



RESPONSIBLE CONDUCT IN RESEARCH
POLICY AND PROCEDURES

1.0 Purpose:

A vital part of Juniata College's educational mission is its support of scholarly research. The institution encourages both faculty and students to pursue their interests and if possible, to do so with external financial support. Juniata College, its faculty, staff and students are committed to conducting research and meeting the highest ethical standards while doing so.

The America COMPETES Act of 2007 (<http://www.govtrack.us/congress/bill.xpd?bill=h110-2272>) establishes that extramurally-supported institutional research and education proposals need to present a plan for "appropriate training and oversight in the responsible and ethical conduct of research."

This policy makes it mandatory for any student interested in conducting externally supported research at Juniata College to meet or exceed the minimum standards of responsible conduct of research established by the National Institutes of Health, National Science Foundation and National Academy of Sciences.

The elements discussed in those standards for the Responsible Conduct in Research will be completed by each student prior to the start of his/her research project in either one of two ways.

- 1) Each student will be required to participate in a research methods course in their discipline prior to being engaged in the research;
 - a. Each research methods course will now include instruction in all nine topics identified under section 4.0 Guidelines.
 - b. It is the responsibility of the department chair in each of the departments to ensure that these topics are adequately addressed in each of the methods courses.
- 2) Or the student will be required to complete online instruction and certification now offered under BI 389 (Biology Research Seminar) through an established relationship between Juniata College and the PEERRS online system of the University of Michigan.

The NIH has specified nine areas for instruction in RCR: Research Misconduct; Protection of Human Subjects; Welfare of Animals; Conflict of Interest; Data Management Practices; Mentor and Trainee Responsibilities; Collaborative Research; Authorship and Publication; and Peer Review.

The faculty member who serves as a research proposal's Principal Investigator (PI) will certify that adequate training, supervision, and mentoring of undergraduate research assistants in the responsible conduct of research has been provided.

All PI's will sign a form for each of their participating students on which the PI indicates that they have provided RCR training appropriate to the discipline, research project, and level of involvement for that student for each relevant NIH instructional area, or they will provide an explanation for why any particular area of training was not completed (e.g. in the case of non-human subjects research). Each participating student will sign the form indicating that they have received appropriate training. The completed training certification forms will be sent to the Provost's Office, which will be responsible for maintaining this documentation for as long as required. (Form is available on the Public Drive – Administration/Grants/Forms and Policies/JC Student RCR Training Certification form)

2.0 Related Policies

Juniata College has multiple related policies in place. The Juniata College Research Integrity Policy clearly states the principles dealing with identifying and managing alleged scientific misconduct in research. The Protection of Human Subjects Policy clearly defines and discusses the IRB established by Juniata College. The Conflict of Interest Policy Statement protects the highest level of integrity in research by setting the principles for dealing with conflicts of interest. The IACUC policy statement at Juniata sets the principles for animal treatment in research. Juniata College also has a biohazard policy that sets the principles for managing handling potentially dangerous material while doing research. Faculty, student and collaborating researchers are additionally expected to abide by each of these related policies.

In addition to the policies referenced in section 4.0 below, other related resources are listed at the end of this policy.

3.0 Scope

This policy and the associated procedures apply to all Juniata College faculty and students engaged in externally funded research. This policy applies to any person paid by, under the control of, or affiliated with the institution in externally supported research, such as faculty, administrators, scientists, trainees, technicians and other staff members, students, fellows, guest researchers, or collaborators.

4.0 Guidelines

In order to comply with this policy, all researchers serving on externally funded research must provide evidence to the principal investigator that they have already completed a research methods course or taken online instruction and received certification in the responsible conduct of research. That responsible conduct instruction must include each of the following topics:

1. Research Misconduct

1.1 Definition

The Office of Science and Technology Policy defines research misconduct as “fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results”ⁱ. All actions that are beyond the scope of accepted practices as well as any reckless, intentional action that can be proven with sufficient evidence will be considered research misconduct.

