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EECS 519

Responsible Conduct of Research

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Based on Materials From:

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1. ORI Introduction to the Responsible Conduct of Research

by Nicholas H. Steneck,
(illustrations by David Zinn)

(online: http://ori.hhs.gov/education/products/RCRintro/index.html)

2. COC & COI – Priorities, Values & Laws

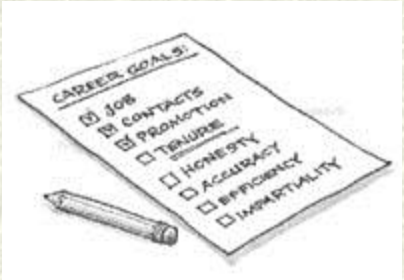
by Joseph L. Schofer

Intro

No “best way”/”universal method”
May vary across disciplines/labs

HONESTY — conveying information truthfully and honoring commitments,
ACCURACY— reporting findings precisely and taking care to avoid errors,
EFFICIENCY— using resources wisely and avoiding waste, and
OBJECTIVITY— letting the facts speak for themselves and avoiding improper bias.

At the very least, responsible research is research that is built on a commitment to these and other important values that define what is meant by integrity in research.



Intro

- The **public** and their professional colleagues **expect** researchers to follow many rules and commonly accepted practices as they go about their work advancing knowledge and putting knowledge to work. Responsible conduct in research is conduct that **meets this expectation**.
- No strict Rules of the Road

- Four basic sources of rules:
  - Professional (self-regulation) codes,
  - government regulations,
  - institutional policies, and
  - personal convictions.

Outline

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- Regulations
- Research Misconduct
- Planning Research
  - The Protection of Human Subjects
    The Welfare of Laboratory Animals
    Conflicts of Interest
- Conducting Research

  Data Management Practices

  Mentor and Trainee Responsibilities
  Collaborative Research
- Reporting and Reviewing Research

  Authorship and Publication
  Peer Review

Professional (self-regulation) code

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- Actually, only after WWII
  - Prior, not much expectations from public
- Rather convoluted:
  - Research arguably does not need specific rules for self-regulation because it is, by definition, an activity that routinely monitors itself.
- Comprehensive descriptions of responsible research practices can be found at:
  - reports and policy statements issued by the National Academy of Sciences, the American Association for the Advancement of Science, the Association of American Medical Colleges, and Sigma Xi;
  - guidance on responsible publication practices published in journals; and
  - a few comprehensive professional codes.

Government Regulations

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- Usually begin in the Congress
  - the 1966 Animal Welfare Act (PL 89-544),
  - the 1974 National Research Act (PL 93-348), and
  - the 1985 Health Research Extension Act (PL 99-158).
- Congress provides guidance on general objectives, but not detailed regulations.
  - Federal agencies in the Executive Branch of government
  - Regulations:
    - Federal agencies must follow provisions set out in the Federal Administrative Procedure Act (5 USC 551-702).
    - It establishes procedures for developing new regulations, including steps for getting public input.
  - Agency Policies and Guidelines:
    - Executive Branch agencies have the authority to issue some policies as part of their normal operation.
    - National Institutes of Health (NIH), for example, has the authority to establish policies for grant awards.

Institutional Policies

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- Research institutions (universities, hospitals, private research companies, and so on) are required by law to have policies that cover various aspects of their research programs if they accept Federal funds. They must have:
  - committees to review human and animal research.
  - procedures for investigating and reporting research misconduct and conflicts of interest.
- Most research institutions have research offices/officers and institutional research policies
- Institutions usually have Web sites that contain some or all of the following information:
  - copies of institutional research policies,
  - links to state and Federal policies,
  - required forms and instructions for completing them,
  - responsible conduct of research training programs, and
  - lists of key personnel.

