been made and one from that person’s department. If it is deemed advisable, one of the non-department members of the ad hoc committee may be an individual with relevant expertise and high professional standing from beyond Dickinson. Neither members of FPC nor members of the Appeals Committee are eligible to serve on this committee; the Deciding Official will sit without vote on the committee.
Allegations of fraud or misconduct in scholarly research undertaken by administrators will follow the same procedures except that the ad hoc committee undertaking the formal investigation will include one administrator.

The RIO shall be responsible for notifying the respondent of the proposed committee membership to give the respondent an opportunity to object to a proposed member based upon a personal, professional, or financial conflict of interest. Objections must be filed within 10 calendar days. The institution will make the final determination of whether a conflict exists.

E. Charge to the Committee and First Meeting

The RIO will prepare a charge for the inquiry committee that:

- Sets forth the time for completion of the inquiry;
- Describes the allegations and any related issues identified during the allegation assessment;
- States that the purpose of the inquiry is to conduct an initial review of the evidence, including the testimony of the respondent, complainant and key witnesses, to determine whether an investigation is warranted, not to determine whether research misconduct definitely occurred or who was responsible;
- States that an investigation is warranted if the committee determines: (1) there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct; and, (2) the allegation may have substance, based on the committee’s review during the inquiry.
- Informs the inquiry committee that they are responsible for preparing or directing the preparation of a written report of the inquiry that meets the requirements of this policy and any sponsor-specific requirements.

At the committee's first meeting, the RIO will review the charge with the committee, discuss the allegations, any related issues, and the appropriate procedures for conducting the inquiry, assist the committee with organizing plans for the inquiry, and answer any questions raised by the committee. The RIO will be present or available throughout the inquiry to advise the committee as needed.

F. Inquiry Process

The inquiry committee will normally interview the complainant, the respondent, and key witnesses as well as examining relevant research records and materials.
Then the inquiry committee will evaluate the evidence, including the testimony obtained during the inquiry. After consultation with the RIO, the committee members will decide whether an investigation is warranted based on the criteria in this policy. The scope of the inquiry is not required to and does not normally include deciding whether misconduct definitely occurred, determining definitely who committed the research misconduct or conducting exhaustive interviews and analyses. However, if a legally sufficient admission of research misconduct is made by the respondent, misconduct may be determined at the inquiry stage if all relevant issues are resolved. In that case, the institution shall promptly consult with ORI to determine the next steps that should be taken. See Section IX.

G. Time for Completion

The inquiry, including preparation of the final inquiry report and the decision of the DO on whether an investigation is warranted, must be completed within 60 calendar days of initiation of the inquiry, unless the RIO determines that circumstances clearly warrant a longer period. If the RIO approves an extension, the inquiry record must include documentation of the reasons for exceeding the 60-day period. In such instances, the respondent will be notified of the extension.

VI. The Inquiry Report

A. Elements of the Inquiry Report

A written inquiry report must be prepared that includes the following information: (1) the name and position of the respondent; (2) a description of the allegations of research misconduct; (3) the external support pertinent to the allegation, including, for example, grant numbers, grant applications, contracts and publications listing the support; (4) the basis for recommending or not recommending that the allegations warrant an investigation; (5) any comments on the draft report by the respondent or complainant (6) the names and titles of the committee members and experts who conducted the inquiry; (7) a summary of the inquiry process used; (8) a list of the research records reviewed; (9) summaries of any interviews; (10) and whether any other actions should be taken if an investigation is not recommended.

General Counsel should review the report for legal sufficiency. Modifications should be made as appropriate in consultation with the RIO and the inquiry committee.

B. Notification to the Respondent and Opportunity to Comment

The RIO shall notify the respondent whether the inquiry found an investigation to be warranted, include a copy of the draft inquiry report for comment within 10
calendar days, and include a copy of or refer to any pertinent agency-specific regulations and the college’s policies and procedures on research misconduct.

Any comments that are submitted by the respondent will be attached to the final inquiry report. Based on the comments, the inquiry committee may revise the draft report as appropriate and prepare it in final form. The committee will deliver the final report to the RIO.

C. Institutional Decision and Notification

1. Decision by Deciding Official

The RIO will transmit the final inquiry report and any comments to the DO, who will determine in writing whether an investigation is warranted. The inquiry is completed when the DO makes this determination.

2. Notification to ORI or Other Pertinent Agencies and Notification to Complainant

Within 30 calendar days of the DO’s decision that an investigation is warranted, the RIO will provide ORI, or other pertinent agency as required by regulation, with the DO’s written decision and a copy of the inquiry report. The RIO will also notify those institutional officials who need to know of the DO's decision. Where PHS funding is involved, the RIO must provide the following information to ORI upon request: (1) the institutional policies and procedures under which the inquiry was conducted; (2) the research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents; and (3) the charges to be considered in the investigation.

3. Documentation of Decision Not to Investigate

If the DO decides that an investigation is not warranted, the RIO shall secure and maintain for 7 years after the termination of the inquiry sufficiently detailed documentation of the inquiry to permit a later assessment by ORI, or any other pertinent agency as required by regulation, of the reasons why an investigation was not conducted.

VII. Conducting the Investigation

A. Initiation and Purpose

The investigation must begin within 30 calendar days after the determination by the DO that an investigation is warranted. The purpose of the investigation is to develop a factual record by exploring the allegations in detail and examining the
evidence in depth, leading to recommended findings on whether research misconduct has been committed, by whom, and to what extent. The investigation will also determine whether there are additional instances of possible research misconduct that would justify broadening the scope beyond the initial allegations. The findings of the investigation must be set forth in an investigation report.

B. Notifying ORI and Respondent; Sequestration of Research Records

On or before the date on which the investigation begins, the RIO must: (1) notify the ORI Director (in the case of PHS funded research) or other pertinent agency (as required by regulation), of the decision to begin the investigation and provide ORI a copy of the inquiry report; and (2) notify the respondent in writing of the allegations to be investigated. The RIO must also give the respondent written notice of any new allegations of research misconduct within a reasonable amount of time of deciding to pursue allegations not addressed during the inquiry or in the initial notice of the investigation.

The RIO will, prior to notifying respondent of the allegations, take all reasonable and practical steps to obtain custody of and sequester in a secure manner all research records and evidence needed to conduct the research misconduct proceedings that were not previously sequestered during the inquiry. The need for additional sequestration of records for the investigation may occur for any number of reasons, including the institution's decision to investigate additional allegations not considered during the inquiry stage or the identification of records during the inquiry process that had not been previously secured. The procedures to be followed for sequestration during the investigation are the same procedures that apply during the inquiry.

C. Appointment of the Investigation Committee

The RIO, in consultation with other institutional officials as appropriate, will appoint an ad hoc investigation committee and the committee chair as soon after the beginning of the investigation as is practical. The investigation committee must consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the investigation and should include individuals with the appropriate scientific expertise to evaluate the evidence and issues related to the allegation, interview the respondent and complainant and conduct the investigation. Individuals appointed to the investigation committee may also have served on the inquiry committee.

The committee will include two faculty members from departments other than that of the individual against whom the allegation has been made and one from that person’s department. One of the non-department members of the ad hoc committee may be an individual with relevant expertise and high professional standing from beyond Dickinson. Neither members of Dickinson’s Faculty
Personnel Committee (FPC) nor members of the Appeals Committee are eligible to serve on this committee; the Deciding Official will sit without vote on the committee.

Allegations of fraud or misconduct in scholarly research undertaken by administrators will follow the same procedures except that the ad hoc committee undertaking the formal investigation will also include one administrator.

The RIO will notify the respondent in writing of the proposed committee membership. The respondent will have 10 calendar days to raise objections to the proposed committee membership based on personal, professional, or financial conflict of interest. The Respondent has an obligation to specifically disclose to the RIO any potential conflicts of interest with the proposed membership. The institution will make the final determination of whether a conflict exists.

D. Charge to the Committee and the First Meeting

1. Charge to the Committee

The RIO will define the subject matter of the investigation in a written charge to the committee that:

- Describes the allegations and related issues identified during the inquiry;
- Identifies the respondent;
- Informs the committee that it must conduct the investigation as prescribed in paragraph E. of this section;
- Defines research misconduct;
- Informs the committee that it must evaluate the evidence and testimony to determine whether, based on a preponderance of the evidence, research misconduct occurred and, if so, the type and extent of it and who was responsible;
- Informs the committee that in order to determine that the respondent committed research misconduct it must find that a preponderance of the evidence establishes that: (1) research misconduct, as defined in this policy, occurred (respondent has the burden of proving by a preponderance of the evidence any affirmative defenses raised, including honest error or a difference of opinion); (2) the research misconduct is a significant departure from accepted practices of the relevant research community; and (3) the respondent committed the research misconduct
intentionally, knowingly, or recklessly; and

- Informs the committee that it must prepare or direct the preparation of a written investigation report that meets the requirements of this policy and any agency-specific reporting requirements.

2. First Meeting

The RIO will convene the first meeting of the investigation committee to review the charge, the inquiry report, and the prescribed procedures and standards for the conduct of the investigation, including the necessity for confidentiality and for developing a specific investigation plan. The investigation committee will be provided with a copy of this statement of policy and procedures, and any sponsor-specific requirements, plus 42 CFR §93. The RIO will be present or available throughout the investigation to advise the committee as needed.

E. Investigation Process

The investigation committee and the RIO must:

- Use diligent efforts to ensure that the investigation is thorough and sufficiently documented and includes examination of all research records and evidence relevant to reaching a decision on the merits of each allegation;

- Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical;

- Interview each respondent, complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation, including witnesses identified by the respondent, and record or transcribe each interview, provide the recording or transcript to the interviewee for correction, and include the recording or transcript in the record of the investigation; and

- Pursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of any additional instances of possible research misconduct, and continue the investigation to completion.

F. Time for Completion

The investigation is to be completed within 120 calendar days of beginning it, including conducting the investigation, preparing the report of findings, providing
the draft report for comment and sending the final report to ORI (for PHS funded activities) or other pertinent agencies as required by regulation. However, if the RIO determines that the investigation will not be completed within this 120-day period, he/she will submit to ORI (or other pertinent agency as required by regulation) a written request for an extension, setting forth the reasons for the delay. The RIO will ensure that periodic progress reports are filed with ORI (or other pertinent agency as required by regulation, if ORI/other pertinent agency grants the request for an extension and directs the filing of such reports.

VIII. The Investigation Report

A. Elements of the Investigation Report

The investigation committee and the RIO are responsible for preparing a written draft report of the investigation that:

- Describes the nature of the allegation of research misconduct, including identification of the respondent;
- Describes and documents the PHS support, including, for example, the numbers of any grants that are involved, grant applications, contracts, and publications listing PHS support;
- Describes the specific allegations of research misconduct considered in the investigation;
- Includes the institutional policies and procedures under which the investigation was conducted;
- Identifies and summarizes the research records and evidence reviewed and identifies any evidence taken into custody but not reviewed; and
- Includes a statement of findings for each allegation of research misconduct identified during the investigation. Each statement of findings must: (1) identify whether the research misconduct was falsification, fabrication, or plagiarism, and whether it was committed intentionally, knowingly, or recklessly; (2) summarize the facts and the analysis that support the conclusion and consider the merits of any reasonable explanation by the respondent, including any effort by respondent to establish by a preponderance of the evidence that he or she did not engage in research misconduct because of honest error or a difference of opinion; (3) identify the specific external support; (4) identify whether any publications need correction or retraction; (5) identify the person(s) responsible for the misconduct; and (6) list any current support or known applications or
proposals for support that the respondent has pending with federal and non-federal agencies.

B. Comments on the Draft Report and Access to Evidence

1. Respondent

The RIO must give the respondent a copy of the draft investigation report for comment and, concurrently, a copy of, or supervised access to the evidence on which the report is based. The respondent will be allowed 30 calendar days from the date he/she received the draft report to submit comments to the RIO. The respondent's comments must be included and considered in the final report.

3. Confidentiality

In distributing the draft report, or portions thereof, to the respondent, the RIO will inform the recipient of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality. For example, the RIO may require that the recipient sign a confidentiality agreement.

All efforts will be made to preserve the confidentiality of all proceedings until any report imposed by law and by sound practice must be made. Should the faculty member against whom the allegations were made request it, however, a statement of the results of the investigation will be made public.

C. Decision by Deciding Official

The RIO will assist the investigation committee in finalizing the draft investigation report, including ensuring that the respondent’s comments are included and considered, and transmit the final investigation report to the DO, who will determine in writing: (1) whether the institution accepts the investigation report, its findings, and the recommended institutional actions; and (2) the appropriate institutional actions in response to the accepted findings of research misconduct. If this determination varies from the findings of the investigation committee, the DO will, as part of his/her written determination, explain in detail the basis for rendering a decision different from the findings of the investigation committee. Alternatively, the DO may return the report to the investigation committee with a request for further fact-finding or analysis.

When a final decision on the case has been reached, the RIO will normally notify both the respondent and the complainant in writing. After informing ORI (in the case of PHS funded activities, or other pertinent agencies as required by
regulation), the DO will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, collaborators of the respondent in the work, or other relevant parties should be notified of the outcome of the case. The RIO is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

D. Appeals

Within 30 calendar days of receipt of the committee’s final investigation report, the Respondent may appeal to either reverse or modify the institution’s findings of research misconduct by filing a written notice of appeal with the RIO specifying in detail one or more of the following grounds of appeal:

- Procedural error in the investigation process that materially affected the outcome;
- Evidence that was not reasonably available during the investigation is now available and would likely have materially affected the outcome;
- Sanctions that are seriously disproportionate to the gravity of the research misconduct.

The Respondent must include with the notice of appeal filed with the RIO all documentation, information, and evidence to be considered in the appeal.

The RIO shall deliver the appeal to the Provost and Dean of the College, along with the investigation report. The Provost, upon reviewing the investigation report and any supporting evidence necessary, shall make the final decision to uphold, reverse, or modify the findings of research misconduct, in writing, within 120 days of the filing of the appeal. The Provost, at his/her sole discretion, shall have the authority to charge the investigating committee with additional investigatory actions as deemed necessary to reaching a decision on the appeal, but all activities and the final decision of the Provost shall be completed within 120 days of the filing of the appeal.

E. Notice to ORI of Institutional Findings and Actions

Unless an extension has been granted, the RIO must, within the 120-day period for completing the investigation (or the 120-day period for completion of any appeal), submit the following to ORI: (1) a copy of the final investigation report with all attachments (and any appeal); (2) a statement of whether the institution accepts the findings of the investigation report (or the outcome of the appeal); (3) a statement of whether the institution found misconduct and, if so, who committed the misconduct; and (4) a description of any pending or completed administrative actions against the respondent.
F. Maintaining Records for Review by ORI

The RIO must maintain and provide to ORI (or other pertinent agencies as required by regulation) upon request “records of research misconduct proceedings”. Unless custody has been transferred to HHS or ORI (or another pertinent agency) has advised in writing that the records no longer need to be retained, records of research misconduct proceedings must be maintained in a secure manner for 7 years after completion of the proceeding or the completion of any PHS proceeding involving the research misconduct allegation. The RIO is also responsible for providing any information, documentation, research records, evidence or clarification requested by ORI or other pertinent agency to carry out its review of an allegation of research misconduct or of the institution’s handling of such an allegation.

IX. Completion of Cases; Reporting Premature Closures to ORI or Other Pertinent Agencies

Generally, all inquiries and investigations will be carried through to completion and all significant issues will be pursued diligently. The RIO must notify ORI (or the pertinent agency as required by regulation) in advance if there are plans to close a case at the inquiry, investigation, or appeal stage on the basis that respondent has admitted guilt, a settlement with the respondent has been reached, or for any other reason, except: (1) closing of a case at the inquiry stage on the basis that an investigation is not warranted; or (2) a finding of no misconduct at the investigation stage, which must be reported to ORI or pertinent federal agency, as prescribed in this policy.

X. Institutional Administrative Actions

If the DO determines that research misconduct is substantiated by the findings, he or she will decide on the appropriate actions to be taken, after consultation with the RIO and other institutional officials, including the Faculty Personnel Committee. Dismissal procedures for adequate cause shall be in line with the procedures laid out in Chapter 4, Section IV (pages 4-26 to 4-29) of the Academic Handbook. The administrative actions may include:

- Withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was found;

- Removal of the responsible person from the particular project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment;
• Restitution of funds to the grantor agency as appropriate; and

• Other action appropriate to the research misconduct (in consultation with existing internal policies/procedures that may apply to the situation).

XI. Other Considerations

A. Termination or Resignation Prior to Completing Inquiry or Investigation

The termination of the respondent's institutional employment, by resignation or otherwise, before or after an allegation of possible research misconduct has been reported, will not preclude or terminate the research misconduct proceeding or otherwise limit any of the institution’s responsibilities under any applicable federal agency regulations.

If the respondent, without admitting to the misconduct, elects to resign his or her position after the institution receives an allegation of research misconduct, the assessment of the allegation will proceed, as well as the inquiry and investigation, as appropriate based on the outcome of the preceding steps. If the respondent refuses to participate in the process after resignation, the RIO and any inquiry or investigation committee will use their best efforts to reach a conclusion concerning the allegations, noting in the report the respondent's failure to cooperate and its effect on the evidence.

B. Restoration of the Respondent's Reputation

Following a final finding of no research misconduct, including ORI or other pertinent agency concurrence, the RIO must, at the request of the respondent, undertake all reasonable and practical efforts to restore the respondent's reputation. Depending on the particular circumstances and the views of the respondent, the RIO should consider notifying those individuals aware of or involved in the investigation of the final outcome, publicizing the final outcome in any forum in which the allegation of research misconduct was previously publicized, and expunging all reference to the research misconduct allegation from the respondent's personnel file. Any institutional actions to restore the respondent's reputation should first be approved by the DO.

C. Protection of the Complainant, Witnesses and Committee Members

During the research misconduct proceeding and upon its completion, regardless of whether the institution or ORI/other pertinent federal agency determines that research misconduct occurred, the RIO must undertake all reasonable and practical efforts to protect the position and reputation of, or to counter potential or actual retaliation against, any complainant who made allegations of research
misconduct in good faith and of any witnesses and committee members who cooperate in good faith with the research misconduct proceeding. The DO will determine, after consulting with the RIO, and with the complainant, witnesses, or committee members, respectively, what steps, if any, are needed to restore their respective positions or reputations or to counter potential or actual retaliation against them. The RIO is responsible for implementing any steps the DO approves.

D. Allegations Not Made in Good Faith

If relevant, the DO will determine whether the complainant’s allegations of research misconduct were made in good faith, or whether a witness or committee member acted in good faith. If the DO determines that there was an absence of good faith he/she will determine in consultation with other institutional officials, including the Faculty Personnel Committee whether any administrative action should be taken against the person who failed to act in good faith.

E. Eventual Disposition/Maintenance of Inquiry and Investigation Reports

The RIO will maintain copies of all the reports for at least seven years (the period required to fulfill reporting obligations to outside agencies). The DO and Provost may also have and maintain copies of reports. The inquiry and investigation reports will NOT become part of the respondent’s personnel file maintained by Human Resource Services.

Relevant CFR citations
42 CFR § 93.214
42 CFR § 93.102
42 CFR § 93.105(b)
42 CFR § 93.310(g)
42 CFR §§ 93.304(c), 93.307(b)
42 CFR §§ 93.304(e), 93.307(f)
42 CFR § 308(a)
42 CFR § 310(c)
42 CFR § 310(g)
42 CFR § 310(g)
42 CFR §§ 93.304(f), 93.312(a)
42 CFR § 93.316
42 CFR § 93.309(c)
42 CFR § 93.304(k)
42 CFR § 93.304(h)
42 CFR § 93.318
42 CFR § 93.307(a)
42 CFR § 93.307(c)
42 CFR §§ 93.305, 93.307(b)
42 CFR § 93.304(b)
42 CFR § 93.307(g)
42 CFR § 93.309(a)
42 CFR § 93.308(a)
Appendix A

Research Integrity Officer Responsibilities

I. General

The Research Integrity Officer (RIO) has lead responsibility for ensuring that the institution:

- Takes all reasonable and practical steps to foster a research environment that promotes the responsible conduct of research, research training, and activities related to that research or research training, discourages research misconduct, and deals promptly with allegations or evidence of possible research misconduct.

- Has written policies and procedures for responding to allegations of research misconduct and reporting information about that response to ORI, as required by 42 CFR Part 93.

- Complies with its written policies and procedures and the requirements of 42 CFR Part 93.

- Informs its institutional members who are subject to 42 CFR Part 93 about its research misconduct policies and procedures and its commitment to compliance with those policies and procedures.

- Takes appropriate interim action during a research misconduct proceeding to protect public health, federal funds and equipment, and the integrity of the PHS supported research process.
II. Notice and Reporting to ORI and Cooperation with ORI

The RIO has lead responsibility for ensuring that the institution:

- Files an annual report with ORI containing the information prescribed by ORI.

- Sends to ORI with the annual report such other aggregated information as ORI may prescribe on the institution’s research misconduct proceedings and the institution’s compliance with 42 CFR Part 93.

- Notifies ORI immediately if, at any time during the research misconduct proceeding, it has reason to believe that health or safety of the public is at risk, HHS resources or interests are threatened, research activities should be suspended, there is reasonable indication of possible violations of civil or criminal law, federal action is required to protect the interests of those involved in the research misconduct proceeding, the institution believes that the research misconduct proceeding may be made public prematurely, or the research community or the public should be informed.

- Provides ORI with the written finding by the responsible institutional official that an investigation is warranted and a copy of the inquiry report, within 30 days of the date on which the finding is made.

- Notifies ORI of the decision to begin an investigation on or before the date the investigation begins.

- Within 120 days of beginning an investigation, or such additional days as may be granted by ORI, (or upon completion of any appeal made available by the institution) provides ORI with the investigation report, a statement of whether the institution accepts the investigation’s findings, a statement of whether the institution found research misconduct and, if so, who committed it, and a description of any pending or completed administrative actions against the respondent.

- Seeks advance ORI approval if the institution plans to close a case at the inquiry, investigation, or appeal stage on the basis that the respondent has admitted guilt, a settlement with the respondent has been reached, or for any other reason, except the closing of a case at the inquiry stage on the basis that an investigation is not warranted or a finding of no misconduct at the investigation stage.

- Cooperates fully with ORI during its oversight review and any subsequent administrative hearings or appeals, including providing all research records and evidence under the institution’s control, custody, or possession and access to all persons within its authority necessary to develop a complete record of relevant evidence.
III. Research Misconduct Proceeding

A. General

The RIO is responsible for:

- Promptly taking all reasonable and practical steps to obtain custody of all research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner.

- Taking all reasonable and practical steps to ensure the cooperation of respondents and other institutional members with research misconduct proceedings, including, but not limited to their providing information, research records and evidence.

