Responsible Conduct of Research (RCR)

A Brief Outline of What Researchers and their Staff Should Know

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INTRODUCTION:

The Cary Institute of Ecosystem Studies takes the stewardship of its sponsored research funding very seriously. In order to maintain diligence over the proper use of outside funding resources and our commitment to the proper education of future researchers, we recognize that we must educate those involved in research in the responsible conduct associated with their research activities.

The Office of Research Integrity (ORI) supports several programs designed to promote education and training in the Responsible Conduct of Research (RCR) that covers the following nine instructional areas:

- Data Acquisition, Management, Sharing and Ownership
- Conflict of Interest and Commitment
- Human Subjects
- Animal Welfare
- Research Misconduct
- Publication Practices and Responsible Authorship
- Mentor / Trainee Responsibilities
- Peer Review
- Collaborative Science

Also included as an important part of Responsible Conduct in Research is the financial management of the grant funds and the appropriate charging of research expenses.

Education in the responsible conduct is essential because unethical or compromised behaviors on the part of researchers lead the pubic to lose trust in the research community. When trust is lost, credibility is lost. When credibility is lost, the chance to improve human life and environmental concerns is lost. When the faith that science can make a difference is lost, funding for research is lost.

I. **FINANCIAL MANAGEMENT – A PI accepts the responsibility of financial management of the award. Once you are PI, you implicitly accept all responsibilities that compromise the role of PI. The PI cannot pick and choose which responsibilities that they want to accept and which they do not. Fiduciary responsibility for the award is also part of the PI's responsibility.**
    - **a.** Expenses charged to sponsored awards must be allowable (costs that meet the sponsor's definition of categories of costs permissible to be charged to the project it funds), reasonable and allocable (directly related to the project);
        - **i.** If unsure check with the grants office

- **b.** The PI is responsible for making determinations about the level of effort committed by himself/herself and others working on the sponsored project.
    - **i.** Salary charged to a sponsored project must reflect the effort that is spent on the project.
- **c.** Charges should never be made to a sponsored project for convenience.
    - **i.** They should never be used as holding account for unrelated expenses.
- **d.** Expenses (including salary) must not be charged to an award simply because all the funds have not been expended.
- **e.** An extension on an award should not be requested simply because there are additional funds left to spend.

II. <u>DATA MANAGEMENT</u> – In research, data means all of the information collected and generated in the course of a research project. It includes research, financial and administrative data related to sponsored projects.

- **a.** Sponsored project agreements are executed between the sponsor and the institution.
    - **i.** Researcher is not a legal part to the agreement.
    - **ii.** The rights and responsibilities that are part of the legal agreement are accorded to the legal entities that are parties to the agreement.
- **b.** OMB Circular A-110 (Section _.53) states that the institution must retain, "financial records, supporting documents, statistical records, and all other records pertinent to an award…."
    - **i.** Deputy Control of the OMB stated in a letter to NSF dated April 11, 1994 that other records noted in OMB Circular A-110 includes research and technical data generated in the course of sponsored projects.
- **c.** The Bayh-Dole Act governs the rights to inventions discovered in the performance of federally sponsored projects.
    - **i.** Places the responsibility on the institution for complying with, reporting, disclosing and licensing requirements.
    - **ii.** OMB Circular A110 (Section_.36) states that the title to "intangible property vests with the recipient (i.e. the institution).
- **d.** Shelby Amendment (Public Law 105-277) was enacted in 1998
    - **i.** Provides that members of the public may use the *Freedom of Information Act* to gain access to research data resulting from federally sponsored projects.
    - **ii.** OMB interpreted this to be limited to be restricted to data which is used by federal agencies in developing federal policy.
    - **iii.** The requirement to provide access to the data is imposed on institutions, not individual researchers since the institution is the legal party to the sponsored agreement.

e. The PI is the gatekeeper to the information that the institution is required to provide access to. The rights of the federal government under sponsored agreements require that institutions have access to and retention of original, primary and raw data, including recordings of such data.
  - **i.** The PI is the steward of the data.
  - **ii.** If the PI leaves the institution, they must either leave the original data and take a copy of the data to the new institution or take the original data and leave a copy that is identical to the original.

f. Stewardship of the data – falls within the purview of the PI and other researchers. It can be delegated to other members of the research project (post-docs, grad students, and other faculty).
  - **i.** No matter how delegated, accountability flows from the PI being responsible to the institution for stewardship of research data just as the institution is responsible to the funding agency.

g. Access to data –
  - **i.** Sometimes sponsors will want access to all the data
  - **ii.** Sometimes access is limited to copies of intended publications or copyrightable material.

