OFFICE OF RESEARCH INTEGRITY AND COMPLIANCE

Assist researchers with meeting the regulatory requirements and ethical standards associated with research

Protect human and animal subjects involved in research

Specific Areas:

- Responsible Conduct of Research Education
- Research Misconduct
- Human Subject Research
- Care and Use of Animals in Research
- Conflict of Interest
- Export Control

http://www.cmu.edu/research-compliance/index.html
DATA

I think we've got enough information now, don't you?

All we have is one 'fact' you made up.

That's plenty. By the time we add an introduction, a few illustrations, and a conclusion, it will look like a graduate thesis.

Calvin & Hobbes, by Bill Watterson
OBJECTIVITY

"You are completely free to carry out whatever research you want, so long as you come to these conclusions."
EDITING?

[Image of a cartoon with two characters discussing scientific results. One character says, "Adding the finishing touches to your report, Jane?" The other character responds, "Erm, yes. I'm just crossing out the "not" of the not significant, because when I review the findings I see there's some stuff I could easily delete...".]
LIFE AS A RESEARCHER
WHAT IS RESPONSIBLE CONDUCT OF RESEARCH (RCR)

RCR is demonstrated through behavior that meets generally accepted, legal and ethical standards for participating in and reporting research activities
TOPICS TYPICALLY INCLUDED IN RCR

Research Misconduct

Planning Research
- Protection of Human Subjects
- Protection of Animal Subjects
- Conflict of Interest

Conducting Research
- Data Collection and Use
- Mentor/Trainee Relationships
- Collaborative Research
- Safety and Security

Reporting Research
- Authorship
STANDARDS OF BEHAVIOR / CONDUCT?

Right vs. Wrong

Variation among individuals and cultures

What is important is that CMU researchers understand what is “right” or “wrong” within this research community

- professional codes
- government regulations
- institutional policies
- personal convictions
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

From the HHS, Office of Research Integrity, *Introduction to Responsible Conduct of Research*
RESEARCH MISCONDUCT

Legal Definition:

- Fabrication, falsification, or plagiarism in proposing, performing or reviewing research, or in reporting research results (42 CFR §93.103)
FALSIFICATION, FABRICATION, PLAGIARISM

Fabrication

- making up data or results and recording or reporting them

Falsification

- 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

Plagiarism

- the appropriation of another person’s ideas, processes, results, or words without giving appropriate credit
Jan Hendrik Schon, physicist working at Bell Labs
Developed revolutionary material
Other physicists could not duplicate
Deleted electronic data files, kept no lab notebooks, cleaned-up data
At least 21 published papers retracted - man co-authors
Fired from Bell Labs
PhD revoked
EXAMPLE - HAUSER

Evolutionary biologist at Harvard - Leader in the field
Grad students conducted work and had different results – coding of animal behavior
Misconduct hearings at Harvard and federal Office of Research Integrity

Chronical of Higher Education Article

Posted 06.21.2011 | College A Harvard psychology professor whose academic record was tarnished last year when he was convicted of scientific misconduct in a university-wide inves...

▪ Feds: Ex-Harvard Prof Faked Data In Experiments

AP | Posted 11.05.2012 | College BOSTON — Federal investigators have found that a Harvard University psychology professor who resigned after being accused of scientific miscondu...
EXAMPLE: KATIYAR

Scientist Who Received Millions From NIH Leaves Alabama Posts

An investigation finds 20 papers by Santosh Katiyar, who studied alternative treatments for cancer, include image manipulation.

By Ivan Oransky, Retraction Watch | May 24, 2018

A professor who received about $5 million in grants from the National Institutes of Health left his posts at the University of Alabama, Birmingham (UAB), and Birmingham VA Medical Center last year after an investigation found evidence of image manipulation in 20 of his papers. Retraction Watch has learned.
EXAMPLE - LACOUR

Reported that a brief conversation about marriage equality with a canvasser who revealed that he or she was gay had a big, lasting effect on the voters’ views, as measured by separate online surveys administered before and after the conversation”.

The research results were widely reported in the scientific and popular press. According to Singal (May 2015), “[The research] rerouted countless researchers’ agendas, inspired activists to change their approach to voter outreach, generated shifts in grant funding, and launched follow-up experiments.”

Lacour engaged a senior, well respected researcher (Green)

Published in December 2014 in Science

Grad student wanted to replicate work- Contacted survey group, analyzed data, unusually high response rate, data very clean → pre-existing data set, manipulated it, and presented as his own

Science retracted the paper on May 28, 2015
SANCTIONS FOR MISCONDUCT

Debarment from participation in federally funded research
Public notice of misconduct
Retraction of publications
Revocation of degree
Loss of employment
WHAT IS HUMAN SUBJECT RESEARCH (HSR)?

*Research* means a systematic investigation including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge; (see 45 CFR 46.102(d)).

*Human Subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. (see 45 CFR 46.102(f)).
WHY WERE IRBS ESTABLISHED?

History

- Tuskegee Syphilis Study (1932-1974)
- Nazi “Medical Research” (1946)
- Virginia Commonwealth University (1999)
- Gene therapy experiment at the University of Pennsylvania (2000)

Risks both physical and psychological in nature
WHAT IS AN IRB?

Committee/Office that reviews research to ensure that subjects are protected from unnecessary research risks

Activities of this committee/office are guided by regulations

- Office for Human Research Protections (OHRP)
- Food and Drug Administration (FDA)
- State and local law
- Institutional Policies

All research involving the use of human research subjects (participants) must be reviewed and approved by the CMU Institutional Review Board (IRB) before the research can be initiated.
PROTECTION OF HUMAN SUBJECTS (45 CFR 46)

A framework to ensure that serious efforts have been made to protect subjects’ rights

Common Rule

Embodies ethical principles of the Belmont Report

- Respect for persons
- Justice
- Beneficence

Consent, voluntariness
CASE STUDY — JESSE GELSINGER

18 year old died as a result of study participation at University of Pennsylvania 1999 Gene Therapy Study

If successful, the therapy the trial was testing would help others, but not Jesse

Informed consent document/process misleading
  ▪ Failed to report that two patients had experienced serious side effects from the gene therapy;
  ▪ Failure to disclose the deaths of monkeys given a similar treatment.
  ▪ PI had a significant financial interest in a company that was commercializing the technology

Jesse didn’t meet inclusion criteria for study - was substituted for another volunteer who dropped out

2 lawsuits
USE OF ANIMALS IN RESEARCH

Animal Welfare Act

The US Public Health Service (PHS) requires institutions to establish and maintain proper measures to ensure the appropriate care and use of all animals involved in research, research training, and biological testing activities conducted or supported by the PHS.

USDA regulates animal welfare

Regulations set forth standards for the humane care and use of animals.
IACUC

Institutional Animal Care and Use Committee
- Review the institution’s animal care program
- Inspect animal facilities
- Review and approve animal research protocols
- Respond to concerns
THE THREE RS

Replacement — use non-animal models

Reduction — use as few animals as possible

Refinement — eliminate or reduce unnecessary pain and distress in animals
HUMAN AND ANIMAL RESEARCH: INVESTIGATOR RESPONSIBILITIES

Describe proposed use of humans and/or animals in grant applications

Obtain IRB / IACUC approval prior to using animals and modifying protocol

Stop research if protocol approval expires

Ensure research is conducted in accordance with institutional policies, regulations

Report any problems or concerns

Ensure lab personnel have proper training and oversight
CONFLICT OF INTEREST IN RESEARCH

Conflict of interest occurs when there is the possibility (or perception of a possibility) that an individual’s private, financial interests or his /her family’s interests may influence the individual’s professional actions, decision or judgment. In research, a conflict may compromise the collection, analysis, and interpretation of data as well as the hiring of staff, procurement of materials, sharing of results, protocol design and use of human subjects.
CONFLICT OF INTEREST: PURPOSE

The purpose of the federal conflict of interest regulations is to promote

“objectivity in research by establishing standards to ensure that there is no reasonable expectation that the design, conduct, or reporting of research funded under federal grants or cooperative agreements will be biased by any conflicting financial interest of an investigator.”
KEYS TO MANAGING CONFLICTS

Disclosure, Disclosure, Disclosure

Monitoring and reviewing research accuracy

Removing individual from decision making
DATA: BASIC CONCEPTS

Its all about the data

Data are any information or observations that are associated with a particular project, including experimental specimens, technologies and products related to the inquiry
DATA: THINGS TO THINK ABOUT

Who owns data
How should data collection be done
Is the data valid
Is the data stored securely
Data analysis
Data sharing & reporting
Who can make decisions about data acquisition, use and storage?
SAFETY AND SECURITY

Management of Laboratories
- Biological, Chemical, Radiological, Laser ...
- Restricted Persons
- Specialized Facilities, BSL II or III, Clean room
AUTHORSHIP AND PUBLICATION

Authorship

- Contribution to Project
- Journal Guidelines for Manuscripts
  - Persons who conceive and design work
  - Persons who collect and interpret data
  - Persons who draft and approve publication
- Importance—who is first?
COMMUNICATION

Good communication is key

Ask questions

Seek clarification

Who is responsible for what?
CASE STUDY #1

Dr. Smith works at the University and is the Principal Investigator on a large research project that is funded by the National Institutes of Health (NIH). However, while Dr. Smith wrote the original grant proposal, he does very little day-to-day work on the project. Instead, the Research Director, Betsy, oversees all aspects of the project, including staff supervision and all data management activities. In addition, Betsy has been lead author on several publications about the project’s research findings.

Who owns the project and its data?

