University of Wisconsin-Milwaukee

Institutional Review Board Updates

FALL 2017

IRB News

In this issue:

We have some big, important changes to share with you this semester. These will affect researchers in all areas. Please read carefully to find out how these apply to you.

New Post-Approval Monitoring Process (page 2)
The IRB office staff and IRB members will begin conducting post-approval monitoring of studies.

New Federal Regulations (page 3)
In January, the federal government issued extensive revisions to the federal regulations governing human subjects research. The changes go into effect January 19, 2018.

-- Also --

Fall Training Sessions (page 3)
As usual, we are offering a number of in-person training sessions this fall.

Contact the IRB Office:

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Important Reminders

- For studies where you collaborate with someone at another institution, you **must** have UWM IRB approval, or a signed deferral agreement in place. Conducting research without prior review and approval from UWM's IRB is noncompliance that must be reported.
- You **must** have IRB approval before beginning any research activities. This includes recruiting participants and scheduling interviews/focus groups. Conducting any research activities before you receive IRB approval is noncompliance that must be reported.
- If you tell the IRB you will provide study-specific training for research personnel (e.g. lab assistants, students, etc.) be sure to document this training. Include, at a minimum:
  - Individual's name
  - Type of training
  - Date

Upcoming IRB Meeting Dates:

- **October 6, 2017**
  Deadline for Full Board submissions: Sep 20
- **November 3, 2017**
  Deadline for Full Board submissions: Oct 18
- **December 1, 2017**
  Deadline for Full Board submissions: Nov 15

Post-Approval Monitoring

Beginning this fall, the IRB will conduct post-approval monitoring visits for selected studies. This means that we will schedule a time with you to review your study processes and files.

The purpose is to verify that the IRB-approved protocol is being followed, which in turn ensures that human subjects are protected. These reviews will also help us identify areas where we can improve our IRB processes, guidance, and training.

For more details, visit our website: https://uwm.edu/irb/submission/post-approval-review/

What studies will be reviewed?

- Any study that has received full board or expedited approval may be selected.
- Initially, however, we will focus on the following types of studies:
  - ◊ More than minimal risk
  - ◊ Federally funded, or
  - ◊ Where problems have been reported.

Who will review my study?

- One or more of the IRB office staff (Melissa, Melody, & Leah), and typically an IRB member as well.

How often will my studies be reviewed?

- No more than one review per fiscal year. We assume that you will extrapolate any lessons learned to other studies you oversee, so conducting more than one review per PI per year would not be an efficient use of time and resources.

How does the process work?

- **Before:** If you are selected for a review, we will email you to schedule a mutually convenient date and time. We will send you detailed information about what to expect, what documents we will review, and a request for any additional information we might need.
- **The day of the meeting:** We will come to your location and review the study files. If we have questions as we go, we'll ask you. Before we leave, we'll give you an oral summary of our review. We'll include things you are doing well, any issues that need to be resolved, and friendly suggestions that might make future studies easier. We also welcome your input for how we can improve our processes.
- **In conjunction with the review of your files:** We will review our own IRB files for accuracy, completeness, and to ensure we followed our processes properly. We want this to be a learning and improvement exercise for all of us.
- **After:** We'll write up our oral summary and send it to you. If any corrective actions are needed, we'll ask you to send us a written response to explain how you have resolved, or will resolve, the issue(s). We'll upload both our letter and your response to the study file in IRBManager.

Fall IRB Training

IRB Basics
This training session covers a basic overview of the IRB, how to prepare a submission, helpful hints, and a demonstration of IRBManager. Repeats monthly.

International Research
Doing research abroad can be a daunting task, and there are many special ethical and practical considerations. Come find out what you need to know – BEFORE you go!

Informed Consent Workshops
Informed consent is a crucial part of human subjects research. It is your responsibility as a researcher to ensure that participants understand what they are agreeing to. These workshops will teach you how to obtain truly informed consent. You can sign up for one or both.

- **Part 1: The consent form.** This workshop will go beyond the templates; you'll learn the art of writing a consent document that your participants can actually understand. You'll see examples of good consents and … less good … consents, and will also have a chance to try your hand at writing with immediate feedback.
- **Part 2: The consent process.** The consent process is not a one-time event that begins with a form and ends with a signature. From recruitment through the end of the study, you'll learn how to obtain consent ethically and respectfully, and ensure that your subjects are willing, understanding participants. You'll also have a chance to role-play an informed consent discussion.

In-Class Presentations
We are also available to give presentations to individual classes. To request an in-class training session, send an email to irbinfo@uwm.edu. Include your name, the location, course title, some date/time options that work for you, and what topic(s) you would like us to cover.

For specific dates and a link to register, please visit our website: http:uwm.edu/irb

New Federal Regulations

Early this year, major changes were announced to the Common Rule (the regulations IRBs follow when reviewing human subjects research). Most of these changes go into effect January 19, 2018.

This fall, we will be revising our policies, procedures and forms to comply with the new regulations. Keep an eye out for additional communications this fall and winter about how these changes will affect you.

Highlights

- New and revised exempt categories
- "Benign behavioral interventions" now qualify as exempt
- IRB review no longer required for certain research in oral history, journalism, etc.
- Additional requirements for the consent document
- "Broad consent" required for storage and future use of identifiable data and specimens
- Elimination of continuing review for expedited studies
- There were NO changes to the expedited categories
- Single IRB review required for multi-institutional studies (effective 1/20/20)