Research Compliance &
Research Integrity: An Overview

Division of Research and Economic Development (D-RED)

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Objectives

- Provide overview major ethical topics in Responsible Conduct of Research (RCR)
- **Discuss legal obligations – federal regulations**
- Raise awareness of procedures and guidelines designed to support the responsible and ethical conduct of research at the University
- Provide overview of MSU RCR Training Plan

Research Ethics

Ethics may be defined as:

- Sets of moral principles or norms that are used to guide moral choices of behaviour and relationships with others. (Blumberg, et al, 2005)
- The moral principles and actions guiding and shaping research. (ESRC, 2004)

Ethics in research - - The set of values, standards, and principles used to distinguish between appropriate and ***acceptable*** conduct and **unacceptable** conduct at all stages of the research process.

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

What is Research Misconduct

Department of Health and Human Services defines research misconduct as:

- ***Fabrication*** – making up results and recording or reporting them.

- ***Falsification*** – manipulating research materials, equipment or processes or changing or omitting results such that the research is not accurately represented.

- ***Plagiarism*** – appropriating someone else's ideas, processes, results or words without giving proper credit.

Deliberate or repeated non-compliance with the regulations can be considered misconduct.

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 (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

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.

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 Biomedical & Social Behavioral 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 subject screening logs

Fabrications:

- Not conducting interviews with subjects and creating records of the interview
- Making up subjects visits/interviews and inserting that record into the study data
- Recording the results of follow-up visits/interviews 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

Criteria for Research Misconduct

- Demonstrates a significant departure from accepted practices

- Has been committed intentionally, or knowingly, or recklessly; and

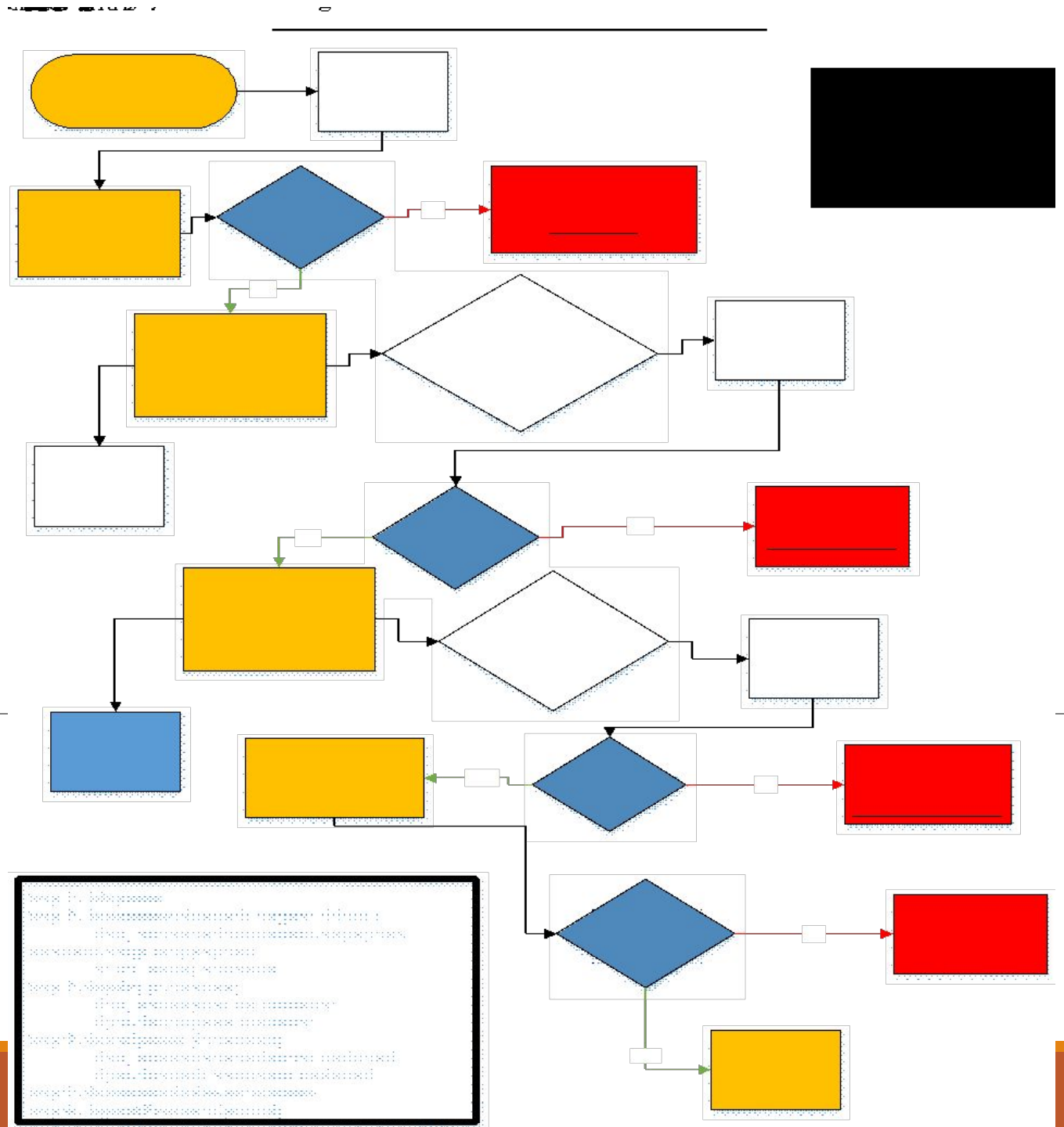
- Can be proven by a preponderance of evidence

