

Ethics and the Responsible Conduct of Research



THE HENRY BELLMON OFFICE OF
Scholar Development and Undergraduate Research

334 Student Union | 405.744.7313 | tim.oneil@okstate.edu

- [What is Research Ethics?](#)
- [OSU Requirements for Training in the Responsible Conduct of Research \(RCR\)](#)
- [CITI Training - RCR Tutorial](#)
- [Conducting Research Responsibly](#)
- [IRB and the Policy for the Protection of Human Subjects in Research](#)
- [IRB Step-by-Step](#)
- [Resources](#)

Seminar Topics



Ethics



[Resources for Research Ethics Education \(RREE\)](#)



“Ethics is knowing the difference between what you have a right to do and what is right to do.”

Potter Stewart

Former Associate Justice of the Supreme Court of the United States

What is Research Ethics?



The ethics of the planning, conduct, and reporting of research.

It is clear that research ethics should include protections of human and animal subjects.

However, not all researchers use human or animal subjects, nor are the ethical dimensions of research confined solely to protections for research subjects. Other ethical challenges are rooted in many dimensions of research, including the:

- Collection, use, and interpretation of research data
- Methods for reporting and reviewing research plans or findings
- Relationships among researchers with one another
- Relationships between researchers and those that will be affected by their research
- Means for responding to misunderstandings, disputes, or misconduct
- Options for promoting ethical conduct in research

Ethical Distinctions



Prescriptive vs. Descriptive claims

It is important not to confuse moral claims about how people ought to behave with descriptive claims about how they in fact do behave.

From the fact that gift authorship or signing off on un-reviewed data may be “common practice” in some contexts, it doesn't follow that they are morally or professionally justified. Nor is morality to be confused with the moral beliefs or ethical codes that a given group or society holds (how some group thinks people should live). A belief in segregation is not morally justified simply because it is widely held by a group of people or given society. Philosophers term this distinction between prescriptive and descriptive claims the “is-ought distinction.”

Ethical Distinctions



Law vs. Morality

The law may or may not conform to the demands of ethics. To take a contemporary example: many believe that the law prohibiting federally funded stem cell research is objectionable on moral (as well as scientific) grounds, i.e., that such research can save lives and prevent much human misery. History is full of examples of bad laws, that is laws now regarded as morally unjustifiable, e.g., the laws of apartheid, laws prohibiting women from voting or inter-racial couples from marrying.

Ethical Distinctions



First-Order Questions

First-order moral questions concern what we should do. Such questions may be very general or quite specific. One might ask whether the tradition of senior authorship should be defended and preserved or, more generally, what are the principles that should go into deciding the issue of senior authorship. Such questions and the substantive proposals regarding how to answer them belong to the domain of what moral philosophers call “normative ethics.”

Ethical Distinctions



Second-Order Questions

Second-order moral questions concern the nature and purpose of morality itself. When someone claims that falsifying data is wrong, what exactly is the standing of this claim? What exactly does the word 'wrong' mean in the conduct of scientific research? And what are we doing when we make claims about right and wrong, scientific integrity and research misconduct? These second-order questions are quite different from the ground-level questions about how to conduct one's private or professional life raised above. They concern the nature of morality rather than its content, i.e., what acts are required, permitted or prohibited. This is the domain of what moral philosophers call "metaethics."

Four-Component Model of Morality

Rest, J. (1986). *Moral Development: Advances in Research and Theory*. New York: Praeger.



Moral sensitivity: person made interpretation of situation in terms of what actions were possible, who (including oneself) would be affected by each course of action, and how the interested parties would regard such effects on their welfare.

Moral reasoning: person must have been able to make a judgment about which course of action was morally right...what he ought to do.

Moral commitment: person must give priority to moral values above other personal values—to do what is morally right.

Moral perseverance or implementation: person must have sufficient perseverance, ego strength, and implementation skills to be able to follow through on his/her intention to behave morally, to withstand fatigue and flagging will, and to overcome obstacles.



“A man without ethics is a wild
beast loosed upon this world.”

Albert Camus

Nobel Prize in Literature, 1957

OSU Requirements for Training in the Responsible Conduct of Research (RCR)



4-0201 Academic Affairs August 2009

OSU Requirements for Training in the Responsible Conduct of Research (RCR)



Policy

2.04 Each student (both undergraduate and graduate) must complete a module appropriate to the department in which they are enrolled within the two calendar months following either:

- A.** the effective date of a pertinent employment action (EA) form providing support from external grant funds;
- B.** enrollment in any course for which research is an integral element of the course – e.g., honors thesis, masters thesis (5000), or doctoral dissertation (6000); or
- C.** conducting activities identified by his/her advisor as involving research.

