St. Joseph Health
Center for Clinical Research

IRB NEWSLETTER

November 2018

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

HRPP Updates

THANK YOU!!!

In the spirit of Thanksgiving we would like to send our sincerest appreciation to all of the members of the SJH IRBs. Your participation in the review of protocols is essential to ensuring the protection of the rights and welfare of research participants and we are thankful for your time and service to the IRB's mission.

On the HRPP's Horizon…

Much like on Thanksgiving, the SJH HRPP has a lot on its plate as we approach the new year:

- **Implementation of the revised Common Rule:** The revised "Federal Policy for the Protection of Human Subjects," also known as the Common Rule, is due to go into effect on January 21, 2019, following a one-year delay. The HRPP Office is in the process of updating policy and guidance documents to ensure compliance with the revised rule. As the compliance date approaches, we will be educating IRB members, staff, and the research community on the requirements for reviewing and conducting research under the revised Common Rule to ensure all are adequately prepared for implementation.

- **AAHRPP Reaccreditation:** Our application to re-apply for accreditation by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) is due on March 15, 2019. AAHRPP accreditation is considered the gold standard for HRPPs and achievement demonstrates an organization's commitment to meeting the highest standards for quality and protection of research participants. The HRPP Office is currently evaluating and revising policies and guidance in order to ensure ongoing compliance with AAHRPP standards. The reaccreditation process will culminate with a site visit in the fall of 2019 which will include interviews of selected IRB members to assess their knowledge of requirements related to review of research involving human participants. Please continue to review these newsletters for continuing education on the IRB review process.
  In preparation for our reaccreditation efforts, Theresa Tuckman has e-mailed you to ensure we have your current contact information – please respond to Theresa's e-mail at your earliest convenience.

If you have any questions regarding the revised Common Rule or the AAHRPP accreditation process, please contact Adam Pucci, HRPP Manager, at Adam.Pucci@stjoe.org.

Criteria for IRB Approval

The regulations governing human participant research outline the criteria that must be met in order for the IRB to approve a protocol (45 CFR 46.111; 50 CFR 56.111.). IRB members are expected to thoroughly review and discuss protocol materials presented for review in relation to the approval criteria. When voting to approve a protocol, IRB members are determining that all of the following criteria are satisfied:

- Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
- Selection of subjects is equitable. In making this assessment, the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
- Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by federal regulations.
- Informed consent will be appropriately documented, in accordance with, and to the extent required by federal regulations.
- Where appropriate (e.g., research presents greater than minimal risk, clinical trials, etc.) the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- Where any of the subjects, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons, are likely to be vulnerable to coercion or undue influence, additional safeguards are included in the study to protect the rights and welfare of these subjects.

Members are encouraged to review the SJH IRB Member Manual to refresh themselves on requirements and standards for IRB review and approval of protocols. See section "Basic IRB Member Responsibilities: Conducting Protocol Review" starting on page 4 of the manual: https://www.stjhs.org/documents/Clinical-Research/IRB-Member-Manual.pdf.