UMBC Office of Research Protections and Compliance

Ethics of Working with Human Participants

and

Responsible Conduct of Research

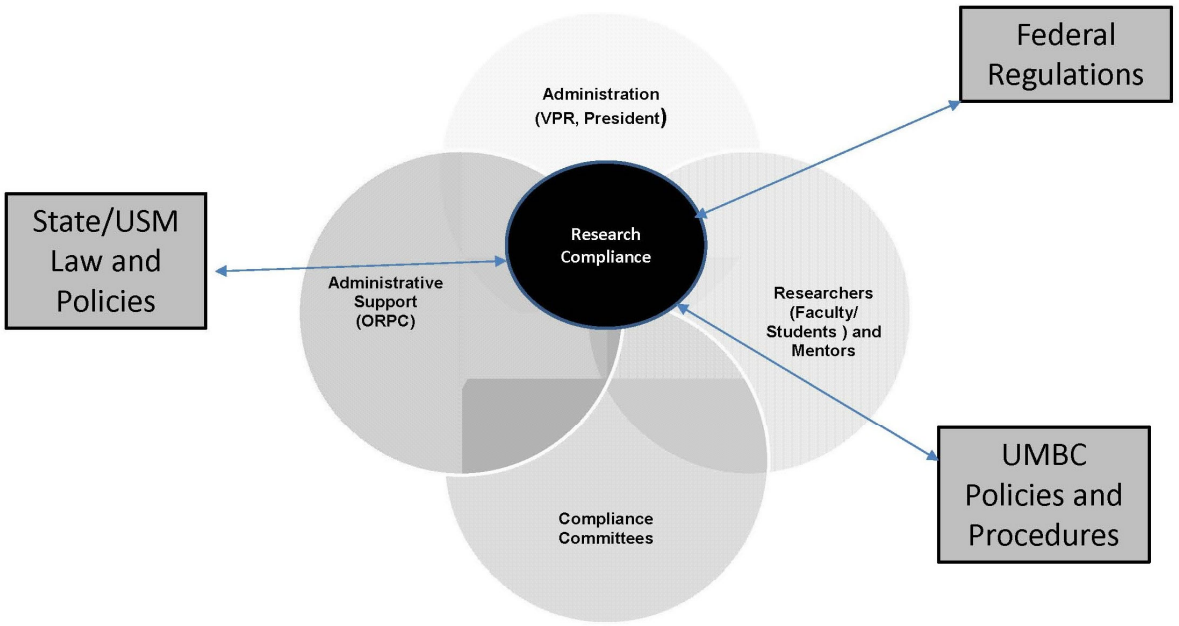
(Fall 2020)

Take aways from today

https://www.theproducersperspective.com/wp-content/uploads/2012/05/take-away.jpg

- History, regulations, laws
- Discussion of what it means to be a responsible researcher and how to conduct research “responsibly”
    - recognize ethical choices, make appropriate decisions and take appropriate actions based on those choices
    - encourage best practices in the conduct of research and scientific investigations
    - Doing the “right thing”
- Basic info about the UMBC IRB program and RCR awareness
- RCR and human subjects education and on-line training

UMBC's Circle of Compliance



Research Ethics

Data Acquisition, Management, Sharing and Ownership	Accurate collection of data and managed properly for confidentiality and privacy purposes
Conflict of Interest & Commitment	Management of real or perceived interference to assure that the interests do not adversely influence the research
Research Misconduct	**Avoid and deal with issues of egregious behavior (i.e. fabrication, falsification, or plagiarism – FFP)**
Publication Practices & Responsible Authorship	Accurate report of the results and an honest and open assessment of the finding
Mentor / Trainee Responsibilities	Clear understanding of mutual responsibilities/proper supervision and a commitment for a productive environment
Peer Review	Evaluation by colleagues with similar knowledge and experience for self-regulation of the discipline
Collaboration	Collaborative research roles should be clarified early discussing and reaching agreement on the details
Human Subjects	**Protection of subjects and compliance with relevant Federal regulations as well as institutional guidelines and policies**
Research Involving Animals	Humane care and use and compliance with relevant Federal regulations as well as institutional guidelines and policies
Safe Laboratory Practices	Safety of all project personnel and proper use of material – biosafety, hazardous materials, etc.

Human Subjects Research Protections Program

- Provide assurance to the federal government the institution will comply with the rules and regulations and provides oversight for the institution's human research use program
- Protect the rights and welfare of individual research subjects
- Ensure voluntary participation via the “consent process” – conversation and documentation
- Evaluate risks

What has Happened in the Past to Help Leads to Ethical and Responsible Research

History teaches us that knowing about the past will help ethical and responsible decisions today.