OSU Requirements for Training in the Responsible Conduct of Research (RCR)



Purpose and Scope

1.03 As a Research-Extensive institution, Oklahoma State University has an obligation to take steps to ensure that its advanced degree recipients, faculty, and research staff have a thorough working knowledge of matters related to responsible research behaviors.

At a minimum, these include: proper citation of other work, plagiarism, research misconduct, intellectual property and copyright, falsification and unwarranted editing of data, conflict of interest, authorship on manuscripts, and mentor-mentee relationships. Other issues (e.g., ethical treatment of animals, human subject protocols, and handling of hazardous materials) may also be appropriate, depending on the discipline of study.

OSU Requirements for Training in the Responsible Conduct of Research (RCR)



Procedure

3.01 Upon an individual's completion of an appropriate module, documentation certifying such completion should be filed in the appropriate departmental office.

Getting Started with the Collaborative Institutional Training Initiative (CITI)
RCR Tutorial Instructions



[Office of University Research Compliance Information Sheet](#)

Getting Started with the Collaborative Institutional Training Initiative (CITI) RCR Tutorial Instructions



Oklahoma State University subscribes to the Collaborative Institutional Training Initiative (CITI) as a component of our training efforts in the responsible conduct of research.

- The online training program titled Responsible Conduct of Research consists of several training courses from which you should choose the one most appropriate to your field or discipline.
- Courses include instructional material, suggested readings, and short quizzes.
- You must earn a cumulative score of 80% to pass/complete a course. Quiz results are recorded and provided to you and to the Office of University Research Compliance.

Getting Started with the Collaborative Institutional Training Initiative (CITI) RCR Tutorial Instructions



To Register as a New User

Open your internet browser and go to the CITI website <https://www.citiprogram.org/>

- Click on “Register,” which is located under “Create an Account.”
- Step 1: Select Oklahoma State University by clicking on the “Participating Institutions” drop down box.
 - Do not select Oklahoma State University Center for Health Sciences. Do not enter anything in the other drop down box fields in Item 1.
- Click on “Continue to Step 2” found at the bottom of the page.

Getting Started with the Collaborative Institutional Training Initiative (CITI) RCR Tutorial Instructions



- Complete Steps 2-6 as directed. Fields marked with an asterisk (*) are required.
- Step 7: Skip Question 1, Question 2, and Question 3. Scroll down to Question 4 “Responsible Conduct of Research” (RCR).
- Select the course most appropriate to your field or discipline.
- Skip Question 5, as this pertains to RCR refresher courses only.

Getting Started with the Collaborative Institutional Training Initiative (CITI) RCR Tutorial Instructions



- Skip Question 6 unless you need to take a course in Conflict of Interest (COI).
- Click on “Complete Registration.”
- Click on “Finalize Registration.”

The final webpage you see explains that you will receive a confirmation email message from CITI with information about how to activate your registration. Before you can use your new CITI account, you will need to open the email message that CITI sends you and click on the activation link. Once you have successfully completed this step, you may return to the CITI website at <https://www.citiprogram.org>, enter your Username and Password and click “Log In.”

Getting Started with the Collaborative Institutional Training Initiative (CITI) RCR Tutorial Instructions



After logging in you will see the CITI Main Menu. Click on “Oklahoma State University Courses.” You will see a list of the courses in which you are enrolled.

If any of the courses you need to complete are not listed, simply click on “Add a Course or Update Learner Groups” within “My Learner Tools.” A new webpage will open that allows you to select additional courses. Once you have made your selection(s), click on “Submit.” You will then be returned to a webpage that will contain the updated list of the courses you have chosen.

Getting Started with the Collaborative Institutional Training Initiative (CITI) RCR Tutorial Instructions



To take a course, click on the course name, which is a hyperlink. Complete the required modules and any associated quizzes. You do not have to complete all of an individual course in one sitting. You can exit the website and return another time to complete unfinished modules. Once a course is completed, print the completion report and keep a copy for your records. CITI will automatically notify the Office of University Research Compliance of your completion results (pass/fail).

If you have questions about this training or need additional information on how to register with CITI, please contact the Office of University Research Compliance at 405-744-1676.