- Providing confidentiality to those involved in the research misconduct proceeding as required by 42 CFR § 93.108, other applicable law, and institutional policy.

- Determining whether each person involved in handling an allegation of research misconduct has an unresolved personal, professional or financial conflict of interest and taking appropriate action, including recusal, to ensure that no person with such a conflict is involved in the research misconduct proceeding.

- Keeping the Deciding Official (DO) and others who need to know apprised of the progress of the review of the allegation of research misconduct.

- In cooperation with other institutional officials, taking all reasonable and practical steps to protect or restore the positions and reputations of good faith complainants, witnesses, and committee members and to counter potential or actual retaliation against them by respondents or other institutional members.

- Making all reasonable and practical efforts, if requested and as appropriate, to protect or restore the reputation of persons alleged to have engaged in research misconduct, but against whom no finding of research misconduct is made.

- Assisting the DO in implementing his/her decision to take administrative action against any complainant, witness, or committee member determined by the DO not to have acted in good faith.

- Maintaining records of the research misconduct proceeding, as defined in 42 CFR § 93.317, in a secure manner for 7 years after completion of the proceeding, or the completion of any ORI proceeding involving the allegation of research misconduct, whichever is later, unless custody of the records has been transferred to ORI or ORI has advised that the records no longer need to be retained.
o Ensuring that administrative actions taken by the institution and ORI are enforced and taking appropriate action to notify other involved parties, such as sponsors, law enforcement agencies, professional societies, and licensing boards, of those actions.

B. Allegation Receipt and Assessment

The RIO is responsible for:

o Consulting confidentially with persons uncertain about whether to submit an allegation of research misconduct.

o Receiving allegations of research misconduct.

o Assessing each allegation of research misconduct to determine if an inquiry is warranted because the allegation falls within the definition of research misconduct, is within the jurisdictional criteria of 42 CFR § 93.102(b), and is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

C. Inquiry

The RIO is responsible for:

o Initiating the inquiry process if it is determined that an inquiry is warranted.

o At the time of, or before beginning the inquiry, making a good faith effort to notify the respondent in writing, if the respondent is known.

o On or before the date on which the respondent is notified, or the inquiry begins, whichever is earlier, taking all reasonable and practical steps to obtain custody of all research records and evidence needed to conduct the research misconduct proceeding, inventorying the records and evidence and sequestering them in a secure manner, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on the instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.

o Appointing an inquiry committee and committee chair as soon after the initiation of the inquiry as is practical.

o Preparing a charge for the inquiry committee in accordance with the institution’s policies and procedures.

o Convening the first meeting of the inquiry committee and at that meeting briefing the committee on the allegations, the charge to the committee, and the appropriate procedures for conducting the inquiry, including the need for confidentiality and for developing a
plan for the inquiry, and assisting the committee with organizational and other issues that may arise.

- Providing the inquiry committee with needed logistical support, e.g., expert advice, including forensic analysis of evidence, and clerical support, including arranging witness interviews and recording or transcribing those interviews.

- Being available or present throughout the inquiry to advise the committee as needed and consulting with the committee prior to its decision on whether to recommend that an investigation is warranted on the basis of the criteria in the institution’s policies and procedures and 42 CFR § 93.307(d).

- Determining whether circumstances clearly warrant a period longer than 60 days to complete the inquiry (including preparation of the final inquiry report and the decision of the DO on whether an investigation is warranted), approving an extension if warranted, and documenting the reasons for exceeding the 60-day period in the record of the research misconduct proceeding.

- Assisting the inquiry committee in preparing a draft inquiry report, sending the respondent a copy of the draft report for comment (and the complainant if the institution’s policies provide that option) within a time period that permits the inquiry to be completed within the allotted time, taking appropriate action to protect the confidentiality of the draft report, receiving any comments from the respondent (and the complainant if the institution’s policies provide that option), and ensuring that the comments are attached to the final inquiry report.

- Receiving the final inquiry report from the inquiry committee and forwarding it, together with any comments the RIO may wish to make, to the DO who will determine in writing whether an investigation is warranted.

- Within 30 days of a DO decision that an investigation is warranted, providing ORI with the written finding and a copy of the inquiry report and notifying those institutional officials who need to know of the decision.

- Notifying the respondent (and the complainant if the institution’s policies provide that option) whether the inquiry found an investigation to be warranted and including in the notice copies of or a reference to 42 CFR Part 93 and the institution’s research misconduct policies and procedures.

- Providing to ORI, upon request, the institutional policies and procedures under which the inquiry was conducted, the research records and evidence reviewed, transcripts or recordings of any interviews, copies of all relevant documents, and the allegations to be considered in the investigation.
If the DO decides that an investigation is not warranted, securing and maintaining for 7 years after the termination of the inquiry sufficiently detailed documentation of the inquiry to permit a later assessment by ORI of the reasons why an investigation was not conducted.

D. Investigation

The RIO is responsible for:

- Initiating the investigation within 30 calendar days after the determination by the DO that an investigation is warranted.

- On or before the date on which the investigation begins: (1) notifying ORI of the decision to begin the investigation and providing ORI a copy of the inquiry report; and (2) notifying the respondent in writing of the allegations to be investigated.

- Prior to notifying respondent of the allegations, taking all reasonable and practical steps to obtain custody of and sequester in a secure manner all research records and evidence needed to conduct the research misconduct proceeding that were not previously sequestered during the inquiry.

- In consultation with other institutional officials as appropriate, appointing an investigation committee and committee chair as soon after the initiation of the investigation as is practical.

- Preparing a charge for the investigation committee in accordance with the institution’s policies and procedures.

- Convening the first meeting of the investigation committee and at that meeting: (1) briefing the committee on the charge, the inquiry report and the procedures and standards for the conduct of the investigation, including the need for confidentiality and developing a specific plan for the investigation; and (2) providing committee members a copy of the institution’s policies and procedures and 42 CFR Part 93.

- Providing the investigation committee with needed logistical support, e.g., expert advice, including forensic analysis of evidence, and clerical support, including arranging interviews with witnesses and recording or transcribing those interviews.

- Being available or present throughout the investigation to advise the committee as needed.

- On behalf of the institution, the RIO is responsible for each of the following steps and for ensuring that the investigation committee: (1) uses diligent efforts to conduct an investigation that includes an examination of all research records and evidence relevant to reaching a decision on the merits of the allegations and that is otherwise thorough and
sufficiently documented; (2) takes reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical; (3) interviews each respondent, complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation, including witnesses identified by the respondent, and records or transcribes each interview, provides the recording or transcript to the interviewee for correction, and includes the recording or transcript in the record of the research misconduct proceeding; and (4) pursues diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of any additional instances of possible research misconduct, and continues the investigation to completion.

- Upon determining that the investigation cannot be completed within 120 days of its initiation (including providing the draft report for comment and sending the final report with any comments to ORI), submitting a request to ORI for an extension of the 120-day period that includes a statement of the reasons for the extension. If the extension is granted, the RIO will file periodic progress reports with ORI.

- Assisting the investigation committee in preparing a draft investigation report that meets the requirements of 42 CFR Part 93 and the institution’s policies and procedures, sending the respondent (and complainant at the institution’s option) a copy of the draft report for his/her comment within 30 days of receipt, taking appropriate action to protect the confidentiality of the draft report, receiving any comments from the respondent (and complainant at the institution’s option) and ensuring that the comments are included and considered in the final investigation report.

- Transmitting the draft investigation report to institutional counsel for a review of its legal sufficiency.

- Assisting the investigation committee in finalizing the draft investigation report and receiving the final report from the committee.

- Transmitting the final investigation report to the DO and: (1) if the DO determines that further fact-finding or analysis is needed, receiving the report back from the DO for that purpose; (2) if the DO determines whether or not to accept the report, its findings and the recommended institutional actions, transmitting to ORI within the time period for completing the investigation, a copy of the final investigation report with all attachments, a statement of whether the institution accepts the findings of the report, a statement of whether the institution found research misconduct, and if so, who committed it, and a description of any pending or completed administrative actions against the respondent; or (3) if the institution provides for an appeal by the respondent that could result in a modification or reversal of the DO’s finding of research misconduct, ensuring that the appeal is completed within 120 days of its filing, or seeking an extension from ORI in writing (with an explanation of the need for the extension) and, upon completion of the appeal, transmitting to ORI a copy of the investigation report with all attachments, a copy of the appeal proceedings, a statement of whether the institution accepts the findings of
the appeal proceeding, a statement of whether the institution found research misconduct, and if so, who committed it, and a description of any pending or completed administrative actions against the respondent.

- When a final decision on the case is reached, the RIO will normally notify both the respondent and the complainant in writing and will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of involved journals, collaborators of the respondent, or other relevant parties should be notified of the outcome of the case.

- Maintaining and providing to ORI upon request all relevant research records and records of the institution’s research misconduct proceeding, including the results of all interviews and the transcripts or recordings of those interviews.
History/Revision Information

Responsible Division/Office: Sponsored Projects and Research Compliance

Effective Date: 1-6-2015

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Policy/Procedure

Under development

Related Information

History/Revision Information

Responsible Division/Office: Sponsored Projects Group

Effective Date:

Last Amended Date:

Next Review Date:

Also Found In:
# Procedures and Policies of the Dickinson College Institutional Animal Care and Use Committee (IACUC)

*Revised and approved 9-16-2014*

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Mission Statement

Dickinson College recognizes its ethical and scientific responsibility for the humane care and use of animals involved in research and education, and enjoins faculty, students, and staff to maintain the highest standards of animal care and consideration.

Dickinson College recognizes and supports the Institutional Animal Care and Use Committee as the agent for its obligations for the humane care and use of animals. The Committee will a) assure all activities involving animals meet the ethical and legal requirements for the humane care and use of animals, and b) educate the Dickinson College community concerning the ethical and regulatory considerations for the humane care of animals.

I. The Institutional Animal Care and Use Committee.

Dickinson College shall establish and maintain an Institutional Animal Care and Use Committee (IACUC) for activities involving animals according to the Guide for the Care and Use of Laboratory Animals (Guide). The IACUC shall promote the humane care and use of animals in accordance with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.

The Dickinson College IACUC is guided by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training." The IACUC will not apply any more stringent standards to the review of research and teaching involving animals unless specifically directed to do so by College policy approved by the appropriate faculty governance bodies.

The IACUC shall ensure that all performance sites engaged in activities involving live vertebrate animals under consortium (subaward) or subcontract agreements have an Animal Welfare Assurance and that the activities have Institutional Animal Care and Use Committee (IACUC) approval.

Consistent with the federal regulations, decisions by the IACUC to disapprove research may not be appealed to any authority outside the IACUC. In all instances, to the best of its abilities, the IACUC will work with investigators to revise protocols that are not approved so as to meet the standards set forth in the regulations. On the other hand, review of research and teaching protocols by the IACUC does not guarantee permission to conduct any particular research project. IACUC approval does not override other College policies or authorities.

II. Applicability

Federal regulations delegate the right solely to the IACUC to determine what must be reviewed. All research and teaching involving the care and use of animals conducted by College employees or students at Dickinson or outside of the College in their capacity as an employee/student is subject to prospective review and approval by the IACUC and may not proceed without it, unless specifically excluded from review by the IACUC.

III. Regulatory Authorities

Dickinson College recognizes the following regulatory and accrediting agencies for the care and use of animals. US Department of Agriculture (USDA)

The Animal Care Staff of the Animal and Plant Health Inspection Service (APHIS) of the United
States Department of Agriculture (USDA) is responsible for enforcing the regulations established by the Secretary of Agriculture under the mandate of the Animal Welfare Act (AWA). These regulations set standards for humane handling, housing, space, feeding and watering, sanitation and ventilation, adequate veterinary care, and transportation. Compliance requirements include annual reports documenting adequate veterinary care and periodic unannounced inspections by APHIS personnel.

Office of Laboratory Animal Welfare (OLAW)

The College maintains an Animal Welfare Assurance (Assurance), approved by the Office of Laboratory Animal Welfare (OLAW), of the Public Health Services. The Assurance indicates the College’s compliance with the program requirements of the Guide. Copies of the Assurance, and the Guide are available upon request to the Institutional Official (IO) responsible for oversight and administration of the IACUC.

OLAW is responsible for the general administration and coordination of PHS policy regarding animal care and use. Federal awarding units may not make an award for a project involving animals unless the institution submitting the application or proposal is on the list of institutions that have an approved Assurance on file with OLAW, and the responsible institutional official has provided verification of approval by the IACUC.

IV. IACUC Responsibilities

The IACUC is responsible for abiding by the commitments as stated in the Assurance. These commitments include, but may not be limited to:

A. Review and evaluation of the institution’s program for the humane care and use of animals in research and teaching at least once every six months.

B. Inspection of all animal facilities for compliance with approved standards for hygiene and animal comfort at least once every six months.

C. Preparation of reports of evaluations and inspections according to PHS Policy IV.B.3., and submission of such reports to the Institutional Official.

D. Reviewing and investigating legitimate concerns involving the care and use of animals resulting from public complaints and from reports of noncompliance received from facility personnel, students, faculty or any other employee of the College or any person having official business with the College.

E. Make written recommendations to the Institutional Official regarding any aspect of the Institution's animal program, facilities, or personnel training, and developing procedures for the submission of research protocols for review

F. Reviewing and approving, requiring modifications, or withholding approval of all protocols, and all changes or amendments to approved protocols in conformity with the federal regulations with regard to care and use of animals in teaching and research.

G. Notifying investigators and the Institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval according to PHS Policy IV.C.4

H. Re-examination, once a year, of all current protocols for the use of USDA covered species, especially the current status of the activity, compliance with the protocol, and adherence to
changes in IACUC policy or procedures.

I. Evaluation of the qualifications of all personnel involved in the care and use of animals.

J. Ensuring that proper training is provided as needed prior to the person being approved to participate in the protocol.

K. Assuring that all animals are provided with proper husbandry and veterinary care, and receive pain-relieving drugs when necessary, and requiring justification for the use of animals in protocols with unrelieved pain or distress.

L. Suspending activities involving animals when necessary and take corrective action and report findings and actions through the Institutional Official to all appropriate funding, regulatory and accrediting agencies.

V. IACUC Structure and Administration

A. Delegation of Authority. The president of the College has the option to delegate to the chief academic officer the responsibilities of the Institutional Official (IO). The IO appoints the IACUC chair and IACUC members, and b) provides oversight to the IACUC. 1

B. Responsibilities. The IACUC will report to the Institutional Official (IO). The IO will provide sufficient resources for the efficient conduct of IACUC business, including an administrative staff person to serve as Administrative Liaison. The Administrative Liaison’s duties include: 1) assisting in the development and implementation of procedures to ensure the efficient flow of all IACUC records; 2) maintaining documentation and records in accordance with federal regulatory requirements; 3) tracking records and the progress of all studies; and 4) ensuring meetings are conducted according to federal regulations, i.e., recording attendance and preparing and distributing materials for meetings. The Administrative Liaison will attend all IACUC meetings, and will report informally to the IACUC Chair, and formally to the IO.

VI. IACUC Membership

The IACUC will have sufficient expertise to review the broad variety of research in which the College becomes involved, will be knowledgeable about all relevant regulatory requirements and will make every effort to be impartial and objective in its review.

A. Appointment of IACUC Chair, Length of Service and Duties. The IACUC chair shall be appointed by the IO for a term of three years. In addition to the responsibilities of IACUC membership, the chair has primary responsibility for conducting IACUC meetings and directing the IACUC staff to ensure operation of the IACUC within all applicable regulatory requirements. The IACUC chair works with members and investigators to ensure that the welfare of animals used in teaching research is adequately protected. The chair shall sign all official IACUC correspondence, unless otherwise indicated, and shall report directly to the IO.

B. Appointment of IACUC Members, Length of Service and Duties. The IO, will appoint members to the IACUC for a term of three years, typically in consultation with current and past members. Members are responsible for ensuring that the rights and welfare of research

1 Dickinson’s president has delegated authority for both responsibilities to the chief academic officer.
subjects are protected. Members vote to approve, require modifications in, disapprove, or
table protocols. Members are expected to attend IACUC meetings on a regular basis, serve as
primary reviewers for research within their expertise, and serve as general reviewers on all
research discussed at convened meetings. A vice-chair may be appointed by the chief
academic officer to manage committee business in the event that the chair has a conflict of
interest.

C. IACUC Membership Requirements. In accordance with the compositional requirements of
PHS Policy IV.A.3.a. and b., membership shall be composed of at least five members, with
varying backgrounds to promote complete and adequate review of animal care research
activities commonly conducted at Dickinson. The IACUC shall include, at minimum, a)
faculty members who represent the many uses of animals in teaching and research at
Dickinson College, b) at least one member whose primary concerns are in nonscientific areas;
c) the attending veterinarian with programmatic responsibilities (or his/her delegate), and d) one person who is not currently affiliated with Dickinson and is not part of the immediate family of a person who is currently affiliated with the College. Members will be drawn from
diverse backgrounds including consideration of race, gender, and cultural backgrounds and
sensitivity to such issues as community attitudes, to promote respect for its advice and
counsel in safeguarding the welfare of animals used in teaching and research. Members must
be committed to the ethical and scientifically sound conduct of research and teaching
involving animals, as well as to the care of animals used for these purposes.

The IACUC may, in its discretion, invite individuals with relevant competence to assist in the
review of issues which require expertise beyond or in addition to that available on the
IACUC. These individuals may not vote.

D. Conflict of Interest. No IACUC member may participate in the IACUC’s initial or continuing
review of any project in which the member has a conflicting interest, except to provide
information requested by the IACUC. Conflicts of interest include, but may not be limited to,
the following:

1. The IACUC member is currently engaged, or expects to be engaged, in the animal
research or teaching project under review

2. The IACUC member has a direct financial interest in the principal investigator or the
entity funding the research proposed by the principal investigator, as defined by the
College and/or federal regulations.

3. The IACUC member and the principal investigator of the application under
consideration share an immediate (rather than extended) familial relationship.

4. The IACUC member has other reasons to feel that he-she cannot render an
independent assessment of an application.

The IACUC member shall disclose the conflict of interest at the following time(s):

1. When the IACUC member is contacted to participate in the review of a project from
a principal investigator with whom the IACUC member has a conflict of interest.

2. Prior to the discussion at a convened meeting of a project for which the IACUC
member has a conflict of interest.
3. Immediately upon discovery of the conflict of interest if at other than the foregoing
times.

The members of the IACUC retain the right to question and discuss other IACUC members
regarding their potential conflicts of interest at the time of protocol submission. The Chair or any
IACUC committee member may request that a member be excused from committee deliberations
on a specific protocol because of possible or perceived conflict of interest.

E. Initial Training, Continuing Education, and Professional Development of IACUC Members.

1. Each IACUC member will be provided with an electronic link to or a copy of the
following:
   i. The PHS Policy for the Humane Care and Use of Laboratory Animals
   ii. The National Research Council (NRC) Guide for the Care and Use of
       Laboratory Animals
   iii. The ARENA/OLAW IACUC Guidebook;
   iv. The AVMA Guidelines on Euthanasia;

2. All members of the IACUC will complete either:
   i. the Essentials for IACUC Members Curriculum located at the American
      Association for Laboratory Animal Science website,
      www.aalaslearninglibrary.org, or
   ii. the specified modules for IACUC training in the Collaborative Institutional

3. All IACUC members will visit the OLAW website at least semi-annually and will
   familiarize themselves with the other pertinent modules and information, e.g.,
   OLAW FAQs, Policies and Laws, Guidance, Educational and other Resources.

4. Attendance at an IACUC 101, IACUC 102, IACUC Advanced, PRIM&R/ARENA
   IACUC meeting, or similar course may be substituted for any required IACUC
   training session.

F. Expectations of IACUC members. IACUC members are expected to a) attend all meetings,
programmatic reviews and facility inspections b) attend introductory and regular training for
investigators and IACUC members, and c) review and maintain knowledge of pertinent
documents concerning appropriate animal care for research and teaching activities at
Dickinson College.

G. Compensation of IACUC Members. Certain IACUC members may be provided with a token
honorarium for their service on the IACUC.

1. Faculty Chair: No compensation is provided, however the Committee Chair is
   exempted from service on college committees, i.e., FPC, P&B, AP&SC as provided
   for in the Faculty Handbook.

2. Community/External Member and Alternate(s): The college, through the Office of
   the Provost and Dean, will provide $100 for each campus meeting attended plus
   mileage.

3. Veterinarian(s): The College, through office of the Provost and Dean, will provide
   compensation at the rate of $80 per hour for on campus meetings plus mileage.
4. **Outside Specialist Reviewers (non-voting):** The College, through office of the Provost and Dean, will provide $100 for each campus meeting attended plus mileage.

**VII. IACUC Meetings**

A. **Schedule.** Meetings will be convened at the call of the chair, or vice-chair acting on behalf of the chair. It is within the discretion of the IACUC chair to cancel or add a meeting in the event there is no business or additional business to conduct. The IACUC must meet in full committee under the following circumstances:

1. to review Humane Use Category E proposals (unalleviated pain and/or distress),
2. to review the results of the semiannual inspections two times per year or,
3. at the request of any voting committee member or the Institutional Official.

B. **Quorum.** A simple majority of the voting members of the IACUC is necessary to convene a meeting of the “full committee” and to conduct IACUC business.

A. If a member of the IACUC is excused because of conflict of interest, and a quorum is no longer present, the protocol will not be considered.

B. Should a member or members of the IACUC not be able to be physically present during a convened meeting, the member(s) may participate in the meeting by speakerphone or other electronic means provided (1) they have had an opportunity to review all materials available to all other members attending the meeting, and (2) provided all committee members, whether attending in person or by phone, can hear and respond to all other members at all times.

C. The IACUC may invite consultants to assist in the review of complex issues. Consultants may not be considered members for determination of a quorum.

C. **Procedure.** All convened IACUC meetings shall be conducted under and pursuant to Robert's Rules of Order.

1. In the absence of the Chair or in instances where the Chair may have a conflict of interest, the Chair shall recuse him/herself and designate the Vice-Chair or another member of the committee to conduct the activities of the Chair.

2. For a research protocol to be approved it must receive the approval of a majority of those members present at the convened meeting. While the committee strives to reach consensus on issues presented for its consideration, it operates by majority rule. Those with opinions differing from the majority may file minority reports, and minority opinions must be included in the minutes of all meetings as well as the semiannual reports to the Institutional Official (IO).

3. At any meeting of the full committee, the committee shall also approve and place the results of, any unrecorded Humane Use Category C (no or momentary pain and/or distress) and D (alleviated pain and/or distress) reviews conducted by designated reviewers among the records of the committee, and shall review the recommendations of any subcommittees pertaining to other animal care and use activities.