Regulations – Personal Responsibility

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- Two limitations
  - **First**, rules generally set minimum standards for behavior rather than strive for the ideal. If you use human subjects in research, you must follow specific rules, but there may be situations in which you should strive for a higher standard of conduct.
  - **Second**, rules will not resolve some of the personal conflicts and moral dilemmas that arise in research. Journals have rules against listing undeserving authors on papers (individuals who have not made significant contributions to the research described in the paper). These same rules do not tell you what to do if the undeserving author can have a significant influence on your career.
- Whatever decision you make when you confront a difficult decision about responsibility in research, you are the one who has to live with the consequences of that decision.

Research Misconduct

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- In December 2000 the Office of Science and Technology Policy (OSTP) in the Executive Office of the President adopted a Federal Policy on Research Misconduct.
  - "research misconduct" is any "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results". Basically, actions which:
    - represent a "significant departure from accepted practices";
    - have been "committed intentionally, or knowingly, or recklessly";
    - and be "proven by a preponderance of evidence."
- Procedures for **reporting and investigation,** must include:
  - the designation of individuals who are authorized to receive and investigate allegations of misconduct,
  - provisions for an initial inquiry to determine whether the allegations have any merit,
  - provisions for a formal investigation to reach conclusions about the truth of the allegations,
  - the designation of an individual who is authorized to weigh (adjudicate) the conclusions reached in the investigation and impose administrative actions to redress the misconduct (sanctions) or take steps to vindicate the person charged, and
  - provisions for reporting findings to ORI.

Institutional Policies

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- Follow the pattern recommended by the Federal Government, but almost always include some additional elements – "local context"
- **Violation of Federal rules.**
- **Abuse of confidentiality**
  - **Undermines the integrity of the research process; many institutions list this explicitly**
- **Authorship and publication violations**
- **Failure to report misconduct**
- **Obstruction of investigations and retaliation**
- **Other:**
  - actions that seriously deviate from commonly accepted practices can be considered research misconduct
  - ASIDE:
    - PHS and NSF combined have averaged no more than 20 to 30 misconduct findings a year… need not be the "whole picture"

Planning the Research

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- In addition to the typical "starters":
  - What causes this particular phenomenon?
  - What would happen if…?
  - How can I find out…?
- Planning should also include:
  - consideration of responsibilities
  - Hazards
  - Fair treatments of personnel
- Which, in many funding cases is essential to demonstrate before a grant is awarded…

Protection of Human Subjects – Federal Regulations

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- Nuremberg Code (1947) + Declaration of Helsinki (1974)
- 1974 Congress required the Department of Health, Education and Welfare (HEW, currently Health and Human Services—HHS) to clarify its rules for the use of human subjects in research
- 1974 Congress called for creation of a National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
- 1991 most Federal departments and agencies that conduct or support human subjects research adopted a common set of regulations for the protection of human subjects referred to as the "Common Rule"
  - Subpart B – Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research.
  - Subpart C – Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisonersas Subjects.
  - Subpart D – Additional Protections for Children Involved as Subjects in Research.

Protection of Human Subjects – Basics

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- **Research:** "systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge"
- **Human subjects**. Human subjects are "living individual(s) about whom an investigator conducting research obtains:
  (1) data through intervention or interaction with the individual; or
  (2) identifiable private information
- **Exempt research**. Some studies that involve humans may be exempt from the requirements in the Federal regulations:
  - research conducted in established or commonly accepted educational settings;
  - research involving the use of educational tests;
  - research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if unidentifiable or publicly available;
  - research and demonstration projects which are conducted by or subject to the approval of department or agency heads; or
  - taste and food quality evaluation and consumer acceptance studies.

Protection of Human Subjects – IRB

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- Federally funded research that uses human subjects must be reviewed and approved by an independent committee called an Institutional Review Board or IRB.
  - risks to subjects are minimized;
  - risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result;
  - selection of subjects is equitable;
  - informed consent will be sought from each prospective subject or the subject's legally authorized representative;
  - informed consent will be appropriately documented;
  - when appropriate, the research plan makes adequateprovision for monitoring the data collected to ensure the safety of subjects; and
  - when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

Protection of Human Subjects – IRB

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Three principles for making judgments:

- **respect for persons** and their right to make decisions for and about themselves without undue influence or coercion from someone else (the researcher in most cases);
- **beneficence** or the obligation to maximize benefits and reduce risks to the subject; and
- **justice** or the obligation to distribute benefits and risks equally without prejudice to particular individuals or groups, such as the mentally disadvantaged or members of a particular race or gender.

