How Other Universities Handle RCR

A brief examination of various universities RCR programs shows that:

Many (200+) use an **exterior program** – often CITI (Collaborational Institute Training Initiative) – at least in part

USC; Alaska-Anchorage; Washington (Grad Students), Purdue, Missouri, South Florida, West Virginia, CUNY (partial), Mississippi, North Texas, Cal-Irvine (partial), Tulane, Montana, Indiana, Rice (partial), Clemson (partial), Connecticut (option), Tennessee (option), Wright State (option), Kentucky, Nrthwestern (partial), UDC, Alabama, Dakota State?, SDSU

Face-to-Face Coursework

Wisconsin (many courses), Rice (discipline specific mentoring?), Wright State (option), Connecticut (option), Tennessee (option), Stanford,

Workshops/Seminars

Wisconsin, Rice (discipline specific mentoring?), Howard U., Wright State (option), Connecticut (option), Tennessee (option), Northwestern (partial), Alabama (post docs)

SDSM&T – Eric James

    How?

    Who should take?

    Tracking compliance?

Responsible Conduct of Research (RCR)

Statutory Requirement:
"The Director shall require that each institution that applies for financial assistance from the Foundation for science and engineering research or education describe in its grant proposal a plan to provide appropriate training and oversight in the responsible and ethical conduct of research to undergraduate students, graduate students, and postdoctoral researchers participating in the proposed research project."

- **Federal Register Notices**
  o NSF's Implementation of Section 7009 of America COMPETES Act
  o NSF's Proposed Implementation of Section 7009 of America COMPETES Act

- RCR Implementation in the Grant Proposal Guide (GPG)
- RCR Implementation in the Award & Administration Guide (AAG)
- RCR Frequently Asked Questions (FAQs)
- International Research Integrity
- NSF-funded Beta Sites
  o Ethics in Science and Engineering National Clearinghouse
  o Online Ethics Center Enhancements and America COMPETES

From the Federal Register:

…NSF does not intend to issue NSF-specified standards and recognizes that training needs may vary depending on specific circumstances of research or the needs of students intending to pursue careers in a variety of science and engineering settings after completing their education. Therefore, it is the responsibility of each institution to determine both the content and the delivery method for the training that will meet the institution's particular needs for RCR training in all areas at that institution for which NSF provides support.

NSF Funded Beta Sites for RCR:

http://www.onlineethics.org/CMS/about/UserGuide/18848.aspx
http://www.umass.edu/sts/digitallibrary/

Several universities are members of CITI-Collaborative Institutional Training Initiative:
https://www.citiprogram.org/rcrpage.asp?language=english&affiliation=100

NIH has RCR requirements and training: http://grants.nih.gov/training/responsibleconduct.htm.
Emphasis areas at NIH include:
a. conflict of interest – personal, professional, and financial
b. policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices
c. mentor/mentee responsibilities and relationships
d. collaborative research including collaborations with industry
e. peer review
f. data acquisition and laboratory tools; management, sharing and ownership
g. research misconduct and policies for handling misconduct
h. responsible authorship and publication
i. the scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research

Responsible Conduct of Research Requirements
NSF and NIH Comparison

	NSF	NIH
What's Required	A plan to provide appropriate training **and oversight**	Instruction in Responsible Conduct of Research
Applicability	Students/Postdocs supported by NSF to conduct research	All NIH institutional Research Training Grants, and individual fellowships /other awards with a training component
Pre-Award	Certification signed by AOR w/ submission. Plan not required in proposals, but "subject to review"	Program described in application, included in peer review; updated description in renewal applications. Reviewers will look at past practices/format/subject matter/faculty participation/duration and frequency of training proposed, will rate as acceptable or not acceptable
Type of Training	Not prescribed, left to institutions to determine	Instruction should include "substantial" face to face conversations, on-line training is NOT sufficient. Minimum of 8 contact hours
Recipients of Training	Undergraduate and graduate students and post-doctoral researchers "supported by NSF to conduct research"	Active involvement in RCR issues "should occur throughout a scientist's career"; Research faculty should participate in the RCR training as role models; all trainees, fellows, participants and scholars receiving support through any NIH training, career development award, research education grant, and dissertation research grant, and any other NIH-funded programs that require RCR training in the FOA. All individuals associated with a project should receive training, regardless of source of support.
Frequency of Training	Not specified	At least once during each career stage, and no less than once every four years
Training Content	Not specified	a. Conflict of interest b. Human subjects, animal welfare, laboratory safety c. Mentor/mentee responsibilities and relationships d. Collaborative research e. Peer review f. Data acquisition, management, sharing and ownership g. Research misconduct and policies for handling misconduct h. Responsible authorship and publication i. Scientists' responsibility to society
Compliance	Institutions must designate one or more persons to oversee compliance; and must verify that training has been received.	Institutions are expected to maintain records sufficient to demonstrate that training has been received.

Responsible Conduct of Research
At
Predominantly Undergraduate
Institutions (PUIs):
A Primer

**Presented to SRA Northeast/Midwest Sectional
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What is integrity in research?
- "Simply good citizenship applied to research." (ORI)
- "Doing the right thing, at the right time, in the right way." (NSF OIG)

What is expected of our campuses?
- A comprehensive institutional system for ensuring that research is conducted efficiently and without waste
- That research results are objective, accurate, and reliable, and accountable
- That our institutions will be in compliance with ethics and compliance mandates governing federally-funded research

Particular Concerns for PUI's
- There are no economies of scale
- Infrastructure is limited
    - There may be only one or two individuals who have the expertise
    - Research administrators (if they exist) need to be multi-faceted, not specialists.
- Institutional leadership may minimize research administration issues. Like research administrators on small campuses, they have to reconcile multiple competing priorities.
- Exceptionalism: Assumption that smaller organizations are not likely to be audited, for example.
- Compliance mandates are often unfunded (or at least under-funded) mandates.
- Resistance to allocating resources to a "small" research base.
- Compliance, done right, is FAR less costly than dealing with the consequences of an infraction.