Conducting Research Responsibly



[Office of University Research Compliance Information Sheet](#)

Conducting Research Responsibly



The Office of the Vice President for Research and Technology Transfer provides programs and services to help faculty, staff, and students meet the ethical and regulatory requirements for the responsible conduct of research. The chart below provides information on basic requirements and how to achieve compliance:

If you...	You need to...
Conduct research, teaching, or testing activities involving live, vertebrate animals	<p>Obtain approval for use of animals in research, teaching, or testing activities from the Institutional Animal Care and Use Committee (IACUC) http://compliance.vpr.okstate.edu/IACUC/iacuc-index.aspx</p> <p>Report any concerns about animal health and safety; perceived deficiencies; or activities of non-compliance to the Office of University Research Compliance, the IACUC, the University's Attending Veterinarian, and/or the Vice President for Research & Technology Transfer</p> <p>Arrange to visit with the Director of Animal Resources and University Attending Veterinarian for animal housing, procedures, anesthesia, analgesia, euthanasia, or other issues specific to animal health and safety</p>

Conducting Research Responsibly



The Office of the Vice President for Research and Technology Transfer provides programs and services to help faculty, staff, and students meet the ethical and regulatory requirements for the responsible conduct of research. The chart below provides information on basic requirements and how to achieve compliance:

If you...	You need to...
Conduct research involving human subjects (including human biological specimens)	Review the Institutional Review Board (IRB) Handbook. Complete required IRB training: http://compliance.vpr.okstate.edu/IRB/training.aspx Obtain approval or exempt determination from the IRB prior to starting research. Visit the IRB website for more information: http://compliance.vpr.okstate.edu/IRB/irb-index.aspx

Conducting Research Responsibly



Additional conditions that may require compliance measures:

- Conduct research with biohazardous material; toxins; Select Agents; human materials; any plant, animal, or human pathogens; transgenic plants or animals; or recombinant DNA.
- Work with radioactive materials and/or ionizing radiation producing equipment such as x-ray units, diffraction units, electron microscopes, turbidity analyzers and densitometers, etc.
- Work with chemicals
- Use biological safety cabinet(s)
- Generate hazardous waste in the laboratory
- Work with and/or operate Class 3b and/or Class 4 lasers

IRB and the Policy for the Protection of Human Subjects in Research



4-0115 RESEARCH November 2011



“The first step in the evolution of ethics is a sense of solidarity with other human beings.”

Albert Schweitzer

Nobel Peace Prize, 1952

IRB and the Policy for the Protection of Human Subjects in Research



Policy

5.01 In accordance with legally binding Federal regulations concerning the protection of human subjects, OSU fulfills its obligation and responsibility through support of its Institutional Review Boards (IRBs). IRBs determine that risks to human subjects are minimized and that the risks posed by participation in research are reasonable in relation to the knowledge expected to result.

IRB and the Policy for the Protection of Human Subjects in Research



Policy

5.01 In performing a comprehensive review, the IRBs must consider ethics, science, and conflicts of interest. Expressly, OSU IRBs:

A. shall review, approve, require modifications in order to secure approval, and/or disapprove all research activities that fall within IRB purview, including proposed amendments based upon consideration of the risks and potential benefits of the research.

...

F. shall notify researchers and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the researcher an opportunity to respond in person or in writing.

...

L. may place restrictions on any study that falls within IRB purview.

IRB and the Policy for the Protection of Human Subjects in Research



Purpose

1.02 OSU, guided by ...ethical principles pertaining to research involving human subjects and bound by federal regulations, has an ethical obligation to safeguard the rights and welfare of people who volunteer to participate in research conducted under the auspices of the University.

...

To this end, OSU requires that, prior to initiation of any human subjects research related activities (i.e., prior to recruitment of subjects and data collection), all research (as defined below) involving human beings as subjects of research, including research with human material obtained from living individuals, be reviewed and approved by the appropriate IRB.

IRB and the Policy for the Protection of Human Subjects in Research



Statement of Principles

2.03 Researchers must treat human subjects in an ethical manner by respecting their personal autonomy and safeguarding their rights and welfare. Moreover, researchers are obligated to maximize possible benefits and minimize potential harms to human subjects. Accordingly, the risks and benefits of research with human subjects should be distributed fairly and without bias.

IRB and the Policy for the Protection of Human Subjects in Research



Definitions

3.01 Research is defined as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge” (45 CFR 46.102[d]). A research project is typically described in a protocol that sets forth specific objectives and systematic procedures designed to reach the stated objectives.

IRB and the Policy for the Protection of Human Subjects in Research



Definitions

3.02 Human subject means “a living individual about whom an Investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information” (45 CFR 46.102[f]).