- researchers should spend time considering whether their work does provide adequate respect for persons, appropriately balances risks and benefits, and is just.

Protection of Human Subjects – Training

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- Many federal agencies will provide some basic (Web-based) training:
  - E.g., on requirement is: "…education on the protection of human research participants for all investigators submitting NIH applications for grants or proposals for contracts or receiving new or non-competing awards for research involving human subjects"
- Typically, the continuing-research should pay attention to:
  - enrolling only those subjects that meet IRB approvedinclusion and exclusion criteria,
  - properly obtaining and documenting informed consent,
  - obtaining prior approval for any deviation from theapproved protocol,
  - keeping accurate records, and
  - promptly reporting to the IRB any unanticipated problems involving risks to subjects or others.

Protection of Human Subjects – Ethics

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- **Informed consent:** research subjects should be fully informed about experiments in which they may participate and give their consent before they enroll.
  - Children?
  - Adults with impaired decision making capacity?
  - Some critically ill patients?
- **Right to withdraw**: research subjects should have the right to withdraw from experiments at any time, but in some cases they cannot. In the final stages of development, mechanical hearts are tested on patients whose own heart is about to fail. But if it has not failed, and once the mechanical heart replaces the weakened heart, there is no turning back
- **Risk without benefit**.
  - In a recent experiment, researchers wanted to test whether a common surgical procedure used to relieve arthritis pain had any benefits. An operation was performed, but the common surgical procedure was not performed on "placebo-testers".

Lab Animals – Rules/Regulations

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- The policies for the appropriate care and use of all animals involved in research, research training, and biological testing activities, postulate that one needs to:
  - know what activities are subject to regulation,
  - understand and follow the rules for project approval,
  - obtain appropriate training, and
  - accept continuing responsibility for compliance through all stages of a project.
- **Federal regulations**. Congress has drafted two important statutes:
  - the 1966 Animal Welfare Act (revised 1970, 1976, 1985, and 1990) and
  - the 1985 Health Research Extension Act, Sec. 495.
- **Guidelines**. "Animal Care Panel" (ACP) established a professional standard for laboratory animal care and facilities.
  - Institutional Policies and Responsibilities;
  - Animal Environment, Housing, and Management;
  - Veterinary Medical Care; and
  - Physical Plant.

Lab Animals – Basic Definitions

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- Federally funded research is guided by two key definitions:
  - **The PHS Policy**, which applies to all PHS-funded activities involving animals, defines "animals" as "any live, vertebrateanimals used or intended for use in research, research training, experimentation, or biological testing or for related purposes."
  - **The Federal Code** that implements the Animal Welfare Act (Title 9) covers warm-blooded animals but excludes "[b]irds, rats of the genus Rattus and mice of the genus Mus bred for use in research, and horses not used for research purposes and other farm animals…."

- IF you plan to use animals in research, teaching, testing and other covered activities, consult with the institutional committee(s) first…

Lab Animals – Institutional issues…

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- Congressionally mandated Institutional Animal Care and Use Committee (IACUC), responsible for:
  - reviewing and approving all animal use research proposals,
  - reviewing the institution's animal care program,
  - inspecting (at least twice a year) the institution's animal facilities,
  - receiving and reviewing concerns raised about the care and use of animals, and
  - submitting reports to the Institutional Official.

- Large animal research programs generally have centralized animal care and use units that provide veterinary support, training in procedures, and advice on analgesics, anesthesia, euthanasia, and occupational health and safety.

Lab Animals – Oversight

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- OLAW, USDA, and a voluntary accreditation program (Association for Assessment and Accreditation of Laboratory Animal Care—AAALAC).
  - comply with applicable rules and policies for animal care and use,
  - provide a description of the institution's program for animal care and use,
  - maintain an appropriate IACUC, and
  - appoint a responsible IO for compliance.