Ethical Principles

- Responsible Stewardship
    - Obligation to use public resources effectively and efficiently
- Public Trust
    - Public has the right to confidence in the reliability of research results
- Respect for Living Beings
    - Human and animal subjects
    - Colleagues and Students
- Regulations apply to federally-funded research.
    - Is it proper or ethical to apply lesser standards to research that is not federally-funded?
- Regulations set the ethical "floor"; they represent minimum standards. Institutions and researchers are free to set and practice higher standards than those in the regulations
- Campus sponsored programs offices have historically focused primarily on fiscal compliance. Audits, likewise, have also emphasized fiscal compliance.
- Federal requirements are for performance as well as fiscal compliance, and performance is coming under increasingly close scrutiny.
    - For example: NSF award language: "By accepting an award, the awardee agrees to comply with the applicable Federal requirements **_and_**…to the prudent management of all expenditures **_and actions_** affecting the award."

Where are we and how did we get here?

The public and regulatory demand for accountability has increased dramatically in last 20 years.

Regulatory history has been largely reactive – in response to abuses and scandals.

Regulation of human subjects research began as an outgrowth of Nazi war crimes tribunals (1940's), and a subsequent series of public outcries about abuse of research participants in the early 1960's to mid 1970's. Current practices were first codified into law and regulation in 1974. Over 50 years of public debate on animal rights and welfare led to the 1966 Animal Welfare Act, and the Health Research Extension Act of 1985 provided the legislative mandate for the PHS policy pertaining explicitly to research and teaching. Research misconduct came under public scrutiny in the 1970s and early 1980s, eventually leading to regulation. This was followed in the 1990s by regulation pertaining to institutional responsibilities for management of investigators' conflicts of interest.

In 2000, NIH began to define "Responsible Conduct of Research" more broadly and holistically, by announcing a policy requiring that all "research staff" receive complete training in 9 areas of research responsibility by October 1, 2003. Following considerable controversy, the ORI policy was officially suspended in February, 2001. ORI continues to advocate for broad-based research ethics training and sponsors training programs and development of training materials.

Requirements for comprehensive institutional plans for RCR training are not very far away. In 2001, NIH began requiring RCR training for all NRSA training grant trainees, requiring grantee institutions to submit their training plan for review prior to

issuance of an award. The 2007 America COMPETES Act, requires that

> "*Institutions that apply for financial assistance ... for science and engineering research or education [from the National Science Foundation] should include a plan in their grant proposals for appropriate training and oversight in the responsible and ethical conduct of research to undergraduate students, graduate students, and postdoctoral researchers who will participate in the proposed research project.*"

To implement this legislative requirement, the National Science Foundation published its plan in the August 20, 2009 Federal register:

> *Effective January 4, 2010, NSF will require that, at the time of proposal submission to NSF, a proposing institution's Authorized Organizational representative certify 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...*
> *NSF also will modify its standard award conditions to clearly stipulate that institutions are responsible for verifying that undergraduate students, graduate students, and postdoctoral researchers supported by NSF to conduct research have received RCR training.*

The NIH RCR Nine

I. Data Management

What is it? Practices related to collection, storage, protection, ownership and sharing of data.

Background: Practices and policies are quite variable across institutions and funding agencies. Not a "regulatory heavy-weight" at present, but can become very important for investigators and institutions if integrity of data is ever called into question.

Minimal Implementation Standards
    Institutional: Clear and well-understood policies related to laboratory notebook and other records retention, data ownership, sample-sharing, and intellectual property; encourage timely publication of publicly-funded data. Provide adequate protections for confidentiality when necessary.
    Investigator: Know data ownership policies of the institution, and those tied to research funding before data collection begins. Establish clear laboratory procedures for protecting the integrity of data. Practice timely publication and sharing once results are validated, encourage sharing with students/staff, create an environment where sharing is positive and not a feared practice

Key Documents:
1. Final NIH Statement on Sharing Research Data, http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html
2. PHS Office for Civil Rights – HIPAA Medical Privacy - National Standards to Protect the Privacy of Personal Health Information http://www.hhs.gov/ocr/hipaa/
3. NSF Grants Policy Manual, Section **7**34: Dissemination and Sharing of Research Results, http://www.nsf.gov/pubs/manuals/gpm05_131/gpm7.jsp#734

II. Conflict of Interest

What is it? Institutions are responsible for ensuring the objectivity of research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under PHS grants or cooperative agreements will be biased by any conflicting financial interest of an Investigator

Background: First regulated in 1995, conflict of interest issues remain a matter of public concern and scrutiny.

Minimal Implementation Standards

Institutional: Policy in place and implemented, sound practices for managing any conflicts, procedures for reporting to NIH re existing conflicts and their management, compliance program (education, implementation, enforcement, audits)

Investigator: Careful review and disclosure of potential conflicts; ensure that students staff are knowledgeable and responsive to conflict of interests/commitments issues, and that they disclose conflicts when necessary

Key Documents
1. 42 CFR Part 50, PHS - Responsibility of Applicants for Promoting Objectivity in Research, 1995, amended 2000 http://ori.dhhs.gov/policies/fedreg42cfr50.shtml
2. PHS Final Rule, NIH Guide, 1995 http://grants1.nih.gov/grants/guide/notice-files/not95-179.html
3. NSF Important Notice: Investigator Financial Disclosure Policy, 1996 http://www.nsf.gov/pubs/1997/iin117/iin117.txt
4. Reminder from NIH on Financial Conflict of Interest Requirements, August 25, 2008 http://grants.nih.gov/grants/policy/coi/requirementes_reminder_20080825.htm

III. Human Subjects

What is it? Regulation of research using human subjects to ensure risks do not outweigh benefits and that the rights of subjects are respected.

Background
- 1962 amendments to Food, Drug, and Cosmetic Act - first law requiring informed consent
- 1974 National Research Act - all research funded by DHEW must be reviewed by IRBs,
- 1979 Belmont Report established ethical principles of respect, beneficence, and justice
- 1991Common Rule [10 CFR 745] – 16 agencies adopt 45 CFR 46 subpart A.
- 2000 NIH grantees must require PHS-funded investigators complete human subjects training

Minimal Implementation Standards

Institution: All research involving human participants must be reviewed and approved by an institutional review board before the research is undertaken. Ensure that human participation in research is fully informed and voluntary, and that risks to participations are minimized and/or disclosed and managed, and that research is monitored to minimize and manage adverse events should they occur. When research is federally funded, enter into a formal agreement (assurance) with OHRP to comply with the regulations pertaining to human subjects research.