Intervention “includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.”

Interaction includes “communication or interpersonal contact between investigator and subject.”

Private information includes “information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.

IRB Step-by-Step



Institutional Review Board Information Sheet

IRB Step-by-Step



Step 1. Review Human Subject Research website.

<http://compliance.okstate.edu/irb/irb-index>

Step 2. Determine if your project needs IRB review.

IRB Step-by-Step



Step 2a. Determine if your project needs IRB review.

Does the research involve obtaining information about living individuals?

If NO, then the study does not involve human subjects. If YES, proceed to the following:

ALL of the following must be NO to qualify as “non-human subject research”:

- Does the study involve intervention or interaction with a “human subject”?
- Does the study involve access to identifiable private information?
- Are data/specimens received by the Investigator with identifiable private information?
- Are the data/specimens coded such that a link exists that could allow the data/specimens to be re-identified?

If you answered YES to any of the questions above, you must proceed to the next set of questions.

IRB Step-by-Step



Step 2b. Determine if your project needs IRB review.

If you answered YES to any of the questions to determine human subject involvement, one of the following must be NO to qualify as “non-research”:

- Will the data/specimens be obtained in a systematic manner?
- Will the intent of the data/specimen collection be for the purpose of contributing to generalizable knowledge?

If you answered NO to either of the preceding questions, you are not conducting research and IRB review is not required.

If you answered YES to both of the preceding questions, then IRB review is required.

IRB Step-by-Step



Step 3. Complete required training.

<http://compliance.vpr.okstate.edu/IRB/training.aspx>

Step 4. Submit IRB application for project review.

<http://compliance.vpr.okstate.edu/IRB/forms.aspx>

Step 5. If necessary, modify research protocol and/or report adverse event(s).

Step 6. Protocol continuation and closure.

IRB Step-by-Step



Review Timeline

The process of review for each application is dependent upon federal regulations found at 45 CFR 46. The review process for each level is summarized in the following table.

Review Level	Number of Reviewers	Estimated Time for Review
Exempt	1	1-10 days
Expedited	1	7-14 days
Full Board	Entire Board	14-60 days

OSU Resources



- Vice President for Research
<http://vpr.okstate.edu/>
- University Research Compliance
<http://compliance.okstate.edu/>
- Institutional Review Board (IRB)
<http://compliance.okstate.edu/irb/irb-index>
- Institutional Animal Care and Use Committee (IACUC)
<http://compliance.okstate.edu/iacuc/iacuc-index>

Other Resources



Adams D, Pimple KD (2005): Research Misconduct and Crime: Lessons from Criminal Science on Preventing Misconduct and Promoting Integrity. *Accountability in Research* 12(3):225-240.

Anderson MS, Horn AS, Risbey KR, Ronning EA, De Vries R, Martinson BC (2007): What Do Mentoring and Training in the Responsible Conduct of Research Have To Do with Scientists' Misbehavior? Findings from a National Survey of NIH-Funded Scientists . *Academic Medicine* 82(9):853-860.

Bulger RE, Heitman E (2007): Expanding Responsible Conduct of Research Instruction across the University. *Academic Medicine*. 82(9):876-878.

Kalichman MW (2006): Ethics and Science: A 0.1% solution. *Issues in Science and Technology* 23:34-36.

Kalichman MW (2007): Responding to Challenges in Educating for the Responsible Conduct of Research, *Academic Medicine*. 82(9):870-875.

Kalichman MW, Plemmons DK (2007): Reported Goals for Responsible Conduct of Research Courses. *Academic Medicine*. 82(9):846-852.

Kalichman MW (2009): Evidence-based research ethics. *The American Journal of Bioethics* 9(6&7): 85-87.

Pimple KD (2002): Six Domains of Research Ethics: A Heuristic Framework for the Responsible Conduct of Research. *Science and Engineering Ethics* 8(2):191-205.

Steneck NH (2006): Fostering Integrity in Research: Definitions, Current Knowledge, and Future Directions. *Science and Engineering Ethics* 12:53-74.

Steneck NH, Bulger RE (2007): The History, Purpose, and Future of Instruction in the Responsible Conduct of Research. *Academic Medicine*. 82(9):829-834.

Vasgird DR (2007): Prevention over Cure: The Administrative Rationale for Education in the Responsible Conduct of Research. *Academic Medicine*. 82(9):835-837.



“Even the most rational approach to ethics is defenseless if there isn't the will to do what is right.”

Alexander Solzhenitsyn
Nobel Prize in Literature, 1970