

IRB NEWSLETTER

August 2018

Greetings IRB Members!

Please read below for current updates on the
SJH Human Research Protection Program.



HRPP Updates

IRB Member Evaluations

In the coming weeks, members will be receiving formal evaluations of their participation on the IRBs for the period of May 1, 2017 to April 30, 2018. As you are aware, IRB members are evaluated annually by the SJH Institutional Official for Research, HRPP staff, and IRB Chairs to identify areas for improvement of members and for the overall committee composition. The evaluations also give us an opportunity to document your significant contributions on the committees and to confirm that members are up-to-date on training, financial / conflict of interest disclosures, etc.

We are pleased to report that this year's evaluations found very little need for individual member improvement. Without exception the current membership of the IRB is comprised of extremely dedicated individuals who prioritize attendance for meetings and actively participate in committee discussions. Members bring extensive experience, special expertise, and unique perspectives to the IRB's deliberations and are consistently focused on ensuring appropriate protections are in place for research participants.

One area identified for improvement is in members alerting the HRPP Office when they are unable to attend meetings. We encourage all voting members to inform Theresa Tuckman, IRB Coordinator, at theresa.tuckman@stjoe.org in advance whenever possible if you will be unable to attend an IRB meeting to allow sufficient time for an alternate to be identified.

The HRPP would like to thank you all for your continued involvement and commitment to the SJH IRBs - your participation is essential to the committees' success.

If you have any questions about the IRB member evaluation process or individual evaluations, please contact Adam Pucci, HRPP Manager, at Adam.Pucci@stjoe.org.

"It is not how much you do, but how much love you put into the doing that matters." — Mother Teresa

HRPP Updates Continued/ OHRP Guidance

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.

Recent OHRP Guidance

Revised Common Rule

In July, the Office for Human Research Protections (OHRP) made available draft guidance related to provisions of the revised "Federal Policy for the Protection of Human Subjects," also known as the Common Rule. Two of the guidance documents will be relevant to the IRB review process when the revised Common Rule goes into effect on January 21, 2019:

- "Scholarly and Journalistic Activities Deemed Not to be Research: 2018 Requirements."

This document provides guidance regarding certain scholarly and journalistic activities that involve collecting information on specific individuals which are deemed not to be research and, accordingly, are not subject to the Common Rule. The guidance can be found here:

<https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/draft-guidance-scholarly-and-journalistic-activities-deemed-not-to-be-research/index.html>

- "Elimination of Institutional Review Board (IRB) Review of Research Applications and Proposals: 2018 Requirements."

This document provides guidance on the elimination of the requirement that IRBs review grant applications or other funding proposals related to research. The guidance document can be found here:

<https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/draft-guidance-elimination-of-irb-review-of-research-applications-and-proposals/index.html>

The guidance documents address provisions of the revised common rule that are expected to minimally impact our IRBs operations given the current makeup of the SJH research portfolio. Nevertheless, as part of our efforts to prepare for the implementation of the revised common rule, the HRPP will review local guidance documents to ensure they are consistent with OHRP's. The HRPP will provide updates regarding implementation of the revised Common Rule as we move closer to its effective date.