III. <u>Conflict of Interest (COI)</u> – conflicts of interest occur when researchers find themselves in situations in which their responsibilities to the institution are or may be compromised by their relationship with an outside entity. It occurs when a research has a financial interest in an outside company that is either sponsoring the research or could benefit from the results of the research.

a. The PHS Regulation (Sections 601 and 607) and the NSF Policy (Section 510) state that the PI and others with decision making authority over the sponsored project must disclose any significant financial interests.
  - **i.** Significant financial interest is defined as $10,000 annual income or 5% equity in a company, whichever is less, or a combination of both.
  - **ii.** Disclosures must be made at least annually but should also be made as soon as a conflicted arises.
  - **iii.** Cary Institute COI policy is located in our policy manual which is located on the Intranet at http://www.ecostudies.org/intranet/hr/Policy_and_Procedure_Manual.pdf
  - **iv.** Examples of Conflict of Interest
    1. PI has a financial interest in a company that will benefit from the results of the research.
    2. Receiving compensation from a company (stipend or consulting fees or board service fees) that will be affected by research study.
  - **v.** Examples of Conflict of Commitment

1. Using institutional resources for private business ventures
2. Dedicating more time than institution allows on private consulting during institutional work time.
3. Failure to get Presidential approval for consulting work performed during work hours.
4. Cary Institute Consulting Policy is located at http://www.ecostudies.org/intranet/hr/Policy_and_Procedure_Manual.pdf

IV. Research Misconduct – The Office of Science and Technology (OSTP) in the Executive Office of the President has issued a definition of misconduct that applies to all agencies and recipients of federal funds.

- **a.** NSF and PHS (including NIH) have implemented this policy.
- **b.** ***Research Misconduct is defined as fabrication, falsification or plagiarism in proposing, performing or reviewing research or in reporting research results.***
  - **i.** *Fabrication* – is making up data or results and recording or reporting them.
  - **ii.** *Falsification* – is manipulating research materials, equipment or processes or changing or omitting data or results such that the research is not accurately represented in the research record.
  - **iii.** *Plagiarism* – is the appropriation of another person's ideas, processes, results or words without giving appropriate credit. This includes taking another's proposal ideas during the review of their proposal.
  - **iv.** *It does not include honest error or differences of opinion***!**
- **c.** The Cary Institute Policy on Scientific Misconduct is located at http://www.ecostudies.org/intranet/hr/Policy_and_Procedure_Manual.pdf
- **d.** Guidelines for how a whistleblower should proceed (Michael Kalichman, UC, San Diego) (Note – federal regulation dictates that the identity of a whistleblower must be protected under penalty of the law. It also states that the whistleblower must be protected from retaliation. The Compliance Office at the Cary Institute of Ecosystem Studies takes this mandate very seriously and will put procedures in place to help ensure that all information and identities are kept confidential and that the whistleblower suffers no reprisals because of their disclosures).
  - **i. Documentation*:*** Have clear documentation of who did what and when it was done.
  - **ii. Rules and Procedures**: Review institutional rules and procedures
  - **iii. Perspective:** Seek the guidance of a trusted colleague, mentor or administrator before making allegations of misconduct. What might appear to be serious could be simply a misunderstanding.

Talk to a mentor, peers, compliance administrator or the person in question.

iv. **Dispute Resolution:** Try to resolve the problem through conflict resolution.

v. **Whistleblower**: The possibility of retribution always exists but it is the responsibility of the Institution and the person charged with compliance to help ensure the protection of the whistleblower.

1. Distinguish between facts and speculation.
2. Ask questions rather than draw conclusions.
3. Whistleblowers are entitled and have the right to institutional protection.
4. ORI policy on research misconduct: http://ori.dhhs.gov/misconduct/
5. ORI policy on Whistleblower protection: http://ori.hhs.gov/misconduct/Guidelines_Whistleblower.shtml

V. MENTOR/TRAINEE RESPONSIBILITIES – *Mentoring is the social foundation of research.* It is the mentor who has the potential to draw the best from the junior person by acting as an adviser, teacher, role model, motivational friend and supportive advocate. It is an ideal way to pass ethical and professional values to the generation following. Institutions that commit themselves to long term development and progress cannot afford to forsake the cultivation of an encouraging, jointly supportive environment. A key element in that cultivation process is the mutually respectful and mindful relationship between mentor and trainee.[2]

a. **University of Michigan** – *A mentoring relationship is a close, individualized relationship that develops over time between a graduate student (research specialist) and/or a post-doc and a faculty member (or others) that includes both caring and guidance.*

b. The education, learning and professional development are central features of the mentor/trainee relationship.