1.2 Reporting and Investigation of Misconduct

Juniata College holds its faculty and students to the highest standards in regards to appropriate behavior in research methods and practices. It is the responsibility of individuals to report misconduct and it is the responsibility of the institution to investigate the allegations. Responsible individuals will be expected to assume full responsibility for their actions, take misconduct seriously and report the apparent misconduct of fellow researchers.

As recommended by the Department of Health and Human Services, Office of Research Integrity (ORI), Juniata College will apply the following provisions for reporting and investigating allegations of misconduct in research:

1. The designation of an individual authorized to receive and investigate allegations of misconduct,
2. Provisions for an initial inquiry to determine whether the allegations have any merit,
3. Provisions for a formal investigation to reach conclusions about the truth of the allegations,
4. The designation of an individual who is authorized to weigh (adjudicate) the conclusions reached in the investigation and impose administrative actions to redress the misconduct (sanctions) or take steps to vindicate the person charged,
5. Provisions for reporting findings to ORI.”ⁱⁱ

(For more information on this topic and Juniata’s detailed policies and procedures, see (\\jcpublic) (P:)\\Administration\\Grants\\Forms and Policies\\Research Integrity and http://grants.nih.gov/grants/research_integrity/index.htm)

2. The Protection of Human Subjects

The Common Rule defines human subjects as “living individual(s) about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information” (§ 46.102(f))ⁱⁱⁱ

All faculty and students conducting research that involves human subjects must comply with all federal regulations that apply. They are also responsible to comply with any additional

regulations that the funders of the specific research project may impose. All individuals involved in the research will also be held responsible for being familiar with the regulations in question as well as getting the proper training needed to be qualified to conduct such research.

As required by law, all individuals involved in conducting federally funded research involving human subjects will need the appropriate approval from the Institutional Review Board and all other suitable institutions.

(For more information on this topic and Juniata's detailed policies and procedures, see <http://services.juniata.edu/catalog/policies/?section=view&policy=571>)

3. The Welfare of Laboratory Animals

Juniata College recognizes the need for animal subjects and recombinant DNA in certain experimentation. All faculty and students involved in animal research are under the jurisdiction of all USDA animal welfare regulations as well as the Public Health Services Policy on Humane Care and Use of Laboratory Animals.

The institution holds all faculty and students involved in animal research responsible to follow all rules and regulations specified by the latest version of the *Guide for the Care and Use of Laboratory Animals*.^{iv}

The responsibilities of persons engaged in the use of live vertebrate animals include:

- be familiar with pertinent rules and regulations;
- submit a protocol for review and approval by the IACUC before proceeding with the acquisition, transportation, housing, or use of any vertebrate animals;
- carry out projects in a respectful manner that minimizes pain and distress to animals;
- maintain appropriate records; and
- provide appropriate training to students, staff, and others involved with animal care and/or use. Such training shall include:
 - 1) proper handling and care procedures for animal species used by the facility,
 - 2) precautions necessary to protect the animal handlers from known risks or disease, and
 - 3) reporting methods for deficiencies in animal care or treatment.

Juniata's Institutional Animal Care and Use Committee (IACUC) monitors care and use of vertebrate animals and reviews program compliance. The Committee functions include:

- carry out annual reviews and evaluation of activities involving animals;

- make recommendations to Principal Investigators, Departments, or the Provost regarding any aspect of the animal program, facilities, or personnel training;
- review, and, if warranted, investigate complaints received from employees or from the public; and
- perform other functions as required by institutional needs and by federal, state, and local authorities.

Inquiries concerning policies should be directed to the IACUC Chair.

(for more information on this topic and Juniata's detailed policies and procedures, see <http://services.juniata.edu/catalog/policies/index.html?section=view&policy=925>)

4. Conflict of Interest

Juniata encourages external interaction and relationships with the public and private sectors to foster its educational mission. The institution is fully aware, however, that a conflict of interest may arise. Conflict of interest can be financial, commitment related, personal and intellectual.