- As for AAALAC
  - Private, non-profit(?)
  - > 650 universities and labs participating…

Lab Animals – Principles…

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- US Government has adopted the following principles for Utilization and Care of Vertebrate Animals Use in Testing, Research and Training
  - follow the rules and regulations for the transportation, care, and use of animals;
  - design and perform research with consideration of relevance to human or animal health, the advancement of knowledge, or the good of society;
  - use appropriate species, quality, and the minimum number of animals to obtain valid results, and consider non-animal models;
  - avoid or minimize pain, discomfort, and distress when consistent with sound scientific practices;
  - use appropriate sedation, analgesia, or anesthesia;
  - painlessly kill animals that will suffer severe or chronic pain or distress that cannot be relieved;
  - feed and house animals appropriately and provide veterinary care as indicated;
  - assure that everyone who is responsible for the care and treatment of animals during the research is appropriately qualified and trained; and
  - defer any exceptions to these principles to the appropriate IACUC.

Lab Animals – Broader Picture

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- Sometime, just cannot avoid…
  - **Pain and suffering**. Some experimental information cannot be gained without subjecting animals to pain and suffering. Researchers who study the effects of severe trauma, such as child abuse, can learn a great deal about physiological change by subjecting animals to different levels of pain and suffering. This can be done by administering mild electric shocks, forcing animals such as rats to swim until they reach exhaustion, or subjecting them to other traumatic treatments. How much pain and suffering is acceptable in experiments is not easily determined.
  - **Concern for different species**. There is widespread agreement that some animals, such as primates and household pets, deserve more protection than other animals, such as worms and clams. There is less agreement about the relative protection that is needed for species within general groups of animals, such as cats, dogs, pigs, rabbits, mice, and rats. What moral considerations set one species apart from another when making decisions about the use to which it can be put in experiments?
  - **Unnecessary experiments**. Members of the public disagree about the use to which animals can reasonably be put in research, testing, and teaching. Animals are used to test the safety of experimental drugs, but should they also be used to test the toxicity of chemicals or cosmetics (as once was common, but has largely been abandoned)?

Conflict of Commitment

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- ***A "Conflict of Commitment" occurs when the time devoted to external activities adversely affects a Faculty Member's capacity to meet University responsibilities.***
  - Pro bono, consulting, external appointments
  - Our responsibilities to NU – quantity & quality – are primary
  - Our outside activities (should) have value to our NU work

Words About Consulting

- Why do it?
- Consulting vs Working
- Limits
  - ≤ 1 day per week
  - not to exceed 39 days during the academic year
    - (that's a lot!!)
- 1 day/week isn't an entitlement
- Summer: if you are 100% on research contract, you don't have a day a week to sell
- Engaging your students
  - Risks: role confusion, bias, coercion
  - Requirement: transparency

Conflicts of Interest

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- Research:
  - advances knowledge,
  - leads to discoveries that will benefit individuals and society,
  - furthers professional advancement, and/or
  - results in personal gain and satisfaction.
- In principle, it should promote sharing ideas, and even encourage that the researchers do have various benefits. However, the conflict of interest should not mess up the responsible research, especially in issues evolving around:
  - financial gain,
  - work commitments, and
  - intellectual and personal matters,

Conflicts of Interest

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- Personal interests and the prospect of financial gain should not improperly influence a researcher's fundamental obligation to truth and honesty.
- Financial interests can provide a strong incentive to overemphasize or underemphasize research findings or even to engage in research misconduct
- Financial interests are not inherently wrong. Researchers are permitted to benefit financially from their work (Bayh-Dole Act, 1980)

Conflict of Interest

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- ***… a "Conflict of Interest" occurs when there is a <u>divergence between a Faculty Member's private interests and his/her professional obligations to the University</u>, such that an independent observer might reasonably question whether the Faculty Member's professional actions or decisions are determined by any considerations other than the best interests of the University.***

COI Examples

- External Financial Interests
  - Controlled investments (vs TIAA_CREF), ownership interest
  - You or close family members
  - >$100k or 5% interest
  - Linked to your work
  - Selling to Northwestern
- Consulting? Possibly
  - Diversion of funds from NU
  - Substantial use of NU resources
- Will this affect your NU work?
  - Biasing focus, findings, direction and progression of students…

Growing a Startup Business

Managing COI

We rely on honest reporting… but we're not fools.

