

# IRB NEWSLETTER

October 2018

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



## HRPP Updates

### Welcome Baby James Pucci!

We are excited to announce the birth of James Pucci, who arrived October 16<sup>th</sup> at St. Joseph Hospital, Orange. Adam and his wife, Gabriella, are doing well, enjoying time with their new baby boy. Please join us in congratulating Adam and his wife, and celebrating the birth of their son!



### 2019 IRB Meeting Schedule

Please reserve time on your 2019 calendars for next year's committee meetings. Outlook appointments will be forwarded to you as well. If you have an assistant who coordinates your calendar, please inform the HRPP Office at [hrpp@stjoe.org](mailto:hrpp@stjoe.org) so we can include them on meeting appointments. As a reminder, please notify the HRPP Office prior to the scheduled meeting dates if you will not be able to attend a meeting. This ensures we have adequate time to identify an alternate, if needed, to satisfy quorum.

Committee #1 Meeting 1 <sup>st</sup> Thursday Each Month; 12:30 pm Pacific	Committee #2 Meeting 3 <sup>rd</sup> Tuesday Each Month; 7:30 am Pacific
January 3 <sup>rd</sup>	January 15 <sup>th</sup>
February 7 <sup>th</sup>	February 19 <sup>st</sup>
March 7 <sup>th</sup>	March 19 <sup>th</sup>
April 4 <sup>th</sup>	April 16 <sup>th</sup>
May 2 <sup>nd</sup>	May 21 <sup>st</sup>
June 6 <sup>th</sup>	June 18 <sup>th</sup>
July 11 <sup>th</sup>	July 23 <sup>rd</sup>
August 1 <sup>st</sup>	August 20 <sup>th</sup>
September 5 <sup>th</sup>	September 17 <sup>th</sup>
October 3 <sup>rd</sup>	October 15 <sup>th</sup>
November 7 <sup>th</sup>	November 19 <sup>th</sup>
December 5 <sup>th</sup>	December 17 <sup>th</sup>

# HRPP Updates/ Recent FDA & 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](mailto:adam.pucci@stjoe.org).

## Recent FDA & OHRP Guidance

The Food and Drug Administration (FDA) and the Office for Human Research Protections (OHRP) have recently released guidance related to the revised "Federal Policy for the Protection of Human Subjects," also known as the Common Rule.

The FDA has issued a guidance document titled, "*Impact of Certain Provisions of the Revised Common Rule on FDA-Regulated Clinical Investigations*," which, as the title suggests, discusses how the revised Common Rule impacts FDA-regulated research. The FDA is not a party to the Common Rule and, as such, clinical investigations of drugs and devices must continue to follow FDA regulations when the Common Rule goes into effect. The FDA provides clarification regarding three provisions on the revised Common Rule:

- The new informed consent requirements of the revised Common Rule are not inconsistent with FDA requirements and may be included in consent forms for FDA-regulated clinical investigations.
- The Common Rule changes to the expedited review procedures do not apply to FDA-regulated clinical investigations.
- The Common Rule changes to the continuing review requirements do not apply to FDA-regulated clinical investigations.

The guidance can be found here:

<https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM623211.pdf>

In August, OHRP announced the websites that will satisfy the revised Common Rule's consent form posting requirement. The revised rule requires that a copy of the consent form for certain clinical investigations be posted on a publicly available federal website within a specific time frame. The websites that have been identified are: ClinicalTrials.gov and a docket folder on Regulations.gov (Docket ID: HHS-OPHS-2018-0021). OHRP is in the process of developing further guidance about the consent form posting requirement.

The effective date of the revised Common Rule is January 21, 2019, and with no further delays announced, the HRPP Office is moving forward with ensuring compliance with the revised rule effective as of this date. In the coming months, educational materials related to the revised Common Rule will be recirculated to IRB members in preparation for implementation.