Juniata College will adhere to all federal, state and local regulations regarding this subject. This may include reporting any potential conflicts as well as their resolutions.

Disclosure:

This policy applies to all Juniata College Officers and employees who have responsibilities for budgets, major purchases, and grant funded projects. All College individuals will complete a Certification of Compliance with the College Conflict of Interest Policy annually (annual certifications are filed with Human Resources).

In addition, research Investigators (defined as the project director or principal investigator and any other person, regardless of title or position, who is *responsible* for the design, conduct, or reporting of research, which may include, for example, students, collaborators, consultants or sub-awardees) on grant funded projects, whether federally funded or not, must complete a Certification of Compliance with the College Conflict of Interest Policy with each grant application and submit it to the Office of Corporate and Foundation Relations. Certifications will be filed in the Provost's office.

Management and Reporting:

In the event that a significant financial interest (SFI) is disclosed by an investigator, Juniata College will review the SFI and determine if it is related to the research and if it results in a Conflict of Interest with that research. If a conflict is determined to exist, Juniata will develop and implement a management plan to minimize the risk of bias in the research. In accordance

with the federal regulations the details of each research Conflict of Interest (to include the name of the investigator, the name of the entity in which the investigator has the SFI, the nature and size of the SFI, the basis for the conflict determination, and the key elements of the management plan) shall be reported to the funding agency. Details of the Conflict of Interest must be made available to the public upon request.

Training:

All Investigators must complete conflict of interest training prior to the start of the funded research and every four years thereafter or when Juniata has a policy change/update. This tutorial can be found at:

- Office of Extramural Research, Financial Conflict of Interest Tutorial
<http://grants.nih.gov/grants/policy/coi/index.htm>

Certification of completion of the training should be submitted to the Provost's office.

(For more information on this topic and Juniata's detailed policies and procedures, see <http://services.juniata.edu/catalog/policies/index.html?section=view&policy=944>)

5. Data Management Practices

Juniata College holds that data ownership will be determined based on conditions imposed by the funders, research institutions and data sources. Faculty and students will be held responsible to be fully aware of all provisions stated in their contracts with the funding organizations.

Juniata College will not be held responsible for any stolen, damaged or loss data. It is the responsibility of the researcher to insure the safety of the information collected.

Data retention and data sharing depend on the funders' preferences. Faculty and students are expected to be familiar, and abide with, Freedom of Information Act requests once their data is published. However, in practice Juniata adheres to the principles of data management consistent with and recommended by the National Institutes of Health.

(For more information on this topic and Juniata's detailed policies and procedures, see the public drive Administration\Grants\Forms and Policies\Juniata Data Management Plan and <http://ori.dhhs.gov/education/products/clinicaltools/data.pdf>)

6. Mentor and Trainee Responsibilities

Juniata encourages proper development of future researchers, both undergraduates and post-doctoral fellows (Juniata is a strictly undergraduate institution and does not offer Masters or PHD's. Juniata does however occasionally employ post-doctoral fellows in research and teaching experiences. For both undergraduate researchers and post-doctoral fellows, Juniata does assign a mentor to guide the development of these researchers.

Juniata College expects mentor and trainee to establish a basic understanding early in the relationship regarding the type of research to be conducted, the time commitment needed, as well as other topics that may arise.

Mentors will be held responsible for their trainees. They are obligated to give proper instructions, proper supervision and reviews to the mentees.

(For more information on this topic, see <http://www1.od.nih.gov/oir/sourcebook/ethic-conduct/mentor-guide.htm>)

7. Collaborative Research

Collaborative research, both between disciplines intra-campus and between researchers at other institutions is broadly encouraged by Juniata.

Some aspects of the collaborative efforts may require formal agreements between the parties involved, and all signatories must work in compliance to the terms set by these agreements. The grants office (and officers) of Juniata College facilitate those agreements between institutions.