- It's not "Don't do it," its "Reveal it, manage it, and do it right."
- Translational work and startup companies
- Reporting COI – annual COI disclosure form
  - http://surveys.mccormick.northwestern.edu/mcc/coi/login.php
  - Most have no conflicts
- McC COI process
  - Protection for university and faculty members
  - Review, meet, analyze, plan, agree, track
  - Self reporting
  - Declaration on OSR-1 & follow-up

COI Management Plans

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- Written agreement
- Reveal relationships
- Protect students
- OK to engage post docs in outside business
- Managing the company
  - Signing agreements for both sides
- Appearance vs. reality

If it looks like a duck…

- … **Faculty Members must ensure that** the **activities of students are not subordinated to the personal commercial interests of the Faculty Member, and that the work of students, support staff, and collaborators is not exploited in the course of a Faculty Member's outside obligations. It is inappropriate for a Faculty Member to assign University tasks to students or support staff for purposes of financial gain for the Faculty Member, rather than for the advancement of the scholarly field or to meet the students' educational needs.**
- **Faculty Members must disclose and receive approval from the department chair or center director for any anticipated use of students' or support staff's time, work, or ideas. A Faculty Member must inform students, support staff, and collaborators if he/she has a personal commercial interest in the research project.**
- …**Part-time involvement of students** in the Compensated Professional/Commercial Activities of Faculty Members (including… activities leading to the development of Compensated Professional/Commercial Activities of Faculty Members) **may, under certain conditions, offer the potential for substantial benefits to the education of the student**. In each case of such involvement, the **Faculty Member must obtain prior approval** from the school dean after discussion with the department chair, student's thesis advisor (if other than the Faculty Member), and the student…
- …the **Faculty Member will be guided by the need to avoid infringement upon the student's academic duties and rights**. Generally, if the Faculty Member has a role in supervising the student's thesis or in supervising the work of the student as a graduate teaching assistant, such outside involvement should not be undertaken. If the Faculty Member does not have a role in supervising the student's thesis and/or the student's work as a teaching assistant, such involvement may be undertaken once approval is obtained from the school dean after discussion with the department chair, student's thesis advisor, and the student.

http://www.research.northwestern.edu/policies/faculty-conflict-of-interest.html#IIIb3

Conflict of Interest

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- Federal regulations require each institution to define administrative procedures for:
  - reporting significant conflicts before any research is undertaken;
  - managing, reducing, or eliminating significant financial conflicts of interest; and
  - providing subsequent information on how the conflicts were handled.
- Financial conflict is defined as:
  - additional earnings in excess of $10,000 a year, or
  - equity interests in excess of 5 percent in an entity that stands to benefit from the research (includes the family members too…).
- Researchers should check their *local* (e.g., state) conflict-of-interest policy.
- Researchers should carefully check and make sure the conflict of interest policies for journals/conferences.

