IRB News

From the Office of the Human Research Protection Program

SPECTRUM HEALTH

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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 is happy to announce two new IRB members: Josh Reynolds, MD is a board certified emergency physician with Emergency Care Specialists. Trained at the University of Pittsburgh, Dr. Reynolds is also Assistant Professor of Research at MSU, and Research Director at GRMEP. Jeffrey Byrnes, PhD Philosophy, University of Essex, UK, is a Visiting Assistant Professor at Grand Valley State University with experience teaching ethics to medical practitioners with a focus on patient autonomy. 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: When can I enroll a Spanish speaking subject on a study?

A1: The IRB may only approve research where selection of subjects is deemed to be equitable, taking into consideration the purposes of the research, current standard medical treatment available, and the setting in which the research will be conducted.

Researchers should consider the primary language of subjects likely to be eligible for their study, the potential benefit from the new intervention/drug/device in relation to the risk profile in comparison to the current standard treatments available, and who will ultimately benefit from the knowledge gained from the research. If the population being studied for a certain medical condition is likely to include Limited English Proficiency (LEP) individuals who could potentially benefit from participation then researchers should consider including them in the research, either by utilizing the short form consent process, or by prospectively translating study documents.

However, even if the researcher would like to recruit LEP subjects the IRB may ultimately determine that the inclusion of LEP subjects may be unsafe because appropriate accommodations to reduce vulnerability are not able to be achieved for a particular study in relation to the risk & benefit ratio. Those concerns include therapeutic misconception, additional research procedures risks and benefits (e.g. research MRI with contrast), how complicated a study may be, and being able to readily communicate with researchers about the study and side effects.

Q2: How do I enroll a Spanish speaking subject on a study?

A2: Once you have IRB approval to include Spanish speaking or Limited English Proficiency (LEP) subjects in your study there are **two options** to consent/enroll them:

*One way is to consent using the Short Form. To begin you should verify that you have interpreters and an IRB-approved Short Form available in the prospective subject's primary language. IRB-approved Short Forms are available on the IRB website in Spanish, Bosnian, and Vietnamese. You will need to contact Spectrum Health Language Services Department and arrange for **two** interpreters to be present for the consent conversation. One interpreter will interpret the consent form and the other will serve as witness to the interpretation. The person obtaining consent will read the IRB-approved English consent a few lines at a time,

the interpreter interprets this into the subject's primary language, and the interpreter serving as witness follows along to ensure everything is translated correctly and nothing is skipped. Once this process is complete and all the subject's questions have been answered the subject can be asked if they wish to participate in the study. If yes, the subjects signs and dates the Short Form consent. (The subject does not sign the English IRB-approved informed consent form (ICF)).The person obtaining consent signs and dates the English IRB-approved informed Consent Form (ICF). The interpreter **witnessing** the interpretation signs and dates the Short Form consent document **AND** the English IRB-approved ICF. Provide a copy of the signed and dated Short Form consent and signed and dated IRB-approved English consent to the subject and place a copy of both in the medical record. File the original signed and dated Short Form consent and signed and dated English IRB-approved informed consent form together with the study regulatory documents. If the study will involve long term use (e.g. more than a few days) of an investigational drug or device, for safety reasons it is recommended that you obtain a fully-translated informed consent form or list of expected side effects for the subject to reference in their primary language.

*The other option is to consent using a fully-translated consent document. (Spectrum Health has a translation services for translating documents into other languages. The contact information and form is available on the Spectrum Health IRB website). Verify the translated informed consent has IRB-approval. Contact Spectrum Health Language Services Department and arrange a date and time to conduct the consent process with an interpreter (only one is required) present. Bring both the English and translated ICF. The English version serves as a reference to the person obtaining consent. The prospective subject should read the translated consent and the person obtaining consent should assess their understanding of what is involved in the research by asking questions through the interpreter. Once the person obtaining consent is convinced the subject comprehends the consent content the subject can be asked if they wish to participate. If yes, the subject signs and dates the translated IRB-approved ICF. The person obtaining the consent signs and dates the translated IRB-approved ICF. The person obtaining consent should document the name of the interpreter in the study enrollment note. Provide a copy of the signed and dated translated IRB-approved ICF to the subject. Place a copy of the signed translated informed consent form in the medical record and file the original signed consent with the study regulatory documents. It is recommended, but not required, to also provide them with a copy of the unsigned English ICF for reference when interacting with other medical providers.

For additional information please refer to the Guidance Document on Consenting Limited English Proficiency (LEP) Subjects found on the website http://www.spectrumhealth.org/hrpp under Policies and Guidance.

Reminder

- **Compensation for Research Injury:** As a reminder, the federal regulations require for any research greater than minimal risk, an explanation as to whether any compensation and medical treatment are available if a research related injury occurs (e.g. emergency room visit for an adverse event related to the investigational drug) while participating on the study. The regulations require potential subjects to know whether or not there is compensation. It does not require compensation to be provided. The details of whether or not compensation is available for medical bills, discomfort, and any other inconvenience caused from a research related injury is outlined in the Clinical Trials Agreement signed between the study sponsor and Spectrum Health. It is important to ensure the informed consent form accurately reflects what was agreed upon in the contract. If the study sponsor is not planning to pay for any medical bills related to a research injury, under any circumstances, it is important for the participant to understand they will likely be responsible for the cost associated with diagnosing and treating the research related injury if their private insurance does not agree to cover the cost. Thus, it is important for potential subjects to check with their insurance company (obtain pre-authorization) before deciding

to participate in this research study involving greater than minimal risk medical treatments or procedures since any cost not covered by insurance could be substantial.

Upcoming Education Sessions

The IRB office will be offering the following education sessions. All education sessions are held at **noon** (last an hour) in the 25 Michigan Street Office Building 3rd Floor, **Suites 3000 & 3001** accessible from the hospital via the HDVCH skyway. Study coordinators, research assistants, sub-investigators and investigators are all welcome to attend. Free parking is available to researchers who work off campus, but must be pre-arranged with the IRB office by emailing irbassist@spectrumhealth.org requesting a parking pass at least 24 hours in advance. The education sessions will be presented on the following dates and topics below. For those unable to attend, copies of the slides are available and can be requested by emailing irbassist@spectrumhealth.org or by contacting our office with questions at 616.486.2031.

Date	**Title & Description**
Monday Jan 11th	IRB101 - Introduction to the IRB review process, applications, etc.
Monday Feb 29th	Review of the Informed Consent Template and HIPAA Template
Wednesday Mar 23	Proposed changes to the federal regulations on human subject protection regulations