**VIII. IACUC Record Keeping and Required Documentation**
The AWA stipulates, “the research facility must maintain documentation of the Committee’s reviews and investigations in response to complaints received in order to demonstrate its compliance with these regulations.” All records that directly relate to applications, proposals, and proposed changes in animal care and use reviewed by IACUC must be maintained and must be accessible to the OLAW with reasonable notice.

A. IACUC Records. Federal regulations require that the IACUC retain all records for at least three years and retain records relating to research for at least three years after the termination of the research protocol. All IACUC records shall be kept in a secure place. Access to IACUC records shall be limited to the IACUC chair, the administrative staff of the IACUC, the IACUC members, and officials of federal and state agencies. IACUC records will include the following:

1. IACUC policies, standard operating procedures (SOP), or best practices
2. IACUC membership roster
3. Curriculum vitae for IACUC members
4. Record of certification of specialized training for IACUC members and principal investigators when required by federal grant or IACUC.
5. IACUC research application files for all submitted protocols, including all required documentation, continuing review reports, and correspondence.
6. Minutes of the convened IACUC meetings
7. IACUC Semi Annual Reports
8. IACUC Assurance documents

The Administrative Liaison shall ensure that a current IACUC membership roster is maintained pursuant

B. Contents of Minutes. The minutes of IACUC meetings shall be compiled by and approved by the IACUC. The following specific information shall be included in the minutes:

1. Attendees by name, absent members, alternate members and the name of the person for whom they are the alternate, consultants, invited investigators and guests, and whether quorum requirements have been met. Members present via teleconference shall be noted as such in the meeting minutes.

2. Actions taken by the IACUC on new and continuation applications; review of protocol and modifications or amendments; protocol deviations; adverse event reports; reports from sponsors; waiver or alteration of elements of informed consent; suspensions or terminations of research; and other actions. Votes on these actions are categorized as "for", "against" and “abstain”. The basis for requiring changes in or disapproving research shall be noted.

3. A list of research approved since the last meeting utilizing expedited review procedures and specific citation for the category of expedited review of the individual protocol, as well as a list of exempt and non-research protocols.

5. Members who absented themselves by name, name of protocol and reason for the conflict.

IX. IACUC Review Requirements

A. All teaching and research studies involving the care and use of animals must be submitted for IACUC review by the principal investigator\(^2\). Submissions should be made by using the IACUC Animal Use Protocol form. This form includes all submission requirements (See appendix A for protocol submission requirements).

B. No activities with animals may begin without prior review and approval by the IACUC.

C. Protocol Submission and Dissemination to the IACUC. Members shall be notified via electronic mail that a new protocol has been submitted and they will be polled to see if any member wishes a full committee review of a Category C or D protocol. If no member requests a full committee review, then the Chair will assign a “designated reviewer” to evaluate Category C and D protocols. All Category E protocols will be reviewed in a full committee meeting called by the Chair.

X. Protocol Categories

The following are the categories of pain and distress for animals used in research and teaching programs.

- **Humane Use Category C** - No or momentary pain and/or distress
- **Humane Use Category D** - Alleviated pain and/or distress
- **Humane Use Category E** - Unalleviated pain and/or distress (corresponding to USDA reporting categories C, D, and E respectively)

XII. Review Procedures

A. Designated Member Review Process (DMR)

1. Protocols will be available via the IACUC web site. All IACUC members shall have access to the web site and will be notified via electronic mail that a protocol has been submitted.

2. The IACUC members shall be polled by the Chair following submission of new protocols to see if a full committee review is requested by any member for a Category C or D submission.

3. If full committee review is required or requested, the Chair shall then call a meeting of the full committee.

4. If full committee review is not requested for a Category C or D research protocol submission, a designated member reviewer appointed by the Chair will then review the protocol. The designated reviewer is encouraged to ask another IACUC member knowledgeable in specific aspects of the protocol for advice as needed. The designated reviewer may also seek advice from experts who are not IACUC members

\(^2\) This includes faculty principal investigators, as well as students who are submitting protocols.
provided the principal investigator’s identity is kept confidential.

5. The designated reviewer has the authority to approve, to withhold approval pending modifications, or to request full committee review of assigned protocols. The Chair, however, communicates with the principal investigator concerning protocol approval, required modifications, clarifications, or notification that a full committee review will occur.

6. Results of designated reviews will be available for the full committee at the next scheduled meeting. The Committee at such meetings shall place results of all reviews completed by designated reviewers among the records of the IACUC.

7. The designated reviewer may begin reviewing the protocols at any time upon receipt and shall complete the review without undue delay. If for some reason, the designated IACUC member cannot review the particular protocol assigned, he or she must let the Chair know immediately so it can be re-assigned.

B. Reviewing the Protocol by DMR

1. The reviewer must provide the Chair with a description of all concerns in an electronic message. These comments should be concise and clearly indicate to which question they refer. The comments should be written in a professional manner (excluding opinions) so that they may be sent to the principal investigator with minimal changes.

2. Any administrative comments will be added to the reviewer’s comments and then be sent to the principal investigator.

C. Protocols Requiring Full Committee Review (FCR)

1. Humane Category E protocols require review by the full Committee because of the high risk of unalleviated pain associated with these protocols. The Committee may request input from other individuals who may be able to assist in the review, but must protect the identity of the principal investigator from disclosure.

2. The Committee will decide on one of the four protocol designations, a) approve, b) withhold approval pending modifications, c) table for substantive changes, or d) disapprove.

3. A vote shall be taken and the minutes shall reflect the number voting for and against the decided upon designation. Those opposing approval of a protocol may submit a minority report. The minutes shall also reflect the discussion of the major issues presented by the protocol.

4. Category E protocols will not be considered if a veterinarian is not in attendance. Committee members submitting a written review and recommendation of a protocol who are not present at a meeting of the full committee will not be considered as a part of the quorum.

XII. Outcome of IACUC Review

A. “Approve as Submitted”

The Chair will inform the principal investigator of the IACUC’s approval. The investigator will be sent an approval notice indicating that animals may be ordered and the research or teaching covered by the protocol begun. The approval notice also includes additional information regarding the principal investigator’s responsibility in regard to modifications, re-approval and termination of the research.
B. “Withhold Approval Pending Modifications”

The IACUC Chair shall notify the principal investigator that the Committee requires minor clarification or modification of certain aspects of the protocol. Upon receipt of satisfactory clarifications or modifications from the principal investigator, the Chair can certify that the clarifications are adequate and proceed as in “Approve as Submitted.” After receiving the clarification, if the information is not adequate or raises new points requiring further minor clarification or modification, the Chair can request additional information from the principal investigator, or bring the investigator’s response to the full IACUC for review. Regardless of the nature of the clarifications or modifications requested, all clarifications or modifications must be incorporated into a revised protocol. This revised document will be the protocol of record. Only when approval has been given can animals be ordered and the animal research begun.

C. “Table for Substantive Changes”

This action requires approval by a majority of the IACUC convened in a regular meeting as described in the section entitled Conduct of Meetings and Quorum. The investigator shall be sent notice by the IACUC Chair describing the reasons for tabling the study and describing the revisions necessary for reconsideration by the IACUC.

D. “Disapprove as Submitted”

This action requires approval by a majority of the IACUC convened in a regular meeting as described in the section entitled Conduct of Meetings and Quorum. The investigator shall be sent notice by the Chair describing the reasons for disapproval. Disapproval of the protocol usually occurs when the IACUC determines that the risk(s) of the procedures outweighs any benefit to be gained. The investigator may discuss the review with the Chair and/or submit a revised protocol for re-review by the full IACUC.

XIII. Continuing Reviews

A. Yearly Re-approval

The IACUC requires that all research involving the care and use of covered species be reviewed annually, as long as the study continues. A reminder to apply for re-approval shall be sent to each principal investigator approximately six to eight weeks prior to the approval anniversary date. The investigator is responsible for making sure the yearly re-approval form is completed and returned to the IACUC Chair no later than two weeks before the expiration of the current protocol. If the protocol is not updated and approved by its anniversary date, it will be put on administrative hold, which means that no animal research will be allowed and no additional animals may be ordered or purchased.

Yearly review of annual reports is performed by the IACUC Chair or his/her designee.

1. Administrative Approvals by the Chair or designee may be performed if there are no changes in protocol, no adverse events, or changes are determined to be insignificant by the IACUC Chair. Such insignificant changes may include:
   i. A change in student assistant or student researcher
   ii. An increase in the number of animals used is less than 10 percent of the number listed in the original protocol.

2. If there are significant changes noted on the annual report, the annual report must be reviewed by the Committee following the review procedure for a new protocol. Designated Member Review (DMR) as well as Full Committee Review (FCR) will be used. The Committee, at its discretion may require an amended, revised, or new
protocol. Significant changes include:

i. Changes in experimental design
ii. Changes in experimental procedure.
iii. The inclusion of additional Principal Investigators on the protocol
iv. An increase in animal numbers in excess of 10 percent of that number listed in the original protocol.
v. Changes in reported levels of pain and distress, or other concerns of the IACUC chair regarding any other aspects of the annual review.

Investigators must notify the IACUC chair, via electronic mail and/or on the Annual Report Form, when a project is terminated.

B. Three-Year Review

Animal care and use activities are approved for a maximum period of three years and cannot be extended past the expiration date. If the activity is not completed before the end of three years, the principal investigator must submit a new proposal, indicating that it is a request for renewal. The renewal will be reviewed in the same way as a new proposal.

XIV. Other IACUC Actions

A. Suspension of Research or Teaching Activity

1. The IACUC may temporarily or permanently stop or suspend any activity that it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the Guide, the Law, the Institution’s Assurance or policies outlined in this publication. The IACUC may permanently suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present. A temporary suspension may be immediately imposed at the direction of the Chair, depending on the severity of the concern giving rise to the suspension. Any such temporary suspension will be reviewed by convened meeting of a quorum of the IACUC as soon as practicable.

2. If the IACUC suspends an activity involving animals, the Institutional Official in consultation with the IACUC shall review the reasons for the suspension, require that appropriate corrective action be taken, and forward a full explanation of the incident and resulting action to the Office of Laboratory Animal Welfare (OLAW), other funding agencies and the USDA as required.

3. Applications and protocols that have been approved by the IACUC may be subject to further appropriate review and approval by officials of Dickinson College. However, those officials may not approve those sections of an application or protocol related to the care and use of animals if they have not been approved by the IACUC.

B. Modifications to Approved Research

1. Modifications are changes to an approved IACUC protocol. Depending on the level of changes proposed, the modifications must be reviewed and approved by either the IACUC or its Chair prior to implementation by the principal investigator. The Chair will first determine whether the changes proposed are minor or of such significance as to merit review by the full IACUC (see below). Minor modifications may be reviewed and approved by the Chair or his/her designee. The decision of the Chair, or
designated reviewer, will be conveyed to the full IACUC at its next meeting. Major modifications must be reviewed and approved by the Committee. The modified protocol will become part of the protocol for the research project and shall become kept among the records maintained by the Committee.

2. Major modifications include, but are not limited to: the production of monoclonal antibodies in mice; changes in category from C to D, or D to E; changes which deviate considerably from the original procedures described by the investigator; changes in the genus used or a request for additional USDA covered animals which exceeding 10% of that approved by the IACUC for the protocol; changes from non-survival to survival surgery or from survival to multiple survival surgery must be referred to the full IACUC for review.

3. The principal investigator’s request for modification should include a complete description and justification of the modifications, and should be sent to the IACUC Chair via electronic mail as an addendum to a copy of the approved protocol.

4. Personnel Changes. It is the principal investigator’s responsibility to request or provide formal training for all personnel who handle animals. This includes students on short-term projects, and temporary as well as permanent employees. No one may work with animals until they have completed the required IACUC training and Occupational Health Risk Assessment and Training.

5. Animal Numbers. The number of animals approved in a protocol is considered to be the number of animals required for the research project. Additional animals are allowed only with the approval of the IACUC. The principal investigator is generally the most knowledgeable person regarding the consequences of his/her study on his/her animals, and is responsible for making an estimation of the numbers of animals in each Humane Use Category and reporting them to the IACUC. The principal investigator may request additional animals by providing adequate justification. Justification includes the reason for the additional animals and the number of additional animals required to complete the study. (See guidance on modifications above).

XV. Monitoring of Animal Care Program

The Dickinson College IACUC has approved the following mechanisms to provide periodic monitoring for compliance with IACUC policy for animal care:

A. IACUC Semiannual Inspections

It is the responsibility of the IACUC to inspect, at least once every six months all of the College’s animal facilities, satellite facilities, individual laboratories, and study areas using the standards in the Guide as the basis for evaluation. (Study areas are those sites where animals are maintained for more than 12 hours and/or are subject to USDA inspection.) A quorum of IACUC members and, ideally, a designee of the Institution’s Facilities Department and the Director of Environmental Health and Safety shall perform the inspections.

This group shall prepare a report of its evaluation, including any minority reports and all such reports shall be added to the next IACUC agenda for discussion. The report must then receive approval of the majority of the voting members of IACUC at a convened meeting. The IACUC Chair shall send letters to all parties (e.g. investigator, department chair, facilities management,
etc.) responsible for animal care informing them of any deficiencies and a deadline for correcting the deficiencies. The IACUC may shut down any facility immediately and for an indeterminate amount of time depending on the severity of the deficiencies. Conditions that seriously affect the health and well being of animals must be reported immediately to the IACUC Chair for action.

B. Investigator Review

The IACUC may ask an investigator to meet with the committee to discuss the review of his/her protocol or discuss compliance with any or all of the requirements of the IACUC.

C. Reminders

IACUC will promptly send notice to investigators who have approved protocols or who have protocols pending of any changes in policy or procedures. Other investigators will find changes to policy or procedure on the IACUC website.

XVI. Additional Considerations

A. Institutional Endorsement

Agencies, which fund research, require certification by an authorized Official of the Institution stating that research involving the care and use of animals as described in the application has been approved by the IACUC. The IACUC Chair will provide the sponsor with appropriate documentation of the IACUC approval. It is the investigator’s responsibility to insure that the description in the IACUC protocol covers all work proposed.

B. External Research

External research is that in which the animals will be housed and/or used at another institution but Dickinson College is to administer the sponsored project through grants or subcontracts. The principal investigator must submit to the IACUC Chair a cover letter, a copy of the protocol reviewed, and an approval letter from the Animal Care and Use Committee of the collaborating institution.

C. Research Involving Administration of Hazardous Materials

To comply with regulations of the US Nuclear Regulatory Commission for the use of radioactive materials, any protocol using radioactive substances in animals requires approval by the Radiation Safety Officer prior to final approval by the IACUC. To comply with both federal and state laws regulating hazardous substances, protocols that involve recombinant DNA, carcinogens, infectious, transmissible or toxic agents require the approval of the Institutional Biosafety Committee and/or the Radiation Safety Officer prior to final approval by the IACUC.

The principal investigator must:

- Submit one copy of the animal protocol to the Radiation Safety Officer for review.
- Receive written approval of the protocol from the Radiation Safety Officer.
- Submit to IACUC written approval of the protocol from the Radiation Safety Officer as part of the review process.
- Notify the attending veterinarian and the Radiation Safety Officer in writing prior to initiation of experimentation.
- Prepare, if required, a briefing statement outlining the hazards being used and any special husbandry and handling requirements. Conduct a briefing session about the hazards for animal care and other potentially exposed personnel using the briefing statement as a basis.
D. Use Of Appropriate Nomenclature When Identifying Research Animals

PHS guidelines require that some mechanism exist within funded institutions for informing investigators of the importance of using standardized nomenclature when identifying the animals they use in biomedical research. Accordingly, the purpose of this policy is to serve as the mechanism by which this information is relayed to all personnel involved in animal research at Dickinson College.

International committees have developed rules for standardized nomenclature of inbred mice, outbred rodents and rabbits. These widely accepted conventions permit accurate description of the animals used in research. Investigators are encouraged to use standard nomenclature conventions (found in supplier catalogs) to describe the genetic background of their experimental animals when placing animal orders, recording scientific data, and in publications. For animals obtained from commercial vendors, the strain (inbred animals) or stock (outbred animals) is that found in the breeder’s price list.
Appendix 1: Preparing Animal Use Protocols

Protocol Preparation

The protocol is the complete description of the research or training plan that involves the care and use of animals. In order to facilitate review, protocols must be prepared carefully and completely in accordance with IACUC Guidelines. The protocols become part of the records maintained by the Committee and are subject to inspection and review by various granting, accrediting and governmental agencies.

A departmental faculty sponsor must review any protocols written by students for completeness and accuracy before they may be submitted for review.

Investigator Certification Statement (Attached to IACUC Protocol)

- I certify that appropriate pain-relieving drugs have been or will be used throughout the entire study to relieve pain or distress whenever it occurs, including postoperative or post procedural care, unless specifically stated otherwise in this protocol.
- I further certify that the activities in this protocol do not unnecessarily duplicate previous experiments.
- I certify that all personnel performing any procedures on animals will receive the proper training and will participate in the training programs available. A description of this training and experience of personnel is provided in this protocol. Proof of such training for all personnel and myself will be provided to the Institutional Animal Care and Use Committee (IACUC) upon request.
- I am not using radioactive materials, infectious agents or other biologically hazardous materials in the animal facility other than those included in this protocol and approved by the appropriate committees.
- I agree to abide by the provisions of the National Research Council Guide for the Care and Use of Laboratory Animals, the Public Health Service Policy on Humane Care and Use of Laboratory Animal, and current United States Department of Agriculture animal care and use regulations.
- If I wish to change any of the procedures or personnel described in this protocol, I will request IACUC approval by submitting the details of the change(s) to the IACUC Chair via electronic mail. If requested, I will submit a new protocol.
- I understand that any failure to comply with the guidelines and requirements set down by the IACUC may result in suspension of my studies.

Review by the Attending Veterinarian

The attending veterinarian must review all category E protocols (those involving unrelieved pain or distress) and all Category D protocols for USDA covered species before the protocols are submitted.

The attending veterinarian shall notify the Chair and the principal investigator, via electronic mail, that he or she has reviewed such protocols, and in the same message will provide the investigator and Chair with any suggestions or recommendations for modifications.

If the principal investigator disagrees with the veterinary recommendations, he or she may forward the protocol to the IACUC for review along with the veterinarian’s recommendations and a statement by the principal investigator regarding his/her reasons for disagreeing with the veterinary recommendations.
Appendix 2 Mistreatment of Animals and Deficiencies in Their Care

IACUC Policy for Review and Investigation of Animal Welfare Concerns (“Whistle Blower”)

Dickinson College requires that the care, use, and treatment of College-owned laboratory animals must be of high quality and in compliance with all applicable laws and regulations. It is important that all persons involved or in any way associated with the use of animals in research know how to report deficiencies in animal care and treatment. There are no restrictions on who at Dickinson can report an alleged incident. Anyone associated with Dickinson College who has knowledge of a deficiency is obligated to report it to College officials. Under no circumstances will good faith reporting of such incidences be detrimental to an individual’s employment or position within Dickinson College.

The definition of animal mistreatment and deficiencies in care include the abusive physical or psychological treatment of an animal and non-compliance with established procedures, policies or protocols.

Background

Congress amended the Animal Welfare Act (AWA) in 1985 in Public Law 99-198. The Secretary of Agriculture was directed to promulgate new rules governing the humane handling, care, and treatment, and transportation of animals by dealers, research facilities, and exhibitors. A requirement under the AWA is that the IACUC, as an agent for the research facility, “review and if warranted, investigate concerns involving the care and use of animals at the research facility resulting from public complaints received and from reports of noncompliance received from laboratory or research facility personnel or employees from reports of noncompliance received from laboratory or research facility personnel or employees [Federal Register Vol. 54, No. 168, Thursday, August 31, 1989, final rule 2.31[e][4]:p. 36152]. “The research facility must maintain documentation of the Committee’s reviews and investigations conducted in response to complaints received in order to demonstrate its compliance with these regulations”. The research facility determines the form and method of such documentation [ibid. p. 36128].

Reporting

It is the responsibility of the IACUC to investigate complaints or concerns about the animal care and use program.

Concerns involving the care and use of animals at Dickinson College may be reported to the Institutional Official or to a member of the IACUC by any employee of the College or any person having official business with the institution. Complaints may be handled in a confidential or anonymous manner if requested by the originator. Should any valid concerns of reprisal be involved, they will be discussed with the Institutional Official, and a report of the pertinent concerns and actions will be submitted to OLAW.

Procedures

The Chair will decide on a case-by-case basis how to proceed based upon the content and context of the complaint or concern. The Chair will ultimately report to the full committee and the Institutional Official any formal complaints. The results of any IACUC investigation shall be reported to Institutional Official. The Institutional Official will provide required reports to funding agencies, OLAW, or the USDA, as appropriate.
Appendix 3: Animal Transfer, Disposition and Euthanasia Policy

The College is committed to minimizing the number of animals needed to satisfactorily conduct its teaching and research activities, while being in full compliance with applicable federal, state, and local laws and regulations. The policy that follows indicates methods for the transfer or disposition of animals, for the disposal of the remains of those requiring euthanasia, and the commitments stated in the Assurance for the euthanasia of animals.

A. Animal Transfers

1. Requests for transfers of animals will be evaluated by the IACUC attending veterinarian may be allowed on a limited, local, case-by-case basis. The following conditions must be met to allow a transfer:
   a) Approval of the attending veterinarian has been secured.
   b) Both sending and receiving IACUC’s have approved the transfer, documentation of which will be retained by the Dickinson IACUC.
   c) Animals may be transferred within a 200 mile radius of Dickinson College.
   d) Animals, if transported by vehicle, must be in the passenger compartment to assure temperature control appropriate to the animal being transferred.
   e) Animals and containers must be packed to avoid injury to the animal.

2. The attending veterinarian will report all such recommendations to the full IACUC at its next meeting.

B. Disposition of organs and tissues

1. Requests for the disposition of animals and their organs and tissues will be evaluated by the IACUC attending veterinarian on a case-by-case basis. The attending veterinarian will report all such recommendations to the full IACUC at its next meeting.

2. Animals that will not be transferred to another approved project will be killed humanely. All animal remains will be disposed of in accordance with local, state and federal laws and regulations.

C. Euthanasia

1. The investigator in charge of the research or teaching protocol, or a qualified designee, shall use only those methods that are recommended and as approved in the protocol by the IACUC.