Data Management Practices

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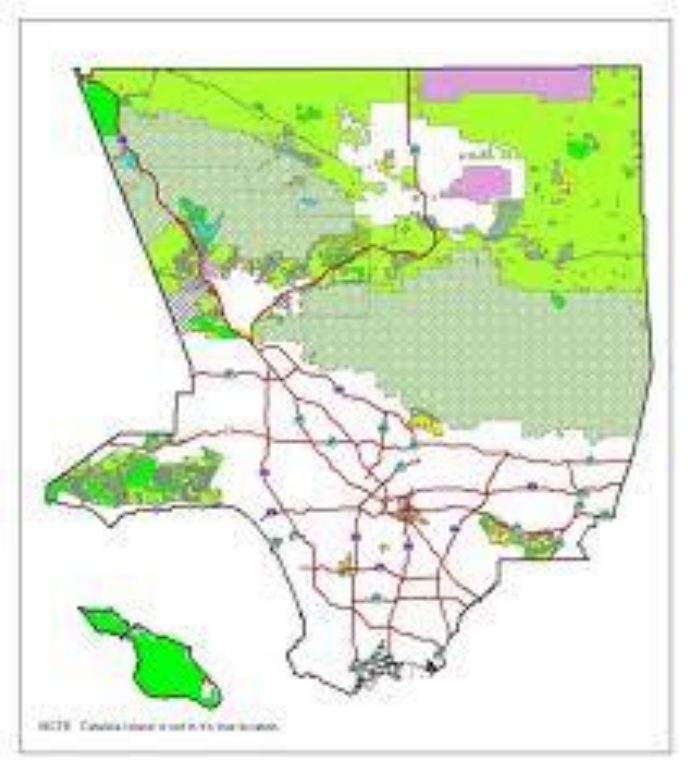
- Data management practices are becoming increasingly complex and should be addressed before any data are collected by taking into consideration **four** important issues:
  - ownership,
  - collection,
  - storage, and
  - sharing.



Data Ownership

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- **Funders**. Funders provide support for research for different reasons. Government is interested in improving the general health and welfare of society. Private companies are interested in profits, along with benefits to society. Philanthropic organizations are interested in advancing particular causes. These different interests translate into different ownership claims:
  - Government gives research institutions the right to use data collected with public funds as an incentive to put research to use for the public good (see the discussion of the Bayh-Dole Act, Chapter 5).
  - Private companies seek to retain the right to the commercial use of data.
  - Philanthropic organizations retain or give away ownership rights depending on their interests.
- **Research institutions**. Support for research is typically awarded to research institutions, not to individual researchers. As the recipients of research funds, research institutions have responsibilities for budgets, regulatory compliance, contractual obligations, and data management.
  - In plain English: the data generated by your research, does belong to the institution…

Data Ownership

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- **Data sources**. Increasingly research subjects and other entities that are the source of data are seeking some control over data derived from them. E.g.,
  - Countries with unique resources, such as tropical rain forests,
  - Individuals with rare medical conditions,
  - Entities with unique databases,
    - have all, at one time or another, claimed ownership of research results based on their data.
- Before you start any research, have answers (preferably in writing) for:
  - Who owns the data I am collecting?
  - What rights do I have to publish the data?
  - Does collecting these data impose any obligations on me?

Data Generation/Collection

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- **Appropriate methods.** Reliable data are vitally dependent on reliable methods.
  - Inappropriate statistics
  - Bias
- **Attention to detail**. Quality research requires attention to detail. Experiments must be set up properly and the results accurately recorded, interpreted, and published.
- **Authorization.** Typically needed for:
  - human and animal subjects in research;
  - hazardous materials and biological agents;
  - information contained in some libraries, databases, and archives;
  - information posted on some Web sites;
  - published photographs and other published information; and
  - other copyrighted or patented processes or materials.

- **Recording.** Make sure to properly maintain both hard-copies and electronic copies.

Data Protection

- Needed for:
  - confirming research findings,
  - establishing priority, or
  - being reanalyzed by other researchers
- **Responsible handling** of data begins with proper storage and protection from accidental damage, loss, or theft.
- **Confidentiality**. Some data are collected with the understanding that only authorized individuals will use them for specific purposes. In such cases, care needs to be taken to assure that privacy agreements are honored
- **Period of retention**. Data should be retained for a reasonable period of time to allow other researchers to check results or to use the data for other purposes (e.g., NIH requires at least 3 years after the expiration of the grant)

Data Sharing

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- It is widely agreed that research data should be shared, but deciding when and with whom raises questions that are sometimes difficult to answer.
  - Researchers are not expected to and in most instances **should not release preliminary data**, that is, data that have not been carefully checked and validated.
  - Researchers **can withhold confirmed or validated data** until they have had time to establish their priority for their work through publication or, in rare cases, a public announcement.
  - Once a researcher has published the results of an experiment, it is ***generally expected*** that all the information about that experiment, including the final data, should be freely available for other researchers to check and use. Some journals formally require that the data published in articles be available to other researchers upon request or stored in public databases.

