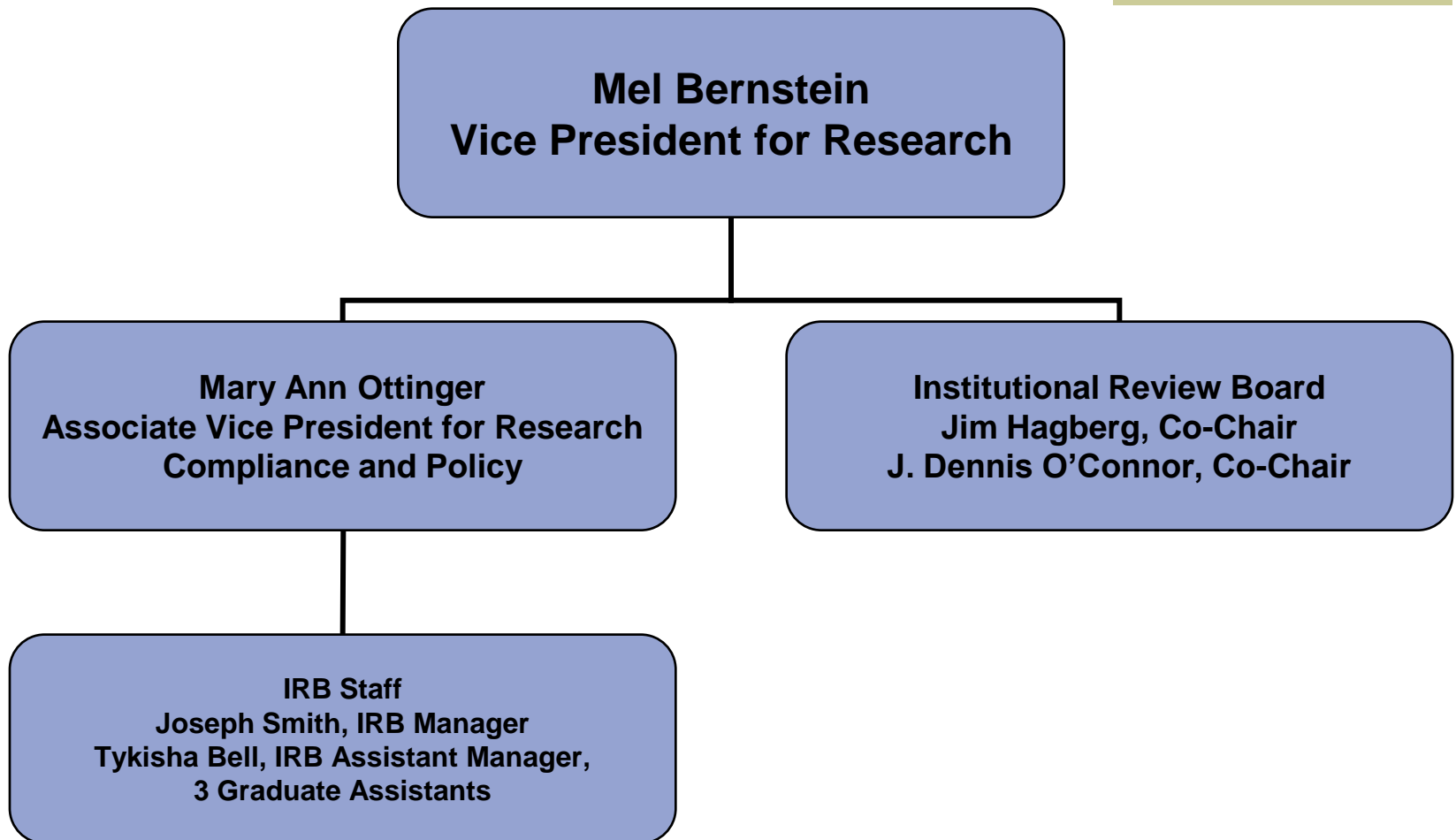


University of Maryland, College Park

IRB Training

Tykisha Bell, MBA
IRB Assistant Manager

IRB Organization



What is the foundation for the IRB policies and procedures?

- Federal Regulations (The Common Rule/45 CFR 46) apply to research funded by 16 Federal agencies
- Federal Wide Assurance (applies The Common Rule to all research)
- Federal guidelines (OHRP and Dept. of Education)
- Recommended practices (PRIM&R and ARENA conferences)
- UMCP IRB requirements
- Preparation for AAHRPP Accreditation

Which activities require IRB approval?