(For more information on this topic, see <http://www.juniata.edu/gifts/cfg/resources.html> or contact the Juniata grants office at 814-641-3442)

8. Authorship and Publication

Juniata College faculty and students may publish their research at a time they see fit. The institution prides itself in the quality of the research published and the quality of the publications in which those publications appear. Juniata further encourages publishing agreements which further allow public access to the research. If such publication agreement allows, Juniata encourages posting the research to public access forums, such as PubMed Central (<http://www.ncbi.nlm.nih.gov/pmc/>)

(For more information on this topic and Juniata's detailed policies and procedures, see <http://services.juniata.edu/catalog/policies/> under the Institutional policies and <http://publicaccess.nih.gov/>

9. Peer Review

Peer review, whether it is for grant proposals or manuscript review, is an essential part of research. Juniata College holds all faculty and students responsible for respecting the quality and confidentiality of the research under review.

(For more information on this topic, see <http://grants.nih.gov/grants/peer/>)

10. Related Resources

Resources have been collected below to assist PI's in providing the required training. To aid in the training process, PI's are encouraged to collaborate with appropriate campus committees including the Institutional Review Board (IRB) and Institutional Animal Care and Use Committee (IACUC).

Other Ethics Training and Resources

North Carolina State University provides online courses

<http://www.ncsu.edu/project/ungradreshhmi/evaluationModule/login.php> in Philosophy of Science, Research Ethics and Animals in Research. Northeastern University has also presented an interesting set of case studies.

The National Academies Press book "On Being a Scientist: Responsible Conduct in Research" is available online at http://www.nap.edu/catalog.php?record_id=4917.

Books & Journals

- Research ethics: a reader (e-book) Elliott & Stern. 1997.

<http://encore.trinity.edu/iii/encore/record/C%7CRb1991383%7CSresearch+ethics%7COrightresult?lang=eng&suite=def>

- Research ethics: cases and materials. Penslar. 1995.

<http://encore.trinity.edu/iii/encore/record/C%7CRb1685183%7CSresearch+ethics%7CP0,1%7COrightresult?lang=eng&suite=def>

- Science and Engineering Ethics <http://www.springer.com/philosophy/ethics/journal/11948>

Disciplinary Codes of Ethics

- American Chemical Society

http://portal.acs.org/portal/acs/corg/content?_nfpb=true&_pageLabel=PP_TRANSITIONMAIN&node_id=1095&use_sec=false&sec_url_var=region1&_uuid=

- Association for Computing Machinery <http://www.acm.org/about/code-of-ethics>

- Society for Neuroscience - Responsible Conduct Regarding Scientific Communication

<http://www.sfn.org/index.cfm?pagename=responsibleConduct>

Additional Resources

- Responsible Conduct of Research at PUIs (CUR 2009)

http://www.uwosh.edu/grants/research_responsibility/CUR09/

- Research Responsibility and Undergraduates (CUR 2002)

<http://www.cur.org/conferences/responsibility/ResRespons.html>

- Resources for Research Ethics Education <http://research-ethics.net/>
- AAAS Integrity in Scientific Research resource page
<http://www.aaas.org/spp/video/resource.htm>
- NAP's Integrity in Scientific Research: Creating an Environment That Promotes Responsible Conduct http://www.nap.edu/catalog.php?record_id=10430
- HHS Office of Research Integrity - Educational Resources
<http://ori.dhhs.gov/education/products/>
- Honor in Science (Sigma Xi) <http://www.sigmaxi.org/programs/ethics/publications.shtml>

ⁱ http://ori.hhs.gov/policies/fed_research_misconduct.shtml

ⁱⁱ For more information regarding the recommendations from the Department of Health and Services regarding investigating and reporting misconduct in research, please refer to <http://www.ori.hhs.gov/documents/rcrintro.pdf>

ⁱⁱⁱ <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>

^{iv} The *Guide* can be found <http://www.nap.edu/readingroom/books/labrats/preface.html>