c. Some problems that can be encountered in the mentor/trainee relationship are: abuse of power, communication failure, gender/ethic bias or harassment.

d. Critical one-on-one relationship.

e. Areas where training should be provided[3]:

i. Scientific Investigation
ii. Communication
iii. Personal Interactions
iv. Career Planning
v. Scientific Responsibility

1. Legal and ethical aspects of conducting research

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VI. <u>COLLABORATIVE RESEARCH -</u> *The scale and complexity of today's….research problems increasing demand that scientists move beyond the confines of their own discipline and explore new organizational models for team science…Many scientists will continue to pursue individual research projects, but they too will be encouraged to make changes in the way they approach scientific enterprise.* – The National Institutes of Health

- **a.** ***Webster's 11th Collegiate Dictionary*** defines collaboration as "working jointly with others or together especially in an intellectual endeavor."
- **b.** Types of collaborative ventures
  - i. Collaborations between researchers within an institution
  - ii. Using the equipment, facilities, staff of a colleague
  - iii. Collaborations between researchers from many institutions
  - iv. Collaborations between institutions and private companies
  - v. Interdisciplinary collaborations or intra-disciplinary collaborations
- **c.** Expectations – problems that arise in collaborative research projects usually arise out of differences in expectations because collaborators have not communicated sufficiently and/or effectively enough to express, understand, and resolve differences in expectations.
- **d.** Know and understand expectations:
  - i. What you are expected to contribute
  - ii. What you expect to get out of the collaboration
  - iii. Publication, authorship and credit
    - **1.** where will results be published/presented
    - **2.** who will be included as authors and in what order
    - **3.** authority to approve presentations and publications
  - iv. Research accountability –
    - **1.** who will have access to original data/and or notes
    - **2.** how often will collaborators meet
- **e.** Written agreements are required for inter-institutional collaborations and cover the following topics:
  - i. <u>Intellectual Property</u>
    - **1.** rights to patentable inventions discovered in the performance of research;
    - **2.** inventions jointly owned by collaborating institutions;
    - **3.** copyright – copyright law automatically gives ownership to the creator of the work.
      - a. Ownership can be negotiated but agreement will more likely address license rights.
    - **4.** use of data – collaborating institutions need to ensure that their researchers have access to research data because the sharing of data is essential to all research projects.

5. data retention and preservation – vital that project and information (collected, analyzed and reported) be maintained after the project closes.
    a. Requirement of federal awards
    b. Necessary to permit verification of research results; provide a record of inventions and inventorship; background data for future research.

ii. Types of Agreements

1. Subaward – agreement between two entities when collaborators of different institutions have a role in the management of a research project, and are listed as CoPIs and/or senior personnel in the proposal.
    a. Contains: work to be done; budget; allowable/unallowable costs; timing of financial and project reports; dispute resolution, award period.
2. Consulting agreement – "work for hire" agreements that are set in place between and individual or firm and an institution. A consultant has no rights to the work performed, the data or information collected or developed or any intellectual property.
3. Faculty Use Agreement – agreement that contains the charges associated with one collaborator using the facilities and equipment at another collaborator's institution. The rates charged should be consistent with rates charged for all users and should be reasonable - based on cost studies.
4. MTA – Material Transfer Agreements – contains provisions concerning liability resulting from the use of material (such as a chemical compound or biological substance) being transferred between institutions. It may include the cost of transporting materials and provisions for leftover materials.

VII. <u>PUBLICATION AND AUTHORSHIP</u> – *To publish is to make public. One can publish by orating, handing out leaflets, writing an article or writing a book. Forgery, fakery, and plagiarism contradict every natural expectation for how scientists act; they challenge every positive image of science that society holds* – **Marcel C. LaFollette**

a. Scientific literature comprises a body of hypotheses, observations statements (including data), theories, descriptions of methods, etc).

b. Plagiarism causes harm to other scientists – theft of ideas can cause harm to a colleague's career and will cause others to refrain from forming collaborative relationships with you. Trust is a key ingredient in collaborative relationships.

c. Deliberate deceptions can harm other scientists and scholars by wasting their time and perhaps other resources.
   i. Anyone relying on scientific literature can be caused injury or be placed in danger.
   ii. They harm the funder and the public by wasting valuable resources

d. Authorship on a publication denotes that one has expertise in the subject matter of the article.