Investigators: Know what research is subject to the regulations. Obtain approval of research protocol prior to initiating research involving human subjects. Complete education on the protection of human research participants. Take responsibility for compliance throughout the project.

Key Documents
1. Belmont Report, http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm, Ethical Principles and Guidelines for the Protection of

Human Subjects of Research, The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979

2. 45 CFR part 46, http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm, Protection of Human Subjects, revised June 2005.
3. Office of NIH History, Timeline of Laws Related to the Protection of Human Subjects http://history.nih.gov/01docs/historical/2020b.htm - Includes links to key documents
4. Policy Notice 00-035: Required education in the protection of human research participants, http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html

What's coming:
On July 1, 2008, OHRP published a Request for Information (RFI) in the Federal Register inviting public comment on whether it should issue additional guidance recommending that institutions engaged in human subjects research implement training and education programs, or develop a regulation requiring the implementation of such training and education programs. (The notice can be accessed at: http://www.hhs.gov/ohrp/documents/fedreg20080701.htm or http://www.hhs.gov/ohrp/documents/fedreg20080701.pdf.)

IV. Animal Welfare

What is it? Standards for the humane care and use of animals in **teaching *and* research.**

Background: Animal research is as carefully regulated as human research, with additional precautions/ethical considerations stemming from the fact that animals cannot give consent. It is also often an issue of significant controversy, requiring institutional and investigator attention to public sentiment and political pressures. Federal involvement in the regulation of animal care and use began with the Animal Welfare Act of 1966, which governs all animal care and use (not just research) and is not limited to federally-funded animal care and use. Researchers who use animals in research (including observational research) and teaching, can come under the jurisdiction of the USDA animal welfare regulations and/or the PHS Policy on Human Care and Use of Laboratory Animals. It is therefore important to be familiar with both.

Minimal Implementation Standards
(NOTE: Standards apply to the use of animals in **teaching and research**.)
Institutional: Register w/ USDA and implement animal program to comply with requirements of the Animal Welfare Act. Ensure that all animal care and use protocols are reviewed by an IACUC, and meet reporting and recordkeeping requirements. Provide adequately for animal environment, housing and management, including disaster planning. For PHS-funded research, enter into a formal agreement (assurance) with the PHS to comply with the PHS Policy on Human Care and Use of Laboratory Animals NOTE: Animal Welfare Act applies whether or not federal funding is involved.
Investigator: adhere to policies and procedures of IACUC, appropriate training, minimize pain and distress to animals, avoid unnecessary use of animals.

Key Documents
1. PHS Policy on Human Care and Use of Laboratory Animals, http://grants1.nih.gov/grants/olaw/references/phspol.htm
2. Animal Welfare Act of 1966 (revised 1970, 1976, 1985 and 1990) http://www.nal.usda.gov/awic/legislat/usdaleg1.htm
3. Animal Welfare Act Regulations Final Rule: 9CFR parts 1 and 2 http://www.nal.usda.gov/awic/legislat/awafin.htm
4. Health Research Extension Act of 1985, Public Law 99-158, "Animals in Research" http://grants1.nih.gov/grants/olaw/references/phspol.htm#Health%20Research%20Extension%20Act%20of%201985

V. Misconduct

What is it? Defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

Background
- 1981 – Rep. Albert Gore, Jr., prompted by disclosure of research misconduct cases at four major research centers in 1980, held first Congressional hearing on the emerging problem.
- 1985 Health Research Extension Act, required HHS to issue a regulation requiring applicant or awardee institutions to establish "an administrative process to review reports of scientific fraud" and "report to the Secretary any investigation of alleged scientific fraud which appears substantial."
- 1989, HERA requirements codified as 42 CFR Part 50, Subpart A.
- March 1989, PHS created the Office of Scientific Integrity (OSI) in the Office of the Director, NIH, with the sole purpose to deal with research misconduct.
- May 1992, OSI and other areas having responsibilities for research misconduct, were consolidated into the Office of Research Integrity (ORI).
- 1999, proposed government wide definition of research misconduct developed by the National Science and Technology Council and published in the *Federal Register*.
- *PHS Policy on Instruction in the Responsible Conduct of Research*, published in the *Federal Register* on December 1, 2000, and suspended on February 20, 2001. The policy remains suspended. Required PHS grantee institutions to provide RCR training to all research staff involved in proposing, performing, reviewing, or reporting research, or who receive research training support with PHS funds or who work on PHS supported research projects.

- June 2005 *PHS Policies on Research Misconduct,* codified at 42 C.F.R. Part 93.

Minimal Implementation Standards:

Institution: Policy and Procedures for addressing allegations of misconduct. Notify funding agency. Investigate and report results. Safeguard rights and welfare of informants and subjects of investigation. File annual report on allegations of misconduct.

Investigator: Adhere to prescribed principles of integrity. Report suspected misconduct. Train research personnel in policies and procedures.

Key Documents
1. Executive Office of the President; Federal Policy on Research Misconduct; Office of Science and Technology Policy. Dec 2000
   http://ori.dhhs.gov/policies/fed_research_misconduct.shtml
2. NSF Important Notice 106, Responsibilities of Institutions and Investigators in the Conduct of Research, April 17, 1989
   http://www.nsf.gov/pubs/stis1996/iin106/iin106.txt
3. Public Health Service, Policies, 42 CFR Part 50 and 92
   http://ori.hhs.gov/documents/42_cfr_parts_50_and_93_2005.pdf

VI. Responsible Authorship

What is it? Necessity to preserve the public trust (and protect public health) by ensuring accuracy in reporting of research results

Discussion: This area has been largely left to the professional societies/journal publishers to regulate. Basic elements include:
- Complete, accurate, and unbiased reporting of methods and results (replicable)
- Accurate attribution of influences (references and notes)
- Avoid duplicate publication and/or dividing research unnecessarily into multiple publications
- Use authorship and acknowledgements appropriately

Minimal Implementation Standards:

Institution: Communicate expectations of responsible authorship; set standards and apply them when reviewing faculty professional activity.