Mentors and Trainees

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- General understanding is that the relationship should begin with:
  - a clear understanding of mutual responsibilities,
  - a commitment to maintain a productive and supportive research environment,
  - proper supervision and review, and
  - an understanding that the main purpose of the relationship is to prepare trainees to become successful researchers.

Mentors and Trainees

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- Trainees need to know:
  - how much time they will be expected to spend on their mentor's research;
  - the criteria that will be used for judging performance and form the basis of letters of recommendation;
  - how responsibilities are shared or divided in the research setting;
  - standard operating procedures, such as the way data are recorded and interpreted; and, most importantly,
  - how credit is assigned, that is, how authorship and ownership are established.
- Mentors need to know that a trainee will:
  - do assigned work in a conscientious way,
  - respect the authority of others working in the research setting,
  - follow research regulations and research protocols, and
  - live by agreements established for authorship and ownership.
- Mentors invest time and resources in trainees.
- Trainees should respect this time and use resources responsibly

Mentors and Trainees

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- What is a good research environment?
  - **Equal treatment**. Research ability is not tied to race, gender, ethnicity, or sexual orientation. These factors have no bearing on one's success as a researcher. Therefore, research environments should not put someone at a disadvantage based on who they are.
  - **Professional practice**. Researchers should maintain research environments that respect accepted practices for the responsible conduct of research. Trainees learn by example as well as formal training. They assume, not unreasonably, that the practices they observe are appropriate practices. Mentors therefore have an obligation to maintain research environments that set appropriate examples.
  - **Training in the responsible conduct of research**. Beginning in 1989 (NIH, and more recently, NSF).

Mentors and Trainees

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- When mentors accept trainees, they assume responsibility for assuring that the persons under their supervision are appropriately and properly trained.
  - assure proper instruction in research methods,
  - foster the intellectual development of the trainee,
  - impart an understanding of responsible research practices, and
  - routinely check to make sure the trainee develops into a responsible researcher.

- OK to delegate some responsibilities to PostDocs
- Important aspects of reviewing/monitoring:
  - reviewing laboratory notebooks and other compilations of data,
  - reading manuscripts prepared by trainees carefully to assure that they are accurate, well-reasoned, and give proper credit to others;
  - meeting with trainees on a regular basis to keep in touch with the work they are doing; and
  - encouraging trainees to present and discuss data at laboratory meetings.
  - Goal: transition to independent researchers…

Collaborative Research

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- Any project that has more than one person working on it requires some collaboration, i.e., working together.
- One person, commonly called the "principal investigator" or PI, is in charge; others work under the PI's direction.
- Collaborative project – groups of researchers who are all more or less equal partners, brings other issues due to:
  - the increasingly complex roles and relationships;
  - common, but not necessarily identical, interests;
  - management requirements; and
  - cultural differences

Collaborative Research

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- Need clear understanding of **roles** and **relationships**
  - the goals of the project and anticipated outcomes;
  - the role each partner in the collaboration will play;
  - how data will be collected, stored, and shared;
  - how changes in the research design will be made;
  - who will be responsible for drafting publications;
  - the criteria that will be used to identify and rank contributing authors;
  - who will be responsible for submitting reports and meeting other requirements;
  - who will be responsible for or have the authority to speak publicly for the collaboration;
  - how intellectual property rights and ownership issues will be resolved; and
  - how the collaboration can be changed and when it will come to an end.

Collaborative Research

- Effective management is essential…
- **Financial management**. The expenditure of Federal research funds is subject to financial management rules issued by the Office of Management and Budget in Circulars A-21 and A-110 ("a must" for every Federally funded project)
- **Training and supervision**. Wherever they work, research staff should be properly trained and supervised. In some instances the training is mandatory.
- **Formal agreements**. Some aspects of collaborative projects must be worked out in advance in formal agreements. For example, when research is carried out in more than one place, it is sometimes necessary to transfer materials from one institution to another:
  - who owns the materials,
  - the use to which they can be put, and
  - proper acknowledgment of the source.

