St. Joseph Health
Center for Clinical Research

IRB NEWSLETTER

February 2018

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

Important Updates

HRPP Updates

Revised Common Rule Delay

In mid-January the Department of Health and Human Services (DHHS) announced a delay to implementation of proposed revisions to the "Federal Policy for the Protection of Human Subjects" (also known as the Common Rule) which were initially set to go into effect on January 19. The new effective date for the revised rule is July 19, 2018; however, DHHS has indicated that the department is seeking to delay implementation even further beyond this date.

The delay means that the provisions of revised common rule will not be implemented at this time. The SJH HRPP will provide updates regarding implementation of the revised rule as more information is received from DHHS.

Annual Disclosure of Financial Interests

All IRB Members should have received an e-mail request to submit an annual Financial Interests Disclosure form. Members who haven't yet submitted the form are encouraged to do so at their earliest convenience. The deadline to submit disclosures is April 16, 2018. See the next page for information on why we require disclosure of financial interests and how potential conflict of interests of IRB members are identified and managed.

Questions about the requirement to disclose financial interests or completing the disclosure form can be directed to Adam Pucci at Adam.Pucci@stjoe.org.

HRPP Staffing Update

Christine Buckley, IRB Coordinator, and Brianna Weed, Research Project Coordinator, have recently left St. Joseph Health. The Center for Clinical Research is in the process of filling the vacant positions. In the meantime, all IRB or HRPP-related questions should be addressed to Susan O'Brien and Adam Pucci via HRPP@stjoe.org.

IRB Member Conflict of Interest

Background

Federal regulations governing IRB membership dictate that "No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB." (45 CFR 46.107(e); 21 CFR 56.107(e))

What constitutes IRB member conflict of interest?

A conflict of interest involves any situation where an IRB member has significant personal, organizational or financial interest which has the potential to bias the design, conduct, reporting, or reviewing of the research. Examples of a conflicting interest would be if the IRB member is:

- Principal Investigator (PI);
- Co-Investigator;
- Receiving funding from the study, as listed in the study budget;
- In a supervisory role over the PI of the study (e.g. faculty advisor);
- Family member of the PI; or
- Responsible for business development at the organization (e.g. director of grants and contracting, the vice president for research, or any other person responsible for raising funds or garnering support for research).

A financial conflict of interest is defined as anything of monetary value, including, but not limited to:

- Salary or other payments for services (e.g., consulting fees or honoraria);
- Equity interests (e.g., stocks, stock options or other ownership interests, excluding any interest arising solely by reason of investment in a business by a mutual, pension, or other institutional investment fund over which the IRB member or his/her immediate family does not exercise control);
- Intellectual property rights (e.g., patents, copyrights and royalties from such rights).

How are potential conflicts of interests identified and managed?

Members disclose financial interests in companies that may sponsor, or whose products may be the object of, clinical research reviewed by the IRB to the HRPP Office. When a study is forwarded for IRB review, HRPP staff identify any members that may have a conflict of interest either due to their role on the study or a financial disclosure. IRB members with a conflicting interest related to a study are asked to recuse themselves from participating in IRB review of the study except to provide information as requested.

What should I do if I have a conflict of interest in a study under review by the IRB?

IRB members who have a conflicting interest related to a study scheduled to undergo IRB review need to disclose the conflicting interest to the HRPP Office and the IRB. The IRB member must recuse themselves during the final IRB discussion and vote on the study