e. Deceptive authorship practices[1]
   i. Authorship by authority – institutional or scientific leaders using their authority to become authors on a publication without doing any of the work appropriately related to the article's content.
      1. Department chair requiring or allowing his/her name to be placed on all documents produced by members of his/her department.
   ii. Gift, courtesy or honorary authorship – as a "courtesy" to prestigious or "useful" colleagues or to help promote the career of a grad student.
      1. Authorship should be given to only those individuals who made credible contributions to the project.
   iii. Political authorship – to prevent disappointment or hurt feelings in colleagues or to gain favor with a supervisor or high level administrative official (even though they did not do work on the project).

f. Any justification for authorship for someone who did not make a contribution to the project is considered deceptive; a false belief that someone contributed in salient ways to the research described in the published report.[1]

g. RULE OF THUMB: *If you are willing to take credit, you must also be willing to take responsibility*.

h. Criteria for authorship – International Committee of Medical Journal Editors (ICJME):
   i. Substantial contribution to conception and design, or acquisition of data, or analysis and interpretation of data;
   ii. Drafting the article or revising it critically for important intellectual content; and
   iii. Final approval of version to be published.

i. In a large collaborative publication:
   i. Identify the individuals (who meet criteria for authorship) who have direct responsibility for the manuscript.

j. Order of authorship should be a joint decision of the co-authors.

VIII. PEER REVIEW [4] – *evaluations by colleagues with similar knowledge and experience. The fate of entire research programs, health initiatives or*

environmental and safety regulations can rest on peer assessment. Researchers who serve as peer reviewers should be mindful of the public as well as the professional consequences of their evaluations.

- **a.** Many important decisions about research depend on advice from peers.
  - i. What projects to fund
  - ii. What findings to publish
  - iii. Who to hire and who to promote
  - iv. Which research is reliable (reviews and testimony)
- **b.** Peer reviews must be
  - i. Timely
  - ii. Thorough
  - iii. Constructive
  - iv. Free from personal bias
  - v. Respectful of the need for confidentiality.
- **c.** Peer reviewers must do their best to determine if the work is internally consistent and conforms to the practices of their field of research, including:
  - i. Assessing whether the research methods are appropriate,
  - ii. Checking calculations and/or confirming the logic of important arguments,
  - iii. Making sure the conclusions are supported by the evidence presented, and
  - iv. Confirming that the relevant literature has been consulted and cited.
- **d.** Research quality can be compromised by:
  - i. Careless mistakes in reporting data or listing citations,
  - ii. Deliberate fabrication and falsification of data,
  - iii. Improper use of material by others (plagiarism),
  - iv. Inaccurate reporting of conflicts of interest, contributors/authors, and
  - v. Failure to mention important prior work, either by others or by the research submitting a paper for publication.
- **e.** How much peer reviewers can or should do to detect these and other deceptive or sloppy practices remain subject to debate.
- **f.** Judging the importance of proposed or published research
  - i. Can the proposer carry out the research and is it important to do so,
  - ii. Are the research results important enough to publish,
  - iii. Has the researcher made important contributions to the filed of study,
  - iv. Is the evidence important enough to be used in setting policy
- **g.** Factors that can sway a reviewer

i. Stature of the researcher or the institution at which the research was conducted,
ii. A preference for one research method over another,
iii. Outcomes of the studies under review.

h. Suggested steps for lessening bias in peer reviews:
i. Write transparent reviews that lays out clearly how it was prepared, the literature used and the reviewer's own bias.
ii. Eliminate anonymous reviews.
1. some argue this would lessen the candor and rigor of the review,
2. others argue it would make reviewers more accountable.

i. ORI suggests that if you have strong feelings about a person or a particular line of investigation, tell the person who asked you to do the review and consider whether or not you can be impartial.

j. Preserving Confidentiality is required during grant reviews, manuscript reviews and personnel reviews. It is *not acceptable* to do any of the following without getting permission:
i. ask someone else to do a review that you were asked to do,
ii. use an idea or information contained in a grant proposal or unpublished manuscript before it becomes publically available,
iii. discuss grant proposals or manuscripts you are reviewing with colleagues in your department or at a professional meeting,
iv. retain a copy of review material – should be shredded after review,
v. discuss personnel or hiring decisions with colleagues who are not part of the review process.

k. *Researchers who are in a position to pass judgment on the work of colleagues have significant power. They can hasten or slow that work; credit or discredit it. They have the power to shape entire fields of research and to influence public policy. If you have that power, make sure that you use it responsibly and with some compassion, knowing that what you say and do directly affects the careers of other researchers…*The Office of Research Integrity.

