St. Joseph Health
Center for Clinical Research

IRB NEWSLETTER

April 2018

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

Important Updates

HRPP Updates

Staff Updates

Welcome Theresa Tuckman!

We are pleased to introduce Theresa Tuckman who joins the HRPP Office as an IRB Coordinator. Theresa brings with her many years of experience in healthcare, biomedical research and regulatory compliance fields. She has worked for more than a decade in support of IRBs at the University of California, Irvine and California State University, Fullerton. Her in-depth knowledge of human research participant protection regulations make her a valuable asset to our team, IRB members, and the research community. Please join us in welcoming Theresa to PSJH!

DHHS Announces Plans to Further Delay Revisions to Common Rule

In mid-April the Department of Health and Human Services (DHHS) announced plans to further delay the implementation of proposed revisions to the "Federal Policy for the Protection of Human Subjects" (also known as the Common Rule) which were most recently set to go into effect on July 19, 2018. The announcement was made via a Notice of Proposed Rulemaking (NPRM) through which DHHS seeks to delay implementation of the majority of the revised Common Rule provisions to January 21, 2019, while permitting institutions to implement three "burden-reducing" provisions on July 19.

"The public trust in what we do is just essential, and we cannot afford to take any chances with the integrity of the research process." — Dr. Francis Collins, Director, NIH

Common Rule Continued/FDA Guidance

The three provisions that are proposed for implementation on the earlier date are: (1) a revised definition of "research," which deems four categories of activities not to be research; (2) eliminating continuing review for certain categories of research; and (3) removing the requirement that IRBs review grant applications related to research.

The DHHS proposal is tentative while the NPRM is under consideration. The SJH HRPP Office will provide updates regarding implementation of provisions of the revised Common Rule as more information is received from DHHS.

Recent FDA Guidance

Payment to Research Subjects

In February the Food and Drug Administration (FDA) published updates to its information sheet on payment to research subjects. The updates clarify that the FDA finds reimbursement for travel expenses to and from the clinical trial site and associated costs such as airfare, parking, and lodging to be acceptable and does not consider such reimbursement to raise issues regarding undue influence.

In general, the information sheet notes that paying research subjects in exchange for their participation (time, inconvenience, discomfort, etc.) is an acceptable practice, but should not be considered a benefit to be weighed as part of the risk/benefit assessment. IRBs should ensure that payment for participation is just and fair and consider whether proposed payment could present an undue influence that may interfere with a potential subject's ability to give voluntary informed consent.

The FDA Payment to Research Subjects - Information Sheet can be reviewed here: https://www.fda.gov/RegulatoryInformation/Guidances/ucm126429.htm

Including Pregnant Women in Clinical Trials

This month the FDA issued draft guidance on the inclusion of pregnant women in clinical trials. The guidance reviews the contexts in which pregnant women may be included in clinical trials as well as the regulations governing their inclusion. The guidance presents the ethical and scientific issues the IRB should consider when reviewing clinical trials involving pregnant women and will serve as a reference to the boards when reviewing research involving this population in the future.

The FDA Draft Guidance Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials can be reviewed here: https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm603873.pdf