Ethical Milestones

Nazi Medical Experiments ***Nuremberg Code - 1947***	**Tearoom Sex Study**	**THN1412 Drug Trial**
Milgram Experiments	**Tuskegee Syphilis experiment** ***Belmont Report 1978*** ***Common Rule 1991***	**Henrietta Lacks**
Guatemala syphilis experiment	**The Monster Study**	**Stanford Prisoner Experiment**

Creation of ethical principles and codes of conduct

Belmont Report

Principle	Application
Respect for persons Individuals should be treated as autonomous agents Persons with diminished autonomy are entitled to protection.	**Informed consent** Subjects, to the degree that they are capable, must be given the opportunity to choose what shall or shall not happen to them The consent process must include three elements: information, comprehension, and voluntariness.
Beneficence Human subjects should not be harmed Research should maximize possible benefits and minimize possible harms.	**Assessment of risks and benefits** The nature and scope of risks and benefits must be assessed in a systematic manner
Justice The benefits and risks of research must be distributed fairly.	**Selection of subjects** There must be fair procedures and outcomes in the selection of research subjects

Common Rule

45CFR46 - Protection of Human Subjects (the Common Rule)

Created the human subjects protective mechanisms and code for the proper and responsible conduct of human research

This regulatory guidance has been incorporated into how investigators conduct "business" with the IRB but more importantly how they interact with people – your research participants.

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Purpose and role of Institutional Review Board

A human research use program involves an Institutional Review Board (IRB) whose members include:

- at least five members (one nonscientist and one from outside the institution)
- Has to be of diverse backgrounds and from various disciplines
- Use subject matter experts to advise on research that falls outside of fields of expertise

Role of the IRB is to evaluate proposal before anyone can conduct research, review risks, protect the rights and welfare of individual research subjects, ensure voluntary participation

The IRB evaluates research by determining

What is research

- Defined in the Common Rule as "a systematic investigation that contributes to generalizable knowledge".

  In other words, for the most part, an investigator will:

  - » be "engaged in research"
  - » proposed an intention to explore a particular topic
  - » interact with a living person
  - » obtain private information or identifiable biospecimens
  - » used, studied or analyzed, which then generates private or identifiable information or biospecimens and
  - » have a plan to "generalize " the information

Research that does not fall within definition does not require review

Who are human subjects

- These are living persons about whom an investigator conducting research obtains ***private*** **information or** ***identifiable*** **biospecimens** through intervention or interaction with that individual

The IRB evaluates looks at what is “minimal risk”

- HHS regulations found in Subpart A (46.102) - the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests
- When reviewing risks, consider the subject population (vulnerable people, such as children, older persons, cognitively impaired, etc. may experience different types of risk) and ensure risks to subjects are minimized and reasonable in relation to anticipated benefits
- Examples include social stigma, loss of employment, legal prosecution, embarrassment which could lead to emotional or psychological harm, social harm, physical harm or financial harm

The IRB evaluates informed consent

What is presented to participants

- **Key information –** provide sufficient detail to aid in decision making
- **Information** – includes research procedure, purpose, risks, benefits, alternatives, etc.
- **Comprehension** – function of intelligence, rationality, maturity and language, presentation of information must be adapted to the subject's capacity
- **Voluntariness** –requires conditions free of coercion and undue influence

The "consent process" includes conversation and documentation

IRB review process

Research

- can be exempt from review, under certain conditions
- can receive expedited review by an IRB representative
- may be reviewed by Full committee

IRB site: https://research.umbc.edu/umbc-irb-protocol-submission-forms-and-procedures/

Responsible Conduct of Research (RCR)

The aim of discussing research ethics is to encourage integrity in the pursuit of scientific investigation and practice among of scientists, scholars, and professionals.

Office of Research Integrity, Department of Health and Human Services

Another aim is to discourage research misconduct

Definition from the Office for Research Integrity (ORI) -42 CFR 93.103

- Research misconduct means fabrication, falsification or plagiarism in proposing, performing or reviewing research, or in reporting research results.

Research Misconduct includes FFP

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 (taking another person's ideas, processes, results, or words without giving appropriate credit)

Materials courtesy of Tony Onofrietti, Office of the Vice President for Research, University of Utah

What Causes Research Misconduct?

- "Bad Apples"
- Academic environment
- Career advancement:
  - Tenure / Fame / Reputation
- Financial rewards
- Poor training in standards and methods
- Conflicts of interest
- Large collaborative groups
- "Remote" laboratory managers

Materials courtesy of Tony Onofrietti, Office of the Vice President for Research, University of Utah

Consequences

Research misconduct consequences are considerable and potentially disastrous:

- can irreparably erode trust among colleagues
- affects accepted practices of the research community
- erode trust between researchers and funding agencies
- make it more difficult for colleagues at the same institution to receive grants
- can cause the public to lose confidence in the ability and integrity of researchers

Georgia Institute of Technology
Research Misconduct
https://rcr.gatech.edu/research-misconduct

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Should consequences matter?

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Key to Remember

Research misconduct does not include honest error, differences of opinion or disputes over authorship or credit

Materials courtesy of Tony Onofrietti, Office of the Vice President for Research, University of Utah

IRB and RCR Training

UMBC uses CITI –registration and information at
http://research.umbc.edu/education-training/

- **IRB courses** - less than minimal risk research; social/behavioral research (expedited/full board), research with pre-existing data, records data or laboratory specimens; health privacy and information security (basics on HIPAA); GCP – Social and Behavioral Research Best Practices for Clinical Research
- **RCR Courses -** Biomedical Sciences, Engineering, Humanities, Physical *Sciences, Social, Behavioral, and Education*

This RCR modules cannot be substituted for required for human subjects research

Questions ?

http://www.umbc.edu/research/ORPC