2. If animals are suffering pain and/or distress exceeding that described in the IACUC approved protocol, they may require euthanasia, which will be performed by the attending veterinarian or a qualified designee, in the absence of the principal investigator. Normally, the IACUC Chair or attending veterinarian will attempt to contact the investigator prior to humanely killing the animal.
Appendix 4: Animal Use and Handling Training Program

Required Training

Any new employee of Dickinson College involved in animal care and use will undergo training prior to beginning her or his duties. The employee's supervisor is primarily responsible for providing this training and for keeping documentation that it has been completed. The content of this training will be reviewed by the IACUC as part of program review. The training will cover each of the following:

- Regulations of the Animal Welfare Act, 9 CFR Section 2.32. and the most recent editions of the Guide and the PHS Policy on Humane Care and Use of Laboratory Animals.
- The training will include instruction/information on research methods that minimize the numbers of animals required to obtain valid results and methods that limit animal pain and distress.
- The employee’s supervisor will provide general training on handling and use of animals. The employee or supervisor may request additional training by the attending veterinarian or the animal care staff.
- Activity-specific training will be provided for individuals in each animal use project. The training will include handling and technical procedures including administration of test substances, use of anesthetics-analgesics-tranquillizers, and sample collection.

Required training for change of species or manipulation

Before any new species, procedures or major change in existing procedures is introduced into a facility or animal activity, all employees caring for or handling the new species or carrying out the procedure will be appropriately trained. The attending veterinarian, supervisor or principal investigator will provide appropriate training. It will be the responsibility of the principle investigator or supervisor to assure and document that the support staff are adequately trained.

Continuing education

It is the responsibility of each principle investigator and supervisor working with laboratory animals to acquire current information in the care and handling of the animals and to update the research technicians and animal care staff accordingly. The Dickinson College Director of Environmental Health and Safety and the attending veterinarian are institutional resources for current technical information and for changes in compliance guidelines or regulations.

Assurance of orientation and training

Each animal activity protocol will include a statement through which the supervisor assures the IACUC in writing that the required orientation and training, including familiarity with the Guide and PHS Policy, were provided prior to initiation of the protocol and that the supervisor will continually acquire current information relevant to the protocol as it becomes available and will provide training as appropriate.
Appendix 5: Occupational Health and Safety Program (OHSP)

Administrative responsibility and policies:

a. The OHSP for personnel who work in the animal facilities or who have frequent contact with animals is under the direction of the Dickinson College Director of Enterprise Risk Management.

b. The Dickinson College Director of Enterprise Risk Management is responsible for management of the OHSP for persons involved in animal care or use. This includes animal care staff and faculty who have frequent or substantial contact with animals. The OHSP elements for immunizations, containment practices, facilities and the use of personal protective equipment are based upon (at a minimum) precautions and guidelines as outlined in the CDC-NIH publication “Biosafety in Microbiological and Biomedical Laboratories.” The elements of the OHSP are based upon the NRC Publication “Occupational Health and Safety in the Care and Use of Research Animals.”

c. All persons who have frequent or substantial contact with animals or who work in animal facilities at least 50% of the time will be subject to participation in the institutional OHSP.

d. The OHSP will also be available on a voluntary basis to any individual employed by the institution who spends a minimal amount of time working with animals or who has only minimal contact with the animals covered by this policy.

e. Personnel are informed of the OHSP through their direct supervisor, and those with frequent or substantial exposure to research animals are provided a health survey/history to complete and return to Dickinson College’s contracted occupational health provider.

f. The OHSP will be provided at no cost to the employee

OHSP elements for new employees:

- informed of the availability and benefits of the OHSP
- medical history taken
- tetanus immunization administered (if not within ten years previous)
- incident and record file established
- safety orientation by the supervisor
- training on the use of personal protective equipment and hygiene

Annual employee OHSP review elements:

- update of the history profile with appropriate actions taken based on the updated information

Incident reports and emergency care:

- emergency care provided
- department chair notified immediately of the incident, i.e. bite wound or sharps injury
- file incident report as soon as possible (preferably within 24 hours) with the Office of Human Resource Services and the Director of Environmental Health and Safety
- notify the Office of Human Resource Services and the Director of Environmental Health and Safety before returning to work

Health surveillance records:

- work assignments/areas
- incidents such as bite wounds or injury from sharps or chemicals
- work related injury or illness
- records reviewed by the IACUC

The immediate supervisors of personnel subject to this OHSP are responsible for training the employee in each of the following:

- the identification of hazards and assessment/reduction of risks
- hygiene and use of personal protective equipment
- precautions for allergies, pregnancy, immunosuppression, other host factors
- emergency and first aid
Appendix 6: Live or Dead Wild Mammals at Dickinson

A. “A protocol shall be submitted to the institutional biosafety committee for all classroom activities, research or other work associated with living or dead wild animals.”

B. Dickinson does not have a USDA license, and therefore is unable to use wild-caught or farm species in research. Under specific, narrowly defined circumstances, a protocol for observational “field studies” of wild animals may be reviewed by the IACUC.

C. Wild mammals can harbor infectious microbes and insects that may infect research animals. In order to protect the health of Dickinson’s research animal colonies, faculty, students and staff must adhere to the procedures outlined below.

- Wild mammals (live or dead), particularly rodents, are not allowed in Dickinson’s vivarium under any circumstance.

- You may not enter Dickinson’s vivarium if you have been working with live or dead wild animals or rodents. Your clothing may harbor infectious agents or insects.

- You may not wear a lab coat in the animal facilities if it has been used while handling live or dead wild animals including rodents. The lab coat could be contaminated.

- Transportation, storage and disposal of dead animals:
  - Dead animals must be transported in sealed plastic bags or a leak proof container.
  - Dead animals must be placed in a sealed plastic bag or leak proof container and stored frozen in a laboratory (not vivarium) freezer.
  - Contact the Environmental Health and Safety Officer to assist in making appropriate arrangements for storage, pick up, and disposal of the carcasses.
Appendix 7: Exportation of Animals to Other Institutions

Rodents owned by Dickinson College can only be shipped to another institution that has assurance of an appropriate animal care and use program. Dickinson’s IACUC will determine the suitability of the recipient institution.

Procedures

A. Dickinson Investigators

1. Ensure that the option to transfer animals to other institutions is included in applicable Dickinson Animal Care and Use protocols.
2. Fill out the form for Record of Animal Exportation in conjunction with the receiving institution. This form is available on the IACUC website.
3. Notify the vivarium technician that a request has been made to send rodents from Dickinson to another institution, and give the current housing location of the rodents to be shipped.
4. The receiving institution will pay for the shipment and necessary shipping materials.

B. Receiving Institutions

1. Contact Dickinson’s IACUC Chair to acquire, complete, and submit form “Record of Animal Exportation”
2. Fax or e-mail a copy of the receiving institution’s IACUC (or equivalent committee) Approval Letter, for the protocol that rodents will be transferred to, to the vivarium technician.

C. Approved Institutions

1. AAALAC International-accredited Institutions
   - Upon receipt of the form “Record of Animal Exportation” and an active protocol approval letter, animals may be exported to the receiving institution.
2. Canadian Council on Animal Care (CCAC) Institutions
   - Institutions which hold the CCAC Certificate of Good Animal Practice may receive animals upon receipt of an active protocol approval letter and form “Record of Animal Exportation.”
3. Institutions within European Union countries:
   - Institutions within these member countries may receive animals upon receipt of an active protocol approval letter and form for Record of Animal Exportation

D. Other institutions

1. Dickinson’s IACUC will decide on a case-by-case basis if shipment can be approved based upon proof of adequate animal care and protocol oversight.
2. Such proof may include a description of the research paradigm for the animals being exported, a letter of protocol approval, a description of the animal care and use program (including type of housing and surveillance program for pathogens), and evidence of program oversight by qualified personnel.
INSTITUTIONAL REVIEW BOARD
STANDARD OPERATING PROCEDURES
DICKINSON COLLEGE

I. Institutional Review Board’s Mandate to Protect Human Subjects
II. Applicability
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Appendix A: Protocol Submission Requirements
Appendix B: Continuing Review Submission Requirements
Appendix C: Discussion of Criteria for “Excluded from Review” Status
Appendix D: Criteria for Exemption Status
Appendix E: Criteria for Expedited Review
I. The Institutional Review Board's Mandate to Protect Human Subjects.

Dickinson College shall establish and maintain an Institutional Review Board (IRB) to promote the protection of the rights and welfare of human research subjects in accordance with federal regulations (45CFR Part 46 and 21CFR Part 56). The IRB performs prospective and continuing review of protocols, the informed consent process and the procedures utilized to enroll subjects in order to ensure that the human subject research is conducted ethically and in compliance with the Belmont Report, and with applicable federal, state, local and institutional requirements.

The Dickinson College IRB will apply only those standards contained within the federal regulations which reflect the principles articulated in the Belmont Report. The IRB will not apply any more stringent standards to the review of research involving human subjects unless specifically directed to do so by College policy approved by the appropriate faculty governance bodies.

Consistent with the federal regulations, decisions by the IRB to disapprove research may not be appealed to any authority outside the IRB. In all instances, to the best of its abilities, the IRB will work with investigators to revise protocols that are not approved so as to meet the standards set forth in the regulations. On the other hand, approval of research by the IRB does not guarantee permission to conduct any particular research project. IRB approval does not override other College policies or authorities.

II. Applicability

Federal regulations delegate the right solely to the IRB to determine what must be reviewed. All research involving human subjects conducted by College employees or students at Dickinson or outside of the College in their capacity as an employee/student is subject to prospective review and approval by the IRB and may not proceed without it, unless specifically exempted or determined to be excluded from review by the IRB.

Appendix C provides a discussion of scholarship and project types that are specifically excluded from IRB review because they are not the kind of research governed by federal regulations. Questions about whether research is excluded from IRB review should be directed to the IRB chair. These IRB standard operating procedures apply to social and/or behavioral research only. They are not designed to cover human subject research that involves biomedical or clinical research or invasive procedures.

III. IRB Administration.

A. Delegation of Authority. The president of the College has the option to delegate to the chief academic officer the responsibilities of a) appointing the IRB chair and IRB members, and b) providing oversight to the IRB.

1 http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

2 If you plan to conduct such research contact the IRB chair so special arrangements for reviewing your research can be made.

3 Dickinson’s president has delegated authority for both responsibilities to the chief academic officer.
B. Responsibilities. The IRB will report to the chief academic officer. The chief academic officer will provide sufficient resources for the efficient conduct of IRB business, including an administrative staff person to serve as Administrative Liaison. The Administrative Liaison’s duties include: 1) assisting in the development and implementation of procedures to ensure the efficient flow of all IRB records; 2) maintaining documentation and records in accordance with federal regulatory requirements; 3) tracking records and the progress of all studies; and 4) ensuring meetings are conducted according to federal regulations, i.e., recording attendance and preparing and distributing materials for meetings. The Administrative Liaison will attend all IRB meetings, and will report informally to the IRB Chair, and formally to the chief academic officer.

IV. IRB Membership.

The IRB will have sufficient expertise to review the broad variety of research in which the College becomes involved, will be knowledgeable about all relevant regulatory requirements and will make every effort to be impartial and objective in its review (45 CFR 46.107(a) and 21 CFR 56.107(a)).

A. Appointment of IRB Chair, Length of Service and Duties. The IRB chair shall be appointed by the chief academic officer for a term of three years. In addition to the responsibilities of IRB membership, the chair has primary responsibility for conducting IRB meetings and directing the IRB staff to ensure operation of the IRB within all applicable regulatory requirements. The IRB chair works with members and investigators to ensure that the rights and welfare of research subjects are adequately protected. The chair shall sign all official IRB correspondence, unless otherwise indicated, and shall report directly to the chief academic officer.

B. Appointment of IRB Members, Length of Service and Duties. The chief academic officer will appoint members to the IRB for a term of three years, typically in consultation with current and past members. Members are responsible for ensuring that the rights and welfare of research subjects are protected. Members vote to approve, require modifications in, disapprove, or table protocols. Members are expected to attend IRB meetings on a regular basis, serve as primary reviewers for research within their expertise, and serve as general reviewers on all research discussed at convened meetings. The IRB chair may designate members of the IRB to review non-research, exempt, and expedited review protocols. A vice-chair may be appointed by the chief academic officer to manage committee business in the event that the chair has a conflict of interest.

C. IRB Membership Requirements. In accordance with the compositional requirements of section 46.107 of 45CFR46, the membership shall be composed of at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted at Dickinson. The IRB shall include at least one member whose primary concerns are in nonscientific areas, and one person who is not currently affiliated with Dickinson and is not part of the immediate family of a person who is currently affiliated with the College. Members will be drawn from diverse backgrounds including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The IRB may, in its discretion, invite individuals with relevant competence to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote.
D. **Specific Duties.** The IRB is responsible for developing procedures for submitting research protocols for review, determining if research protocols are in conformity with the federal regulations with regard to use of human subjects in research, reviewing approved research projects on a continuing basis (at a minimum of once a year), reporting to the chief academic of the College any serious or continuing noncompliance by investigators with the conditions outlined in the project as approved, and reporting to the Secretary of Health and Human Services any serious or continuing noncompliance by investigators who are funded by the Department of Health and Human Services.

E. **Conflict of Interest.** No IRB member may participate in the IRB’s initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. Conflicts of interest include, but may not be limited to, the following:

1. The IRB member is currently engaged, or expects to be engaged, in the human subjects research project under review, as defined in the *(45CFR Part 46 and 21CFR Part 56).*
2. The IRB member has a direct financial interest in the principal investigator or the entity funding the research proposed by the principal investigator, as defined by the College and/or federal regulations.
3. The IRB member and the principal investigator of the application under consideration share an immediate (rather than extended) familial relationship.
4. The IRB member has other reasons to feel that he-she cannot render an independent assessment of an application.

The IRB member shall disclose the conflict of interest at the following time(s):

1. When the IRB member is contacted to participate in the review of a project from a principal investigator with whom the IRB member has a conflict of interest.
2. Prior to the discussion at a convened meeting of a project for which the IRB member has a conflict of interest.
3. Immediately upon discovery of the conflict of interest if at other than the foregoing times.

The members of the IRB retain the right to question other IRB members regarding their potential conflicts of interest at the time of protocol submission, and bring discussions of such potential conflicts forward to the committee as a whole.

F. **Initial Training, Continuing Education, and Professional Development of IRB Members.** IRB members shall receive a copy of these IRB standard operating procedures to review research from an ethical and regulatory perspective. In addition, all IRB members must complete the initial educational module(s) on human subjects research that is available through the Collaborative Institutional Training Initiative (CITI) online training. Specific information on these resources will be made available by the Administrative Liaison on the IRB website. Members are expected to become familiar with the federal regulations and *Belmont Report.*

G. **Compensation of IRB Members.** IRB members are provided with a token honorarium for their service on the IRB.

1. Faculty members may elect to a) be exempt from other committee service for the duration of IRB service, b) receive a small stipend of $1000.00 for each year of service on the board.
2. A member of the IRB that is not affiliated with the College is compensated at the rate of $100 per meeting plus $300 per semester in which protocols are reviewed by the community member.
V. IRB Meetings

A. Schedule. Meetings will be convened at the call of the chair when the chair judges the meeting to be necessary or advantageous, or upon the receipt of a joint written request of three or more members. The IRB should meet no less than two times per year. It is within the discretion of the IRB chair to cancel or add a meeting in the event there is no business or additional business to conduct.

B. Quorum. The IRB will abide by meeting quorum requirements as stated in 45 CFR 46.108(b). A majority of the membership, including at least one member whose primary concerns are in nonscientific areas, and one person who is not currently affiliated with the institution, shall constitute a quorum and is required in order to convene a meeting for the review of research protocols. Members may be present in person or audio (telephone) or interactive teleconference. Members present via teleconference shall be noted as such in the meeting minutes, which shall also indicate that the members received all pertinent information prior to the meeting and were able to actively and equally participate in all discussions.

C. Procedure. All convened IRB meetings shall be conducted under and pursuant to Robert's Rules of Order. For a research protocol to be approved it must receive the approval of a majority of those members present at the convened meeting. At a convened IRB meeting, any member may request that an activity that has been approved under the expedited procedure be reviewed by the IRB in accordance with non-expedited procedures. A vote of the members shall be taken concerning the request and the majority shall decide the issue. In cases where research activities were initially approved under expedited procedures and subsequently reviewed by non-expedited procedures, the decisions reached at the convened meeting shall supersede any decisions made through the expedited review.

VI. Substance of IRB Review

A. Principal investigators’ Submission to IRB. All research studies involving human subjects must be submitted for IRB review by the principal investigator. Submissions should be made through the online system using the IRB submission template form. This form includes all submission requirements (see appendix A for submission requirements). The principal investigator must request either exemption from IRB review, expedited review, or full board review.

B. IRB Review and Approval of Research

1. Initial Review and Categorization of Study: The chair or the chair’s designee will review the submitted protocol and determine its status for IRB review (non-research, exempt, expedited review or full board review). Unless the protocol is categorized as exempt from IRB review under 45 CFR 46.101(b) (and described in appendix D), or does not meet the criteria for human subjects research (45 CFR 46.102(d) and (f)), all human subjects research must be prospectively reviewed and approved by the IRB. For those studies that qualify as exempt or do not meet the criteria for human subjects research, the chair or the chair’s designee(s) from the IRB membership will designate the study as such and notify the principal investigator and the chair. The IRB chair or the chair’s…

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4 This includes faculty principal investigators, as well as students who are submitting protocols.
designee(s) from the IRB membership may deem a protocol exempt after obtaining enough information from the investigator to determine whether the claimed exemption applies. Prior to each IRB meeting, the chair will provide the IRB members a description of all protocols that have been deemed exempt since the last IRB meeting. No action on the exempt protocols is required by the IRB members, although they can read exempt proposals and raise concerns. (No continuing reviews or renewals are required for exempt or non-research protocols.)

2. **Expedited Review Procedure:** For studies determined to be eligible for expedited review, the chair or the chair’s designee(s) from the IRB membership will review the proposed research and determine if the criteria for expedited review as described in the federal regulations ([56 FR 28012, 28022 June 18, 1991, as amended at 70 FR36328, June 23, 2005] and included in appendix E) have been met. If so, the Administrative Liaison will ensure that the principal investigator has submitted all the required materials and the chair will then review the proposed research and assess whether the study should be approved by expedited review according to the criteria for IRB approval of research (section V-C). A proposal cannot be disapproved through the expedited review procedure. A decision to approve a proposal through the expedited review procedure will be communicated in writing to the principal investigator, to the IRB members, and to the chief academic officer. IRB members will review the protocol and approval decision and alert the Chair if there is a question or potential issue of concern before or at the next scheduled meeting. Approved protocols are approved for a period of up to one year as determined by the IRB at the time of approval. Approved protocols will also require submission of a continuing review report at the completion of the study or within one year of approval date, whichever comes first (described in Appendix B, and reviewed in section V-B4).

3. **Full Review Procedure:** For non-exempt studies that do not meet the criteria for Expedited Review or if expedited approval is not given, then the protocol must go to the IRB for full board review. The Administrative Liaison will ensure that the principal investigator has submitted all the required materials, and will add this protocol to the agenda of the next meeting. The IRB members will review the proposed research in preparation for discussion at the next meeting. The proposal is discussed at the meeting, and a majority vote from all present members is required for approval. The chair will notify the principal investigator and the chief academic officer in writing of the IRB’s approval, conditional approval pending minor changes, need for major changes before review, tabling, or disapproval (with explanation). Approved protocols are approved for a period of up to one year as determined by the IRB. Approved protocols will also require submission of continuing review at the completion of the study or within one year of approval date, whichever comes first (described in appendix B, and reviewed in section VI-B4).

4. **Continuing/Annual Review:** The IRB is required to conduct substantive and meaningful continuing review of research. Such reviews shall be conducted at intervals appropriate to the degree of risk of the project, but not less than once per year. (See Appendix B.) The IRB requires that the principal investigator submit a continuing review report within the time period approved. The IRB
chair shall review the protocol file at the time of the continuing review. The IRB may observe or have a third party observe the consent process and the research per 45 CFR 46.109. The principal investigator indicates on the continuing review report if he or she is requesting continuation of the proposal for up to one more year or is terminating the protocol. Where the IRB determines that the project involves a high risk to the welfare or safety of subjects, it will require review more often than annually and will notify the investigator and the chief academic officer of the schedule for review. This must be done before approval has expired. The chair can approve continuation of research originally approved by expedited review. Approval is discussed at the next meeting and can be affirmed or rescinded. All other continuing reviews must be reviewed by the full board.

5. Suspension/Termination: The IRB has authority to suspend or terminate approval of research that is not being conducted in accordance with its requirements or that has been associated with unexpected serious harm to subjects. When approval is suspended or terminated, the IRB will provide a written statement of its action and the reasons for its action to the investigator and the chief academic officer. (45 CFR 46.113)

C. Criteria for IRB Approval of Research. In order to approve any proposed research to be conducted at the College, the IRB shall determine that all of the following requirements of 45 CFR 46.111(a) (1-7) are satisfied, as quoted below in italics.

(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied

(1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject’s legally authorized representative, in accordance with, and to the extent required by § 46.116.

1. To satisfy the requirements of 45 CFR 46.116, the following information will be provided to each subject:
a. A statement that the study involves research, an explanation of the purposes of the research the expected duration of the subject's participation, a description of the procedures to be followed and identification of any procedures which are experimental;
b. A description of any reasonably foreseeable risks or discomforts to the subject;
c. A description of any benefits to the subject or to others which may reasonably be expected from the research;
d. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
e. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
f. For research involving more than minimal risk, an explanation as to whether any compensation and/or medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
g. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights and whom to contact in the event of a research-related injury to the subject; and
h. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled.

2. When appropriate, one or more of the following elements of information shall also be provided to each subject:

a. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable; Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
b. Any additional costs to the subject that may result from participation in the research; The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
c. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
d. The approximate number of subjects involved in the study.

3. The IRB may approve a consent procedure that does not include or alters some or all of the elements of informed consent set forth in this section. The IRB may waive the requirements to obtain informed consent, provided the IRB finds and documents that all the conditions below are met:

a. The research involves no more than minimal risk to the subjects;
b. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
c. The research could not practicably be carried out without the waiver or alteration;
d. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by § 46.117.

1. To satisfy the requirements of 45 CFR 46.117, the consent form may be either of the following:

   a. A written consent document that embodies the elements of informed consent stated above. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator should give either the subject or the representative adequate opportunity to read the document before it is signed; or

   b. A short form written consent document stating that the elements of informed consent as noted above have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

2. The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects, if it finds either:

   a. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

   b. That the research presents no more than minimal risk of harm to subjects, and involves no procedures, for which written consent is normally required outside of the research context.

3. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

   (b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or
educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

D. Actions Taken at Convened Meeting. IRB actions for initial or continuing review of research will include the following:

1. **Approved** with no changes or no additional changes. The research may proceed.
2. **Approved with minor changes** that are clearly delineated by the IRB so the investigator may simply concur with the IRB's revisions. The research may proceed after the required changes are made and verified by the chair.
3. **Tabled.** Tabled research applications are approvable but require substantive changes or additional substantive information that must be reviewed at a subsequent convened subsequent meeting of the IRB. The research may proceed only after the convened IRB meeting has reviewed and approved the required changes to the research or the information provided.
4. **Not Approved.** The IRB has determined that the research, as submitted, may not be conducted by the investigator(s). If the IRB disapproves a research protocol, it shall include in its written notification a statement of the reasons for its decision and afford the investigator an opportunity to respond in person or in writing.