Authorships and Publications

- Responsible publication in research should ideally meet some ***minimum standards***.
- All forms of publication should present:
  - a full and fair description of the work undertaken,
  - an accurate report of the results, and
  - an honest and open assessment of the findings.

- When assessing the completeness of a publication, the main questions are:
  - what they did (methods),
  - what they discovered (results), and
  - what they make of their discovery (discussion).

Authorships and Publications

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- The names that appear at the beginning of a paper let others know who conducted the research and should get credit for it.
- Consequently, the authors listed on papers should fairly and accurately represent the person or persons responsible for the work in question.
- **Contribution**. Authorship is generally limited to individuals who make significant contributions to the work that is reported. This includes anyone who:
  - was intimately involved in the conception and design of the research,
  - assumed responsibility for data collection and interpretation,
  - participated in drafting the publication, and
  - approved the final version of the publication.

Authorships and Publications

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- **Importance**. Authors are usually listed in their order of importance, with the designation first or last author carrying special weight, although practices may vary by discipline.

- **Corresponding or primary author**. Many journals now require one author, called the corresponding or primary author, to assume responsibility for all aspects of a publication, including:
  - the accuracy of the data,
  - the names listed as authors (all deserve authorship and no one has been neglected),
  - approval of the final draft by all authors, and
  - handling all correspondence and responding to inquiries.

Peer Reviewing

- Many important decisions about research depend on advice from peers, including:
  - which projects to fund (grant reviews),
  - which research findings to publish (manuscript reviews),
  - which scholars to hire and promote (personnel reviews), and
  - which research is reliable (literature reviews and expert testimony).
- Peer review can make or break professional careers and directly influence public policy. Hence, at bare minimum it needs to be:
  - timely,
  - thorough,
  - constructive,
  - free from personal bias, and
  - respectful of the need for confidentiality.

Peer Reviewing

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- Things that can sway judgment
  - Issues of quality, e.g.,
    - assessing whether the research methods are appropriate;
    - checking calculations and/or confirming the logic of important arguments;
    - making sure the conclusions are supported by the evidence presented; and
    - confirming that the relevant literature has been consulted and cited.
  - Other issues that can compromise the overall quality
    - careless mistakes made in reporting data and/or listing citations;
    - the deliberate fabrication and falsification of data;
    - improper use of material by others (plagiarism);
    - inaccurate reporting of conflicts of interest, contributors/authors; and
    - the failure to mention important prior work, either by others or by the researcher submitting a paper for publication.

- Do NOT discuss the reviews with the authors ((double) blind review)
- Remember to do all the "homework"

Peer Reviewing

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- What could "cloud" the mind when reviewing (No-No's):
  - the stature of the researcher who conducted the research or the institution at which the research was conducted;
  - country of origin;
  - a preference for one research method over another, e.g., a clinical versus a laboratory approach; and
  - the outcome of the studies under review.
- Remember to preserve the confidentiality:
  - grant reviews,
  - manuscript reviews, and
  - personnel reviews.

Lastly:

- Go to the CITI web site:
  - https://www.citiprogram.org/enroll/courseregistration1.asp?language=english
- Select **New Users Register Here.**
- From the drop-down menu of participating institutions, select **Northwestern University.**
- You will see a number of steps listed. To set up your account, follow steps 2 through 5. It is important that you use your NU netid as your username, but password can be different. For Step 5 use your Northwestern e-mail address. For Step 6 answer "No" and Step 7 can also be "No".
- Answer the Northwestern University questions.
- On the CITI Course Enrollment Procedure page scroll down to the bottom of the page and respond to the CITI Course Enrollment Questions 1 and 2, only if applicable to you. Otherwise skip questions 1 and 2. Skip questions 3 and 4. On question 5 you either enroll as Responsible Conduct of Research for Graduate students and post-docs OR Responsible Conduct of Research for Undergraduate students.
- Select "No" on the Select your institution of organization page.
- On the main menu page you can "Enter" your training and do as much as you want and then come back to it. Graduate students and post-docs have six modules and Undergraduate students have three modules. You are expected to score **at least 80% in each module**: