IRB News

From the Office of the Research Integrity

SPECTRUM HEALTH

Spring Edition 2017

Contact Information

For IRB Questions

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IRB Manager

News: Be All That You Can Be! Become an IRB Member

Are you or anyone you know interested in helping protect the safety, rights, and welfare of individuals who volunteer to participate in research studies? If you answered **YES**, the following opportunity may be of interest to you.

The Spectrum Health IRB is looking for individuals both with and without science backgrounds, as well as community members. Our committee is made up of a diverse membership; all members regardless of job title, level of education, or any other differences are essential to the review process. Each member brings varying opinions from their respective backgrounds to decide how best to safeguard the rights and welfare of human subjects in research.

If you would like to be a part of this amazing opportunity and become a member of the Spectrum Health IRB, please contact us at 616-486-2031 or email irbassist@spectrumhealth.org.

Q&A with the IRB Office on Waivers of Informed Consent

Q1: One of my collegues told me that I should request a waiver of informed consent for my study. What is a waiver?

A1: HHS regulations allow the IRB to waive the requirement for obtaining informed consent or parental permission or to approve a consent procedure that leaves out or alters some or all of the elements of informed consent otherwise required under 45 CFR 46.116(a) and (b). Waiving the requirement for obtaining informed consent or parental permission means that the IRB has determined that investigators need not obtain the subjects' informed consent to participate in research.

Q2: I have a minimal risk study. Is that enough to waive informed consent?

A2: No. There are actually four conditions that must be met in order for the IRB to waive or alter the requirement of informed consent under 45 CFR 45.116(d). The following ***four*** conditions must be met:

1. The research involves no more than minimal risk to the participants;
2. The waiver or alteration will not adversely affect the rights and welfare of the participants;
3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the participants will be provided with additional pertinent information after participation.

Q3: I have a retrospective study. Can informed consent be waived?

A3: Maybe. Not all retrospective studies are alike. Some of the questions the IRB might ask are:

1. Is this a retrospective review of medical records from patients currently seen regularly in clinic?
2. Is this a retrospective review of medical records from patients seen years ago? (ie: 1991-2001 subjects with terminal cancer)?

These questions help the IRB determine if condition (3) above is met. In the first scenario, contact information of potential subjects could be readily available and the research could be practicably carried out and in the second scenario the age of the records and potential that subjects maybe expired may limit that possibility.

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From the Office of the Human Research Protection Program

Q4: I have an FDA regulated study, can I waive informed consent?
A4: No. FDA regulated studies are **NOT** eligible for waiver or alteration of consent except for emergency use or planned emergency research, which are both very rare situations.

Q5: I believe that contacting subjects and requiring informed consent will slow down the process of my study; therefore, it can't be practicably carried out. Can informed consent be waived?
A5: No, not based on this information alone. The mere inconvenience in contacting individuals is not a justification for concluding that obtaining informed consent is impracticable.

Reminders and Notices

- **Reminder:** Spectrum Health has an upcoming Association for the Accreditation of Human Research Protection Programs (AAHRPP) reaccreditation site visit coming up. Spectrum Health received initial accreditation in winter of 2009 and reaccreditation in 2012. The first reaccreditation is conducted three years post initial accreditation and then every 5 years after that. Accreditation demonstrates that we provide research subjects safeguards that surpass the threshold of regulatory requirements. We anticipate AAHRPP site visitors will be visiting Spectrum Health sometime this summer. They have reviewed our policies and procedures and during the 2-3 days they are here they will review records and interview a wide range of individuals who are involved in human subjects' research, including investigators, research staff, IRB members, IRB staff etc., to assess their familiarity with and commitment to the institution's policies and procedures relating to human subjects' research. Investigators will be contacted directly if chosen to meet with the AAHRPP team.
- **Notice:** A new email has been created for all research COI communications, researchcoi@spectrumhealth.org. Going forward, please send all COI new user requests and questions to this email.
- **Notice:** Coming Soon – A New Research & Clinical Trials Website
- **Notice:** Coming Soon – An Online Research Intake Form. The new intake form will include an expanded list of questions that are critically important to kick-start the required administrative and regulatory processes that support our research efforts. If you would like to volunteer to beta test the intake form or if you have any questions or concerns, please contact ResearchAssist.

Upcoming Education Sessions

IRB Lunch and Learn: The New Common Rule
Presented by Leah Voigt, JD, MPH, Chief Privacy and Research Integrity Officer
Tuesday, May 30th, 2017
12pm to 1pm
25 Michigan, Conference Rooms 3000/3001

Reliance Agreements and the Growing Request

Do you want to enter into a reliance agreement with another organization for a study you wish to conduct? Has another organization approached you to enter into a reliance agreement to conduct a study together? The IRB has been receiving many requests for reliance agreements with many different organizations. Although each reliance agreement is viewed as a case by case basis, typically, Spectrum Health enters into Reliance Agreements when it benefits Spectrum Health and its patients.

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From the Office of the Human Research Protection Program

Spectrum Health considers entering into a reliance agreement to rely on another IRB when (1) there is federally funded research where the reliance is a requirement to participate in the study and (2) when the agreement is reciprocal. Spectrum Health considers entering into a reliance agreement where we would become the IRB of record when (1) we want to support another organization and offer IRB services as part of our commitment to the community and (2) when we may be incidentally engaged in the research.

There is a misconception that entering into a reliance agreement makes the jobs of the study staff easier. In reality, most reliance agreements add double the work for the study staff. Once a reliance agreement is entered into, the study staff needs to know what reporting requirements are placed upon them going forward. There are now times they report to the local IRB, the relied upon IRB, and both. Every reliance agreement is different and it is the study staffs' responsibility to make sure they are reporting to whom they need to, how often, and within what amount of time.