- The PI, Dr. Smith
- The Research Director, Betsy
- The University
- The National Institutes of Health
- No one person or organization

From Guidelines for Responsible Data Management in Scientific Research.
CASE STUDY #2

Part of the data collection methodology for Dr. Smith’s study includes distributing a 12-page self-administered questionnaire to participants; they must fill out and initial each page of the questionnaire to confirm completion.

One day on his way home from conducting an interview with a subject, the Research Assistant, Joel, needed to write directions for a friend and he reached in his bag and grabbed the first piece of paper that he could find. Joel accidentally ripped the back page off of one of the completed questionnaires to write the directions, which he then gave to his friend. He didn’t realize this until a few hours later, when he was reviewing the data that he had collected that day.

Joel thought that he remembered the participant’s answer on the last page of the survey, since they were mostly demographic questions.

What should Joel do?

- Staple a new page and fill out the subject’s responses since he remembers them.
- Contact the subject and ask her to complete the page of the questionnaire again.
- Omit the participant’s questionnaire from the study, his/her partial data is invalid.
- Just pretend like he doesn’t know what happened to the last page.

From Guidelines for Responsible Data Management in Scientific Research
CASE STUDY #3

After completing the first phase of data analysis, 1 of the 3 main hypotheses of Dr. Smith and the research team was proven correct. However, the team also found some results from another facet of the project that they were not expecting. While these secondary results do not directly impact Dr. Smith’s primary research questions, they may affect at least 3 other investigator’s research. The results appear to be pretty definitive, but data analysis is still being conducted on other parts of the project.

The 2 Research Associates working on the project, Samantha and Enrique are insistent that the team should immediately publish their findings in a journal since the results may have implications for other PI’s work. Dr. Smith and Betsy, the Research Director, do not intend to publish any results for at least another year, since the research is ongoing and some questions are still unanswered.

What should the research team do?

- They should publish the results in a journal as soon as possible.
- They should tell the funding agency about the findings, and let the agency disseminate the information if it wants.
- They should contact the other researchers to let them know the preliminary results.
- They should do nothing; they aren’t legally allowed to share their results until all the data have been fully validated.

From Guidelines for Responsible Data Management in Scientific Research
CASE STUDY #4

After collecting data for about a year, Dr. Smith’s research team revisited their original research questions. They decided to investigate an additional hypothesis related to a new issue that arose during the study. This change required adding about a dozen new questions to the self-administered questionnaire.

One day, the Research Assistant, Joel realized that they had been administering the revised survey to subjects, but the institutional Review Board (IRB) had not yet approved the changes.

Whose responsibility was it to make sure that data collection did not continue until the IRB approved the changes?

- The PI, Dr. Smith.
- The Research Director, Betsy.
- The Research Associates, Samantha and Enrique.
- The Research Assistant, Joel.

From Guidelines for Responsible Data Management in Scientific Research
CASE STUDY #5

A few weeks after Dr. Smith added the new questions to the self-administered questionnaire, it occurred to the Research Assistant, Heather, that the data collection methodology could be changed slightly. She realized that the first questionnaire that was administered to subjects (a survey on attitudes) now included information that provided answers to the questions on a subsequent questionnaire (a knowledge pre-test).

Heather realized that it would make much more sense to administer the knowledge test before the attitude questionnaire.

How should Heather proceed?

- Heather should make the changes with her subjects and start administering the knowledge test before the attitude questionnaire.
- Heather should tell her fellow Research Assistants about the change so that they can all follow the same methodology.
- Before proceeding, Heather should ask Dr. Smith for permission to make the change. Dr. Smith may have a particular reason for wanting to ask the attitude questions first.
- Heather shouldn’t do anything until she refers to the communication plan to determine Dr. Smith’s system for revising methodology.

From Guidelines for Responsible Data Management in Scientific Research
CASE STUDY #6

You are a post-doctoral fellow in a research group. A fellow postdoc who is relatively new to the group and whose native language is different than the one used in the lab is preparing a funding proposal with the PI for a government agency and comes to you for help with a draft. In the course of the conversation, you find out that the PI has given the postdoc several previously submitted proposals from the lab to use as examples but has not given clear guidance on how to use them. The postdoc’s draft proposal contains original text describing the research to be performed, which requires some editing. The draft also contains several large blocks of text that were simply copied and pasted from the example proposals. The agency’s submission deadline is coming up quickly and you are preparing your own proposal for funding.

Do you consider this conduct plagiarism?

What would you tell the other postdoc?

What steps should the PI take to ensure that students and postdocs are familiar with appropriate practices when using previous work?

From Doing Global Science: A Guide to Responsible Conduct in the Global Research Enterprise.
PARTING THOUGHTS

Ask questions – seek clarification

Don’t assume

Communicate, communicate, communicate
RESOURCES:

Office of Human Research Protection: http://www.hhs.gov/ohrp/


NIH Conflicts of Interest: http://grants.nih.gov/grants/policy/coi/

HHS Office of Research Integrity: http://ori.dhhs.gov/