RESPONSIBLE CONDUCT OF RESEARCH (RCR)

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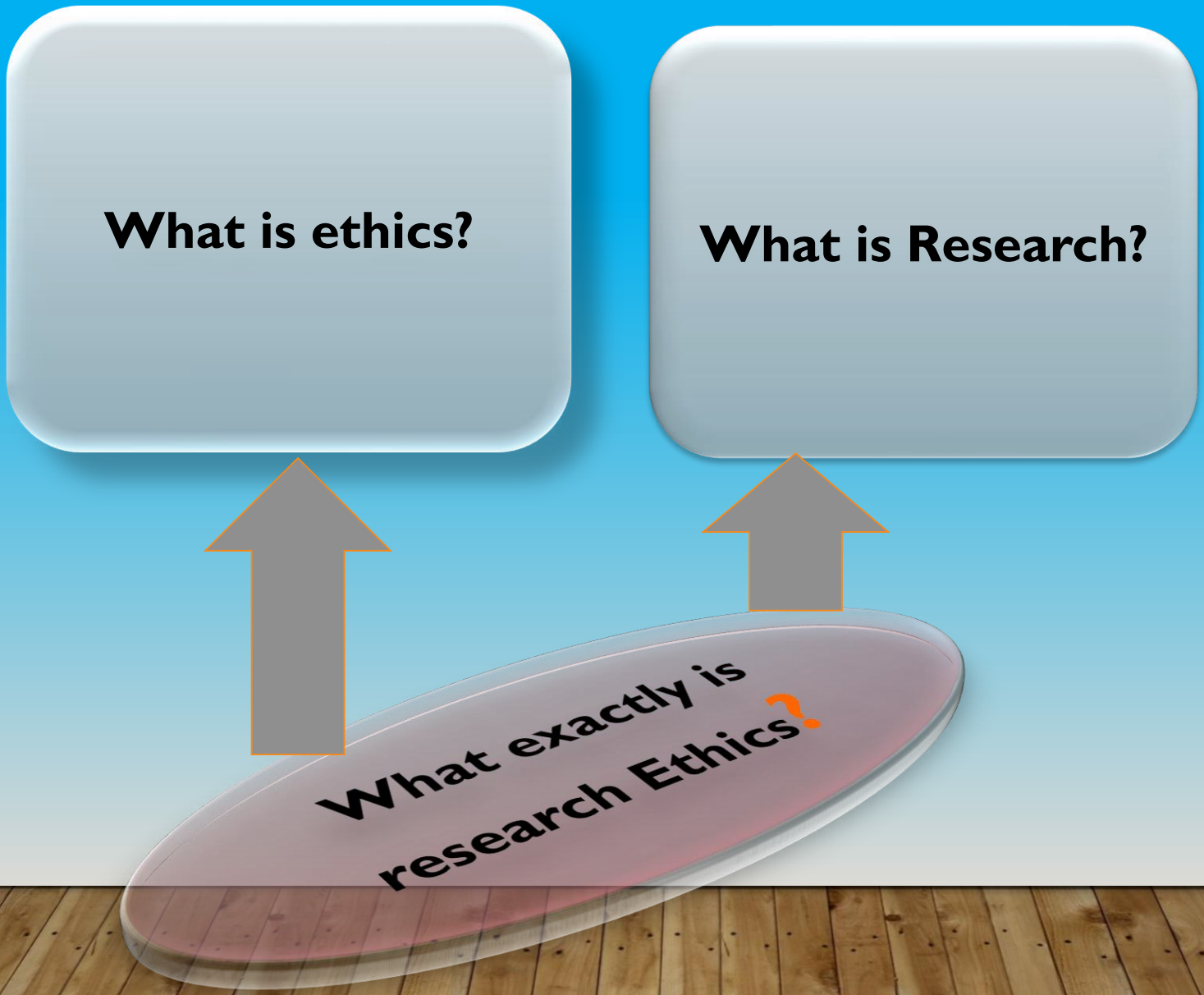

What is ethics?
What is Research?
What exactly is research Ethics?

RESEARCH ETHICS

Ethics may be defined as:

- The moral principles and actions guiding and shaping research. (ESRC, 2004)

- ***Research - -*** "systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge" (The Common Rule)

- ***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.

OBJECTIVES

- Provide overview of major ethical topics in RCR
- Highlight Cases of Research Misconduct
- Provide overview of MSU RCR Training Plan

INTRODUCTION

- Why Discuss RCR?