- All research involving human subjects requires prior IRB approval
- What is research? (based on The Common Rule and University policy)
- What are human subjects? (based on The Common Rule)

Research

- A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (The Common Rule).
- May include Master's theses and doctoral dissertations.

Human Subject

- A living individual about whom an investigator (whether professional or student) conducting research obtains
 1. data through intervention or interaction with the individual, or
 2. **identifiable** private information

Does my project require IRB review?

- Request for Determination of Non-Human Subject or Non-Research form may be used by faculty, staff and students who are not sure whether their activity requires IRB review.
- Faculty and staff who submit a completed [Request for Determination of Non-Human Subject or Non-Research Form](#) to the IRB will receive written documentation on whether the activity requires IRB review.

When is an IRB Authorization Agreement used?

This form is used when University of Maryland College Park (UMCP) engages in research with:

- An organization/institution with whom UMCP currently does not have a cooperative review arrangement, and
- Either UMCP or the collaborating organization/institution provides IRB (human subject) review to avoid dual review

Belmont Report Ethical Principals

- **Respect for Persons**
- **Beneficence**
- **Justice**



Are the Ethical Principles and Regulations Applicable to Social and Behavioral Sciences Research ?

- The Milgram Study- Yale University
 - Deception
- The Zimbardo Study – Stanford University
 - physical and psychological abuse
- The Twin Study – Virginia Commonwealth University
 - Third party consent violation

Criteria for IRB Approval

- Are risks to subjects minimized?
- Are risks to subjects reasonable in relation to anticipated benefits?
- Is the selection of subjects equitable?
- Will informed consent be sought from each prospective subject or the subject's legally authorized representative, in accordance with and to the extent required by 45 CFR 46?
- Will informed consent be appropriately documented, in accordance with and to the extent required by The Common Rule?

Criteria for IRB Approval (Continued)

- Data Monitoring -

When appropriate, will the research plan make adequate provision for monitoring the data collected to ensure the safety of the subject?

- Confidentiality -

When appropriate, are there adequate provisions to protect the privacy of subjects and maintain the confidentiality of data?

- Vulnerable Subjects -

When some or all of the subjects are likely to be vulnerable to coercion or undue influence have additional safeguards been included in the study to protect the rights and welfare of these subjects?

IRB Initial Application

- Download the most recent application form from the website
- Submit the face page with all required signatures, funding agency, and ORAA Proposal Number (if applicable)
- All 10 sections of the initial application must be completed
- All supporting materials, such as:
 - consent forms
 - recruitment materials (ads, flyers, letters)
 - questionnaires
 - Original grant application materials for HHS funded research

Common Problems with IRB Applications

- Investigators use outdated application forms.
- Describe data with identifiers as anonymous instead of confidential.
- Include an inadequate description of the risk (States that risks are minimal without listing specific risks.)
- Consent forms (adults over 18 yrs. old) and Assent forms (minors under 18 yrs. old) reading level is too complex.

Consent Form Guidelines

- Avoid use of the word “understand”
 - Ex. I understand I will do this...
- Use second person (You) instead of first person (I)
 - Ex. You will be asked to...
- Provide details information for research involving audiotaping and videotaping (Who will have access to the tapes? Final disposition)
- Avoid describing the risk as “minimal.” If applicable, may include a statement that there are no known risks associated with participation.

Additional Tips on Consent Forms

- Course credit and monetary compensation are incentives and not considered as benefits
- Incentives should be listed in the procedures section, not the benefits section



Waiver of Informed Consent

- Investigators can request waivers for some or all elements of the informed consent document:
- IRB Criteria for Waiving Informed Consent Elements
 - (1) the research involves no more than minimal risk to the subjects;
 - (2) the waiver or alteration will not adversely affect the rights and welfare of the subjects;
 - (3) the research could not practicably be carried out without the waiver or alteration; and
 - (4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Waiver of Consent Documentation

An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

- (1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
- (2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

3 Levels of IRB Review

- Exempt - exempt research
- Expedited - nonexempt research
- Full Board - nonexempt research

Exempt vs. Nonexempt Research

- Per University policy, exempt research must be approved by the IRB Manager before research can begin.
- Per Federal regulations, nonexempt research must be reviewed and approved by the IRB Co-chair or IRB full board committee depending on the degree of risk.

