IRB News

From the Office of the Human Research Protection Program

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IRB Contact Information

For IRB Questions Email or Phone:
irbassist@spectrumhealth.org

616-486-2031

IRB Website:
www.spectrumhealth.org/hrpp

For IRB Policies:
www.spectrumhealth.org/researchpolicies

For IRB Forms:

https://login.irbmanager.com

News: New IRB Members

The Spectrum Health Office of the IRB was sad to see one of our dedicated IRB members, Clinical Ethicist, Michael Wassenaar, PhD, leave to pursue an opportunity creating his own business. We appreciate his years of service and dedication to the IRB. We are happy to announce five new IRB members: Wendy Laraway, PharmD, from the Spectrum Health investigational pharmacy, David Weinandy, PhD, faculty at Aquinas College, Anita Jones, MPA, member of the Spectrum Health Executive Patient and Family Advisory Council, Kate Paasch, BA, program manager for a staffing company, and Dave King, BS, MBA, retired medical technologist and health information system consultant. We believe they will be valuable contributors and reviewers for the community at large and Spectrum Health patients.

Q&A with the IRB Office

Q1: What should you do if a subject becomes incarcerated while on study?

A1: You should notify your sponsor and the IRB via a Reportable New Information form. Being incarcerated while on an interventional research study can potentially place the participant at increased risk of harm due to being unable to be in direct contact with the Principal Investigator and research team. Incarceration includes being placed on "house arrest" or "released on bail" since both still place restrictions on a participant's freedom to travel. Whether or not the participant will be able to remain on the study will depend on what type of research study they are participating on. The IRB will work with the sponsor and Principal Investigator to determine what is best for the participant and what additional human subject protections may be applicable to the situation.

Q2: What should you do if you have a concern about how the investigator or another study member is conducting a portion of a human subject research study?

A2: You should first try to follow the normal channels of addressing the concern, such as a crucial conversation with the individual or contacting your supervisor. If these are not viable options, or if the situation has not improved, you can submit your concern to the IRB Office for assistance and review. Contact the IRB Office at 616.486.2031 or via irbassist@spectrumhealth.org, and request to speak to one of our IRB analysts. You may also contact the IRB Director or IRB Supervisor directly. If you wish to anonymously report a concern that is not being addressed by the research team you can contact Global Compliance a 3rd party contracted by the Spectrum Health Office of Organizational Integrity and Compliance at 1.877.319.0266 or https://spectrumhealth.alertline.com/gcs/welcome

Notices and Reminders

- **New Guidance Documents Available:** The Spectrum Health IRB has issued two new guidance documents on protecting patient privacy in research using electronic medical data and minimizing undue influence when recruiting students, employees and healthy volunteers. They are located on the IRB website under Policies and Guidance, www.spectrumhealth.org/researchpolicies

- **IRB Form Change:** As a reminder, in the unlikely event the research team receives an updated Investigator Brochure (IB) that contains new or updated risk information not previously reported to the research team and IRB it must be promptly submitted to the IRB on a Reportable New Information (RNI) form. The IRB will also be

interested if and when a revised protocol and/or informed consent document will be provided based on this new risk information. However, if a revised IB contains only administrative updates or the added new risk information has already been submitted to the IRB previously (e.g., the protocol and informed consent form have already been amended with the new risk information based on other information) then the IRB does not required prompt notification via a RNI form. Instead, the revised IB can be submitted on a modification form for review.

- **Registering on clinicaltrials.gov:** The Spectrum Health IRB would like to remind investigators and research team members that the majority of investigator initiated clinical trials studying a drug or medical device, regardless if the drug or medical device is already on the market, must be registered on clinicaltrials.gov per federal requirement FDAAA 8801. Contact the Spectrum Health Office of Research Administration at researchassist@spectrumhealth.org to register a study. In addition, please be aware the mandate also requires you submit the final results of the clinical trial. For more information on which clinical trials are required to register and how to submit the results please reference the clinicaltrials.gov website: https://www.clinicaltrials.gov/ct2/manage-recs/fdaaa

Meet One of Our New IRB Members: Wendy Laraway, PharmD

Wendy Laraway is the Investigational Drug Service Pharmacist for Spectrum Health. She earned her BS in Pharmacy from Ferris State University. She has held many roles in her 20+ years with Spectrum Health including managing the Special Care Hospital pharmacy. The past 6 years that she has spent in the Investigation Drug Service role have been challenging, exciting and rewarding. She enjoys being able to support the Primary Investigators and Clinical Research Associates with their work in clinical trials. Wendy decided to become an IRB member to further support the community that we serve because she is inspired by the new therapies that may offer life-saving treatments or new therapies that may have a huge impact on patients' medical care. While not working or serving on the IRB, Wendy enjoys gardening, knitting, and hiking.

If you see Wendy, please be sure to thank her for all of the work she has contributed by serving as an IRB member.

Congratulations

- Congratulations to IRB staff member Torrey Horness. Torrey was recently certified by PRIM&R (Public Responsibility in Medicine and Research) as a Certified IRB Professional by passing the CIP® exam. This very comprehensive certification exam assesses an individual's knowledge and comprehension regarding the interpretation and application of the regulations that govern human subjects' research (FDA, OHRP, and OCR). Nice work, Torrey!