- ✓ Develop a common foundation
- ✓ Promote best practices
- ✓ Protect professional reputation
- ✓ Comply with Regulatory Requirement
- ✓ 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)
- Human Subjects Research
- Animal Subjects Research
- Conflict of Interest

- Collaborative Research
- Authorship & Publication
- Data Acquisition & Mgt.
  (Selection; Collection; Analysis Handling; Reporting & publishing; Ownership)
- Peer Review
- Mentoring

- Detrimental Research Practices
- Rigor & Reproducibility
- Export Controls
- Research Security
- Conflict of Commitment

OFFICE OF RESEARCH INTEGRITY (ORI)

http://ori.hhs.gov

- Oversees PHS research integrity activities on behalf of Secretary for HHS
  - Promotes the integrity of PHS-supported extramural and intramural research programs
  - Responds effectively to allegations of research misconduct

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)

- **Authorship disputes**

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 novel and not common knowledge
- Results … reporting data, presenting figures, or tables that represent another investigator's research results

AVOIDING PLAGIARISM

- **Keep track of your sources.** Using words or ideas from a source you forgot that you'd consulted is still plagiarism. A citation management tool will help you keep track of your sources as you conduct your secondary research or literature review.
- **Cite.** Properly identifying the original source of borrowed information or concept is key to avoiding plagiarism.
- **Quote, Paraphrase, Summarize.** Put the borrowed word (s) in quotes, or state the borrowed ideas in your own words.

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!*

POSSIBLE CONSEQUENCES

- Damaged scholarly reputation
- Loss of job (tenure, faculty rank)
- Withdrawn journal articles/papers
- Expulsion from review boards/professional associations
- Rescinded degree(s)/awards
- Diminished self-concept

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

MISCONDUCT INVESTIGATION STEPS

Allegation -> Assessment ->

Inquiry -> Investigation ->

Recommendation -> Sanction

CONFIDENTIAL PROCEEDINGs

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

KEY PRINCIPLES IN THE NUREMBERG CODE:

- Voluntary consent of the human subject – capacity to consent, freedom from coercion and an understanding of risks and benefits involved; and freedom to bring the experiment to an end.
- Minimization of risk and harm.
- The science and the study design must yield fruitful outcomes.

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

The IRB

What is an IRB?

- **Institutional Review Board (IRB)**

- **IRB Composition:** diverse membership requirements
  - **Men + Women | Various disciplines | Scientists + Non-scientists | At Least One Community Member**

- **FIVE Members**

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**

IACUC BASICS:

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 on a benchtop!
- Some advanced skills can’t be taught using non-animal models/dummies

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

“Covered Species”

- Animal Welfare Act covers **dogs, cats, rabbits, guinea pigs, hamsters, gerbils, nonhuman primates, marine mammals, captive wildlife, and domestic livestock species used in nonagricultural research and teaching**. Excluded are **birds, rats of the genus Rattus and mice of the genus Mus.**
- USDA Covers **All live or dead warm-blooded animals used in research** 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, rats of the genus Rattus, and mice of the genus Mus bred for research**. This also excludes "cold-blooded" animals such as fish, reptiles, and amphibians.

WHAT IS IACUC?

- The Institutional Animal Care and Use Committee (IACUC) (pronounced eye-a-cook) reviews all research proposals involving animal subjects.
- The IACUC will review any research or teaching activity involving live animals to ensure humane and ethical care of the animals.

IACUC Composition

- IACUC = Institutional Animal Care and Use Committee
- Comprised of at least 5 members (below) and their alternates
  - Community/ Non-affiliated Member (non-animal user)
  - Veterinarian
  - Scientist
  - Non-scientist
  - Another person (duplicate any of the above)
- An IACUC must have at least 5 members if the institution has a PHS Assurance and receives federal funding

IACUC Function and Responsibility

- 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”
- How do they do that

IACUC responsibilities Cont'd

- Inspect animal care and use areas- all areas housing animals (at least) every 6 months
- Semi-annual program review (program of humane care and use of animals)
- Submit reports of reviews and inspections to the Institutional Official every 6 months
- Suspend activities not in compliance
- Investigate deficiencies in animal care and use

- The **IACUC** will either approve your research or require revisions be made
- If it is found that you collected data BEFORE being approved by the IACUC, **the IACUC will has authority to terminate your study and confiscate all data.**

GOOD PRACTICES

- **Follow IRB/IACUC Protocols**
  - Seek IRB/IACUC approval for changes
  - Self-audit for compliance
  - Review primary data
  - Set standards for data acquisition, data storage & transfers

AUTHORSHIP
ALL CONTRIBUTING AND RESPONSIBLE

IMPORTANT

- Initial idea
- Research plan
- Regular review
- Doing the work
- Analyzing results
- Writing it up

LESS IMPORTANT

- Provides funding
- Occasional advice
- Does an assay
- Edits

First authorship requires both major work and major writing

PEER REVIEW

Review of:

- Grant/Contract proposals
- Publications
- Appointments
- Promotions
- IRB/IACUC submissions
- Data monitoring

They require:

- Objective review
- Expert assessment
- Openness to innovation
- Withdrawal if possible conflict of interest
- Absolute confidentiality

MENTORING

- **The job of the mentor is to facilitate the success of the trainee.**
  (Trainees, try to find a mentor who cares about your success.)
- **Explicit moral climate. Do the right thing always!**
  (The research team needs ethical guidance from its leaders)
- **Open communication. Enthusiasm for innovation and failures.**
  (What can we learn? rather than, you made a mistake!)
- **Explicit guidelines for records, data management, authorship**

DOCTORAL STUDIES

Doctoral studies should:

- Be designed so that students and professors together work with mutual respect to ensure the student achieves established educational goals. Both parties must be committed to the attainment of these goals.
- Be carried out with zero tolerance of all forms of partiality, plagiarism, exertion of undue influence or coercion or other impropriety during teaching and examinations.

DOCTORAL STUDIES CONT'D

- lead to the doctoral student developing his/her independence and, after graduation, possessing the capacity to carry out research of good scientific quality.
- Ensure that the doctoral student, after graduation, is well versed in the ethical problems relevant to his/her own research field.

WHY RESEARCHERS GO WRONG

Imperfect humans sometimes doing imperfect things, for a variety of reasons:

- – "Misdemeanor"-level of wrongs that we try to justify (e.g., taking shortcuts) – Missing something, especially with new methods or technology
- – Involvement in research ethics violations through the wrongs of others
- – Sometimes lack of clarity on the right thing to do
- – Self-deception and other psychological tendencies

WHY RESEARCHERS GO WRONG (CONT'D)

Professional Pressures:

- Publish or perish
- Tenure/Promotion
- "Keeping up" with peers
- Securing grants
- Being first to a discovery

All of these encourage shortcuts and "misdemeanors," or worse

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

SUMMARY – *RCR AT THE INDIVIDUAL LEVEL (CONT'D)*

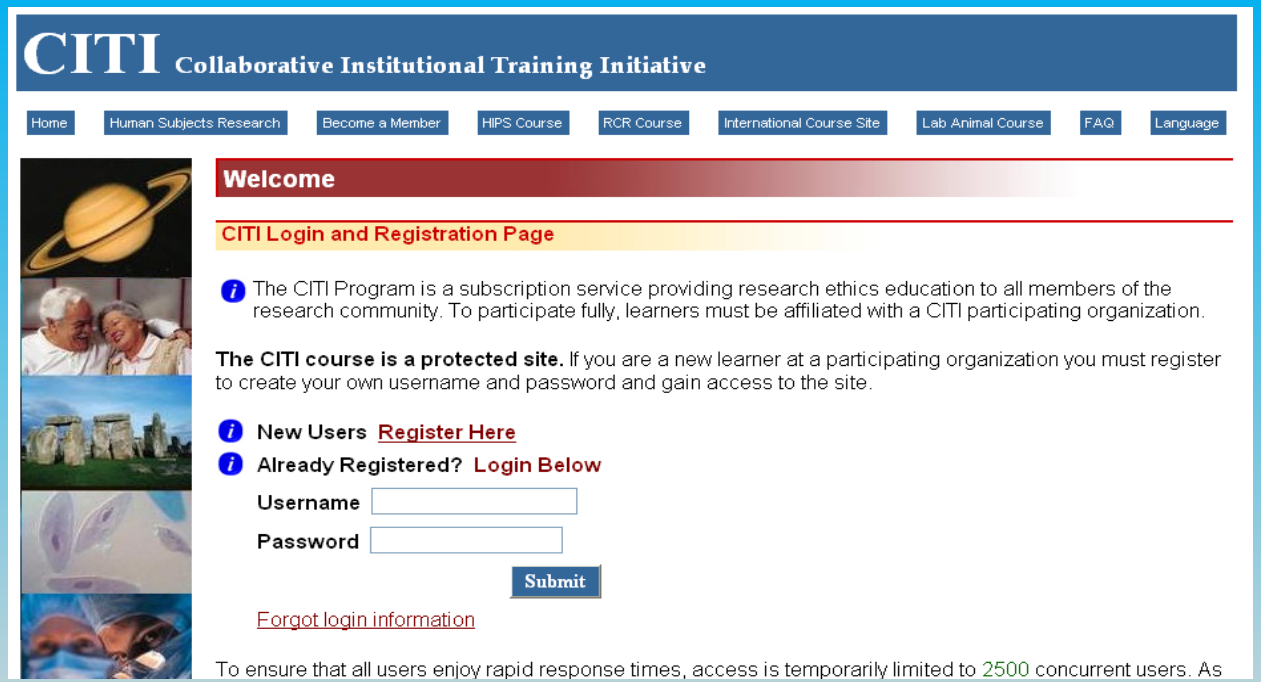
- Carefully and thoughtfully mentor students and junior scientists
- Assume personal responsibility for avoiding or managing conflicts of interest
- Take responsibility for protecting human subjects
- Take responsibility for the humane care and use of animal subjects
- Appropriately record research results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

