IRB News

From the Office of Research Integrity

SPECTRUM HEALTH

Winter Edition 2016

Contact Information

For IRB Questions

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IRB Manager

New Website Address

As you may have noticed, the website has a new look and the IRB now has a new web address. Please save this link in your favorites: http://www.spectrumhealth.org/research-and-clinical-trials/how-we-can-help/who-we-are/human-research-protection-program

Investigational Drug Shortages / Substitutions in Research

A shortage of an investigational drug and/or substitution of a different drug is considered a potential ***unanticipated problem*** and therefore needs to be reported to the IRB promptly (i.e., within 5 business days) via the Reportable New Information xForm. However, since substitution of a drug is to prevent an apparent immediate hazard to subjects, such changes can be made prior to IRB review. As part of this report, please describe:

- The actions taken to address the shortage
- Whether study enrollment has been suspended
- Whether the drug(s) that will be substituted are considered standard of care or whether they are investigational
- Any change in risks to participants, especially any increase, that may occur as a result of the shortage and/or substitution
- Effect of potential study outcomes, if known (e.g., study may be closed prematurely)
- What information will be conveyed to participants, how the information will be provided, and when the information will be disseminated - a revised consent form or consent form addendum may be appropriate
- Any documentation received from the study sponsor related to the shortage and any actions recommended or required

The IRB will review the report to determine if any additional action is required and convey its determination to the research team. If a drug shortage and/or substitution is not temporary and is expected to be in place for the life of the study, a change of protocol and informed consent should be submitted to the IRB as a modification. If there is a drug shortage for a non-investigational drug being used as part of the clinical trial, please contact the IRB and one of the IRB analysts will be happy to assist you and navigate the process.

2016 IRB Year End Statistics

764: Active research projects overseen by the SH IRB; 95% of these projects are biomedical; 5% are social/behavioral research
322: New studies submitted for IRB review in the last 12 months
2415: Number of submissions the IRB received in the 12 months
26: Average number of calendar days from submission of a new greater than minimal risk study and convened IRB review; 34: Average number of calendar days from submission of a minimal risk study and IRB approval

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Upcoming AAHRPP Reaccreditation:

Q: What is AAHRPP?
A: The Association for Accreditation of Human Research Protection Programs is an independent, not-profit accrediting body that provides the "gold standard" of assurance that an organization's HRPP meets rigorous standards for ethics, quality and protection.

Q: Why does Spectrum Health choose to be accredited with AAHRPP?
A: AAHRPP accreditation is our public affirmation of the commitment we have to protecting research participants. By earning the AAHRPP accreditation seal, Spectrum Health is placed among the world's most respected, trustworthy research organizations.

Q: How long is the reaccreditation process?
A: There are several steps and phases to the process:

1. Preparation and submission of application for reaccreditation - December of 2016
2. On-Site Evaluation (Expected to occur summer of 2017)
    a. Additional information will be included in the spring newsletter.
3. Council Review (December of 2017)
4. Notification of reaccreditation status around December (2018)

Q: How can I find more information about AAHRPP?
A: If you would like more information, please visit **http://www.aahrpp.org/**

SAFE Program

The IRB and SAFE program are integrated components of the larger Office of Research Integrity; they are separate entities with related, but different charges. The SAFE program conducts post-approval monitoring and provides ongoing education and support to PIs and research teams involved in the conduct of human subject research. The program offers several types of services available to the research community such as compliance activities, consultation, and education. A few examples of the services that can be requested are listed below:

- Preparatory Review
  The PI or research staff may request this type of review. In most cases, all documents for the entire study (regulatory, consents, & charts) are reviewed. You should contact the SAFE team if you need assistance with preparation for an external audit, when there has been staff turnover within the study team, or there is a new staff member involved in the study. A preparatory review can help identify issues prior to external audit.
- Consent Observation
  The PI or research staff may request to have a member of the SAFE team observe the consent process. Consenting a potential subject can be sensitive and our main focus is to confirm that the information in the application, consent document, and any other written material on file is communicated accurately and in a non-coercive manner. Consent observation is a helpful tool because it provides real-time feedback and education. If you would like to schedule a review or observation, please contact the SAFE Program via email at SAFEassist@spectrumhealth.org.