PROMISE program review of

- Responsible Conduct of Research
- Ethics of Working with Human Participants
- CITI Training and Kuali Protocols

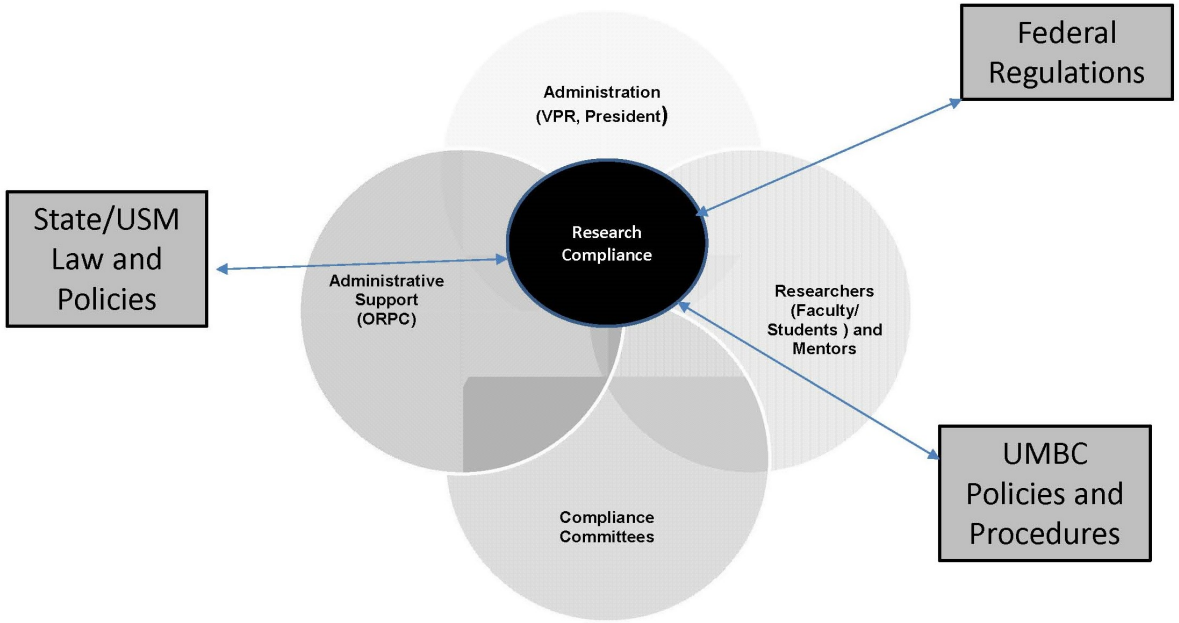
(Fall 2021)

Take aways from today

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

- History, regulations, laws
- Contributes to the 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
- Basic info about the UMBC IRB program and RCR awareness
- Doing the "right thing"
- 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.

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

Research misconduct is defined by regulation (42 CFR 93.103) and the Definition from the Office for Research Integrity (ORI) as:

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

Should consequences matter?

It’s important to identify, discuss and avoid actions of FFP but:

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

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Human Research Protections Program

- Provide assurance to the federal government that UMBC will comply with the rules and regulations and perform oversight of UMBC's human research use program
- Create an environment of respect for, and understanding of, the rights and welfare of research participant
- Ensure the central ethical principles of research involving human subjects are followed and guide the IRBs in confirming that the rights and welfare of research participants are protected.
- Promote excellence in the conduct of research

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 Guides

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** Participants have the freedom to make voluntary decisions regarding whether or not to participate in research without coercion, undue influence, or exploitation Investigators have obligation to review, discuss, answer questions and follow participant's wishes
Beneficence Human subjects should not be harmed Research should maximize possible benefits and minimize possible harms.	**Assessment of risks and benefits** Research must have a favorable risk/benefit ratio, be designed to maximize benefits and minimize harms
Justice The benefits and risks of research must be distributed fairly.	**Selection of subjects** There must be an equitable selection of research participants so that the benefits and burdens are shared equitably and population groups are not excluded and/or exploited in research

Common Rule

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

Laws set by the U.S. Department of Health and Human Services (DHHS) to protect persons from risks in research. These were created to ensure human participants (including vulnerable persons, such as children) are protected and to help set protective mechanisms and code for the proper and responsible conduct of human research

This regulatory guidance instructs how IRBs conduct "business" to more importantly provide guidance to assist investigators interact with research participants.