UMCP Exemption Policy

- Research activities must be limited to the 6 exempt categories in order to qualify for exemption (e.g. must not involve an intervention except for Exempt Category 1)):

<http://www.umresearch.umd.edu/IRB/exemption%20categories.html>

- Follows the basic ethical principles outlined in The Belmont Report
- Involves no greater than minimal risk
- Meets Federal guidelines and University policy requirements.

Research Activities That Do Not Qualify for Exemption

- Surveys and interviews with children
- Review of private information that is collected after the IRB application has been submitted (not existing data)
- Research involving prisoners
- Surveys and interviews with person-identifiable responses in which the disclosure outside of the research could be damaging to the subject's reputation, employability or financial standing or place the subject at risk of civil or criminal liability

Expedited Review

- Nonexempt research that:

1. presents no greater than minimal risks and;
2. must involve procedures listed in 1 or more of the 9 expedited review categories:

http://www.hhs.gov/ohrp/humansubjects/guidance/expedite_d98.htm

Expedited Reviews (Continued)

The Most Frequently Used Expedited Review Category

- **Expedited Review Category 7** - research on **individual or group characteristics or behavior** (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing **survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.**

Full Board Review

- Research involving greater than minimal risk
- Expertise reviewers (primary and secondary) evaluate the research and provide their recommendation to fellow committee members and determine whether the study is approved as is, approved pending specific changes, tabled or disapproved.

Procedures for Requesting an Addendum/Modification

Addendum: This is a modification to a currently IRB Approved protocol. Also known as an amendment. Any changes to an IRB Approved protocol (Exempt/Expedited/Full Board) must be submitted to and approved by the IRB prior to implementation.

****NEW UPDATE****

- The UMCP IRB will no longer accepting an email request for an Addendum Request without an Addendum Application Form attached. Addendum Applications Forms may be submitted via email, campus mail or in person.
- Instructions are posted on the IRB website

Renewal Application or Closure Report

If you answer Yes to any of the below questions a Renewal Application must be submitted:

1. Will future research activities involve obtaining data through intervention or interaction with human subjects?
2. Will future research activities involve obtaining identifiable private information about living individuals? (Information is identifiable if subjects can be identified directly or through identifiers linked to the subjects?)
3. Will future research activities include analyzing **identifiable** private information about living individuals?

Important tips on submitting renewal applications

****NEW UPDATE****

- The IRB will no longer accept Renewal Applications after a protocol expires. There will be no “grace period” for a Renewal Application received after the Expiration Date of the protocol. The UMCP IRB and Federal Regulations do not permit extensions of human subject research projects beyond the IRB Approval dates.
- Download the new Renewal application on the website
- Check the expiration date of your approval period (found on your approval letter) to determine when to submit your renewal.

Closure Report

- A protocol is eligible for closure if:
 - a) data collection is complete
 - b) there is no more participant contact (including follow-up interviews, calls, surveys)
 - c) the only research activity remaining is data analysis of de-identified data.



Reporting Requirements

- Serious and unanticipated events involving risks to subjects or others please contact the IRB immediately in written explaining the event.

Online Training

- CITI training
www.citiprogram.org
- Register as a new user or if you are already registered login with your username and password.
- Take the liaison exam for University of Maryland College Park.



The screenshot shows the CITI website interface. At the top is a blue header with the text "CITI Collaborative Institutional Training Initiative". Below the header is a navigation bar with buttons for "Home", "About Us", "Become a Member", "HPS Course", "RCR Course", "International Course Site", "Lab Animal Course", "FAQ", and "Idioms". The main content area has a red "Welcome" banner, followed by a yellow "CITI Login and Registration Page" banner. A blue information icon is followed by text explaining the CITI Program as a subscription service. Below this, another blue information icon is followed by text stating that the CITI course is a protected site and that new learners must register. There are two blue information icons: one for "New Users Register Here" and one for "Already Registered? Login Below". Below these are input fields for "Username" and "Password", and a blue "Submit" button. At the bottom, there is a red link for "Forgot login information". On the left side of the page, there is a vertical column of five small images: a planet Saturn, an elderly couple, Stonehenge, a microscopic view of cells, and a person in a lab coat.

Questions, Concerns, & Suggestions

- **General Questions**

301-405-4212

irb@umd.edu

- **IRB Manager**

Joseph Smith, M.A & C.I.M

301-405-0678 (telephone)

jsmith@umresearch.umd.edu

- **IRB Assistant Manager**

Tykisha Bell, M.B.A.

301-405-7326 (telephone)

tbell@umresearch.umd.edu

