Responsible Conduct of Research (RCR)

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Objectives

Provide overview major ethical topics in RCR

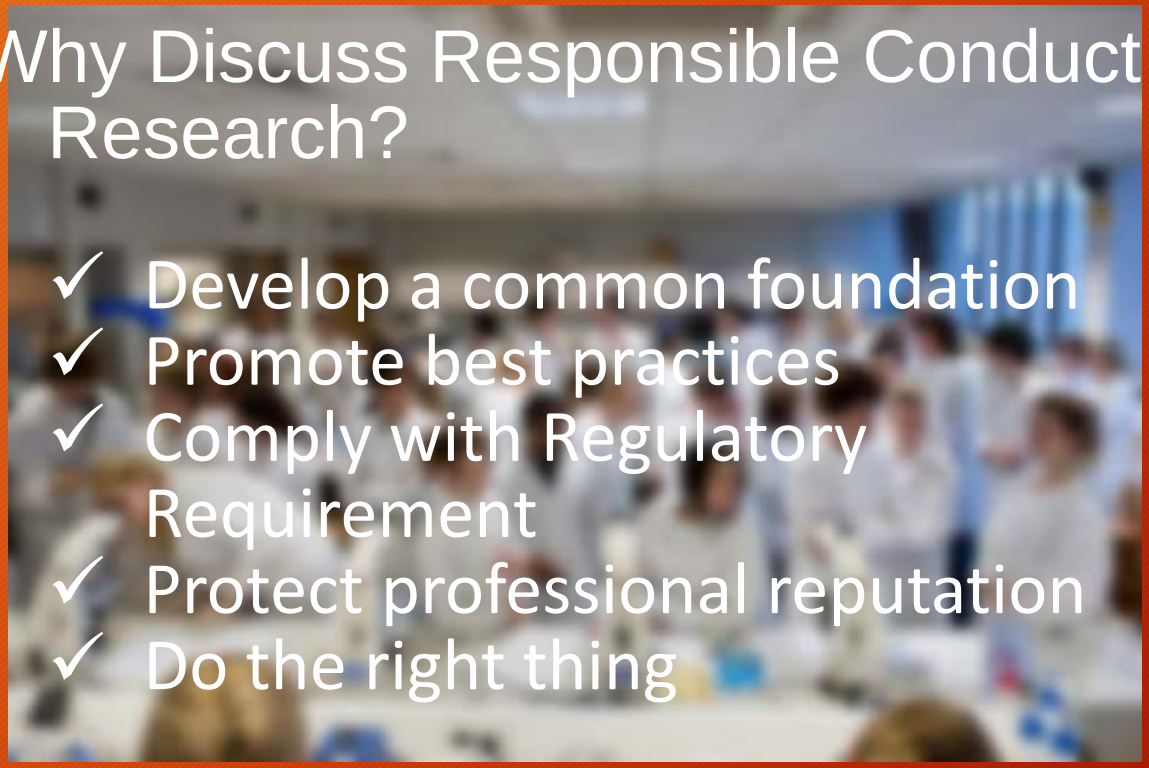
Discuss legal obligations – federal regulations

Highlight Cases of Research Misconduct

Provide overview of MSU RCR Training Plan

Introduction

- Why Discuss Responsible Conduct of Research?



- ✓ Develop a common foundation
- ✓ Promote best practices
- ✓ Comply with Regulatory Requirement
- ✓ Protect professional reputation
- ✓ Do the right thing

Foundation of Shared Values

TRUST— Core ethical value in the scientific pursuit of the truth

HONESTY — Conveying information truthfully and honoring commitments

ACCURACY— Reporting findings precisely and taking care to avoid errors

OBJECTIVITY— Letting the facts speak for themselves and avoiding bias

CORE ELEMENTS of RCR

- Research Misconduct - (FFP)
- Collaborative Research
- Human Subjects Research
- Authorship & Publication
- Data Acquisition & Management
- Animal Subjects Research
- Peer Review
- Conflict of Interest
- Mentoring

FEDERAL REGULATIONS

- NIH
  - NIH requires that all trainees, fellows, participants, and scholars receiving support through any NIH training, career development award (individual or institutional), research, education grant, and dissertation research grant must receive instruction in responsible conduct of research.

- NSF
  - Institutions are required to verify that Principal Investigators , undergraduate students, graduate students, and postdoctoral researchers who are supported with NSF funds to conduct research have received responsible conduct of research (RCR) training .

