University of Wisconsin-Milwaukee

Institutional Review Board Updates

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IRB News and Updates

Contact the IRB Office:
Melissa Spadanuda
IRB Manager
spadanud@uwm.edu
414-229-3173

Melody Harries
IRB Administrator
harries@uwm.edu
414-229-3182

So far this academic year, the IRB has reviewed more than 250 new study submissions. We are always grateful to our IRB members for their time and expertise!

We have had some changes to our membership as well:

Erin Parcell (Communication) joined the IRB this spring. Her professional interests are in personal relationship communication, focusing on families, romantic relationships, and military families. She joined the IRB to learn more about how other scholars conduct their studies and says she is "honored" to serve on the IRB and help make sure ethical standards are being met at UWM. In her free time, she enjoys hiking, camping, biking, yoga, and spending time with her husband, daughter, and dog.

Melody Harries joined us as the new IRB Administrator in February. Melody spent four years as a Research Compliance Analyst in the IRB office at Aurora Health Care, and more recently taught German at Concordia University as an adjunct instructor. She spends nice days biking, gardening and generally using any excuse to avoid being inside. When forced indoors, she turns to reading, teaching herself to knit, and playing the piano. She can often be found in the center of a mob consisting of two children, a husband, a dog, and/or a rambunctious cat.

University Headlines Feature IRB Members

IRB Chair Aaron Buseh and long-time IRB member Sandra Millon-Underwood were featured in UWM's 2016 Research Report for their work examining attitudes toward genetic research in African-Americans and African immigrants. Partnering with another IRB member, Fessahaye Mebrahtu, and his organization, the Pan African Community Association, the research revealed important information on the issue of trust in researchers—and the lack thereof—among this population.

To read the full article, go to: http://uwm.edu/news/trust-is-key-to-boosting-diversity-in-genetics-research/

Upcoming IRB meeting Dates:

- June 3, 2016 (deadline for Full Board submissions is May 18)
- July (TBD due to July 4th holiday)

Screening Potential Subjects for Studies

In your excitement to enroll a study participant, don't forget to verify that the potential subject meets your eligibility criteria! If you think someone else already screened them, double check. If there's nothing to double check, screen them again anyway (and start documenting your screening process).

Every subject should be screened for every inclusion/exclusion criteria before enrolling in a study, every time. This protects the integrity of the study data, ensures that only appropriate subjects are in a study, and keeps 17-year-olds from (illegally!) consenting for themselves.

In-depth Issue Spotlight: Device Research

While it's true that UWM researchers don't generally cut people open and put implants in them, we still have medical device research going on. The type of IRB review needed depends on the device and how it is being used.

Approved/cleared devices, being used according to their intended purpose. This is the most common use of devices we see here at UWM. As long as you use the device as intended / labeled, there is usually nothing else the IRB needs to do. However, the IRB may need additional information to verify that the device is being used as intended.

Non-Significant Risk (NSR) devices. These are devices that do NOT meet the definition of a Significant Risk Device (see below). Sometimes these are newly created devices, while other times they are a marketed device that has been modified in some way. The IRB must make the determination that it meets the criteria for NSR, if the FDA has not already made this determination. An NSR determination for a device is not the same thing as a minimal risk determination for a study. A device may have an NSR determination, but the study may still be considered more than minimal risk.

Significant Risk (SR) devices. A significant risk device is intended to diagnose, treat, cure or mitigate a disease or condition, and presents the potential for serious risk to the health, safety or welfare of a subject. These too can be either newly created devices or modifications to a marketed device. They require an Investigational Device Exemption (IDE) from FDA before they can be used in research. The IRB will need the IDE number or a copy of the IDE approval letter.

An important thing to know: if you are using a new device, whether SR or NSR, be sure to follow all FDA requirements for labeling, monitoring, and reporting.

The following items are all classified as medical devices. Some of them might surprise you!

- Electric wheelchairs
- Pacemakers
- Sutures
- Contact lenses
- Certain smartphone apps
- Pulse oximeters
- Contraceptive devices
- Dialysis machines
- Catheters
- Tissue adhesives used in surgery
- Injection needles
- Menstrual pads
- Dental filling materials
- Pregnancy tests
- ECG machines
- Hospital beds
- Nasal cannulas
- Stents
- Ultrasound machines
- Defibrillators
- Hearing aids
- Bandages
- Computer-guided robotic surgery
- Examination gloves