Investigators: Adhere to principles and standards.

Key Documents
1. Society for Neuroscience, *Responsible Conduct Regarding Scientific Communication,* 1998.
   http://www.sfn.org/index.cfm?pagename=responsibleConduct
2. International Committee of Medical Journal Editors, *Uniform Requirements for Manuscripts Submitted to Biomedical Journals, 2001.* www.icmje.org

VII. Mentor/Trainee Relationships

What is it? The "social foundation of research"; an essential element of research training. When done well, mentoring provides training opportunities in research conduct, management, and ethics.

Discussion: This area has largely been left to the professional societies and organizations to develop and support. Other than the standard requirements pertaining to personnel actions, no legal mandates exist at present.

Minimal Implementation Standards:

Institution: Clearly communicate expectations and standards, provide resources for mentors and students to support their respective roles and address concerns or allegations of inappropriate behavior.

Individual: Provide respectful, supportive, encouraging environment for trainees. Model and support rigorous ethical standards in the conduct of research.

Key Documents:
1. Adviser, Teacher, Role Model, Friend, On Being A Mentor to Students in Science and Engineering, National Academy of Sciences, 1997. Available online at:
   http://www.nap.edu/openbook.php?isbn=0309063639

VIII. Peer Review

What is it? Careful peer review should ensure accuracy and significance of published reports of research findings, and protect the reputations of authors.

Discussion: This area has been largely left to the professional societies/journal publishers to regulate. There are no statutory or regulatory mandates at this time.

Minimal Implementation Standards (Individual):
1. When deciding to review:
   a. Appropriate expertise
   b. Conflicts of interest
   c. Time available, ability to meet deadlines
2. As a reviewer:
   a. Confidentiality
   b. Allegiance is to the journal, not the author
   c. Maintain standards of rigor (responsibility is to prevent publication of flawed research)
   d. Reviewer's role is to provide disciplinary expertise/focus, not to edit
   e. Be aware of personal biases and their possible influence on the review
   f. Be alert for ethical concerns (flawed IRB review, author conflicts of interest, etc.)
3. Writing the review:
   a. Be constructive, collegial, bolster your arguments w/appropriate citations
   b. Avoid snide remarks, personal attacks
   c. Maintain the **confidentiality** of the review process, even after the paper is published

(adapted from: Sara Rockwell, Ethics of Peer Review: A Guide for Manuscript Reviewers, Yale University School of Medicine, http://ori.hhs.gov/education/products/yale/prethics.pdf

IX. Collaborative Science

What is it? Two or more researchers, often at two or more institutions, with shared "ownership", responsibility, and (often) funding for a common project.

Discussion: This is a largely unregulated area of research management at this time. However, in multi-investigator and/or multi-institutional projects, institutions should attend to matters of data, materials and intellectual property ownership; management of grant funds and equipment; and subcontracting issues which may trigger other regulatory mandates.

Minimum Implementation Standards

Institutions should have clear policies regarding subagreements, data and intellectual property and management, and provide support for same. Research administrators at collaborating institutions should maintain open lines of communication and discuss roles, expectations, and responsibilities in detail at the outset of a project. Encourage and assist PI's to do same with their research partners.

Individual: Like any relationship, successful research collaboration takes work. Clearly defining roles, expectations, and responsibilities at the outset – even to the point of a written agreement – can stave off potential problems. Clear communication with research partners is essential, around matters of data management and sharing, authorship, shared resources, institutional and disciplinary cultures, Work with institution's research administration office to develop protocols for managing potential conflicts.

WRAP-UP DISCUSSION

Strategies for Success
- Clearly articulate rules and expectations; set standards and make them explicit
- Clearly define roles and responsibilities; align responsibility and authority
- Provide timely notification of mandates, policies and procedures
- Be responsive: to inquiries, allegations of misconduct, and the need for timely processing of paperwork
- Limit bureaucracy; be respectful of researchers' time
- Compliance with Rules and Regulations

How do you get there?
- Make guidance easily available: on web, in manuals, in person
- Know and implement the rules; reinforce the importance of integrity Document policies and procedures; make them easily accessible and easy to followProvide training: workshops, class guest lectures, online formats
- Maintain current knowledge of the regulatory climate and trends.
- Openly model ethical behavior
- Encourage PI's to consult with campus experts and authorities

Integrity Takes All of Us

Educate
Communicate
Enforce
Learn
Oversight
Document
REPEAT

Resources Guide
For
Responsible Conduct of Research
At
Predominantly Undergraduate Institutions

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Organizations:

AAHRPP – Association for the Accreditation of Human Research Programs
www.aahrpp.org

PRIM&R – Public Responsibility in Medicine and Research. www.primr.org

AAALAC – Association for Assessment and Accreditation of Laboratory Animal Care
www.aaalac.org

Poynter Center for the Study of Ethics and American Institutions at Indiana University, Teaching Research Ethics conference, http://poynter.indiana.edu/tre/

HCCA - Health Care Compliance Association – www.hcca-info.org
Offers a Research Compliance Academy, and certification in health care research compliance (CHRC)

APPE – Association for Practical and Professional Ethics,
http://www.indiana.edu/~appe/index.html

The Hastings Center: A non-partisan research institution dedicated to bioethics and the public interest. Journal publications include: *Hastings Center Report* and *IRB – Ethics and Human Research*. Available online for free/or paper by subscription. www.thehastingscenter.org

National Academy for Engineering, Center for Engineering, Ethics, and Society (CEES)
http://www.nae.edu/nae/engethicscen.nsf?OpenDatabase . Includes an Online Ethics Center with training materials at: www.onlineethics.org

E-Lists and Newsletters:

ORI Email List: http://ori.hhs.gov/StayInformed/email.shtml

ORI Newsletters: http://ori.hhs.gov/publications/newsletters.shtml

Report on Research Compliance, newsletter (paper and online) published by NCURA, NACUBO, and Atlantic Information Services, Inc. (cost: $368-468))

Books and Handbooks:

ORI Introduction to Responsible Conduct of Research, by Nicholas Steneck, PhD. Downloadable version: http://ori.hhs.gov/documents/rcrintro.pdf;
Print version: http://bookstore.gpo.gov/collections/ori-research.jsp

National Academy of Sciences et al., *On Being a Scientist: Responsible Conduct in Research.* National Academy Press, third edition, 2009. Free on line at http://www.nap.edu/catalog.php?record_id=12192 , print copies available for purchase. Video to accompany text to be published soon.