What is NOT Misconduct

1. honest, unintentional error

2. honest differences of opinion

Dealing with Misconduct - STEPS



Research Ethics and Human Subject Protections

Why Do Human Research Subjects Need Protection?

Pivotal Events	Ethical Milestones
The Nazi Experiments	Nuremberg Code 1947
Tuskegee Syphilis Study	National Commission for the Protection of Human Subjects of Biomedical & Behavioral Research 1974

* Belmont Report 1978
* Common Rule 1991

Summary of Nuremberg Code

- Voluntary consent of the human subject is essential
- Experiment should yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature
- Experiment should be so designed on a knowledge of the problem under study that the anticipated results will justify the performance of the experiment.
- Experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury
- No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur

The Belmont Report:

Ethical Principles and Guidelines for the Protection of Human Subjects of Research, April 18, 1979

Respect for Persons ("Be courteous")

- Allow informed choice where participants can choose for themselves.
- Provide additional protections for those who need it.
- Derived concepts: Informed consent, Respect for privacy

Beneficence ("Do good")

- We are obligated to protect persons from harm by clearly identifying and maximizing anticipated benefits while minimizing possible risks of harm.
- Derived concepts: Good research design, Competent investigators, Favorable risk/benefit analysis.

Justice ("Be fair.")

- Requires that the benefits and burdens of research be distributed fairly.
- Derived concepts: Equitable selection of subjects.

The Consent Process

- Informed consent is not a single event or just a form to be signed
- Informed consent is an educational process that takes place between the investigator and the prospective subject

The basic elements of the consent process include:

- full disclosure of the nature of the research and the subject's participation
- adequate comprehension on the part of the potential subjects
- the subject's voluntary choice to participate

Basic Elements of Consent

- Research
  - Purpose
  - Duration
  - Procedures
- Risks
- Benefits
- Alternatives
- Confidentiality
- Compensation
- Whom to Contact
- Right to Refuse or Withdraw

IRB Review of Research

All research projects are categorized into one of three categories for the IRB review process. Each category is different in the level of scrutiny and submission procedures. The IRB is responsible for making the final decision on the category under which a research project falls.

- **Full Board Review**
- **Expedited**
- **Exempt**

Take Home Points

- Submit the research protocol to the IRB for review and approval
- Protect research participants from harm
- Get informed consent
- Be sure participation in study is voluntary
- Collect data anonymously or keep data confidential
- Maximize benefits and minimize risks
- Report research findings accurately
- Consider responsibilities to research colleagues and the general public

Ethics & Animal Subjects Research

Why are animals used in research?

- Living organisms with complex anatomic systems may respond differently to chemical or biological entities than simple, single celled organisms
- Current regulatory guidelines require the use of animals for testing unless there is an approved alternative
- Some basic research can’t be done by bio-chemical experiments!
- Some advanced skills can’t be taught using non-animal models/dummies

Non-animal alternatives must be used, when reasonable and available

- Legislation led to organizations looking for alternatives to animal testing
- The 1993 Revitalization Act charged the National Institutes of Health (NIH) with developing research methods that do not require animals, that reduce the number of animals used, and that produce less pain and distress in animals
- Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) was formed

“Covered Species”

- Living or dead animal which is:
- Dog, Cat, Non-human Primate, Guinea pig, Hamster, Rabbit, Rodents or any other warm-blooded animal **used for, or intended for use in** research, teaching, testing, experimentation, or exhibition, or as a pet *except*
  - birds *bred for use* in research
  - Cold-blooded vertebrates

Researchers are required to look for alternatives to using animals, and to use the “3 R’s

What are the “3 R’s” ???

- Reduction:
  - Reduce the number of animals used
  - Use enough to make the data valid
- Refinement:
  - Refine techniques and procedures to reduce pain and distress
- Replacement:
  - Replace animals with non-animal techniques or a lower species

IACUC Responsibilities

- Based on two federal laws
  - Health Research Extension Act of 1985
  - Animal Welfare Act (AWA) Amendments of 1985

- Primary goal is to “facilitate compliance with applicable laws, regulations and policies consistent with the performance of appropriate and productive scientific endeavors”

IACUC Responsibilities Cont'd

- Review and Approve animal use protocols prior to research being performed

- Review all protocols annually and provide continuing oversight (post-approval monitoring)

- The IACUC will either approve your research or require that revisions be made to the protocol
- Data collection may not commence Prior to IACUC approval; non-compliance may cause **the IACUC to terminate your study and confiscate all data.**