Office of Research Integrity (ORI)

http://ori.dhhs.gov

- Oversees PHS research integrity activities on behalf of Secretary for HHS
- 1 exception – FDA oversees their own regulatory research activities

Office of Research Integrity (ORI)

Mission: To promote the integrity of PHS-supported extramural and intramural research programs

- Respond effectively to allegations of research misconduct
- Promote research integrity

RESEARCH MISCONDUCT

- Fabrication
- Falsification
- Plagiarism

Definition of Research Misconduct

- Fabrication is making up data or results and recording or reporting them
- 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
- Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit

Definition of Research Misconduct

NOTE:

- Research misconduct does not include honest error or differences of opinion

  (42 CFR Part 93.103)

Proof of Research Misconduct

Requires -

- That there be a significant departure from accepted practices of the relevant research community, and
- The misconduct be committed intentionally, knowingly, or recklessly; and
- The allegation be proven by a preponderance of the evidence, (42 CFR Part 93.104)

A Closer Look at Plagiarism

- Appropriation means using or taking something that is not yours
  - Plagiarism is using another person's words or ideas without proper attribution
  - Plagiarism is academically dishonest because faculty, scholars, and students are expected to do original work

Understanding the Definition

Plagiarism means taking or using any of the following intellectual property without permission or giving credit:

- Words … rearranging phrases, copying a string of consecutive words, or paraphrasing extensively
- Ideas … using original information learned from confidential reviews, conference presentations, etc.

Understanding the Definition (cont'd)

- Processes … adopting or using research methods described by another investigator, especially when the research method is not common knowledge
- Results … using or reporting data, figures, or tables that represent another investigator's research results

Preventing Plagiarism

- Understand the difference between "common knowledge" and "original" ideas

- Do the right thing
  - Give credit, mark direct quotations, and use reference citations – *use disciplinary standards!*
  - Follow your conscience

Research Misconduct in Clinical Research

Behaviors that **are** considered research misconduct:

- Falsifications:
  - Substitutions of one subject's record for another's
  - Changing research record to favor the study's hypothesis
  - Altering eligibility dates and eligibility test results
  - Falsifying dates on patient screening logs
- Fabrications:
  - Not conducting interviews with subjects and creating records of the interview
  - Making up patient visits and inserting that record into the medical chart
  - Recording the results of follow-up visits with deceased subjects

Types of data that have been falsified or fabricated in clinical studies

- **Interviews**
- **Entry criteria**
- **Screening logs**
- **Approval forms**
- **Follow-up exams/data**
- **Consent forms**
- **Test scores**
- **Laboratory results**
- **Patient data**
- **Number of subjects**
- **Dates of procedures**
- **Protocol**
- **Study results**

Possible Consequences

- ↓ scholarly reputation damaged
- Loss of job (RA/TA,faculty)
- ↓ self-concept diminished
- ↓ grades
- Dissertation rejected
- Expulsion from university/no degree/degree rescinded
- Expulsion from professional organizations

Recent Research Misconduct Cases

Case Examples (*excerpted from ORI*):

- Case I

Falsification of assay data:

- 3 years exclusion from Federal contracting or sub-contracting
- 3 years voluntary exclusion from serving on PHS advisory board and/or peer review committee

- Case II

Falsification of experimental data:

- 2 years supervision of any research undertaken
- 2 years certification to ORI by employing institution that any of investigator's research is based on legitimately derived data
- 2 years voluntary exclusion from serving on PHS advisory board and/or peer review committee

Recent Research Misconduct Cases (cont'd)

Case Examples (excerpted from ORI):

- Case III

Falsification of figures in journal manuscript:

- 3 years supervision of any research undertaken
- 3 years voluntary exclusion from serving on PHS advisory board and/or peer review committee
- 3 years certification to ORI by employing institution that any of investigator's research is based on legitimately derived data

- Case IV

Falsification of research records:

- 2 years supervision of any research undertaken
- 2 years voluntary exclusion from serving on PHS advisory board and/or peer review committee, or as consultant
- 2 years certification to ORI by employing institution that any of investigator's research is based on legitimately derived data

RCR at the Individual Level:

- Intellectual honesty in proposing, performing, and reporting research
- Accuracy in representing contributions
- Fairness in peer review
- Transparency in conflicts of interest

RCR at the Individual Level:

- Carefully and thoughtfully mentor students and junior scientists
- Assume personal responsibility for avoiding or managing conflicts
- Take responsibility for protecting human subjects and for the humane care of animals
- Appropriately record research results and retaining research records

How can RCR be Implemented at MSU?

- Provide leadership in RCR
- Facilitate productive interactions between trainees, postdocs and faculty mentors
- Advocate adherence to rules regarding the conduct of research
- Provide training to both faculty mentors, junior scientists, and students tailored to their respective needs

MSU RCR TRAINING Plan

- One-on-one Discussions
- Discipline-specific Courses
- Group Case Studies Discussion

- ❑ On-Line Course
- ❑ Presentations

MSU Plan Cont'd

www.citiprogram.org

MSU Plan, Cont'd

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- Biomedical Science
- Humanities
- Physical Sciences
- Social and Behavioral Sciences
- Engineers
- Administrators

Thank You!

keep talking!!

Questions?

Comments?

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