ORI Handbook for Institutional Research Integrity Officers:
http://ori.hhs.gov/publications/rio_handbook.shtml

ORI Guidelines for Institutions and Whistleblowers: Responding to Possible Retaliation against Whistleblowers in Extramural Research http://ori.hhs.gov/documents/guidelines_whistle.pdf

Guidelines for the conduct of research within the Public Health Service:
http://ori.hhs.gov/documents/guide_conduct_research.pdf
(This is a nice, succinct statement of the basic principles of research ethics.)

PHS Guide for the Care and Use of Laboratory Animals
http://www.nap.edu/openbook.php?record_id=5140

Joan E. Sieber, *Planning Ethically Responsible Research: A Guide for Students and Internal Review Boards.* Sage Publications, 1992.

Creating an Infrastructure for Training in the Responsible Conduct of Research: The University of Pittsburgh's Experience. <u>Academic Medicine.</u> 81(2):119-127, February 2006
http://www.academicmedicine.org/pt/re/acmed/abstract.00001888-200602000-00004.htm;jsessionid=LHxNyxWQShmYdKM49vlZlG2RDJrpnGQ4bt259Nt3tTTjNtnL8Q11!523807009!181195628!8091!-1

Training Materials:

The Collaborative Institutional Training Initiative (CITI) - www.citiprogram.org
On-line subscriber-based training in.
- Protection of Human Research Subjects Biomedical Focus
- Protection of Human Research Subjects Social and Behavioral Focus.
- Protection of Human Research Subjects Refresher
- Good Clinical Practice
- Health Information Privacy and Security Course (HIPS)
- Laboratory Animal Welfare for investigators and IACUC Members
- Responsible Conduct of Research (RCR) - Free

WebGURU: Guide to Research for Undergraduates, http://www.webguru.neu.edu/index.php. An interactive web site that includes "information on all the technical aspects of undergraduate research including lab safety, record keeping, experimental design, data analysis, technical writing, oral presentations, intellectual property, etc". Includes links to resources and training materials. Hosted by Northeastern University, with funding from NSF and the Camille and Henry Dreyfuss Foundation.

Center on Materials and Devices for Information Technology Research, Interactive Tutorials for Educational Institutions. www.responsibleresearch.org. Free.

US Dept. HHS, Office of Research Integrity (ORI), Peer Review Quick Guide: Detecting Common Mistakes and Considering Dilemmas in Peer Review. http://www.ori.hhs.gov/education/products/niu_peerreview/index.htm

Research Conduct and Ethics Instruction Materials for use by the NIH Community http://www1.od.nih.gov/oir/sourcebook/ResEthicsCases/cases-toc.htm (includes useful case studies and links to reference materials)

American Association for the Advancement of Science, Research Integrity Videos http://www.aaas.org/spp/video/ . Series of 5 9-minute video case studies with resource and discussion guides.

U.S. Dept of Health and Human Service Office of Research Integrity and the Center for Ethics and Values in the Sciences, In the Lab: Mentors and Students Behind the Scenes, DVD with Guide and Case studies.

ORI educational resources web page: http://ori.hhs.gov/education/products/ Follow the tabs at the top of the page for topical lists of materials.

NIH Office of Extramural Research Tutorial on Financial Conflicts of Interest http://grants2.nih.gov/grants/policy/coi/tutorial/fcoi.htm (*New*: certificate capability)

PHS Policy on Human Care and Use of Laboratory Animals Tutorial http://grants1.nih.gov/grants/olaw/tutorial/index.htm

Journals:

Accountability in Research – http://www.tandf.co.uk/journals/titles/08989621.asp

Ethics and Behavior – http://www.tandf.co.uk/journals/titles/10508422.asp

Journal of Empirical Research on Human Research Ethics – http://www.ucpressjournals.com/journal.asp?j=jer

Science and Engineering Ethics – http://www.springer.com/philosophy/ethics/journal/11948#8085218705268172855

ILAR Journal (Institute for Laboratory Animal Research) - http://dels.nas.edu/ilar_n/ilarjournal/journal.shtml

Government Resources:

US Dept of Health and Human Services, Office for Human Research Protections (OHRP), http://www.hhs.gov/ohrp/

NSF Grant Proposal Guide http://www.nsf.gov/publications/pub_summ.jsp?ods_key=gpg

Office of NIH History, Timeline of Laws Related to the Protection of Human Subjects
http://history.nih.gov/about/timelines_laws_human.html - Includes links to key documents.

Office of NIH History, Timeline of Laws Related to Animal Subjects
http://history.nih.gov/about/timelines_laws_animal.html - Includes links to key documents.

HHS Office of Research Integrity, About ORI – History, http://ori.dhhs.gov/about/history.shtml

NIH Office for Laboratory Animal Welfare (OLAW) http://grants1.nih.gov/grants/olaw/

NIH Fact Sheet on the Benefits of Animals in Research
http://science.education.nih.gov/AnimalResearchFS06.pdf

USDA Animal Welfare Information Center (AWIC), http://awic.nal.usda.gov

NIH: HIPPA Privacy Rule, Information for Researchers http://privacyruleandresearch.nih.gov

Resource Centers and Guides:

NSF-funded Beta Sites
- Ethics in Science and Engineering National Clearinghouse

- Online Ethics Center Enhancements and America COMPETES

RESEARCH INTEGRITY – THE INSTITUTIONAL PERSPECTIVE

Camille Nebeker
Director, Division of Research Affairs
San Diego State University

Debra Schaller-Demers
Director, Research Outreach and Compliance
Memorial Sloan-Kettering Cancer Center
New York City

Daniel R. Vasgird,
Director, Office of Research Integrity & Compliance
West Virginia University

SRA Joint Northeast/Midwest Section Meeting
April 26, 2010, 1:15-2:45pm

1

Learning Objectives

- Describe what an institution can do to understand and influence a climate of research integrity.