VII. IRB Record Keeping and Required Documentation.

A. **IRB Records.** Federal regulations require that the IRB retain all records for at least three years and retain records relating to research for at least three years after the termination of the research protocol. All IRB records shall be kept in a secure place. Access to IRB records shall be limited to the IRB chair, the administrative staff of the IRB, the IRB members, and officials of federal and state agencies. IRB records will include the following:
   1. IRB policies or standard operating procedures (SOP)
   2. IRB membership roster
   3. Curriculum vitae for IRB members
   4. Record of certification of human subjects training for IRB members and principal investigators when required by federal grant or IRB.
   5. IRB research application files for all submitted protocols, including all required documentation, continuing review reports, and correspondence.
   6. Minutes of the convened IRB meetings

The Administrative Liaison shall ensure that a current IRB membership roster is maintained pursuant to 45 CFR 46.103(b)(3).

B. **Contents of Minutes.** The minutes of IRB meetings shall be compiled by the approved by the IRB. The following specific information shall be included in the minutes:
   1. Attendees by name, absent members, alternate members and the name of the person for whom they are the alternate, consultants, invited investigators and guests, and whether quorum requirements have been met. Members present via teleconference shall be noted as such in the meeting minutes.
   2. Actions taken by the IRB on new and continuation applications; review of protocol and informed consent modifications or amendments; protocol deviations; adverse event reports; reports from sponsors; waiver or alteration of elements of informed consent; suspensions or terminations of research; and other actions. Votes on these actions are categorized as "for", "against" and "abstain". The basis for requiring changes in or disapproving research shall be noted.
3. A list of research approved since the last meeting utilizing expedited review procedures and specific citation for the category of expedited review of the individual protocol, as well as a list of exempt and non-research protocols.


5. Members who absented themselves by name, name of protocol and reason for the conflict.

VIII. Additional Considerations.

A. Certificates of Confidentiality. The IRB may determine that special protections are needed to protect subjects from the risks of investigative or judicial processes in research projects that include the collection of highly sensitive information about individually identifiable subjects necessary to achieve the research objectives. Research will be considered sensitive if it involves the collection of information in any of the following categories:

1. Information relating to sexual attitudes, preferences or practices;
2. Information relating to the use of alcohol, drugs or other addictive products;
3. Information relating to illegal conduct;
4. Information that if released could reasonably be damaging to an individual's financial standing, employability or reputation within the community; Information that would normally be recorded in a patient's medical record and the disclosure of which could reasonably lead to social stigmatization or discrimination;
5. Information pertaining to an individual's psychological well-being or mental health.

For such sensitive information the IRB may require that the investigator obtain a certificate of confidentiality from the Department of Health and Human Services. Federal funding is not a prerequisite to a determination such that a certificate of confidentiality is necessary. The purpose of the certificate of confidentiality is to protect against any involuntary release of sensitive information about individual subjects for use in federal, state or local civil, criminal, administrative or other legal proceedings. The certificate does not prohibit the disclosure of information by an investigator including, but not limited to, child abuse or a communicable disease. The investigator must detail in the informed consent document what information will and will not be protected by the certificate of confidentiality.

B. Reporting Unanticipated Problems and Adverse Events. Any adverse events or unanticipated problems involving subjects of any IRB-approved study must be reported to the IRB as soon as possible, but no later than thirty days from the event’s occurrence. Deaths or other serious adverse events should be reported to the IRB as soon as possible, but no later than five days after the event’s occurrence. If an adverse event occurs at a study site other than the College, the principal investigator must promptly notify all IRBs governing the protocol.

C. Review of Standard Operating Procedures (SOP). The IRB shall review the IRB SOP at a minimum of every five years. Recommended revisions to the SOP will be discussed and decided on by the full IRB.

D. Protocol Amendments. If a principal investigator would like to make a change to an already approved protocol or exempt protocol, he or she can submit an amendment to the protocol through the online system. Minor changes can be reviewed and approved by the chair, and discussed at the next meeting. Major changes are typically referred to the full IRB for
discussion and action at the next meeting. No investigator may make changes to a protocol prior to IRB approval.

IX. Consultants to IRB (Departmental Reviewers and Faculty Mentors)

The IRB may engage individuals to pre-review protocols for the IRB. These individuals will come from the ranks of the Dickinson faculty and may have varying backgrounds to promote complete and adequate review of research activities commonly conducted at Dickinson.

A. Appointment of IRB consultants. Length of Service. The IRB Chair shall informally ask members from various academic departments to serve on an annual basis. Terms of service are flexible (at least one semester) and may change depending on the faculty member’s workload, sabbatical, or extenuating circumstances.

B. Specific Duties. There are two categories of consultants.

a. Departmental reviewers will serve as points of contact for members of their department who need assistance in preparing IRB protocols. Departmental reviewers will have access to the online protocol submission system and have the responsibility of pre-reviewing protocols for completeness and appropriateness prior to IRB review. They may, upon request, provide a non-official and non-binding opinion and advice to those submitting protocols, as well as to the IRB.

Departmental reviewers are generally selected from the academic departments from which most faculty and student protocols originate. This may include (but is not limited to):

- Anthropology
- Education
- International Business and & Management
- Languages
- Psychology
- Sociology

b. Faculty supervisors will serve as points of contact for the students in their courses who need assistance in preparing IRB protocols. Faculty supervisors will have access to the online protocol submission system and have the responsibility of pre-reviewing student protocols for completeness and appropriateness prior to IRB review. They may, upon request, provide non-official and non-binding opinion and advice to those submitting protocols, as well as to the IRB.

Neither category of consultant may vote on IRB issues.

C. Initial Training, Continuing Education, and Professional Development of IRB Consultants. IRB consultants shall receive a copy of these IRB standard operating procedures to review research from an ethical and regulatory perspective. In addition, all IRB consultants must complete the initial educational module(s) on human subjects research that is available through the Collaborative Institutional Training Initiative (CITI) online training. Specific information on these resources will be made available by the Administrative Liaison on the IRB website. Members are expected to become familiar with the federal regulations and the Belmont Report.

D. Compensation of IRB Consultants. IRB consultants are not compensated.
Appendix A – Protocol Submission Requirements

The online system provides a template for protocol submission, the IRB Membership List, Federal
Regulations and Mandatory Education information⁵. Requested information includes the following:

- Name of P.I. and co-P.I.s
- Project title
- Purpose of study
- Background
- Location of study
- Duration of project
- Research plan
- Statistical considerations
- Incentives for subjects
- Subject population
- Potential risks & benefits to subjects
- Description of informed consent
- Confidentiality and data security
- Funding source
- Requested review type
- If applicable, copies of all data collection tools, questionnaires, interview/survey forms,
  assessment materials, and descriptions of materials that subjects will encounter.
- If applicable, advertisement(s) for subject recruitment. If the forms of advertisement for
  recruitment contain more than the title, purpose of the study, protocol summary, basic eligibility
  criteria, study site location(s), and how to contact the study site for further information, they must
  be submitted to and approved by the IRB prior to distribution or publication of the material.
- If applicable, documentation of training in the protection of human research subjects, and
  curriculum vitae for each investigator listed on the application.
- If applicable, a Conflict of Interest form for each investigator listed on the application (see note
  below).
- If applicable, a Request for Access to Protected Health Information for a Research Purpose and/or
  Research Authorization Form (see note below).

⁵ HIPAA regulations and forms, conflict of interest forms, request for access to protected health information for a
research purpose form and/or research authorization form will be available offline from the IRB Chair or
Administrator.
Appendix B – Continuing/Annual Review Submission Requirements
(Request for Termination or Continuation)

All protocols approved by Expedited or Full IRB review are required to have a continuing review submitted by the principal investigator four weeks prior to the end of the one-year approval period. The PI will be prompted for this information through the online system, and the continuing review information can be submitted through this system. Requested information includes:

- Total # Subjects Enrolled Since Last Continuing Review
- Total # Subjects Enrolled in Study to Date
- Total # Subjects Who Have Died
- Total # Subjects Who Have Completed Study
- Total # Subjects Still Active
- Request for permission to continue and reason, or termination
- Unforeseen/Adverse Events (and describe)
Appendix C– Discussion of Criteria for Excluded from Review Status

In general, scholarly research that involves human subjects falls under the oversight of the IRB. However, there are exceptions to this blanket statement. Some scholarship that involves human subjects may, nonetheless, fall entirely outside the oversight of the IRB. The IRB refers to this scholarship as “excluded”, and it does not need to be seen by the IRB. The diagnostic protocol survey on the IRB Mentor online system, a departmental reviewer, or the IRB chair can help you determine whether a given project might fall under IRB oversight.

Grounds for Exclusion: Defining “Research” for Regulatory Purposes

Generally, three common types of study will be excluded from IRB oversight:

1. Institutional research: research designed to evaluate internal institutional programs
2. Classroom exercises: educational exercises designed to teach research skills
3. Oral history: open-ended interviews with identifiable individuals who give their interviews with “informed consent.”

One of the ways in which scholarship is excluded from IRB oversight is that it does not fit the narrow definition of “research” for the specific regulatory purposes of the IRB. The Common Rule defines “research” as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge” (45 CFR 46.102.d). “Generalizable knowledge” includes activities that are intended to lead to publicly presented results. Institutional research for internal College use is not considered “research” under this definition. Similarly, classroom exercises, involving interactions with human participants which are part of an educational program, and are not designed to advance generalizable knowledge, are not covered by this regulation. However, classroom projects which have a very high likelihood of being disseminated to a scholarly audience outside the College, for example as a conference paper or poster session, should be submitted to the departmental IRB representative. Campus presentations that are not advertised to the general public are not considered “public.”

Scholarship that does not contribute to generalizable knowledge, or is not systematic, likewise is not considered “research” for the narrow regulatory purposes of the IRB, and is excluded from oversight by the IRB. For instance, oral history activities that document historical events or individual experiences are considered excluded because they do not involve the type of systematic research defined by federal regulations. However oral history activities that are designed to generalize findings, draw conclusions, or inform policy would be governed by the IRB process. Only those oral history projects that conform to the regulatory definition of research will now need to submit their research protocols for IRB review. (This exclusionary policy is not, of course, a commentary on the quality of such scholarship.) Excluded scholarship does not need to go through any level of IRB review; it does not need to go to the departmental reviewer, though it may be useful to consult the IRB chair or a departmental reviewer if you are unclear about how to proceed. Investigators are advised to consult the IRB to determine whether their oral history project requires IRB review.

If your project is not excluded from IRB oversight, you will need to submit a protocol to IRB for a) certification of exempt status, b) expedited reviewed or, c) full review using the IRB Mentor online system.

*The "Common Rule" is the term used by seventeen federal agencies who have adopted the same regulations governing human subjects of research. For a list of these agencies see: [http://www.hhs.gov/ohrp/humansubjects/commonrule/index.html](http://www.hhs.gov/ohrp/humansubjects/commonrule/index.html)
Appendix D – Criteria for Exemption Status

Exemption Criteria: All research that is potentially exempt from IRB review shall be submitted to the IRB chair with a request for exemption status. Research activities in which the only involvement of human subjects will be in one or more of the categories listed below are exempt from IRB review pursuant as quoted from 45 CFR 46.101:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
   (i) research on regular and special education instructional strategies, or
   (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
   (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
   (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:
   (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available, or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects conducted by or subject to the approval of department or agency heads designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed, or (ii) if a food is consumed that contains a food ingredient at or below the level found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe by the Food and Drug Administration, or approved by the Environmental Protection Agency, or the Food Safety and Inspection Service of the U.S. Department of Agriculture.
APPENDIX E – Criteria for Expedited Review

Expedited Approval: Federal regulations permit the IRB chair to review and approve proposed research through an expedited procedure if the proposed research activities (a) present no more than minimal risk to human subjects, and (b) involve only procedures listed in one or more of the categories in 45 CFR 46.110 and 21 CFR 56.110 (as quoted below).

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
   a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
   b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger-stick, heel-stick, ear stick, or venipuncture as follows:
   a. From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
   b. From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples:
   (a) hair and nail clippings in a nondisfiguring manner;
   (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat);
   (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

   Examples:
(a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject’s privacy;
(b) weighing or testing sensory acuity;
(c) magnetic resonance imaging;
(d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
(e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b) (4). This listing refers only to research that is not exempt.)

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b) (2) and (b) (3). This listing refers only to research that is not exempt.)

8. Continuing review of research previously approved by the convened IRB as follows:
   a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
   b. where no subjects have been enrolled and no additional risks have been identified; or
   c. where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.
I. INTRODUCTION

Dickinson College recognizes the importance of conducting a broad spectrum of investigative research as well as classroom and laboratory educational activities that require the use of recombinant DNA technology or infectious agents, and/or involve human tissue or body fluids, or involve animals that may carry zoonotic disease. Cognizant that these activities may be accompanied by some risks, the College requires that these activities be reviewed and approved by an Institutional Biosafety Committee (IBC) to ensure that they are conducted in a safe and appropriate manner, and in accordance with the current editions of the NIH Guidelines For Research Involving Recombinant DNA Molecules, the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories, and the Occupational Safety & Health Administration (OSHA) Standards for Bloodborne Pathogens. Adherence to this policy shall not exempt investigators employing recombinant DNA molecules or infectious agents in their research from compliance with other applicable laws, regulations or policies (e.g. research with human subjects, vertebrate animals, or radioactive materials). The appropriate paperwork must also be filed with the Institutional Review Board for the Protection of Human Subjects (IRB), the Institutional Animal Care and Use Committee (IACUC), and the Radiation Safety Officer.

II. DEFINITIONS

• Recombinant DNA molecules are defined as either (i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate inside a living cell, or (ii) DNA molecules that result from the replication of those described in (i). Synthetic DNA segments likely to yield a potentially harmful polynucleotide or polypeptide (e.g. a toxin or pharmacologically active agent) shall be considered as equivalent to their natural DNA counterpart. If the synthetic DNA segment is not expressed in vivo as a biologically active polynucleotide or polypeptide product, it is exempt from this policy.

• Infectious agents are defined as those biological agents, both pathogenic and non-pathogenic, known to infect human as well as selected animal agents that may pose theoretical risks if inoculated into humans.

III. APPLICABILITY

This policy is applicable to all research, teaching, and outreach activities involving recombinant DNA or infectious agents that are conducted at or sponsored by (or under the aegis of) Dickinson College. No activity involving the construction or handling of recombinant DNA molecules or the use of infectious agents shall be initiated without the review and approval of the appropriate registration documents by the Dickinson College Institutional Biosafety Committee.

IV. INSTITUTIONAL BIOSAFETY COMMITTEE

An Institutional Biosafety Committee (IBC) comprised of College faculty and staff appointed by the Provost and at least two outside community members shall fulfill the responsibilities described in this policy and in the Guidelines for Research Involving Recombinant DNA Molecules, Biosafety in Microbiological and Biomedical Laboratories, and OSHA Standards for Bloodborne Pathogens.

A. Committee Membership

The IBC members shall be selected so that they collectively have experience and expertise in recombinant DNA technology and infectious organisms and the capability to assess the safety of such activities and any potential risk to public health or the environment. At least two members shall not be affiliated with Dickinson College (apart from membership on the IBC) and shall represent the interest of the community area with respect to the health and protection of the environment. The Administrative Liaison, under the direction of the Provost of the College, and the Director of Environmental Health and Safety shall also be a member.

B. Meetings

The IBC shall meet as needed, but at least once per year. A schedule of meetings shall be publicly posted when feasible. Meetings will be open to the public consistent with protection of privacy and proprietary information.

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interests. A quorum for conducting business shall consist of 2/3 of the current members except that at least one member not affiliated with Dickinson College (apart from serving the IBC) must be present. The meetings will follow recognized parliamentary procedure.

C. Reports
The IBC will report publicly to the College community concerning the performance of its assigned functions by making available a copy of the approved minutes of each IBC meeting. Copies may be obtained from the Provost’s Office or from the Chair of the IBC.

The IBC may redact proprietary or private information captured in the minutes and other publicly accessible documents, but will do so judiciously and consistently for all documents requested by the public. The definition of “public” shall be interpreted in its broadest sense – as referring to all peoples and entities. The criteria used in determining which information will be redacted include, but are not limited to:

- Trade secret information and other confidential commercial information
- Home telephone numbers and home addresses of IBC members
- Specific information whose disclosure would directly compromise institutional or national security.

In addition to any redacted report, minutes or other documents made necessary to protect the information set forth above, the IBC shall also maintain a full report without redactions that shall not be publicly available.

D. Conflicts of Interest
Members of the IBC shall not participate in the review and approval of applications under consideration by the IBC when a conflict of interest exists. Conflicts of interest include, but are not limited to, the following:

- The IBC member is currently engaged, or expects to be engaged, in the research project under review, as defined in the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines).
- The IBC member has a direct financial interest in the PI or the entity funding the research proposed by the PI, as defined by the college and/or NIH Guidelines.
- The IBC member and the PI of the application under consideration share a familial relationship.
- The IBC member has other reasons to feel that he-she cannot render an independent assessment of an application.

The IBC member shall disclose the conflict of interest at the following time:

- When the IBC member is contacted to participate in the review of a project from a PI with whom the IBC member has a conflict of interest.
- Prior to the discussion at a convened meeting of a project for which the IBC member has a conflict of interest.
- Immediately upon discovery of the conflict of interest if at other than the foregoing times.

An IBC Vice-Chair will be appointed to manage committee business in the event that the Chair has a conflict of interest.

Although an IBC member shall be recused from voting on the final disposition of projects for which she/he has a conflict of interest, the IBC member shall nevertheless remain eligible to provide information related to the review of the proposal to the IBC.

V. FORMS AND PROCEDURES
A. Each investigator/instructor using recombinant DNA molecules or infectious organisms is required to submit the registration document (protocol)* as described below. *These registration documents are currently combined into a single form.
• **Registration Document for Research/Teaching Involving Recombinant DNA**: for those investigators/instructors employing recombinant DNA molecules and technology, including the construction and use of transgenic animals, and transfection of mammalian cell lines. Investigators conducting "exempt experiments" must still submit a registration form to the IBC. However, investigators completing this registration document need not complete an additional registration document for infectious agents for the same project.

• **Registration Document for Research/Teaching Involving Infectious Agents**: for those investigators/instructors employing infectious agents in their research and teaching, but not involving recombinant DNA technology

• **Registration Document for Research/Teaching Involving Human Tissue or Body Fluids**: for those investigators/instructors employing human tissue or body fluids, including saliva, urine, blood, or primary human cell cultures.

• **Registration Document for Research/Teaching Involving Wild-Caught or Random Source Animals or Animal Tissues**: for those investigators/instructors employing animals that may carry zoonotic disease.

In addition, any substantive changes in procedures or type of recombinant DNA molecules/infectious agents should be reported to the IBC. At the very least, an annual renewal form must submitted each year for each approved registration. A new registration document must be completed every three years (every five years for classroom projects).

**B. Review Procedures**

When a protocol is submitted, a copy will be sent to all committee members via electronic mail.

1. The committee chair, on behalf of the committee, will ask the Principal Investigator to respond to questions and requests for revisions or clarifications. The chair will arrange a meeting of the committee to review, and then vote on the protocol.

2. Once the committee is satisfied that the protocol is in compliance with the policies and guidelines noted in Section VI, A (below), they should recommend approval of the protocol to the committee chair. The chair, on behalf of the committee, sends the Principal Investigator official notification that she or he may begin the research described in the protocol and reports the protocol’s approval at the next full committee meeting.

**VI. FUNCTIONS AND RESPONSIBILITIES OF THE IBC**

**A.** On behalf of Dickinson College, the IBC shall review all protocols to assure compliance with this policy and the NIH *Guidelines for Research Involving Recombinant DNA Molecules*, the CDC *Biosafety in Microbiological and Biomedical Laboratories*, and the OSHA *Standards for Bloodborne Pathogens*.

**B.** On behalf of Dickinson College, the IBC shall conduct periodic self-studies of the effectiveness of College policy on biosafety and the implementation procedures, reporting the results to the Provost and recommending any needed revisions. This will involve responsibility for:

1. Reviewing the registration submission for the appropriateness of biosafety procedures and assignment to the proper biosafety containment levels of experiments;

2. Reporting within 30 days to the College Environmental Health and Safety Office and the Administrative Liaison identified problems with or violations of the guidelines and research-related accidents or illnesses; the IBC along with the Administrative Liaison, under the direction of the Provost, has responsibility for communication with external sponsoring and monitoring agencies;

3. Participating with the College Environmental Health and Safety Office in the development of emergency plans to deal with accidental spills and personnel contamination resulting from research;

4. Insuring through periodic inspections that laboratory standards are rigorously followed.

**C.** On behalf of Dickinson College, the IBC may investigate issues and reports of unanticipated problems or serious or continuing non-compliance, and undertake a range of possible actions in response. These
include but are not limited to: suspension of protocol; termination of protocol; IBC consultation with institutional officials, including the Faculty Personnel Committee.

VII. INVESTIGATOR'S RESPONSIBILITIES
The Principal Investigator is responsible for reviewing this policy and complying with its requirements. Specifically, he/she will:

A. Determine whether the research is subject to Section III-A, III-B, III-C, III-D, III-E of the NIH Guidelines, or is exempt research. The IBC Chair or Biosafety Officer (BSO) is available to assist the Principal Investigator in making this determination.

B. File the appropriate Registration Document and an Annual Renewal form for each project for review and approval, and meet all the requirements of the NIH Guidelines for Research Involving Recombinant DNA Molecules, the CDC Biosafety in Microbiological and Biomedical Laboratories, and the OSHA Standards for Blood borne Pathogens prior to initiating research subject to the NIH Guidelines. This registration (see Section IV, above) includes:
   a. Proposing physical and biological containment levels in accordance with the NIH Guidelines when registering research with the IBC.
   b. Proposing appropriate microbiological practices and laboratory techniques to be used for the research.

C. Under certain unusual circumstances:
   a. Seeking OBA’s determination of containment for experiments that require case-by-case review.
   b. Petitioning OBA, with notice to the IBC, for proposed exemptions from the NIH Guidelines.
   c. Seeking NIH approval, in addition to IBC approval, to conduct experiments specified in Sections III-A and III-B of the NIH Guidelines.