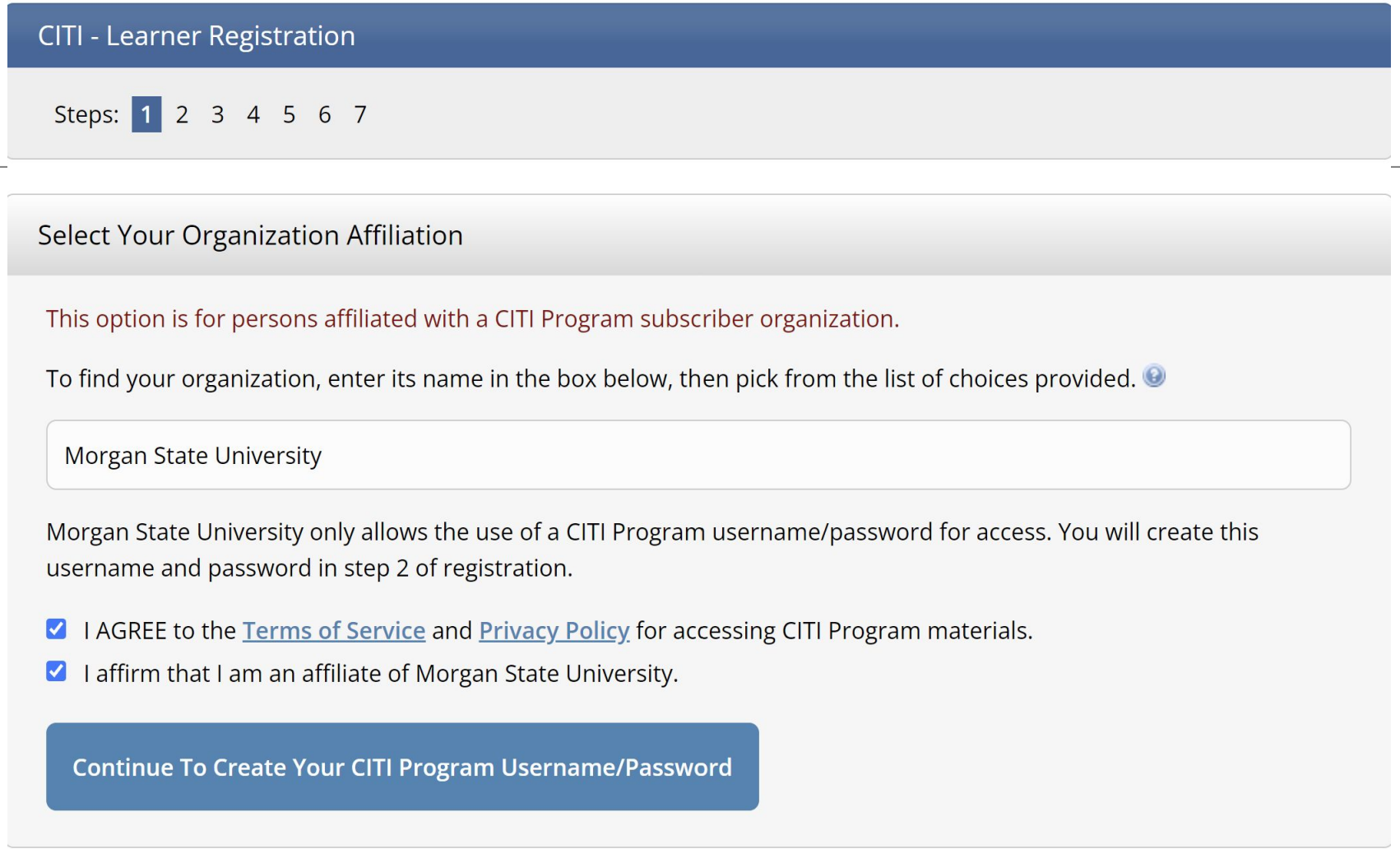
MSU RCR TRAINING Plan

- One-on-one Discussions
- Discipline-specific Courses
- Group Case Studies Discussion
  - Presentations
    - CITI On-Line Course

MSU Plan Cont'd

www.citiprogram.org

CITI Cont'd


CITI - Learner Registration
Steps: 1 2 3 4 5 6 7
Select Your Organization Affiliation
This option is for persons affiliated with a CITI Program subscriber organization.
To find your organization, enter its name in the box below, then pick from the list of choices provided.
Morgan State University
Morgan State University only allows the use of a CITI Program username/password for access. You will create this username and password in step 2 of registration.
I AGREE to the Terms of Service and Privacy Policy for accessing CITI Program materials.
I affirm that I am an affiliate of Morgan State University.
Continue To Create Your CITI Program Username/Password
or

Summary – RCR at the Individual Level:

Conducting research with integrity, honesty and accuracy must be something to which every scientist/researcher should proudly aspire --

- 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 (cont'd):

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

Thank You!

Let's keep talking!!

Questions?

Comments?

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