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 or identifiable information or identifiable biospecimens through intervention or interaction with that individual
- Also determined as data that includes private or identifiable information or identifiable biospecimens

The IRB evaluates “minimal risks”

- The regulations say risks are “… 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.”
- Basically what a participants would consider significant in deciding whether or not to participate in the study.
- Examples include social stigma, loss of employment, legal prosecution, embarrassment, invasion of privacy as well as emotional, psychological harm, social, physical or financial harms.
- IRBs consider of vulnerable populations (such as children, older persons, cognitively impaired, etc.) who may experience different types of risk
- Risks have to be reasonable in relation to anticipated benefits

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 protocols are submitted for review using Kuali Protocols, UMBCs web-based application portal

Details at https://research.umbc.edu/umbc-irb-protocol-submission-forms-and-procedures/

Access the course at https://www.citiprogram.org.

CITI PROGRAM

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The Trusted Standard in Research, Ethics, and Compliance Training

The Collaborative Institutional Training Initiative (CITI Program) is dedicated to serving the training needs of colleges and universities, healthcare institutions, technology and research organizations, and governmental agencies, as they foster integrity and professional advancement of their learners.

Demo a Course | Benefits for Organizations

Celebrating 21 Years of Serving the

Don’t already have CITI account, choose log in through my institution

English

LOG IN | LOG IN THROUGH MY INSTITUTION | REGISTER

Organizations listed here use "Single Sign On" (SSO) for CITI Program access.

SSO requires a username and password issued by the organization.

Click on the organization name for SSO login instructions.

If your institution is not listed here, it does not use Single Sign On. Click on the "Log In" tab (if you already have a CITI Program account) or the "Register" tab (if you are new to CITI Program and creating an account for the first time).

University of Maryland Baltimore

University of Maryland College Park

University of Maryland, Baltimore County

University of Massachusetts Amherst

University of Massachusetts Boston

University of Miami/Jackson Health System

University of Minnesota

University of Missouri - Kansas City

Now you're at the course curriculum screen. Scroll down to Question 3 (Responsible Conduct of Research Courses) and choose course applicable to your discipline. *Scroll to the bottom and click Complete Registration.*

Select Curriculum

University of Maryland, Baltimore County

CITI Course Enrollment Procedure

The CITI Program offered by the University of Maryland, Baltimore County provides courses in Human Subjects Protection, Lab Animal Welfare, US Export Control course and The Responsible Conduct of Research. You will be provided one or more enrollment categories below. Please read these categories carefully to make the best choice.

CITI Curriculum Selection

You may enroll in multiple courses. You may complete the courses sequentially or in parallel. You should use multiple login sessions. You do have the option of changing your course selections later. Use the "Add a course or update your Learner Group" link on the "Learner Main Menu" to come back here to change or update your course selections.

Please choose one of the below courses that addresses your training requirement.

- The Human Subject Courses
- Animal care and use training
- Responsible Conduct of Research (RCR)
- Financial Conflicts of Interest Training
- US Export Control course
- Biosafety Training
- Information Security

If you have any questions, please contact us at compliance@umbc.edu. Thank you.

Question 3

Responsible Conduct of Research (RCR) Courses

Maryland, Baltimore County, choose one or more of the learner groups related to your discipline. Please review the UMBC web page for more information. If you have questions or need additional information about the training requirements, please contact the Office for Research Protections and Compliance at compliance@umbc.edu or 410-455- 2737 These courses are designed for post-doctoral associates, staff, graduate students, and undergraduate students to assist i meeting UMBC's responsible conduct of research training requirements. The modules contain text, embedded case studies AND quizzes. These topics are customized for a number of specific disciplines including Biomedical, Humanities, Social and Behavioral, and Physical Sciences, and Engineering. **PLEASE NOTE:** The RCR modules cannot be substituted for the basic courses required for human subjects research or laboratory animal welfare.