- Describe approaches to integrating research ethics education within the institution.

- Identify stakeholders and their role in developing a culture that values responsible and ethical research practices.

Format

- Each speaker will provide an overview of their institutional perspective on research integrity and organizational infrastructure.
- Institutions include:
  - SDSU – a public, university w/o medical school
  - Sloan Kettering – a comprehensive cancer center
  - WVU – a public university with a major health sciences center
- Q&A will follow.

SDSU Institutional Descriptors

- Large, public, urban university
- 32,000 undergraduates and graduates
- 15 Ph.D programs, 84 Masters programs
- Commitment to engage undergraduate in research
- Centralized Responsible Conduct of Research
  - Training and Programs for IRB, IACUC, IBC, COI, IP, RI, etc.

Why Worry?

- Wasted Resources
  - Funding
  - Time and effort
- Corruption of scientific record
- Decreased public confidence
  - ↑ regulation
  - ↓ funding
- Decreased trust among scientists
  - ↑ barriers to collaboration
  - ↓ recruits

SDSU Institutional Perspective

- Who are the stakeholders?
- What are the institutional values around research integrity?
- How is that communicated?
- What approaches have been taken?
- How is pro-activity in research integrity perceived?
- How have regulations influenced programs?
- Progress to date.

SDSU Institutional Process

1. Needs assessment
2. Establish goals
3. Develop proposal
4. Identify resources – financial, material and people
5. Identified special circumstances:
   - Unusual concerns, specialized areas of research?
   - Audience (grad students, postdocs, staff, etc.)?
   - Existing programs? Faculty?
   - Surveys and/or meetings for perspectives of trainees and faculty

Research Integrity Components

- Research Misconduct
- Research Planning
  - Research Subjects, Conflict of Interest, Biosafety
- Research Conduct and Management
  - Mentoring and Trainees, Data Management, Collaboration
- Research Reporting
  - Authorship, Peer Review, Publication, Social Responsibility
- Institutional Commitment

SDSU Institutional Program

1. Leverage local resources
   a. Research methods courses
2. Train faculty – teaching and mentoring
3. Options for training (regardless of compliance requirements)
   a. Courses – in class, hybrid, web-based
   b. Lectures
   c. Seminar Series
4. Evaluate and make changes as needed

Getting Expertise

How to acquire the expertise needed?

- Train-the-trainer courses
- RCR Education Committee: http://www.rcrec.org
- Research Ethics.Net: http://research-ethics.net/index/
- RCR Education Resources: http://rcrec.org/rcr
- Network: RCR meetings, contact other instructors
- Office of Research Integrity

RESPONSIBLE CONDUCT OF RESEARCH

AT
MEMORIAL SLOAN–KETTERING CANCER CENTER
NEW YORK CITY

Debra Schaller-Demers, MSOM
Director, Research Outreach and Compliance
RCR Course Director

RCR at MSKCC

The course, now in its third* year, is a collaborative effort of the
Office of Postdoctoral Affairs and the division of
Research and Technology Management.

*Prior to 2008, MSKCC participated in the Tri-Institutional RCR Course
with Weill Cornell Medical School and the Rockefeller University, which
had been in existence since the early 1990's.
I coordinated/directed that course from 2002-2007. In 2004, we initiated a
new format combining an online web-based curriculum and live face-to-
face sessions.

The online course was developed by
Michael Kalichman, UCSD and **Frank Macrina**, VCU.
It was the first version of the Internet course they developed for
Responsible Conduct of Research Education Consortium (RCREC*)
member use.

*Now known as for ***Responsible Conduct of Research Education Committee –***
*a sub-committee of **Association for Practical & Professional Ethics** (APPE)*

RCR at MSKCC

As of September 2008, all MSKCC research trainees are required to complete the course by either institutional policy and/or federal regulation.

Who MUST Participate:
- All 1st year Gerstner Sloan-Kettering graduate students
- All 1st year postdoctoral researchers and participants in clinical fellowship programs, at the discretion of the program director
- Individuals appointed to NIH funded National Research Service Award Institutional Training Programs (NRSA T32, T34)
- Individuals appointed to NSF funded projects under the America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science (COMPETES) Act (August 2007).

*Postdoctoral researchers include the ranks of Research Fellow, Research Scholar, and Research Associate. Postdoctoral researchers appointed between 9/1 and 8/31 will be required to attend.

Participants who fall into one of the above-mentioned groups, **MUST take the course** and will receive a certificate of completion for successfully passing all assignments and attending four (4) live sessions All course components MUST be completed within the stated time frame. The course is open to other interested individuals at MSKCC.

RCR at MSKCC

Course Goals and Objectives:

- **<u>Awareness</u>:** heighten awareness of participants to ethical considerations relevant to the conduct of research
- **<u>Knowledge</u>:** inform participants of federal, state, and institutional policies, regulations, and procedures
- **<u>Skills</u>:** provide participants with critical analysis and problem solving skills for ethical decision-making

Course Components & Criteria:
Participants are required to complete the eight (8) online topic modules, which include a ten question short answer exam for each topic, and attend all four (4) live sessions: an Orientation plus three (3) face-to-face case study analysis sessions led by a faculty facilitator.

RCR at MSKCC

Eight Topic Modules

- Research Misconduct (including Whistleblowing and Dispute Resolution)
- Data Management
- Use of Animal Subjects
- Use of Human Subjects
- Conflicts of Interest
- Authorship
- Publication and Peer Review
- Collaboration and Mentoring

THE RESPONSIBLE CONDUCT OF RESEARCH AT WVU

Daniel R. Vasgird, PhD

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"Most universities have not done all they should to protect the integrity of their research. Many have not even shown that they are seriously concerned about doing so."

Derek Bok, Former Harvard President
Universities in the Marketplace

National Academy of Sciences

To maintain (public) confidence and trust in this (the scientific) enterprise, researchers must protect the *empirical objectivity* of research, the *unbiased reporting* of results and the *open sharing* of that information for the good of society.