D. Make available to laboratory staff and students copies of the registration documents and other protocols that describe potential biohazards and the specific precautions to be taken;

E. Provide appropriate instruction and training in practices and techniques necessary to ensure laboratory safety;

F. Supervise the laboratory staff to ensure that appropriate safety techniques and procedures are employed;

G. Report in writing to the IBC any significant problems pertaining to the operation and implementation of containment practices and procedures.
Dickinson College

GRANTS FINANCIAL ADMINISTRATION POLICIES
Financial Responsibility

Policy/Procedure

PURPOSE:
To establish responsibility for the financial administration of sponsored projects.

POLICY:
1. Agreements for sponsored projects are entered into in the name of Dickinson College by the Sponsored Projects Group.
2. The principal investigator is directly responsible for the management and administration of the sponsored project within the administrative constraints imposed by the sponsor and in accordance with College policy. In this capacity, the principal investigator (PI) authorizes all direct cost expenditures of project funds and is responsible for reviewing and approving all project related expenditures and cost transfers.
3. As part of their responsibilities, PI’s are required to meet with the Sponsored Projects Group regarding the proper administration and implementation of their project at the inception of the project, and then periodically as may be required by the Sponsored Projects Group.
4. Changes to project budgets or expenditures, which require institutional or sponsor prior approval, must be reviewed, approved, and processed by Sponsored Projects Group in accordance with policies on Direct Costs.
5. Financial Operations Grants Accounting will generate and provide quarterly statements of project expenditures to the responsible principal investigator. Financial Operations will also provide electronic access to project accounts to allow the responsible PI to monitor the project budget.
6. It is the responsibility of the principal investigator to review their project accounts online to ensure the accuracy and appropriateness of postings, to review each quarterly statement for accuracy and completeness and to initiate corrections, when appropriate, in not less than 90 days.
7. Expenditure corrections occurring after 90 days must be approved by the Director of Grant Accounting in the Sponsored Research Group or by the next higher level as appropriate.
8. The principal investigator in consultation with his/her department chairperson and/or Provost and Dean, shall advise Sponsored Projects Group as to the desired disposition of a deficit or disallowance in a sponsored project account. In no case shall the disposition be to another grant, contract or similarly restricted account. In the absence of such advice, the over expenditure or disallowance will be transferred to an appropriate unrestricted account.

Related Information
Policy on Direct Costs

**History/Revision Information**

**Responsible Division/Office:** Sponsored Projects Group

**Effective Date:**

**Last Amended Date:**

**Next Review Date:**

**Also Found In:**
Accounting Authority & Responsibility

PURPOSE
To assign authority and responsibility for the accounting for sponsored projects.

POLICY:
1. Sponsored Projects Group, in consultation with the Financial Operations Office is responsible for:
   a. Establishing and maintaining funds for sponsored projects;
   b. Enforcing all sponsor rules and regulations and College policies governing the financial administration of sponsored projects;
   c. Establishing policies and procedures to ensure compliance with sponsored project agreements, regulations, or other requirements relative to the funding of expenditures and financial reporting; and
   d. Establishing and maintaining procedures regarding the collection of funds from the sponsoring agency.
2. Sponsored Projects Group will establish unique fund values for sponsored projects, within the College’s general ledger system, as follows:
   a. A single fund will be established for each new sponsored project upon receipt of the Notice of Award or fully signed contract;
   b. Multiple funds will be established for sponsored projects when the activity is conducted at both an on-campus and off-campus location and the negotiated on and off-campus F&A rates are applied, accordingly;
   c. Multiple funds will be established for a sponsored project when the project comprises multiple tasks or activities and the F&A rate awarded, or authorized and applied to each task or activity is at a different percentage.
   d. A cost share account linked to the sponsored project fund will be established to track required institutional cost share on that specific project.
3. An advance account may be established prior to the actual receipt of the award when the principal investigator needs to initiate the project and, as a result, incur expense (salary or other direct cost) and is reasonably assured that the award will be made. However, the fund will only be established upon submission of a Request for Advance Account signed by the Principal Investigator and approved by the department chairperson and Provost and Dean or his/her designees.
4. In the event that an advance account has been established in advance of formal award notification, the College accepts financial responsibility for any non-reimbursed costs. See policies on Financial Responsibility.
5. Commingling of sponsored projects funds from sponsors or other sources is not allowable.
6. Sub-accounts may be authorized to facilitate the accounting of project related expenses with the approval of Sponsored Projects Group.
Related Information

Financial Responsibility Policy

History/Revision Information

Responsible Division/Office: Sponsored Projects Group

Effective Date:

Last Amended Date:

Next Review Date:

Also Found In:
Cost Accounting Standards (CAS)

Policy/Procedure

PURPOSE:
To ensure compliance with the Federal Cost Accounting Standards applicable to educational institutions, as follows:
1. CAS 501: Consistency in Estimating, Accumulating and Reporting Costs
2. CAS 502: Consistency in Allocating Costs Incurred for the Same Purpose
3. CAS 505: Accounting for Unallowable Costs
4. CAS 506: Cost Accounting Period

POLICY:
1. Principal Investigators must ensure compliance with CAS 501 by maintaining consistency in the manner in which budgets are prepared for proposal submission and funds are budgeted and expenses accounted for after awards are received.
2. Costs incurred for the same purpose, in like circumstances, must be given consistent treatment in the accounting system in order to comply with CAS 502. That is, each type of cost must be charged consistently as either a direct cost or as part of the F&A rate costs (unrestricted fund).
3. Unallowable costs must be identified and excluded from any billing, claim, or proposal submitted to the Federal government.
4. Rates (e.g. service center, F&A) used for estimating, accumulating, and reporting costs must be based on the costs incurred during the College fiscal year.
5. The Sponsored Projects Group is responsible for determining the appropriate treatment of costs and for the maintenance of the CAS Disclosure Statement.

Related Information

History/Revision Information

Responsible Division/Office: Sponsored Projects Group
Effective Date:

Last Amended Date:

Next Review Date:

Also Found In:
Acceptance of Awards

PURPOSE:
To ensure that grants, contracts and other agreements whether monetary or not, in support of sponsored projects are in compliance with College policies.

POLICY:
1. It is the policy of the College that, prior to any commitments either formal or informal, agreements for sponsored projects shall be reviewed by:
   a. Sponsored Projects Group, and, when appropriate
   b. the Provost and Dean of the College
   c. the Vice President of Finance, and/or
   d. the Office of General Counsel
2. Authority to execute such agreements and amendments thereto on behalf of Dickinson College has been delegated to the Provost and Dean, and Vice President of Finance. Principal Investigators are not authorized to execute any agreements or amendments to agreements on behalf of the College.
3. Agreements or amendments thereto that may conflict with College policies will be referred by Sponsored Projects Group to the Provost and Dean for review and approval prior to acceptance.
4. The Provost and Dean may refer such documents to the Academic Program & Standards Committee (AP&SC) and/or the Planning & Budget Committee (P&B) for a final recommendation on their acceptance.

Related Information

History/Revision Information

Responsible Division/Office: Sponsored Projects Group

Effective Date:

Last Amended Date: 8-26-2015

Next Review Date:

Also Found In:
Negotiation of Awards, Cooperative Agreements, Subawards, and Subcontracts

**Policy/Procedure**

**PURPOSE:**
To ensure that the terms and conditions of agreements for sponsored projects comply with established College policies and to establish authority for negotiations.

**POLICY:**
1. Negotiation of the terms and conditions of sponsored project agreements is the joint responsibility of Sponsored Projects Group and the principal investigator(s) of the project.
2. If the sponsored research agreement involves the licensing of existing intellectual property the College’s General Counsel will assume primary responsibility for negotiation of the sponsored research agreement.
3. The principal investigator(s) is (are) responsible for the scientific or academic content of the project and must ensure that the agreement reflects his/her understanding of what is proposed to be accomplished. Likewise, any technical or progress reports or other similar deliverables must be acceptable to the principal investigator(s).
4. Sponsored Projects Group is responsible for ensuring that the agreement is in compliance with College policies and that from a business perspective it is an equitable arrangement. The budget must be acceptable to the principal investigator, his/her department chairperson and the Provost and Dean as well as to Sponsored Projects Group.
5. Sponsored Projects Group shall consult with the Office of the Provost and Dean, and General Counsel on agreements which raise legal issues, e.g., by deviating substantially from standard terms and conditions or previously approved agreements.

**Related Information**

**History/Revision Information**

**Responsible Division/Office:** Sponsored Projects Group

**Effective Date:**

**Last Amended Date:**
Next Review Date:

Also Found In:
Budgets

Policy/Procedure

PURPOSE: To establish responsibility for preparation and submission of sponsored project budgets.

POLICY:

1. The principal investigator is responsible for preparing a budget within the amount of the award as indicated in the Account Information Sheet (AIS) and in accordance with any budgetary constraints imposed by the sponsor.

2. The budget is entered into the financial accounting spreadsheet and maintained by the responsible Financial Operations administrator.
   a. Project funds may be obligated only after a project account number has been assigned and entered into the financial accounting spreadsheet by Financial Operations.
   b. Budgets must be revised upon any monetary adjustment of an award.

Related Information

History/Revision Information

Responsible Division/Office: Sponsored Projects Group

Effective Date:

Last Amended Date:

Next Review Date:

Also Found In:
Federal Direct Cost Expenditures

PURPOSE:
To establish guidelines for the charging and approval of direct cost expenditures on federal awards.

DEFINITION:
The cost of a sponsored project is comprised of both direct costs incident to its performance plus a portion of the Facility and Administrative (F&A) costs of the College. Direct costs are those that can be specifically identified with a particular sponsored project, an instructional activity, or any other institutional activity relatively easily and with a high degree of accuracy. Typical costs charged directly to a sponsored project include but are not limited to: the compensation of employees working on the project; employee benefits; the cost of supplies and equipment used in the performance of the project; travel; subawards costs; service center charges; human subject fees and long distance telephone costs.

POLICY:
1. The principal investigator is responsible for the management and administration of his/her award within the constraints imposed by the sponsor and in accordance with College policies. All expenditures of project funds must adhere to policies regarding Procurement of Goods and Services.
2. In some cases, the terms and conditions of the award may require that the sponsor give specific approval for certain direct costs either as part of the specific grant or contract, or subsequent to the initiation of the project as noted in 2CFR 200.407.
3. Pre-award costs may be allowable if a detailed request to the Federal awarding agency is submitted and approved by that agency. 2CFR200.407, 458. The authority to submit direct cost prior approvals resides with the College. The College has further delegated this authority to the Sponsored Projects Group. The Principal Investigator will provide to Sponsored Research Group any necessary documentation, and Sponsored Research Group will maintain any/all documentation regarding the appropriateness of the expense in conjunction with the project, and apply the factors of allowability, allocability, and reasonableness regarding the cost prior to processing the expenditure request.
4. For federal contracts, prior approvals are often required for certain direct cost expenditures, and it is the principal investigator’s responsibility to ensure that such approvals are obtained, in writing, through Sponsored Projects Group from the agency before funds are expended.
5. In order for a direct cost to be an allowable cost on a sponsored project, the cost must be:
a. Reasonable. The cost must be necessary for the performance of the award and reflect the action that a prudent person would have taken.
b. Allocable. The cost can easily be identified with the project and assigned to the project in accordance with benefits received.
c. Consistently Applied. The cost must be accounted for consistently as either a direct cost or as an F&A cost.
d. The fact that a proposed cost is awarded as requested by an applicant does not in itself indicate a determination of allowability.

6. Sponsor limitations on specific items of direct cost expenditures are included in, or referred to, the Account Information Sheet (AIS) or the Notice of Award.

7. The principal investigator must maintain adequate supporting documentation to relate expenditures to the purpose of the award.

8. Certain costs may not be charged to sponsored projects either as direct costs or as part of the F&A rate. See policies regarding Unallowable Costs.

9. Administrative and clerical salaries should not normally be charged directly to federally sponsored projects. Other costs not normally charged directly include office supplies, postage, telephone line and equipment costs and membership costs. In order to charge these costs directly to Federal projects, the following conditions must be met:
   a. The costs must be clearly identified in the College approved proposal budget with a detailed explanation provided which justifies the necessity for the costs. In such cases where detailed budgets are not provided to the sponsor and therefore such costs are not evident, specific prior approval of Sponsored Projects Group is required. If such costs are determined to be necessary after the award is received and not included in the proposal a determination of allowability must be made by Sponsored Projects Group as well as determining sponsor prior approval requirements;
      NOTE: For some sponsors, the fact that a proposal cost is awarded as requested by an applicant does not in itself indicate a determination of allowability;
   b. The costs must be specifically identified with the project. Individuals performing administrative or clerical activities can accomplish that through certified effort reports;
   c. The project must conform with the cost principles set forth in the OMB Uniform Guidance 2 CFR 200.400-475.
   d. The Direct Costs meet the requirements set forth in 2 CFR 200-413.

**Related Information**

Procurement of Goods and Services

Unallowable Costs
History/Revision Information

Responsible Division/Office: Sponsored Projects Group

Effective Date:

Last Amended Date: 8-26-2015

Next Review Date:

Also Found In:
Direct Cost Expenditures for Non-Federal Organizations

**Policy/Procedure**

**PURPOSE:**
To establish guidelines for the charging and approval of expenditures on awards from nonfederal sponsors which do not reimburse the College at the approved Facility and Administrative cost rate.

**DEFINITION:**
The cost of a sponsored project is comprised of both direct costs incident to its performance plus a portion of the Facility and Administrative (F&A) costs of the College. Direct costs are those costs that can be specifically identified with a particular sponsored project, an instructional activity, or any other institutional activity relatively easily and with a high degree of accuracy. Typical costs charged directly to a sponsored project include but are not limited to: the compensation of employees working on the project; employee benefits; the cost of supplies and equipment used solely in the performance of the project; travel; sub-awards costs; service center charges; human subject fees and long distance telephone costs.

**POLICY:**
1. In order for the College to recover costs that are typically included in our Facility and Administrative rate from sponsors that do not reimburse the College at the full approved rate, PIs and centers are encouraged to include the costs identified below in proposals to these sponsors for grant and contract awards. The items of cost that may be requested for reimbursement are:
   a. Administrative and Clerical Salaries
   b. Telephone line charges
   c. Website and ISP costs
   d. Space costs
   e. Office Supplies
   f. IRB and IACUC review fees
   g. Environmental Health and Radiation Safety fees for waste disposal and radiation safety tests.

   Sponsor approval must be granted in the terms and conditions of the award prior to charging these costs to any project.

2. As with federally sponsored projects, the principal investigator is responsible for the management and administration of his/her award within the
constraints imposed by the sponsor and in accordance with College policy. The principal investigator must authorize all expenditures of project funds.

3. Documentation of the appropriateness of these expenses in relation to the project must be maintained by the department. Appropriateness of the cost must also be considered prior to processing the expenditure. The factors for assessing appropriateness are allowability, allocability, and reasonableness as explained below:
   a. Allowability. The expense must be permitted by the sponsor and in accordance with College policy.
   b. Allocability. The cost can easily be identified with the project and assigned to the project in accordance with benefits received.
   c. Reasonableness. The cost must be necessary for the performance of the award and reflect the action that a prudent person would have taken.

4. Sponsor limitations on specific items of direct cost expenditures are included in, or referred to, the Account Information Sheet (AIS) or the Notice of Award.

5. Certain costs may not be charged to sponsored projects either as direct costs or as part of the F&A rate. See policies for a description of unallowable costs.

### Related Information

- Unallowable costs
- F&A rate policies
- Budgets
- Federal Direct Cost Expenditures

### History/Revision Information

**Responsible Division/Office:** Sponsored Projects Group

**Effective Date:**

**Last Amended Date:** 8-26-2015

**Next Review Date:**

**Also Found In:**
Unallowable Costs

Policy/Procedure

PURPOSE:
To establish policy for the accounting of costs which are unallowable charges against federally sponsored projects.

POLICY:
1. The following costs are unallowable charges to sponsored projects as either direct costs or as part of the F&A rate, as specified and detailed in the Uniform Guidance 2 CFR 200.420-475.
   a. advertising, other than for help wanted or for the procurement of goods or services necessary for the performance of the award (e.g. human subjects)
   b. advisory councils
   c. alcoholic beverages
   d. certain audit services as defined in 2 CFR 200.425
   e. bad debt expense
   f. bonding costs
   g. entertainment, unless specifically provided for in the award
   h. fines and penalties
   i. first class travel
   j. goods and services for personal use, such as automobiles
   k. housing and personal living expenses for officers
   l. internal interest expense
   m. memberships in social, dining or country clubs
2. In addition to the specific costs listed above, costs associated with the following activities are unallowable direct charges to sponsored projects. They must be identified and accounted for in funds specified for their purpose:
   a. alumni activities
   b. commencement and convocation costs
   c. executive and legislative lobbying
   d. fund raising costs investment management costs
   e. losses on sponsored agreements
   f. general public relations costs
   g. costs for prosecuting claims against the Federal government
   h. restricted fund overdrafts

Related Information
Grant Accounting – Facilities and Administrative Charge

Policy/Procedure

PURPOSE:
This policy governs the charging of Facilities and Administrative costs to sponsored agreements.

POLICY:
Per OMB Uniform Guidance 2 CFR 200.414-415 Dickinson College requires the use of the Facilities and Administrative Rate in effect at the time of the initial award throughout the life of the sponsored agreement.

Related Information

History/Revision Information

Responsible Division/Office: Sponsored Projects Group

Effective Date:

Last Amended Date: 8-26-2015

Next Review Date:

Also Found In:
Recovery of Facilities and Administrative (F&A) Costs

Policy/Procedure

PURPOSE:
To establish policy regarding the charging of Facilities and Administrative (F&A) Costs to Sponsored Projects. (Note: the term “F&A” replaces “indirect costs” (IDC) and “overhead”.)

DEFINITION:
The total costs of a sponsored project include (a) those directly attributable to its performance, e.g., salaries of project personnel, supplies, materials, equipment and travel, and (b) F&A costs, e.g., depreciation of buildings and equipment, utilities, administration and libraries. These latter costs are recovered through the application of an F&A cost rate, calculated in accordance with the cost principles set forth in the Office of Management and Budget Uniform Guidance 2 CFR 200.56, 2 CFR 200.414-415 et al.

POLICY:
1. It is the policy of the College to charge all sponsored projects F&A costs at the appropriate federally approved rate. The only exceptions to this policy are as follows:
   a. Awards from not for profit sponsors which have a stated policy of awarding funds with an F&A cost at other than the negotiated rate, e.g. foundations and charitable organizations;
   b. Other awards which have been specifically approved by the Provost and Dean at an F&A cost rate other than the negotiated rate in accordance with Item 2. below.
2. All waivers of F&A cost recovery on sponsored projects must be approved by the Provost and Dean of the College, and the Vice President for Finance.
3. The College negotiates with the Federal Government F&A cost rates for the following categories:
   a. Research (on/off campus)
   b. Other Sponsored Projects
4. F&A recovery supports the general spending budget of the College and is not redistributed to individual departments of Principal Investigators.
5. The F&A rate for an award throughout the life of the sponsored agreement is the rate that is in effect at the time of the initial award per 2 CFR 220.414.(e.1)

Related Information

Current F&A cost rates are available on the Corporate, Foundation and Government Support website at the following URL:
http://www.dickinson.edu/info/20276/corporate_foundation_and_government_support/2303/cost_rates_and_useful_info

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Negotiation of Facilities and Administrative (F&A) Cost and Employee Benefit Rates

Policy/Procedure

PURPOSE:
To designate responsibility for negotiation of F&A cost and employee benefit rates with the Federal government for expenses incurred in the performance of federally sponsored agreements.

POLICY:
1. The Vice President for Finance or his/her designee has final authority over the negotiation of, and is the College official responsible for signing the formal F&A cost and employee benefit agreement with the federal government.
2. Financial Operations is responsible for (a) initiating the negotiation process, (b) providing access to the detailed supporting documents required by the Federal negotiator, and (c) responding to the negotiator’s questions.
3. Other College managers, as designated by the Vice President for Finance and Treasurer, may assist in the negotiation process.

Related Information

See OMB Uniform Guidance 2 CFR 200.414-415

History/Revision Information

Responsible Division/Office: Sponsored Projects Group
Effective Date: 8-26-2015
Last Amended Date:
Next Review Date:
Also Found In:
Facilities and Administrative (F&A) Cost Rate Proposal Preparation

**Policy/Procedure**

**PURPOSE:**
To provide policy regarding the preparation of the sponsored project Federal F&A cost rate proposal submitted to and negotiated with the Department of Health and Human Services (DHHS).

**POLICY:**
1. Financial Operations is responsible for the preparation of the periodic F&A cost rate proposal submitted to the College’s cognizant Federal agency, the Department of Health and Human Services (DHHS).
2. The proposal will be based on expenses incurred during the College’s most recently completed fiscal year.
3. The proposal will be prepared using the guidelines contained in Office of Management and Budget Uniform Guidance 2 CFR 200.414-415
4. The proposal will be reviewed and approved by the Vice President for Finance prior to being submitted to DHHS.

**Related Information**

**History/Revision Information**

**Responsible Division/Office:** Sponsored Projects Group

**Effective Date:** 8-26-2015

**Last Amended Date:**

**Next Review Date:**

**Also Found In:**
Cost Sharing - Matching

**Policy/Procedure**

PURPOSE: To establish policy for the identification, funding, accounting, and reporting of cost sharing or matching requirements in conjunction with a sponsored project.

DEFINITION: Cost Sharing or Cost Matching means a specific portion of the project or program costs that is not funded by the sponsor.

Types of Cost Sharing:

1. Mandatory: Refers to those costs which are either required by the terms of the award or by federal statute that the College must contribute toward the project in order for an award to be made.
2. Voluntary Committed: Any cost associated with a project, which has been identified in the proposal, but for which funding has not been requested from the sponsor. Some common examples include:
   a. A percentage of effort for faculty or senior researchers included in a proposal budget or stated in the text of the proposal for which compensation is not requested; and
   b. The purchase of equipment for the project, identified in the proposal, for which funds have not been requested.
3. Voluntary Uncommitted: Any cost associated with a project and not funded by the sponsor, which has not been identified in the proposal, or in any other communication to the sponsor as a commitment of the College. Any effort of faculty or senior researchers that is over and above that which is committed and budgeted for in a sponsored agreement:
   a. Donated faculty effort on a project over and above that which was proposed for the project; or
   b. Academic year effort on a project for which only summer salary was proposed also would be considered uncommitted cost sharing if such effort were not listed either on the budget page, or in the body of the proposal.
4. In-kind/Matching: Refers to the requirement of some sponsored projects that grant funds be matched in some proportion with non-sponsored project funds, or that the grantee participate to some extent in the cost of the project. Matching requirements may be in the form of an actual cash expenditure of funds, or may be an “in-kind” match, which is the value of non-cash contributions to the project.

*Under Federal research proposals, voluntary committed cost sharing is not expected unless otherwise noted in the funding opportunity solicitation*
OMB Uniform Guidance Requirements for Cost Sharing on Federal awards to be acceptable (OMB Uniform Guidance 2 CFR 200.306):

For all Federal awards, any shared costs or matching funds and all contributions, including cash and third party in-kind must be accepted as part of the recipient’s cost sharing or matching when such contributions meet all of the following criteria:

- Are verifiable from the recipients records; Are not included as contributions for any other federally-assisted project or program;
- Are necessary and reasonable for proper and efficient accomplishment of project objectives;
- Are allowable under Cost Principles outlined in 2 CFR 200.306 Subpart E (volunteer services)
- Are not paid by the federal government under another award, except where authorized by federal statute to be used for cost sharing or matching; and
- Are provided in the approved budget when required by the federal awarding agency.
- Conform to other provisions 2 CFR 200.306 as applicable.

POLICY:

1. College policy is to provide only the minimum amount of cost sharing necessary to meet sponsors’ requirements and discourages voluntary committed cost sharing.
2. Compliance with Federal regulations and cost accounting standards requires that all cost shared expenses be treated in a consistent and uniform manner in proposal preparation and in the financial accounting and reporting of these expenses to sponsors.
3. Mandatory or voluntary committed cost sharing or required in-kind matching must be clearly indicated on the Proposal Transmittal and Approval Form.
4. Documentation must be attached to the proposal detailing the proposed cost sharing, and list the source of funding for the cost shared expense, and who approved the cost share. Such documentation must include the Proposal Transmittal and Approval Form; it may also include any other approvals from budget officers, as appropriate.
5. The Sponsored Projects Group is responsible for maintaining records of all project related costs, which represent cost sharing through the use of a separate “ORG (602600) fund tied to the general ledger which will be established by Financial Operations.
6. The responsible department must account for all mandatory and voluntary committed cost sharing and provide this information to Sponsored Projects Group for financial reporting purposes in cases where a separate “ORG (602600) fund is not appropriate i.e. sabbatical leave.
7. Funds used to meet matching requirements may be used only once.

Note:
Effort devoted to a project over and above the effort charged to the project, (or formally cost shared) need not be identified and reported if there is no reduction to other teaching or research and/or any other duties.
Related Information

History/Revision Information

Responsible Division/Office: Sponsored Projects Group

Effective Date:

Last Amended Date: 8-26-2015

Next Review Date:

Also Found In:
Procurement of Goods & Services

**Policy/Procedure**

**PURPOSE:**
To establish responsibility for the procurement of goods and services with sponsored project funds.

**POLICY:**
1. Goods and services funded by sponsored projects shall be acquired in accordance with established College policy as set forth in the Financial Operation Accounting Policy and Procedures, and any additional restrictions imposed by the sponsor.
2. Sponsored Projects Group, in consultation with the Office of the Provost and Dean and General Counsel as appropriate, is responsible for the negotiation, preparation and administration of subawards where a material portion of the scope of work or supported activity is to be accomplished by another institution or organization.

**Related Information**

Financial Operations Accounting Policies and Procedures

**History/Revision Information**

**Responsible Division/Office:** Sponsored Projects Group

**Effective Date:**

**Last Amended Date:**

**Next Review Date:**

**Also Found In:**
Advances of Cash from External Sponsors

Policy/Procedure

PURPOSE:
Some federal agencies and some non-federal sponsors provide cash in advance of the work to be performed under a sponsored project. This policy establishes the appropriate accounting treatment of these cash advances.

• OMB Uniform Guidance 2CFR 200.305 (9) requires that cash advances be deposited into an interest bearing account, and that interest earned on those advances be remitted annually to the Department of Health and Human Services (DHHS), Payment Management System.
• Non-federal sponsors that provide cash advances and require that the cash be deposited into interest bearing accounts, may require that the interest earned be returned to the sponsor, or used to further the objectives of the award, depending on the terms of the award.

POLICY:
1. Sponsored projects awarded to the College as described above must be credited with interest income on positive cash balances.
2. Sponsored Projects Group will ensure that all such Sponsored Projects will be identified and designated as funds to earn interest income.
3. The Financial Operations will post the amount of any interest income earned on the funds identified by Sponsored Projects Group on a quarterly basis, calculated on the positive balance at the end of the prior quarter times the Commonfund’s Participant Net Credited Rate, as shown on the bank statement in the last month of the quarter.
4. Interest earned on all federally supported projects will be reported to the sponsor as required at termination, and then transferred to a designated holding account.
5. Within 90 days of the close of each fiscal year (close of ADJ period), the total amount of interest income earned on federal funds within the fiscal year will be remitted to DHHS.
6. Interest earned on non-federal awards will be accounted for in accordance with the terms of the specific award.
7. This policy does not apply to awards funded under a letter of credit.

Related Information

History/Revision Information
Responsible Division/Office: Sponsored Projects Group

Effective Date:

Last Amended Date: 8-26-2015

Next Review Date:

Also Found In:
Expense Approval and Documentation Requirements

Policy/Procedure

PURPOSE:
To provide an understanding of what documentation is required indicating approval for expenses charged to sponsored projects.

POLICY:
1. No charge may be made against a fund without the appropriate approval of the Provost and others as required by Sponsored Projects policies on Direct Cost Expenditures, Procurement of Goods and Services, and other College acquisition policies as may be in effect.
2. All expenses charged to a sponsored program must be necessary, reasonable, and allowable for the conduct of the project.
3. All expenses charged to a sponsored program must be supported by dated original documentation identifying the fund charged and approval of the PI.
4. Approval documentation may be in the form of a signed and dated fax, memo, letter, or log by the PI or email directly from the PI to the individual executing any financial transaction including but not limited to cost transfers, salary allocations, purchase orders, or journal entries.
5. Documentation, electronic or other, must be available and accessible at all times for audit purposes. If an approval is obtained via email hard copy must be retained.
6. All documentation must be retained in accordance with Sponsored Projects and College policies on Record Retention.

Related Information

Federal Direct Cost Expenditures
Direct Cost Expenditures for Non-Federal Organizations
Procurement of Goods and Service
Record Retention

History/Revision Information

Responsible Division/Office: Sponsored Projects Group
Effective Date:

Last Amended Date:

Next Review Date:

Also Found In:
Cost Transfers and Payroll Reallocations

Policy/Procedure

PURPOSE:
To ensure the allowability and timeliness of transfers of incurred costs, both payroll and other direct costs, to sponsored projects.

DEFINITION:
A cost transfer is defined as the moving of an expense to a sponsored project (including but not limited to clinical trials, training grants, research grants/contracts/cooperative agreements as identified in policies in Administration of Projects) when the expense was initially charged to another account. Cost transfers, or moving an expense, include salary charges transferred through payroll reallocations as well as other direct costs. A pattern of cost transfers from a sponsored project may also indicate poor awards management.

POLICY:
1. The principal investigator is responsible for ensuring that transfers of costs to sponsored projects, which represent corrections of errors, are made promptly. Transfers must be supported by documentation which contains a full explanation of how the error occurred and a correlation of the charge to the project to which the transfer is being made. Explanations such as “to correct an error” or “to transfer to correct project” are unacceptable.
2. Prudence dictates that care must be exercised in making any cost transfer, especially transfers made after termination date of a project and/or the reporting period of a project (i.e. annual financial reports). Transfers of costs to any sponsored project account are allowable only where there is direct benefit to the project account being charged. The transfer of an overdraft or any direct cost item incurred in the conduct of one sponsored project may not be transferred to another sponsored project account merely for the sake of resolving a deficit or an allowability issue.
3. Cost transfers must be prepared and submitted within 90 days from month end in which the transaction appears on the fund.
4. Cost transfers may be made, provided the following conditions are met:
   a. The cost is a proper and allowable charge to the project;
   b. The transfer is supported by adequate documentation fully explaining the circumstances under which the error occurred and certified by the principal investigator and business administrator, as described in 1. above; and
   c. Transfers which are not made promptly due to extenuating circumstances, must include an adequate explanation why there was a delay in correcting the error.

Related Information
Administration of Projects

**History/Revision Information**

**Responsible Division/Office:** Sponsored Projects Group

**Effective Date:**

**Last Amended Date:**

**Next Review Date:**

**Also Found In:**
Effort Reporting

Policy/Procedure

PURPOSE: To comply with the federal Office of Management and Budget’s Uniform Guidance 2 CFR 200.430 and other sponsor requirements for certifying that effort expended on a project is at least commensurate with the salary charged against the sponsored project.

POLICY:
1. The College employs an after-the-fact effort reporting system for the following categories of College employees:
   a. faculty
   b. students
   c. all administrative and professional staff or employees paid by stipend or salary
2. Individual effort reports are required for employees identified above for each fiscal year in which a portion of their salary is charged to a sponsored project. Summer effort reporting is required for a faculty member whose appointment is for the academic year (i.e., 9 months) and also conducts summer research.
3. The effort report must represent, in percentages totaling 100%, a reasonable estimate of an employee’s College compensated effort for the period. Faculty must sign their own individual effort reports. Effort reports must be completed and signed either by the employee, the principal investigator, or a responsible official (business administrator or chairperson) using a suitable means of verification that the reported effort was expended.
4. The effort report form must account for all effort for which the College compensates the individual. Even where the number of hours of effort the individual expends each week substantially exceeds the “normal” workweek of 35, 37.5, or 40 hours, effort percentages must be based on total effort, not hours.
5. College compensated effort includes all research, teaching, administration, clinical activity, and any other activity for which an individual received compensation from the College. Excluded from effort reporting is overload compensation, or compensation received from sources other than the College, such as compensation from outside consulting work permitted by the College.
6. Effort distributions should be reasonable estimates of activities, recognizing that research, instruction, and clinical activity are often inextricably intertwined and estimates will be necessary in most cases.
7. Certain sponsors may impose a limit on the annual rate of salary reimbursement. Nevertheless, investigators must still devote the full committed effort as proposed and awarded without regard to the salary reimbursement limitation. Effort reports for individuals earning in excess of the capped amount must be completed in accordance
with the specific guidelines developed and published by Sponsored Projects Group for calculating and reporting that effort.

8. Mandatory or voluntary committed cost sharing must be reported. Where some or all effort an individual expends on a specific sponsored research project is not funded by the project sponsor but is mandated by the sponsor or where the individual has clearly committed to uncompensated effort to the project in the application, that effort must be reported as unfunded activity (cost sharing) on the effort report form. This unfunded effort is captured in the accounting ledger within the linked Cost Share account for the sponsored program.

9. Sponsored Projects Group is responsible for the distribution, collection and retention of all effort reports. Individually reported data will be made available by Sponsored Projects Group only to authorized auditors. Any other use of this information will be in accordance with advice and consent of appropriate faculty members with due regard for individual confidentiality.

10. Departments and/or principal investigators are required to return appropriately signed effort reports to Sponsored Projects Group within 45 working days of receipt of the forms.

11. Effort reports will be sent out by the Sponsored Projects Group within 60 days following the fiscal year end (June 30).

12. Payroll screen prints of salary reallocations must accompany a modified effort report to ensure that the certified effort report agrees with the salary charged.

13. Cost disallowances on sponsored projects resulting from a department’s failure to return effort reports or the submission of inaccurate effort reports to Sponsored Projects Group will be reviewed with the Provost and Dean, or Vice President for Finance. If disallowances are not satisfactorily resolved, the costs will be charged to the department’s unrestricted budget.

**Related Information**

Faculty Summer Effort & Salary

**History/Revision Information**

**Responsible Division/Office:** Sponsored Projects Group

**Effective Date:**

**Last Amended Date:**

**Next Review Date:**

**Also Found In:**
Accounting for Matching Gifts to Sponsored Projects

Policy/Procedure

PURPOSE:
To ensure compliance with financial reporting and audit requirements under individual sponsored project agreements which stipulate matching gift requirements.

POLICY:
1. Gifts intended to be used as part of a sponsored project matching gift requirement must be identified by the Corporate, Foundation and Government Support Office and processed through Financial Operations.
2. The restricted gift will be recorded in the cost share ORG associated with the sponsored project. Financial Operations and the Sponsored Projects Group will coordinate efforts to ensure proper accounting for the project match.

Related Information

History/Revision Information

Responsible Division/Office: Sponsored Projects Group
Effective Date:
Last Amended Date:
Next Review Date:
Also Found In:
Grant Accounting – Pledge and Pledge Payments

Policy/Procedure

PURPOSE:
This policy governs the recording of grants and grant pledges in Banner.

POLICY:
When a new award is received, the Sponsored Projects Group will determine if pledges are to be recorded or if it will be entered as a straight gift. Awards whose project dates span more than one fiscal year will be entered as a pledge.

**Accounting for a Pre-Paid Grant (funds received up-front):**
Gift Recorder - record cash received
- 10401 Cash    Debit
- 23107 Deferred Income    Credit
Finance – recognize income as expenses are incurred
- 23107 Deferred Income    Debit
- 53105 Income    Credit

**Accounting for a Reimbursable Grant (request funds after spending):**
Gift Recorder – record cash received
- 10401 Cash    Debit
- 11202 Grant Receivable    Credit
Finance – recognize income
- 11202 Grant Receivable    Debit
- 53105 Income    Credit

**Accounting for a pledge and pledge payment on a grant:**
Gift Recorder – record Pledge
- 13108 Pledge Receivables    Debit
- 23107 Deferred Income    Credit
Gift Recorder – record Pledge Payment
- 10401 Cash    Debit
- 13108 Pledge Receivables    Credit
Finance - recognize income as expenses are incurred
- 23107 Deferred Income    Debit
- 53105 Income    Credit

Related Information
History/Revision Information

Responsible Division/Office: Sponsored Projects Group

Effective Date:

Last Amended Date:

Next Review Date:

Also Found In:
Accounting for Program Income

Policy/Procedure

PURPOSE:
To establish accounting policy for program income earned on sponsored projects. Certain sponsored projects generate income which, depending on sponsor regulations or the terms of the award, either is required to be remitted to the sponsor, or may be used as additional project support.

DEFINITION:
Program income is gross income earned that is directly generated by a sponsored activity or earned as a result of the sponsored activity. Federal regulations (OMB Uniform Guidance 2 CFR 200.307) provide three alternatives for accounting for program income if the federal awarding agency does not specify how program income is to be used or does not issue prior approval regarding its use:
- Additive method whereby the income is added to the funds committed to the project to further the objectives of the award;
- Matching, used to finance the non-federal share of the project; or
- Deductive method whereby the funds are used to reduce the federal share of the project.

Program income earned on non-federal awards must be accounted for according to the terms and conditions of the award.

POLICY:
1. Sponsored Projects Group will establish a separate fund to account for program income when the additive method is required to be used, unless the amount of program income is nominal, i.e., less than $5,000. The fund will have the same F&A rate as the sponsored project fund.
2. When matching is required, the program income must be deposited and accounted for in the cost share fund established for that specific sponsored project.
3. The deductive method will necessitate that the Project Billable Amount for the fund be reduced by the amount of program income since the income is required to off-set the sponsor share of the project cost.
4. Types of program income include, but are not limited to:
   a. Income from fees or service performed;
   b. Rental fees; or
   c. Proceeds from the sale of tangible property or items fabricated under an award.
      Note: Income earned from license fees and royalties on patents and
copyrighted material is not considered program income for federal awards unless agency regulations or the terms and conditions of the award provide otherwise. Refer also to the terms and conditions of non-federal awards for the requirements related to patent and copyright income.

5. Program income received must be deposited by the recipient into account 54104 in order to preclude the commingling of such funds with regular project payments received from the sponsor.

6. Awards in which Gross Program income may be off-set by the costs of collecting the income to enable reporting Net Program Income, the Program Income fund is to be set-up to account separately for the costs of collecting and spending the Program Income.

7. Sponsored Projects Group has the responsibility to report program income earned, and, when applicable, to either remit such income to the sponsor or to apply the income as funding for related project expenses in accordance with sponsor requirements.

Related Information

History/Revision Information

Responsible Division/Office: Sponsored Projects Group

Effective Date:

Last Amended Date: 8-26-2015

Next Review Date:

Also Found In:
Sponsored Project Payments

**Policy/Procedure**

**PURPOSE:**
To establish the authority and responsibility for the deposit of payments on sponsored projects.

**POLICY:**
1. Sponsored Projects Group has the sole authority and responsibility for the deposit of cash received as payment on sponsored projects, and for the identification and posting of those payments to the appropriate sponsored project fund.
2. Checks and accompanying correspondence received representing payment on sponsored projects must be forwarded to Sponsored Projects Group immediately upon receipt.

**Related Information**

**History/Revision Information**

**Responsible Division/Office:** Sponsored Projects Group

**Effective Date:**

**Last Amended Date:**

**Next Review Date:**

**Also Found In:**
Funding under Letter of Credit Agreements

Policy/Procedure

PURPOSE:
To establish authority and responsibility for the request and maintenance of letter of credit agreements funding sponsored programs.

POLICY:
1. Sponsored Projects Group, in consultation with the Financial Operations Office is responsible for:
   a. Establishing letter of credit funding agreements between the College and federal sponsors when applicable;
   b. Establishing and maintaining processes and systems to ensure compliance with cash request and financial reporting requirements; and
   c. Determining periodic cash requirements and initiating payment requests.
2. Sponsored Projects Group will ensure that cash receipts under letter of credit agreements are timed as closely as possible to cash disbursements. Any interest due on Federal cash will be calculated and paid to the appropriate sponsor by Sponsored Projects Group in accordance with applicable Federal regulations.

Related Information

History/Revision Information

Responsible Division/Office: Sponsored Projects Group

Effective Date:

Last Amended Date:

Next Review Date:

Also Found In:
Direct Billing of Project Expenses

Policy/Procedure

PURPOSE:
To establish responsibility for the direct billing of sponsored project expenses.

POLICY:
1. Sponsored Projects Group is responsible for issuing requests for advance payment, payment by schedule, invoices, vouchers and any other financial instrument required to effect funding under sponsored project agreements. Exceptions to this responsibility must receive the prior approval of Sponsored Projects Group in consultation with the Financial Operations Office.
2. Sponsored Projects Group is authorized to issue a payment request, if necessary, to legally execute an agreement between the College and a sponsor.
3. The financial accounting system represents the official record supporting any invoice or voucher issued.
4. Sponsored Projects Group is authorized to conduct reviews to ensure that expenditures billed to a sponsor are authorized and allowable under terms and conditions of awards and are in accordance with College and sponsor policy.

Related Information

History/Revision Information

Responsible Division/Office: Sponsored Projects Group

Effective Date:

Last Amended Date:

Next Review Date:

Also Found In:
Delinquent Payment/Nonpayment of Project Costs by Sponsors

**Policy/Procedure**

**PURPOSE:**
To establish responsibility for the resolution of delinquent payment and/or nonpayment of project costs by sponsors.

**POLICY:**
1. Sponsored Projects Group will notify the principal investigator in the event that a) collection on invoices submitted to sponsors or b) scheduled payments due from sponsors are unduly delinquent or in question. Notification will be made as soon as the information is available to Sponsored Projects Group. In addition, it is the responsibility of the principal investigator to notify Sponsored Projects Group’s Director of Grants Administration of any unduly delinquent or in question invoices or scheduled payments.
2. Sponsored Projects Group in consultation with the principal investigator and/or the school/department will be responsible for ascertaining the reasons for nonpayment.
3. In the event that it is determined that payment for costs incurred is not forthcoming, Sponsored Projects Group, in conjunction with the principal investigator, the senior school business official and the Office of the Vice President and General Counsel may seek legal remedy, if warranted.
4. Should all prudent collection efforts fail and unless compelling circumstances dictate otherwise as determined by the Sponsored Projects Group, uncollectible claims will be written-off to the appropriate academic department or College division.

**Related Information**

**History/Revision Information**

**Responsible Division/Office:** Sponsored Projects Group

**Effective Date:**

**Last Amended Date:**
Next Review Date:

Also Found In:
Interim and Final Financial Reports

**Policy/Procedure**

**PURPOSE:**
To ensure compliance with OMB Uniform Guidance 2 CFR 200.327-329 and other sponsors’ policies regarding the timely submission of financial reports of expenditures.

**POLICY:**
1. Sponsored Projects Group is responsible for the preparation and submission of interim and final financial reports required under sponsored project agreements. They are also responsible for maintaining procedures required to ensure full compliance with the financial reporting of all such agreements.
2. Interim and final financial reports must be submitted by the due date prescribed by the terms of the award. These reports will be retained in accordance with the sponsor’s and the College’s record retention policy.
3. The general ledger system represents the official record supporting all required financial statements.
4. Sponsored Projects Group is responsible for conducting desk reviews to ensure that reported expenditures are authorized and allowable under terms and conditions of awards and are in accordance with College and sponsor policy.
5. Sponsored Projects Group has the authority to request documentation in support of any questioned charge, as well as the authority to exclude from any financial billing or reporting all costs deemed questionable and/or unsupported.

**Related Information**

**History/Revision Information**

**Responsible Division/Office:** Sponsored Projects Group

**Effective Date:**

**Last Amended Date:**

**Next Review Date:**
Also Found In:
Final Financial Reports

Policy/Procedure

PURPOSE:
To ensure that the submission of revised final financial reports are completed in a timely fashion so as to mitigate any financial loss to the College or return of funds with interest to the sponsor.

POLICY:
1. Submission of revised final financial reports is generally discouraged but may be necessary in cases that benefit the sponsor or report unavoidable additional expenditures.

2. Submission of revised final financial reports indicating additional expenses under the approved awarded amount may require sponsor prior approval. Sponsored Projects Group must be contacted immediately to determine the appropriate action.

3. Authorities:
   a. The Grants and Sponsored Projects Accounting (GaSP) is responsible for reviewing any financial report revision request.
   b. The Corporate Foundation and Government Support Office (CF&GS) is responsible for assessing the requirements of the sponsor.
   c. A senior business officer (or his/her designee, normally the Director of Grants Accounting) is responsible for approval or denial of requests.

4. The process for revising a final financial report will be as follows:
   a. The Grants and Sponsored Projects Accounting (GaSP), in consultation with CF&GS, will review and/or revise expenditures as appropriate. *Additional expenditures included in the revised final financial report are subject to the terms and conditions of the award i.e., rebudgeting restrictions, allowability, allocability, reasonableness, etc., and College policies.
   b. After consultation with GaSP and CF&GS staff, a senior business officer (or his/her designee, normally the Director of Grants Accounting) will approve or deny the request.
   c. The Director of Grant Accounting will notify the principal investigator and senior business officer of the approval/denial of the request.
   d. If the request is approved, the Director of Grants Accounting will
      i. request the necessary financial documentation supporting the revised expenditures.
      ii. devise a corrective plan outlining future action to avoid unwarranted submissions of revised final financial reports.
e. Preparation of the revised final financial report will be completed and submitted to the sponsor by GaSP.