IX. THE PROTECTION OF HUMAN SUBJECTS[4] – *living individual(s) about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual or (2) identifiable private information*. The authority to make decisions on the need for approval rests with the Institutional Review Board (IRB). **Surveys can fall under IRB review**.

a. Research – The Common Rule defines research as "systematic" investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge (§46.102(d)). A project or study is research if:

i. it is conducted with the intention of drawing conclusions that have some general applicability, and
ii. it uses a commonly accepted scientific method.

b. Exempt Research – studies that fall into the following categories could qualify for exemptions:
i. Research conducted in established or commonly accepted educational settings;
ii. Research involving the use of educational tests;
iii. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if unidentifiable or publicly available;
iv. Research and demonstration projects which are conducted by or subject to the approval of department of agency heads;
v. Taste and food quality evaluation and consumer acceptance studies.
vi. **Note: the decision about whether studies are exempt from the requirements of the Common Rule must be made by the IRB or an appropriate institutional official and not by the investigator.**

c. Main concern of IRBs when evaluating research (§46.111(a)):
i. Risks to subjects are minimized,
ii. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably expected to result.
iii. Selection of the subjects is equitable,
iv. Informed consent will be sought from each prospective subject or the subject's legally authorized representatives.
v. Informed consent will be appropriately documented,
vi. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of the subjects, and
vii. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain confidentiality of data.

X. WELFARE OF LABORATORY ANIMALS[4] – *Animal research is as carefully regulated as animal research. In most cases, animal research is conducted for the benefit of humans, not animals. In addition, animals cannot consent to participate in the experiments or comment on the treatment.*

a. ***The Guide for the Care and Use of Laboratory Animals*** ***(http://www.nap.edu/openbook.php?record_id=5140)*** **–** provides guidance on Institutional Policies and Regulations and Animal Environment, Housing and Management.

b. **Animal defined:**

i. The PHS policy, which applies to all PHS-funded activities involving animals, defines animals as "*any live, vertebrate animals used or intended for use in research, research training, experimentation, or biological testing or for related purposes."*
ii. The Federal Code that implements the Animal Welfare Act (Title 9) covers warm-blooded animals but excludes, '*birds, rats of genus Rattus and mice of the genus Mus bred for use in research, and horses not used for research purposes and other farm animals….'*

c. Many institutions apply uniform and consistent standards to all activities involving animals regardless of the source of funding or legal requirement as a way of ensuring broad compliance with all regulations.

d. Researchers are not authorized to make decisions about covered or excluded animals in research. Need to consult with the IACUC – Animal Care and Use Committee.

e. IACUC are appointed by the institution but have independent authority. Their responsibility include:
i. Reviewing and approving all animal use research proposals,
ii. Reviewing institutions animal care program,
iii. Inspecting animal facilities at least twice a year
iv. Receiving and reviewing concerns raised about the care and use of animals, and
v. Submitting reports to the Institutional Official (At Cary Institute – Marie Smith at extension 202).

f. Three "Rs of Alternatives devised by Russell and Burch in 1959:
i. Replacement – using non-animal models such as microorganisms or cell culture techniques, computer simulations or lower species;
ii. Reduction – using methods aimed at reducing the numbers of animals such as minimization of variability, appropriate selection of animal model, minimization of animal loss, and careful experimental design,
iii. Refinement – the elimination or the reduction of unnecessary pain and distress.

http://www.nap.edu/openbook.php?record_id=5140References:

NIH TRAINING - http://phrp.nihtraining.com/users/login.php
CITIPROGRAM – www.citiprogram.org

National Institutes of Health, Office of the Director; *A Guide to Training and Mentoring in the Intramural Research Program at NIH*

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Steneck, Nicholas H.; *ORI: Introduction to the Responsible Conduct of Research;* Department of Health and Human Services Office of Research Integrity, Revised August 2007.

Training Resources: The Citiprogram Training – online training located at **http://ori.dhhs.gov/education/products/**

Endnote Acknowledgements:

1. ***Excerpted in part from*** **CITIPROGRAM –** **www.citiprogram.org**
2. ***From the RCR tutorial at Columbia University (http://ori.hhs.gov/education/products/columbia_wbt_mentoring/foundation/index.htm)*** **and** ***the CITI Program module on Mentoring (www.citiprogram.org)***
3. **NIH –** ***Guide to Training and Mentoring in the Intramural Research Program at NIH***
4. **Excerpted from ORI:** ***Introduction to the Responsible Conduct of Research***