National Academy of Sciences Primary Recommendations

- **Research institutions should promote integrity in research through top-down commitment to RCR through strong supervision, communication, socialization, etc.**

- **Research institutions should offer effective educational programs that enhance RCR.**

- **Research institutions should perform self-assessments to determine areas of need.**

ORIC Mission:

Foster a culture of integrity and compliance within the University directed at ensuring that participants in the West Virginia University research enterprise internalize and pursue the goal of self-directed responsible conduct of research.

ORIC Core Areas

1) Human research protections
2) Animal use and care in research
3) Conflict of interest
4) Institutional Biosafety
5) Export Control
6) RCR E&T (CITI online): #s 1, 2, & 3 above plus:
   a) Data acquisition, management, sharing & ownership
   b) Mentor/trainee relationships
   c) Publication practices & responsible authorship
   d) Peer review
   e) Collaborative science
   f) Research misconduct

WVU RCR Initiatives

- Mandatory CITI online RCR program for all graduate students (incl. medical, dental, pharmacy & nursing) and post-doctoral fellows.

- Two semester-long RCR courses to fulfill HHS requirement.

- New University-wide research ethics seminar series.

- ORIC staff do RCR core area presentations to departments based on need and request.

"MANAGING EXTERNALLY FUNDED RESEARCH PROGRAMS: A GUIDE TO EFFECTIVE MANAGEMENT PRACTICES" – COGR

Research integrity is now listed as a basic principle of quality management by COGR,

emphasizing that it is no longer enough for administrators to presume that it is being attended to informally.

Federal Sentencing Guidelines for Organizations (FSGO) Compliance Elements

- **Implementing written policies & procedures;**
- **Designating compliance officer & committee;**
- **Careful delegation of authority;**
- *Conducting effective training and education;*
- *Developing effective lines of communication;*
- **Conducting internal monitoring and auditing;**
- *Enforcing standards through well-publicized disciplinary guidelines;* **and**
- **Responding promptly to detected problems.**

Prevention Over Cure:
The Administrative Preference for RCR Emphasis and Development

(vs. "Government Imposed Compliance Plans")

HHS Research Misconduct Final Rule (June, 2005)

Universities must:

- **Have research misconduct P&P's**
- *Foster an environment that promotes RCR*
- **Deal with allegations or possible evidence of research misconduct promptly**

"Instruction in
*the responsible conduct of
research need not be driven by
federal mandates*, for it derives
from a premise fundamental to
doing good science: *the
responsible conduct of research
is not distinct from research.*"
–ORI RCR Guidance, 2005

COLLEGES AND UNIVERSITIES RATE AGREEMENT

EIN #:

DATE: September 1, 2009

INSTITUTION:
South Dakota School of Mines and Technology
501 E. St. Joseph Street

FILING REF.: The preceding
Agreement was dated
November 30, 2007

Rapid City   SD   57701-3995

The rates approved in this agreement are for use on grants, contracts and other
agreements with the Federal Government, subject to the conditions in Section III.

SECTION I: FACILITIES AND ADMINISTRATIVE COST RATES*

RATE TYPES: FIXED   FINAL   PROV.(PROVISIONAL)   PRED.(PREDETERMINED)

TYPE	EFFECTIVE PERIOD FROM	TO	RATE(%)	LOCATIONS	APPLICABLE TO
PRED.	07/01/09	06/30/12	37.0	On-Campus	All Programs
PROV.	07/01/12	06/30/13	37.0	On-Campus	All Programs

*BASE:
Modified total direct costs, consisting of all salaries and wages,
fringe benefits, materials, supplies, services, travel and subgrants
and subcontracts up to the first $25,000 of each subgrant or subcontract
(regardless of the period covered by the subgrant or subcontract).
Modified total direct costs shall exclude equipment, capital
expenditures, charges for patient care, tuition remission, rental
costs of off-site facilities, scholarships, and fellowships as well as
the portion of each subgrant and subcontract in excess of $25,000.

(1)   U71084

Student Affairs Committee
AY 2011

Report on Campus Academic Advising Practices

The following report is drafted in response to the motion from the Senate that the Student Affair Committee review campus-wide advising practices and policies and inform the Senate of the current status of student advising activities.

The Student Affairs Committee developed a survey regarding academic advising practices and sought response from the Department Heads and Chairs. The Head/Chairs were asked to comment on the practices of their department with regard to five questions. The complete responses from the departments are at the end of the document.

Advising Questions – General Summary
1.   How does your department/unit organize undergraduate academic advising?

By class standing or with "permanent" advisor assignment/choice

2.   How are students assigned an advisor and what is the procedure for advising meetings?

Initial assignment is usually made by AES with changes after that coming at the discression of the student or the faculty following some conversations to balance loads and match student-faculty relationships.

Meetings are scheduled via email or as part of a course requirement.

3.   How often do students meet with an advisor?

After the freshman year, meetings are usually as the student needs or in preparation for a degree audit. There is significant variety in the frequency of meetings based on individual student cases.

4.   Are advising meetings required?

No, but many department have requirements for freshmen and for degree audits. Some departments are considering making meetings required.

5.   Do you feel that students are receiving high-quality academic advising?

Mixed – many departments report issues with WebAdvisor and student self-advising or student's ignoring advice.

Advising Question Responses

   1. **How does your department/unit organize undergraduate academic advising?**

Discussed at department meetings and finalized in meetings between department head and staff

We use an open advising system. All files are kept in the office. A student may see any advisor. The advisor documents the front of the chart as to the date and advising that was accomplished.

Students are assigned a permanent advisor with whom they remain until they graduate. Generally an advisor takes on a class at a time, although sometimes initial assignments may be spread out depending on the current advising loads of faculty. Transfer students are advised by the program coordinators.

We separate by class standing. Justin Meyer takes the 1st (and perhaps 2nd)year students and I take the rest.

Every year we pick some freshmen advisors, since we no longer have the mentor program the freshmen advisors change so a person can advise from freshmen to senior. Every spring we shift advisees in an attempt to balance loads. Every semester we sponsor a departmental advising session so any student can show up and get advising. Every semester we do send an email to all majors that encourages them to visit with their advisor.

Very informally, we tell them they can visit the physics professor of their choosing.

Advising is divided/assigned according to the IS student's specialization. For the most part, IS advisors have chosen a particular specialization on which to concentrate.