- [ ] Biomedical Research
- [ ] Social and Behavioral Research
- [ ] Physical Science Research
- [ ] Humanities Research
- [ ] Engineering Research
- [ ] None

<u>DO NOT</u> select any of these modules to fulfill IRB requirements (human subject research). If you take the RCR course, it will not count towards the IRB's requirement for training. Need a cumulative score of 75% passing on ALL quizzes in each module

Printing a Completion Certificate. You can do this at any time once successfully completing module. ORPC does not need a copy but instructor/department might. Also, complete the course evaluation, if you like. Will help CITI improve their course

University of Maryland, Baltimore County

ID 1103

CITI Export Compliance

Name	Stage	Completion Date	Expiration Date	Record ID
Timothy Sparklin	1	29-Nov-2011	N/A	7134194

Completion Report

Completion Reports are transcripts of your course work, and include all quiz scores. Part 1 shows scores "frozen" at the time you completed and passed the course. Part 2 reflects scores for any subsequent quiz attempts.

View / Print | Copy Link

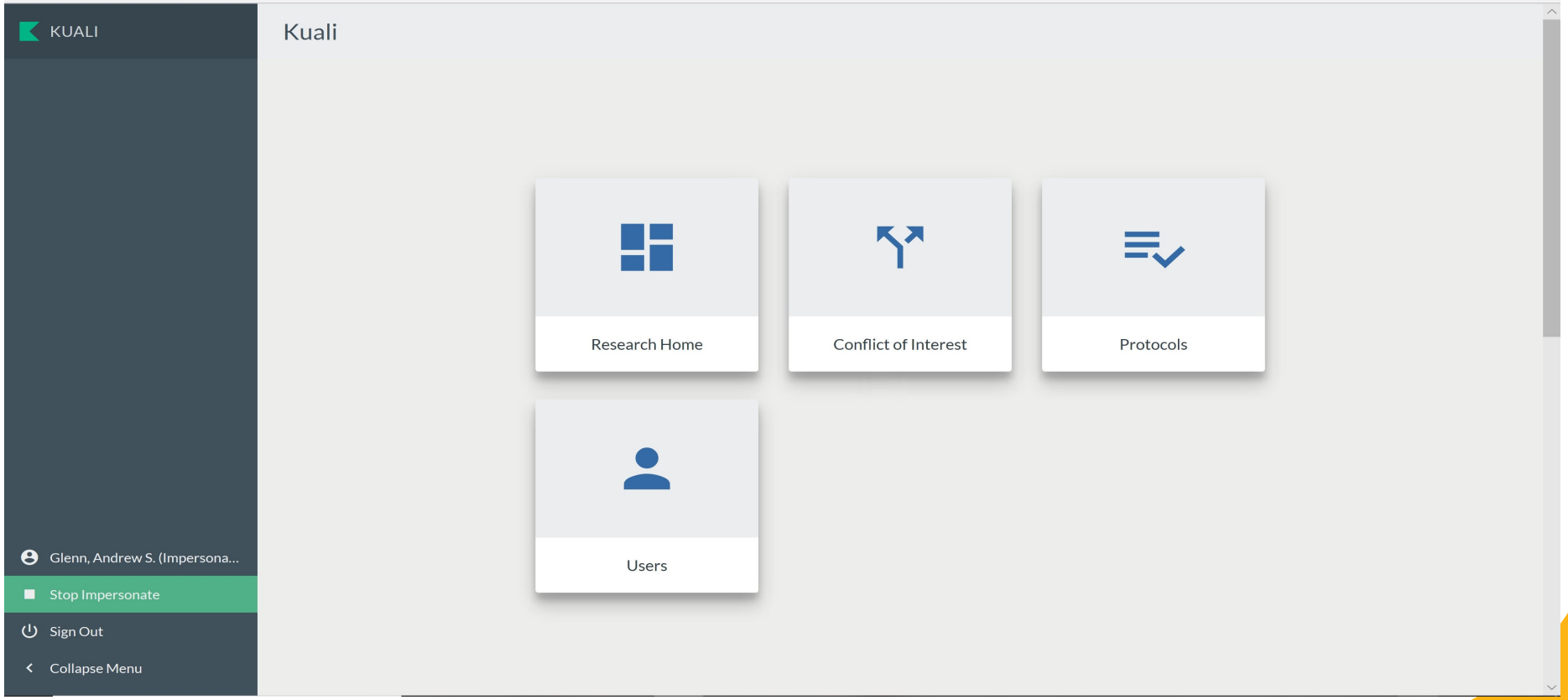
Completion Certificate

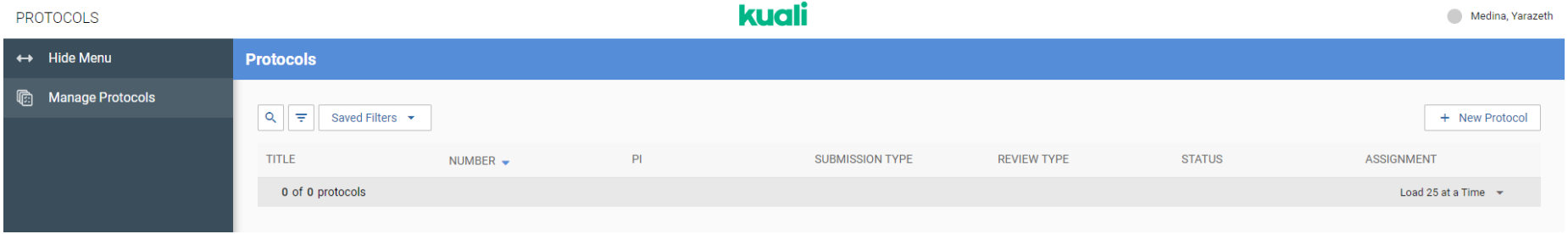
Completion Certificates are "diplomas" that reflect course completion, but do not include quiz scores. Certificates are suitable for sharing with persons who do not need to see your quiz results, or posting online.

View / Print | Copy Link

Add to LinkedIn

Kuali Protocols for IRB – log in using UMBC credentials





What Kuali IRB does (just like the paper versions):

Creates a Protocol
Stores all relevant research documents
Allows access for all research team personnel
Use for other post approval functions

User Guide available at
https://umbc.box.com/s/37nm9b55w7j7ze6wqa09luxdyfi8ijn7

myUMBC Classic

Tim Sparklin | Log Out