5. A revised final financial report wherein the College claims less in expenditures than were originally reported is required regardless of timeframe and requires the approvals in Item 3 above.

Related Information

History/Revision Information

Responsible Division/Office: Sponsored Projects Group

Effective Date:

Last Amended Date:

Next Review Date:

Also Found In:
Sponsored Projects Close-out

**Policy/Procedure**

**PURPOSE:**
To establish responsibility for the orderly and timely close-out of completed sponsored projects in accordance with sponsor requirements.

**POLICY:**
1. The principal investigator is responsible for the preparation and timely submission of all required progress, programmatic, or technical reports.
2. Sponsored Projects Group is responsible for the preparation and submission of final financial reports and invoices, and/or final invoices or final vouchers.
3. Reports of sponsor-owned equipment normally are to be prepared and submitted by Sponsored Projects Group in cooperation with the principal investigator and his/her department.
4. When required, invention reports are to be prepared by the principal investigator. All such reports must be signed on behalf of the College by Sponsored Projects Group after verification from General Counsel.

**Related Information**

**History/Revision Information**

- **Responsible Division/Office:** Sponsored Projects Group
- **Effective Date:**
- **Last Amended Date:**
- **Next Review Date:**
- **Also Found In:**
Account Close-out

Policy/Procedure

PURPOSE:
To establish the authority and responsibility for the close-out of sponsored project accounts.

POLICY:
1. The principal investigator is responsible for all direct cost charges to the sponsored project account. Cost transfers adjusting recorded expenses must have the principal investigator’s approval.
2. Funds may not be obligated after the termination date of the sponsored agreement. The principal investigator is responsible for ensuring that any purchase orders for equipment, supplies, or other materials or services are executed prior to the close of business on the final day of the award performance period (budget period) and that they are authorized, allowable, and necessary for the completion of the project.
3. Sponsored Projects Group is responsible for:
   a. Establishing and implementing procedures to ensure that financial reports are issued in a timely manner;
   b. Reviewing the account code categories used on FOAPALs;
   c. Reconciling Facilities and Administrative Costs and employee benefits expenses charged to accounts and making any necessary adjustments;
   d. Preparing and submitting the final report of expenditures in accordance with sponsor requirements;
   e. Reconciling expenditures to receipts and inactivating the account; and
   f. Sponsored Projects Group has the authority to request and, in the absence of timely resolution, to post journal entries to fund cost sharing, unallowable costs or other disallowances.
4. Sponsored Projects Group will issue financial reports based upon the general ledger activity at the close of an interim and/or final budget period, consistent with established financial reporting and account close-out procedures. The principal investigator and/or designee must ensure that, prior to financial reporting, all expenses are allowable and allocable to the project and that any required adjustments to expenses are posted in compliance with accounting reporting and close-out policies and procedures.

Related Information
History/Revision Information

Responsible Division/Office: Sponsored Projects Group

Effective Date:

Last Amended Date:

Next Review Date:

Also Found In:
Write-off of Overdrafts and Disallowances

Policy/Procedure

PURPOSE:
To establish responsibility regarding unresolved sponsored project overdrafts and disallowances.

DEFINITIONS:
Overdrafts are comprised of salary and/or other direct cost expenditures which exceed the authorized total award amount. In certain instances, the overdraft may consist of the amount of the expenditure which exceeds an approved, but restricted, individual line item award amount.

Disallowances are salary or other costs charged to a project fund account that are deemed to be unallowable by either:
- Federal regulations, terms of Federal and private contracts or agreements, or
- costs incurred and submitted to the project sponsor for reimbursement but directly denied as reimbursable by that sponsor, or
- costs that are disallowed as the result of an audit.

POLICY:
1. Cost disallowances, if considered allocable to the project, should be funded via a journal voucher from a funding source other than a sponsored program.
2. Unallowable costs that are specifically deemed not reimbursable by the sponsor, or specifically deemed to be unallowable by the provisions of OMB’s Uniform Guidance, shall not be charged to a sponsored program fund.
3. Sponsored Project Group Financial Administrators, in consultation with the Principal Investigator, are responsible for expeditiously resolving direct cost overdrafts and/or disallowances on sponsored project funds, prior to the submission of the Financial Status Report (FSR).
4. Sponsored Projects Group will follow-up to ensure the successful and timely resolution of such overdrafts and/or disallowances.

Related Information

History/Revision Information

Responsible Division/Office: Sponsored Projects Group
PURPOSE:
To establish responsibility for the coordination of external audits, reviews, inquiries, and investigations of sponsored projects.

POLICY:
1. Requests from an outside agency to conduct either financial or programmatic audit, review, inquiry, or investigation (“review”) of a sponsored project must be directed, in writing, to Sponsored Projects Group.
2. Sponsored Projects Group will notify Financial Operations and the responsible department of an impending “review.”
3. An entrance and exit conference will be a required part of the “review” process.
4. During the “review,” every effort must be made by the responsible parties to provide sufficient documentation and/or an adequate explanation to written requests for information, in order to preclude cost disallowances or other deficiency findings.
5. On visits to any other administrative areas of the College, auditors/investigators must be accompanied by Sponsored Projects Group personnel at all times.
6. Cost disallowances cited in an audit/review report which cannot be refuted must be transferred immediately from the sponsored project account to the unrestricted operating account or another appropriate non-sponsored project account of the college or center.

Related Information

History/Revision Information

Responsible Division/Office: Sponsored Projects Group

Effective Date:

Last Amended Date:

Next Review Date:

Also Found In:
Compliance with Subrecipient Standards of OMB Circular 2 CFR part 200, Subpart F Audits (formerly “OMB Circular A-133”)

Policy/Procedure

PURPOSE:
To establish responsibility for compliance with the Office of Management and Budget (OMB) 2 CFR 200 Subpart F (Audits of States, Local Governments, and Non-Profit Organizations) as it relates to the College’s responsibilities in making awards to subrecipients.

POLICY:
1. Prior to submitting a College proposal to a federal sponsor that includes the above defined subrecipient, Sponsored Projects Group will ensure that the subrecipient has supplied the College with a letter of intent signed by an authorized institutional official, scope of work, debarment certification, budget, and F&A Cost Rate Agreement if appropriate.
2. Sponsored Projects Group is responsible for administering Federal funds granted to subrecipients. The award package or subaward will include the following information:
   a. Catalog of Federal Domestic Assistance (CFDA) title and number;
   b. award name and number;
   c. award year;
   d. an indication of the name of the awarding Federal agency. If all of this information is not available, Sponsored Projects Group will provide the best information available to describe the Federal award.
3. Sponsored Projects Group will advise subrecipients of requirements imposed on them by Federal laws, regulations and the provisions of contracts, grant or collaborative agreements as well as any supplemental requirements imposed by the College.
4. The principal investigator is responsible for monitoring the activities of subrecipients, as necessary, to ensure that Federal awards are being used for their authorized purpose and that performance goals are achieved. In doing so, the principal investigator is required to review and approve all technical and financial reports (including invoices). Principal investigator concerns regarding the contents of any required report(s) must be brought to the immediate attention of Sponsored Projects Group.
5. Sponsored Projects Group will generate a list of subrecipients once each year and will request each subrecipient to submit the appropriate correspondence as detailed in Item 7 below. If a subrecipient fails to submit its correspondence in a timely fashion, Sponsored Projects Group will take such action as necessary to obtain the report, including withholding of payment to the subrecipient.
6. In those instances where audit findings impact the College, Sponsored Projects Group will issue a decision within six months after receipt of the subrecipient’s reporting package and will follow up with the subrecipient to determine if appropriate and timely corrective action has taken place.

7. Each Federal subagreement is to include a clause incorporating the requirements of OMB 2 CFR 200 Subpart F that call for the subrecipient to have an audit conducted in accordance with the Circular and to submit a copy of its most recent OMB Subpart F reporting package to the College annually in all instances where the audit discloses findings related to the Federal award(s) provided by the College. In the event that no findings are reported, the subrecipient will provide written notification that an audit was conducted in accordance with the provisions of OMB Subpart F, the schedule of findings and questioned costs disclosed no audit findings relating to Federal awards provided by the College, and the summary schedule of prior audit findings did not report on the status of any audit findings relating to the Federal award(s) provided by the College. See Subrecipient Certification Form.

8. Sponsored Projects Group is responsible for reviewing submissions from Covered Subrecipients to identify those with findings related to Federal awards provided by the College.

9. If Sponsored Projects Group determines that an audit report includes findings of material noncompliance with federal laws and regulations, they shall notify the Controller, and together, they will discuss the findings with the principal investigator to determine an appropriate plan of action which may include adjustment of the College’s records, demand for repayment from the subrecipient, or other remedial action.

10. Sponsored Projects Group will ensure that subawards contain language permitting the College and/or its auditors to access the subrecipient’s records and financial statements as necessary for the College to comply with OMB Subpart F.

Related Information

Subrecipient Certification Form (See CF&GS Website)
http://www.dickinson.edu/info/20276/corporate_foundation_and_government_support/1932/sponsored_projects_office_spo

History/Revision Information

Responsible Division/Office: Sponsored Projects Group

Effective Date:

Last Amended Date:

Next Review Date:
Also Found In:
Monitoring Subrecipients Not Subject to OMB Circular 2 CFR part 200, Subpart F Audits (formerly “OMB Circular A-133”)

Policy/Procedure

PURPOSE:
To establish responsibility for monitoring subrecipients receiving federal funds but not subject to the Office of Management and Budget’s 2 CFR 200 Subpart F audits (Audits of States, Local Governments, and Non-Profit Organizations).

DEFINITION:
Subrecipients not subject to OMB Subpart F are defined as for-profit and those non-profit organizations not meeting the federal expenditure threshold of $500,000 per annum.

POLICY:
1. Prior to submitting a College proposal to a federal sponsor that includes the above defined subrecipient, Sponsored Projects Group will ensure that the subrecipient has supplied the College with a letter of intent signed by an authorized institutional official, scope of work, budget, and F&A Cost Rate Agreement if appropriate.
2. Sponsored Projects Group at the time of issuing the subaward and deemed necessary, will request and review a Dun & Bradstreet report and/or in the case of an NIH prime subaward, consult the HHS OIG Corporate Integrity Agreements and Settlement Agreement with Integrity Provisions list and request an audited financial statement.
3. Sponsored Projects Group is responsible for administering federal funds granted to subrecipients. The subaward package will include the following information:
   a. Catalog of Federal Domestic Assistance (CDFA) title and number;
   b. award name and number;
   c. award year;
   d. indicate if the award is considered Research and Development;
   e. name of the awarding federal agency;
   f. scope of work; and
   g. budget. If all of the above information is not available, Sponsored Projects Group will provide the best information possible to describe the Federal award.
4. Sponsored Projects Group will advise the subrecipient of requirements imposed on them by Federal laws, regulations and the provisions of contracts, grant and cooperative agreements, as well as any supplemental requirements imposed by the College. The following supplemental requirements will typically be imposed irrespective of the amount of the subaward:
a. a certification indicating that the subrecipient is not debarred or suspended from receiving federal funds and notification of the College if its status should change;
b. a certification indicating that the subrecipient will notify the College if it becomes subject to OMB Subpart F;
c. submission of audited financial reports;
d. review of subrecipient financial and prior performance reports;
e. findings in any audit which impact the fiduciary management of the subaward must be submitted to the College;
f. perform tax financial audits of subrecipient;
g. non-compliance with the terms and the conditions of the subaward may result in the withholding of payment and/or immediate termination; and
h. request or conduct a financial audit of the subrecipient to be performed by an external, College, and/or federal auditor.

In cases where prior experience with the subrecipient or the nature of the organization indicates additional risk, the following conditions may be imposed:
   i. perform site visits of subrecipient to review financial and programmatic records and observe operations;
   ii. payments will be made on a cost-reimbursable or milestone basis; and
   iii. checks of references regarding other awards performed for federal sponsors.

Factors such as the size of the subaward, the complexity of the compliance requirements, and risk of subrecipient non-compliance as assessed by the College may influence the nature and extent of monitoring procedures.

5. The principal investigator is responsible for monitoring the activities of subrecipients, as necessary, to ensure that Federal awards are being used for their authorized purpose and that performance goals are achieved. In doing so, the principal investigator is required to review and approve all technical and financial reports. Principal investigator concerns regarding the contents of any required report(s) must be brought to the immediate attention of Sponsored Projects Group.

6. Sponsored Projects Group will monitor the subrecipient according to the conditions selected for the subrecipient in Item 4 above.

7. If Sponsored Projects Group determines that an audit report includes findings or material noncompliance with federal laws and regulations, they shall notify the Comptroller, and together, they will discuss the findings with the principal investigator and the responsible business administrator to determine an appropriate plan of action which may include adjustment of the College’s records, demand for repayment from the subrecipient, or other remedial action.

**Related Information**

**History/Revision Information**
Record Retention

Policy/Procedure

PURPOSE:
To establish responsibility for the retention of records, including documentation supporting project expenditures, in accordance with the sponsors’ requirements.

POLICY:
1. All records which support sponsored project activities must be retained as follows:

<table>
<thead>
<tr>
<th>Record Category</th>
<th>Retention Schedule</th>
<th>Responsible Office</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grants administration records including awards, contracts and cooperative agreements, progress reports, invention and property reports</td>
<td>up to 7* years after completion of project/research**, as specified by individual agency requirements (please take a moment to read the explanations of the asterisks set forth below, these apply to all uses of “up to 7” and “completion of research “found on this page)</td>
<td>Sponsored Projects Group</td>
</tr>
<tr>
<td>Financial records including Financial Status Reports (FSRs), periodic financial reports</td>
<td>up to 7 years after completion of research</td>
<td>Sponsored Projects Group and Financial Operations</td>
</tr>
<tr>
<td>Scientific records</td>
<td>up to 7 years after completion of research**</td>
<td>Principal Investigator</td>
</tr>
<tr>
<td>Grant Proposals and Pre-Award Documents</td>
<td>permanent</td>
<td>Sponsored Projects Group</td>
</tr>
</tbody>
</table>

*This retention period is a maximum retention period. Lesser retention periods are dictated by applicable agency(s) requirements.

**“Completion of Research” refers to the period after the final close out of the grant and after all final documents have been submitted. These submitted documents include Financial Status Reports, Progress Reports, Invention Reports and Property Reports.

- Federal Sponsors:
  Grants: In general - records must be retained for a period of three years
from the date of submission of the final Financial Status Report to the sponsor, see 2 CFR 200-333.

Contracts: In general, records must be retained for a period of three years from the date of payment of the final invoice by the sponsor.

- Non-Federal Sponsors:
  Records should be retained following the same guidelines required by Federal sponsors, unless the terms of the agreement specify otherwise.

2. If a department is uncertain as to whether or not the record retention requirements have been satisfied, the records should not be destroyed without the advice and consent of Sponsored Projects Group.
Sponsored Projects Compliance Education Program Requirements

Purpose: To establish the requirement for individuals who carry out functions related to sponsored projects administration for a compliance education program; (SPCEP) identifies the responsible individual who will determine these individuals; and outlines the basic components of the compliance education program.

Policy:
1. Individuals who have any of the following administrative responsibilities related to sponsored projects are required to participate in the SPCEP:
   a) assist faculty with the preparation of proposals requiring the individual to make determinations of allowability, allocability, and reasonableness in accordance with sponsor guidelines, federal regulations, and College policies/procedures and regulatory requirements;
   b) review and approve expenditures in accordance with College policies;
   c) provide counsel and advice to faculty regarding proposal preparation, budget preparation;
   d) provide counsel and advice to faculty, PIs, department or office staff regarding proposal preparation, budget preparation;
   e) review and approve proposals;
   f) provide counsel and advice to faculty and to other personnel regarding cost transfers, effort reporting or overall award management;
   g) have financial audit responsibility;
   h) are responsible for the monitoring of awards, reviewing financial reports for accuracy and compliance and assuring that charges are allowable, properly allocated and reasonable; are responsible for the submission of financial reports/invoices to sponsor; and
   i) assistance and/or participation in the monitoring of sponsor requirements regarding the timely submission of required non-financial reports.

2. The Provost and Dean (or his/her designee) is responsible for:
   a) identifying those individuals in their operations who fulfill any of the above roles and/or functions;
   b) ensuring that the identified individuals successfully fulfill the requirements of the SPCEP; and
   c) ensuring that all new hires (including internal transfers) to a department fulfilling the above roles and/or functions fulfill the requirement of the SPCEP.

3. SPCEP may include any/all of the following
a) Regular attendance at monthly and other meetings of SPG
b) Regular attendance at annual professional meetings and workshops regarding sponsored projects administration, e.g., ECUBO, NCURA national and regional, SPA and FRA workshops
c) Monitoring and participating in sponsored project administration listservs, e.g. CLASP RESADM-L etc.

Related Information

History/Revision Information

Responsible Division/Office: Sponsored Projects Group

Effective Date:

Last Amended Date:

Next Review Date:

Also Found In:
POLICY XV-N: Property Standards – Equipment Acquisition and Management

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Policy/Procedure

PURPOSE:
To establish policy for the accounting of the acquisition and management of equipment funded by federally sponsored projects.

DEFINITION:
Equipment is an item with a unit cost of $5,000 or more, and a useful life of one year or more. Most sponsors permit the acquisition of special purpose equipment to be used in research activities. Purchases of general purpose equipment such as office furniture, computers, etc. are not allowable.

POLICY ON ACQUISITION:
1. The Principal Investigator must ascertain the specific acquisition requirements of the award from which the equipment will be purchased before it is ordered, and must abide by those requirements.

2. The College’s Procurement Process found at http://www.dickinson.edu/departments/finops/WitteProcurementprocess.pdf dictates the policy on equipment acquisitions unless more specific guidelines are offered under the Federal Awarding agency or OMB Circular A-110 Procurement Standards (2CFR 215.40 – 215.48). Important notes of interest in this section of OMB A-110 are:
   a. Written procurement policies are required
   b. Avoid unnecessary purchases
   c. Analyze lease versus buy
   d. Solicitations for goods must include:
      i. Description of technical requirements
      ii. Requirements that bidder must fulfill
iii. Positive efforts must be made to use minority-owned, small, or women owned businesses
e. Must make available to federal awarding agency, pre-award and procurement documents, when:
   i. Procurement is expected to exceed the simplified acquisition threshold fixed at 41 U.S.C. 403 (11) (currently at $100,000) and is to be awarded without competition or only one bid is received
   ii. Procurement over $100,000 specifies a “brand” name
   iii. Purchase is awarded to other than the low bidder
f. Procurement records must include basis for contractor selection, justification for lack of competition when bids or offers are not obtained, basis for award cost or price.

POLICY ON EQUIPMENT MANAGEMENT:
1. Policy and procedure set forth in OMB Circular A-110 Equipment (2CFR 215.34) will be adhered to for any equipment acquired with federal funds. Highlights from this policy include:
   a. Title shall vest in the recipient of federal funds (the College).
   b. Federally funded equipment may not be used to provide services to non-Federal outside organizations, for a fee that is less that private companies charge, unless exceptions by Federal statute are allowed.
   c. Equipment will be used on the original project first, then on other federally funded projects.
   d. Equipment may be used on other projects, subject to c. above, if available.
   e. When acquiring replacement equipment, the federal awarding agency may give approval to use the equipment to be replaced as a trade-in or sell it and use the proceeds to offset costs of the replacement equipment.
   f. Property management system must include:
      i. Description of Equipment
      ii. Manufacturer’s serial # or model #
      iii. Source of equipment including award #
      iv. Whether title vests in recipient of federal government
      v. Acquisition date and cost
      vi. Information on calculation of % funded by federal government
      vii. Location and condition of equipment and date reported
      viii. Unit acquisition cost
      ix. Date of disposal, sales price, or method used to determine current market value where a recipient compensates the Federal awarding agency
   g. Equipment owned by Federal government must be identified as such
   h. Physical inventory must be taken every two years, with results reconciled.
   Must verify the existence, current utilization, and condition of equipment.
   i. Adequate safeguards to prevent loss must be in effect.
   j. When equipment with a unit fair market value of $5,000 or more is no longer needed, it may be used for other activities provided that the Federal awarding
agency is compensated based on the guidelines in A-110. Consult with the Sponsored Projects Office for guidance.

Related Information

History/Revision Information

Responsible Division/Office: Sponsored Projects Group

Effective Date:

Last Amended Date:

Next Review Date:

Also Found In: http://www.dickinson.edu/departments/finops/WitteProcurementprocess.pdf
College Service Centers

Policy/Procedure

PURPOSE:
To ensure compliance with Federal regulations for accurately developing and costing service center charges to federally sponsored projects.

DEFINITION:
A service center is defined as a department, or functional unit within a department, which performs specific technical or administrative services for a fee. An example of a service center is the college’s print shop.

POLICY:
1. Services provided are charged directly to all users, including sponsored agreements, and based on actual use of the services, through a schedule of cost rates that do not discriminate against federally supported projects of the institution. Charges for services provided to sponsored projects must be made monthly, to accommodate accurate accounting and facilitate timely financial reporting of sponsored projects.
2. Charges for services rendered are to be structured to recover not more than the aggregate cost of the services. It is not necessary that the rates charged for services are equal to the cost of providing those services during any one fiscal year, as long as the rates are reviewed periodically and adjusted, at least annually, with the intent to balance revenue with expenses over a period normally no greater than three years.

Related Information

History/Revision Information

Responsible Division/Office: Sponsored Projects Group

Effective Date:

Last Amended Date:
Administration of Clinical Trials

**Policy/Procedure**

**PURPOSE:**
To ensure that funds received for the clinical testing of pharmaceuticals and medical devices (“clinical trials”) are administered in accordance with College policies, sponsor requirements and federal regulations.

**POLICY:**
1. All externally funded clinical trials must be approved in accordance with policies regarding Approval and Submission of Awards, as well as by the College’s Institutional Review Board (IRB) and Institutional Biosafety Committee (IBC), and performed under the terms of a formal clinical trial agreement which has been executed on behalf of the College by Sponsored Projects Group.
2. All externally funded clinical trials will be accounted for in a sponsored project fund established by Sponsored Projects Group.
3. The Principal Investigator is responsible for managing the clinical trial in accordance with the terms of the clinical trial agreement and protocol, College policies and applicable Federal regulations. It is also the Principal Investigator’s responsibility to submit required reports and other appropriate information to the Sponsored Project Group and to the sponsor.

**Related Information**

Approval and Submission of Awards
Dickinson Institutional Review Board (IRB):
http://www.dickinson.edu/homepage/78/institutional_review_board

Dickinson Institutional Biosafety Committee (IBC):
http://www.dickinson.edu/homepage/89/institutional_biosafety_committee

**History/Revision Information**

**Responsible Division/Office:** Sponsored Projects Group