Each Prof takes a specific class, Frosh, Soph, Jr, Sr

Kathy Crawford in AES assigns all the first time full time CEE freshmen to me at the beginning of Fall semester.

All faculty members are advisors except for new professors who have yet to become familiar with the curriculum. Advising aids such as curriculum flowcharts are available for students on the department web site.

   2. **How are students assigned an advisor and what is the procedure for advising meetings?**

Department head and one other faculty advise all incoming freshmen. Sophomores are distributed as 1 above.

Transfer students are initially assigned to Dr. Karlin. First Year students initially assigned to Dr. Kellogg. Students quickly adjust to the open advising system.

GEOL: Students are assigned a frosh advisor who meets with them as part of IS 110. After the first year they are assigned a permanent advisor. Transfer students are advised by the chair (until this year); now by the Geol program coordinator (Paterson).

GEOE: Students are assigned to a permanent advisor freshman year and stay with that advisor until graduation. Faculty take turns being the freshman advisor.

Kathy Crawford gives Justin all 1ˢᵗ year students, and I get the rest. I ask the students to meet with me. Justin meets them in IS 110.

Yes they are assigned to advisors and every spring we shift advisees in an effort to balance the load.

I have no idea if there is a mechanism in place outside of our informal procedure.

Freshmen: Freshman IS majors are assigned to Kathy Antonen, who serves as the freshman advisor/mentor. She works with them in IS 110 and independently. IS-ATM students are typically reassigned to Capehart/Kliche near the end of the fall semester/start of spring semester. IS-HLTH and IS-STS students are reassigned (by Kathy and Sue) to other IS advisors during the spring semester. Kathy sees them through registration for spring and the next fall before turning them over.
Transfers: All incoming transfer students in IS-HLTH and IS-STS are assigned to the program coordinator (Sue). I meet with them to discuss transfer credits, the IS program, and fall/spring registration. They are typically reassigned (by me) to an advisor in their specialization by the end of Sept. IS-ATM transfers go straight to Capehart or Kliche.

Meetings are scheduled by email with the Frosh, others are scheduled by the student on an as needed basis, Srs meet with Dept Head to conduct a degree audit (mutually arranged by the two parties)

In the Spring semester I hand off my advisees to the professors in our department who I feel is the best fit to the students. This is based usually on what their specific interests are In CEE. They will keep this advisor until graduation.

The types of advisors are graduate advisor, transfer advisor, all others. Students are assigned to balance the number of students being advised. The graduate advisor works with graduate students until they have chosen their graduate committee. New freshman students are automatically scheduled for a zero credit mentoring class where they meet the department faculty, staff, and peer advisors. During this mentoring class they register for the next semester courses using WebAdvisor.

3. **How often do students meet with an advisor?**

Email or walk in.

Varies – some meet regularly; some we wish WebAdvisor were not available; we can place holds and have considered a number of formal options for doing so but have as yet not gone that route

As needed. Some students meet frequently, others do not.

There are some advisees that I can advise with e-mail. Others I have to meet with every semester

They are encouraged to meet with their advisor every semester.

There is no formal schedule, we meet on an as needed basis.

Freshmen meet with Kathy 3-4 times during the fall semester and at least once or twice in the spring. Beyond the freshman year, it's up to the advisee/advisor to set up meetings as needed.

Frosh meet at least once per semester, others on an as needed basis, Sr degree audit occurs during the semester before graduation

I try to see the students in the first year about 2-3 times. This is sometimes difficult to do since students don't always reply to emails or phone calls. I have decided to put an advisor hold for all freshmen to see me before they can register for the spring semester. This will begin in the fall 2011 semester.

This depends on the student needs. Some students meet with their advisor many times during the semester and others navigate the curriculum using the catalog and flowchart needing little assistance from their advisor. The department has an open door policy and students may drop by with advising questions when they need help.

4. **Are advising meetings required?**

No

No

Generally no, but some classes have assignments that require advisor meetings at critical junctures.

Not yet, but the department is considering making a required meeting with a signature.

We have added a required visit that students MUST visit with their advisor to complete a degree audit in their fall semester of their senior year. This requirement is required as part of their capstone course in their major.

No

Advising meetings are required for freshmen. (IS 110 makes it easier to monitor.) Older students must meet with advisors to complete the IS Letter of Intent/Worksheet at the end of their junior year. In between those two years, who knows? The IS program does not mandate a certain number of required advising meetings.

No

No but I stress to them that it is important.

Only In situations such as:
          a WebAdvisor hold on registration,
          a report of academic problems such as a def at midterm,
          problems of progress towards graduation are identified.

5. **Do you feel that students are receiving high-quality academic advising?**

If they seek their advisor, then yes. If not, the ME department is too large to go looking for individuals unless some critical issue is raised by admissions.

Everything is on the department web site. A great deal of effort and thought went into the organization of the site to give the students flexibility, advise on interest areas, and degree requirements. Students are provided information for a 4 year, 4.5 year, and 5 year curriculum flow. Degree checks begin two semesters ahead. So far, we have not violated prerequisite requirements for courses or failed to graduate a student for falling through the cracks. Academic advising is good, but time consuming, and WebAdvisor actually makes it a bit more difficult and apparently doesn't always keep them out of courses requiring prerequisites

I don't know how to define that. I think that their advising is adequate.

Not all of them, no.

Quality varies greatly. We do work hard to upkeep advising materials and we do encourage students to visit with their advisor.

In general I do not think students are well advised. Some students require more attention than others. Web Advisor creates an environment in which students very easily self advise, sometimes with not-so-great results!

It's hit or miss. The good students want frequent, hands-on advising and they seek out the help they need. Marginal students and those who don't know what they want to do following graduation tend to put off advising. Some advisors contact their advisees every semester; others wait for the students to contact them. There appears to be a fair amount of peer-to-peer advising in IS since so many students are taking the same sequence of courses. We are surveying our IS majors this year (once last spring/once this fall) on their perceptions of IS advising as part of our ongoing assessment efforts.

Yes, most of the time.

To the best of my ability I do at the freshmen level. I am not sure what the other professors require once I have handed the student off to them.

Yes