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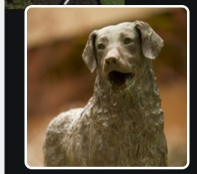

Office of Research Protections and Compliance

Institutional Group • 321 people

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PINNED ITEMS (most recently pinned first)

Updates to the Kuali COI User Guide

The User Guide has updated information for creating, updating and submitting a conflict of interest (COI) disclosure. All disclosures are submitting via Kuali COI. If you'd like to follow along...

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SACHRP federal advisory meeting July 21-22, 2021

Guidance for the use of participants in research

The Secretary's Advisory Committee on Human Research Protections (SACHRP) is a federal advisory committee that provides advice and recommendations to the Secretary of HHS on issues pertaining to...

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Additional CITI training module

FERPA added to Information Privacy and Security course

The ORPC has obtained for the campus community a CITI training module that describes investigators responsibilities for research using Family Educational Rights and Privacy Act (FERPA) data. ...

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APR 28

Kuali IRB Protocol Focus Group

We'd like to hear your comments and suggestions

6:00 PM · Online

Come and join your ORPC colleagues in this virtual focus group session (via WebEx) as a way to "take the pulse" of the campus community to gather perspectives about how well Kuali is working as...

New Post | New Event

Events

AUG 24 — Kuali drop in session with the ORPC
12:00 PM · Online

AUG 26 — Kuali drop in session with the ORPC
6:00 PM · Online

SEP 14 — Kuali drop in session with the ORPC
12:00 PM · Online

SEP 16 — Kuali drop in session with the ORPC
6:00 PM · Online

Questions ?

Contact us at compliance@umbc.edu