St. Joseph Health
Center for Clinical Research

IRB NEWSLETTER

September 2018

Greetings IRB Members!
Please read below for current updates on the
SJH Human Research Protection Program.

HRPP Updates

Staff Updates

Welcome back Susan O'Brien!

We are very happy to report that Susan O'Brien, Lead IRB Coordinator, returned from medical leave on September 4th. Please join us in welcoming Susan back to the HRPP Office.

Susan and Theresa Tuckman, IRB Coordinator, are now your primary points of contact for IRB-related issues. The best way to reach them is via the HRPP Office general e-mail at hrpp@stjoe.org. Susan can be reached directly at susan.obrien@stjoe.org or (949) 381-4907, and Theresa can be reached directly at theresa.tuckman@stjoe.org or (949) 381-4903.

2018 PRIM&R Advancing Ethical Research Conference

Public Responsibility in Medicine and Research (PRIM&R) is holding its annual Advancing Ethical Research (AER) Conference November 15-17 in San Diego. This is the premier national conference for issues related to human participant protections, institutional review boards, etc. Members with conference funding available are encouraged to consider attending. Information about the conference can be found here: https://www.primr.org/aer18/.

HRPP staff will be attending the conference and sharing any relevant new information with the committees.

Seeking IRB Member

We are still actively seeking a member living in the community of one of our ministries with a non-scientific background, and who is unaffiliated with SJH, to join SJH IRB Committee #2 as a primary voting member. If you know of an individual who meets this criteria and is interested in serving on the SJH IRB, please put this individual in touch with Adam Pucci, HRPP Manager, at adam.pucci@stjoe.org.

Elements of Informed Consent

One the IRB's primary responsibilities in reviewing research involving human participants is evaluating the adequacy of the informed consent process and form(s). The regulations governing human participant research outline the elements that must be provided to participants during the informed consent process (45 CFR 46.116; 21 CFR 50.25). When reviewing informed consent forms, IRB members are to ensure that the following elements are included:

Basic Elements of Informed Consent:

- ✓ A statement that the study involves research, an explanation of the purpose of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
- ✓ A description of any reasonably foreseeable risks or discomforts to the subject.
- ✓ A description of any benefits to the subject or to others which may reasonably be expected from the research.
- ✓ A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
- ✓ A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained *(for FDA-regulated research only)* and that notes the possibility that the Food and Drug Administration may inspect the records.
- ✓ For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
- ✓ An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
- ✓ A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Elements of Informed Consent Continued

Additional Elements of Informed Consent (to be included when appropriate):

- ✓ A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.
- ✓ Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
- ✓ Any additional costs to the subject that may result from participation in the research.
- ✓ The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
- ✓ A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.
- ✓ The approximate number of subjects involved in the study.

Additional Informed Consent Requirements:

- ✓ No informed consent may include any exculpatory language through which the subject is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.
- ✓ *(For FDA-regulated research only:)* The following statement shall be provided to each subject participating in an applicable clinical trial: "A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."
- ✓ Consent should be sought only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.
- ✓ The information that is given to the subject shall be in a language understandable to the subject or the representative.

Members are encouraged to review the SJH HRPP Informed Consent Guidance for additional information on the requirements and standards for informed consent: https://www.stjhs.org/documents/Clinical-Research/Informed-Consent-Guidance.pdf.