MSU RCR TRAINING PLAN

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

- ❑ Presentations
- ❑ Online Courses

MSU PLAN CONT'D



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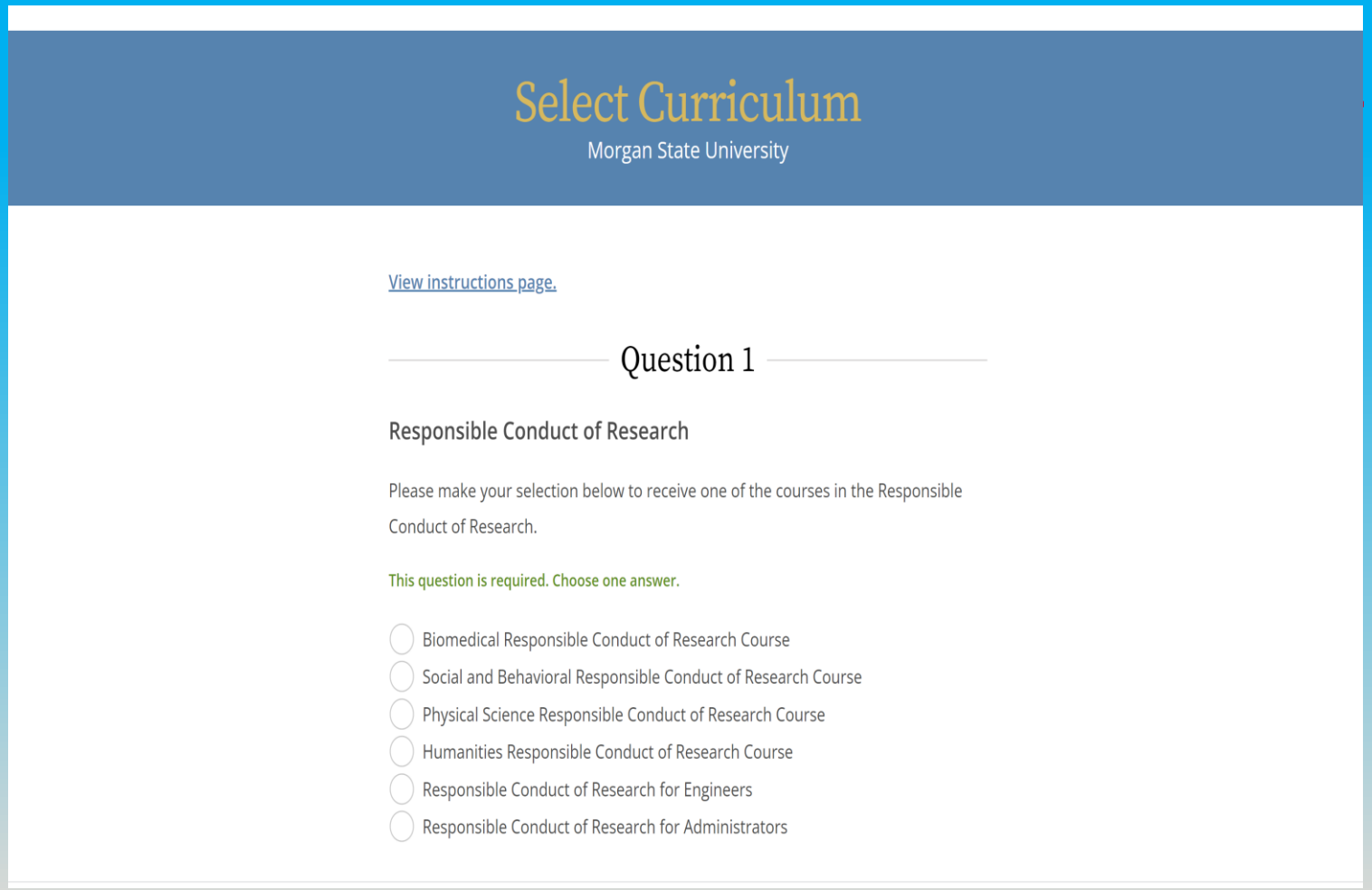
MSU PLAN CONT'D



THANK YOU!

Questions?

Comments?

keep talking research ethics!!