# IRB Student Seminar

Human Subjects Protections at Montana State University Billings

Presented by the Office of Research Compliance

and IRB Co-Chairs, Drs. Alex Shafer and Anna Talafuse

MONTANA STATE UNIVERSITY BILLINGS

# IRB Function

- The purpose of the IRB is to review research protocol proposals and to ensure the rights and welfare of human subjects are adequately protected.
- Follow the principles of the Belmont Report
  - Respect for Persons
  - Beneficence
  - Justice

# How to Ensure the Belmont Principles are Followed?

- **Respect**
  - Use an Informed Consent Process
  - Respect for Privacy
- **Beneficence**
  - Good research design
  - Competent investigators/researchers
  - Favorable risk-benefit analysis
- **Justice**
  - Equitable selections of subjects

# Criteria for IRB Approval

- **Risks are Minimized** (Consistent with a sound research design and does not unnecessarily expose subjects to risk)
- **Risks are Reasonable in Relation to Benefits**
- **Selection of Subjects is Equitable**
- **Informed Consent will be Sought** for Each Prospective Subject
- **Informed Consent will Be Documented**
- Research Plan Adequately Provides for **Monitoring the Data Collected to Ensure Safety** of the Subjects
- Research Plan Adequately **Protects the Privacy of Subjects and Maintains Confidentiality**
- When some (or all) of the subjects are likely to be vulnerable to coercion or undue influence, **additional safeguards** need to be included in the protocol to protect the rights and welfare of these subjects.

# Elements of Informed Consent

1. Purpose of the research project
2. Procedures
3. Risk and discomforts
4. Benefits
5. Alternatives to participation
6. Confidentiality
7. Request for more information
8. Refusal or withdrawal
9. Injury statement
10. Consent/Assent Statement
11. Signatures

# Consent Details

- Voluntary and informed consent
  - Written in 8th grade reading level or lower!
  - Separate signature for audio/videotape
- Parental consent or vulnerable populations
  - Needs to include child assent form as well (unless unable to provide assent)
  - If unable to consent/assent need to have a good, well-explained reason as to why

# Anonymity vs. Confidentiality

- Anonymous
  - No link between name/identity and person
  - If identifiers are removed at data entry, CAN be anonymous
  - Note this involves specifics of details collected, not simply names
- Confidential
  - Have a link, even for a short time (e.g., some longitudinal studies where you retest the same variables over time)
  - Cannot be both in one study
  - If you want to disclose a name you must address this in consent form!

# Other IRB Documentation

- Location Permission Letter: signed on letterhead by the head of the organization/ director of the space
- Data Collection Instrument: survey, interview question, test, data table, etc.
- Conflict of Interest: If you have any personal/ financial connections to the project (e.g., the study is held at your place of work)

# What if my Study Changes?

- Alterations must be sent to IRB as an amendment (a modification to an approved project)
- Remember that the application is a signed document specifying very specific procedures and details
- Examples:
  - Number of subjects
  - Criteria for participant recruitment
  - Adding new data collection sites
  - Altering an instrument (e.g., add items to a survey)
  - Someone leaves project or new person is brought on

# Submission Process

- Student applications require signatures, but these can be collected electronically through DocuSign. We are happy to help you through the DocuSign process!
- Email applications to irb@msubillings.edu
- Deliver physical applications to McMullen 205

# MSUB IRB Process

- All forms and materials are available on the Office of Research Compliance website: www.msubillings.edu/orc/
  - Application Form
  - CITI training link
  - IRB Checklist
  - Application Examples
  - Consent/Assent Form Examples
  - Conflict of Interest Procedures

# IRB Decides if a Project is:

- **Exempt** (IRB makes that decision--you still need to submit)
  - Studies of existing records where subjects cannot be identified
  - Surveys that do not deal with sensitive issues
    - Substance abuse, sexual behavior or criminal activity
- **Expedited** Review
  - Recording data from subjects ≥ 18 years old and
  - Using noninvasive procedures routinely employed in clinical practice
  - Moderate exercise by healthy volunteers
- **Full** Review
  - Does not meet Exempt/Expedited
  - Involves a Protected Status Participant

# IRB Review Timeline

- Applications are forwarded electronically to the Chair upon receipt. The PI, faculty sponsor, and co-PIs are copied on the email.
- The Chair determines which review status applies.
  - Exempt or Expedited: the Chair will respond to the PI within 10 days with a decision or a request for modification

# Full Review Timeline

- Applications involving protected populations, intentional deception, or more than minimal risk require review by the full IRB.
  - Full reviews occur monthly. Check the ORC website for meeting dates and plan accordingly.
  - The Chair may request modifications or additional information from the PI prior to or, as is very common, after the meeting.
  - Could take a month or longer to be approved.

# Suggestions for Quick Review

- **#1 Use Simple Terminology.**
  - Do not use discipline-specific jargon. Remember: Your application is **not** your thesis paper. The IRB only cares to know what actions you are taking and how it might affect human subjects.
- **#2 Consider ALL Risks.**
  - Do not say, “There are no risks,” because there is always some risk, though it may be minimal.
  - Some common risks many don’t consider:
    - Embarrassment
    - Discomfort
    - Fear of loss of favor (common with teachers, coaches, etc.)

# Suggestions for Quick Review

- **#3 Carefully Construct Consent & Assent Forms**
  - Adults require consent forms; children require assent forms.
  - Consent form readable at an 8th grade level.
  - Assent forms should be in language that is understandable to the child(ren).
- **#4 Understand Confidential vs. Anonymous Studies**
  - ONLY CHECK ONE!
  - Confidential: Personal information is collected but kept secure.
  - Anonymous: No personally-identifying information is collected.

# Suggestions for Quick Review

- **#5 Don't Forget Your Attachments**
  - Most IRB applications require:
    - CITI Training
    - Consent/Assent Forms
    - Location Approval
- **#6 Read the Conflict of Interest Section Carefully**
  - DO NOT CHECK ALL THE BOXES.
  - If you might monetarily gain from this study, the IRB needs to know.
  - If the study is being performed at your place of work (outside of MSUB), you should report that as a potential conflict of interest.

# Suggestions for Quick Review

- **#7 Spelling, Grammar & Clarity**
  - Always review and edit your writing!
    - Review not just for grammar, but for clarity. Would someone who doesn't know you, isn't in your field or familiar with its jargon, be able to understand exactly what human subjects will be doing in your project, what are the objectives, outcomes, etc.?
  - Suggestion: Type out application into a separate document, then copy and paste into the IRB application. This way, Word will help catch some spelling/grammatical errors.

# Questions?

- Jenay Cross, Office of Research Compliance, irb@msubillings.edu
- Cindy Bell, Office of Research Compliance, cbell@msubillings.edu
- Dr. Alex Shafer, IRB Co-Chair, alex.shafer@msubillings.edu
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# Q&A Session