

# IRB NEWSLETTER

March 2018

## Greetings IRB Members!

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



## Important Updates

### HRPP Updates

#### **Welcome New IRB Member – Daniel Dwyer!**

Dr. Dwyer is the Executive Director of Theology and Ethics for Providence St. Joseph Health (PSJH). He holds a Ph.D. in Urban Social Institutions, a Master of Science in Social Work and a Master of Theology in Health Care Mission. He brings over 30 years of leadership experience within healthcare systems, hospitals, medical colleges, etc. in the areas of quality, ethics, palliative care, resource utilization, risk management, physician relations, community health, and leadership formation. In his current position, Dr. Dwyer provides ethics consultations, education, and program development services across PSJH. Dr. Dwyer has participated on several IRBs in his career and this experience along with his extensive background in healthcare ethics will be a tremendous asset to the SJH IRBs in their mission to protect the rights and welfare of research participants.

Dr. Dwyer is a primary voting member of IRB #1 and an alternate member for IRB #2. Please join us in welcoming Dr. Dwyer to the SJH IRBs!

#### **IRB Membership**

The appointment of a new member is a great time for all members to review the expectations and responsibilities of IRB membership. Please review the last two pages of this newsletter for a review of the important role members play on the IRB.

# Important Updates Continued

## HRPP Updates

### Staffing Updates

#### **Welcome Emily Reynolds!**

We are pleased to introduce Emily Reynolds who joins the Center for Clinical Research as a Research Project Coordinator. Emily has several years of experience as a clinical research coordinator supporting multiple drug and device protocols and brings valuable knowledge and understanding of the clinical research field which is essential to her primary role in assisting the research community with their submissions to the HRPP and CORA. In the coming months, Emily will be providing significant administrative support to the IRB. Please join us in welcoming Emily to PSJH!

#### **Get well soon Susan O'Brien!**

Susan O'Brien, Lead IRB Coordinator, has taken a medical leave of absence beginning on March 22, 2018. We expect Susan to be back in the office in approximately 6 weeks and will be wishing her a speedy return.

Adam Pucci, HRPP Manager, will be the primary point of contact for IRB-related issues while Susan is out ([Adam.Pucci@stjoe.org](mailto:Adam.Pucci@stjoe.org).) You can also contact Emily Reynolds at [Emily.Reynolds@stjoe.org](mailto:Emily.Reynolds@stjoe.org) or Doreen Robinson, CCR Director, at [Doreen.robinson@stjoe.org](mailto:Doreen.robinson@stjoe.org) for assistance.

### **Reminder - Annual Disclosure of Financial Interests**

The deadline to submit previously distributed annual Financial Interests Disclosure forms is April 16, 2018. Members who haven't yet submitted the form are encouraged to do so at their earliest convenience. All relationships that may be perceived as or pose a conflict of interest (financial or otherwise) for the preceding 12 months (CY17) should be disclosed on this form. Should you need an additional form sent to you, please contact [HRPP@stjoe.org](mailto:HRPP@stjoe.org).

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

# IRB Membership

Each member of the St. Joseph Health Institutional Review Boards plays a crucial role in supporting the IRBs' mission of protecting the rights and welfare of human research participants.

IRBs are mandated to include members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution and who are sufficiently qualified through experience, expertise, diversity and sensitivity to community attitudes to promote respect for their advice and counsel. [45 CFR 46.107; 21 CFR 56.107] Accordingly, the SJH IRBs have recruited members with expertise in various medical disciplines from across the St. Joseph Health system. In addition, the IRBs include members of the local communities where research is conducted to bring the important perspective of the general public in these areas along with that of potential research participants. Each individual member may bring scientific expertise, knowledge of professional practice guidelines, awareness of community standards, personal experience, and regulatory knowledge necessary for the boards as a whole to fulfill their oversight responsibilities.

A member's main contribution is through their participation in IRB meetings, lending their knowledge and perspectives during the review of research protocols. Collectively, members are responsible for ensuring that each protocol reviewed by the board meets the 8 criteria for IRB approval:

- *Risks to subjects are minimized.*
- *Risks are reasonable in relation to benefits.*
- *Selection of participants is equitable.*
- *Informed consent will be sought from participants.*
- *Informed consent will be appropriately documented.*
- *Data monitoring plan adequately ensures participant safety.*
- *Adequate plans to protect participant privacy and maintain confidentiality.*
- *Inclusion of safeguards to protect participants likely to be vulnerable to coercion or undue influence.*

Members are expected to thoroughly review new protocols presented on agendas circulated a week before each meeting and consider them in relation to the approval criteria – voting to approve a protocol means you are satisfied all of the above criteria are met. Members are encouraged to ask questions and raise any concerns they may have regarding a given protocol during the meeting discussion. Each member brings a unique perspective and every one's thoughts are welcome. To facilitate timely reviews, members with significant concerns regarding a protocol should bring them to the attention of HRPP staff in the days preceding a meeting so that the investigators may be asked to address the concerns prior to the IRB's review.

IRB members are also responsible for reviewing amendments and requests for continuing review of ongoing protocols and ensuring these continue to meet the approval criteria, along with evaluating reports of potential non-compliance and unanticipated problems involving risks to subjects or others.

# IRB Membership Continued

The IRB cannot conduct reviews unless a majority of members are present at a meeting to vote, so IRB membership comes with a commitment to attend as many scheduled meetings as possible. If unable to attend a scheduled IRB meeting, members are encouraged to notify HRPP staff as early as possible so an alternate member can be invited to participate on their behalf.

Members must disclose any potential conflicting interests in protocols undergoing IRB review and recuse themselves during the final IRB deliberation and vote on any such protocols.

Members must also maintain the confidentiality of IRB meeting discussions, including protocol-related information and other member's comments. To foster open discourse and because the IRB sees sensitive information regarding non-compliance issues, members are asked not to share the content of IRB discussions in their department, with family, or any other outside settings.

In addition to possessing scientific, medical and professional expertise and awareness of community attitudes, members are also required to be knowledgeable of regulations governing research with human participants as well as relevant SJH policies and procedures and apply this knowledge during the review of protocols. Members receive training in the regulations via the Collaborative Institutional Training Initiative (CITI) upon appointment to the IRB and every two years thereafter. Members also review and have access to SJH policies and procedures via the HRPP website: <https://www.stjhs.org/center-for-clinical-research/human-research-protections-program>. Ongoing education is also provided during IRB meeting discussions and via monthly newsletters.

Members are encouraged to periodically review the IRB Member Manual for a refresher on the IRB review process, regulations, and a thorough rundown of IRB member responsibilities: <https://www.stjhs.org/documents/Clinical-Research/IRB-Member-Manual.pdf>

Questions regarding IRB membership, regulations, policies or procedures, etc. are encouraged and can be directed to Adam Pucci at [Adam.Pucci@stjoe.org](mailto:Adam.Pucci@stjoe.org).

**We thank all of our members for their time, effort,  
dedication and commitment to ensuring that the rights  
and welfare of human research participants across the St.  
Joseph Health system are protected!**