St. Joseph Health
Center for Clinical Research

IRB NEWSLETTER

July 2018

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

Important Updates

Membership Updates

This month we sadly say goodbye to several members and warmly welcome new ones.

Farewell, Dr. Wagman

After over 5 years of outstanding dedication and leadership for the protection of human subjects in research conducted across St. Joseph Health (SJH) as the Chair for Institutional Review Board (IRB) Committee #2, Lawrence Wagman, MD, will be ending his term effective August 30, 2018. He will be transitioning to Clinical Professor of Surgery and the Inland Empire Physician Regional Director for City of Hope's Community Cancer Programs. As many of you know, his leadership and expertise have been an invaluable contribution to the success of the SJH IRB and he will truly be missed. Please join us in extending best wishes on his next chapter at City of Hope.

Goodbye, Natalie Ramello & Brenda McMillin

Two members representing compliance have recently left the SJH IRBs. Natalie Ramello, a primary voting member of IRB #1, and alternate member of IRB #2, is departing to pursue other opportunities after nearly five years of service to the committee. Brenda McMillin, a primary voting member of IRB #2, has resigned due to competing personal commitments after nearly three years of service.

Natalie and Brenda were tremendous resources to the IRBs for matters related to healthcare compliance. Please join us in wishing them well and thanking them for their time and dedication to the SJH IRBs.

"Medicine is a science of uncertainty and an art of probability." — William Osler

Membership Updates Continued

Welcome New IRB Member – David Lane!

Dr. Lane is the System Chief Compliance Officer for Providence St. Joseph Health (PSJH). He holds a Ph.D. in Educational Psychology and after many years in education and research in this field, he has established an impressive resume serving in leadership positions in healthcare compliance at a variety of prominent institutions. At PSJH, Dr. Lane is responsible for oversight, development, and implementation of the health system's compliance plan. Dr. Lane's extensive background in healthcare compliance will be a valuable asset to the SJH IRBs in their mission to protect the rights and welfare of research participants in a manner consistent with regulatory requirements.

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

Hello Again, Cambria Haydon

Cambria has been serving as an alternate member of IRB #1 since 2013 and has graciously agreed to serve a primary voting member of that committee, as well as an alternate member of IRB #2. Cambria is a Regional Compliance Director for PSJH and her considerable expertise in healthcare compliance will continue to be beneficial to the committees in her more prominent role.

Please join us in our appreciation of Cambria taking on an expanded role in the SJH IRBs!

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.

HRPP/IRB Updates

Recent FDA Guidance

Including Adolescent Patients in Oncology Clinical Trials

In June, the Food and Drug Administration (FDA) issued draft guidance on the inclusion of adolescent patients in adult oncology clinical trials. The guidance notes that access to potentially effective therapies may be delayed for adolescents as their age often excludes them from new drug trials. FDA is recommending that the participation of adolescents be considered in disease- and target-appropriate oncology clinical trials to allow them earlier access to new treatments. The guidance offers criteria for including adolescent patients in different trial phases and offers recommendations for dosing and safety monitoring when adolescents are included in clinical trials. The guidance reminds IRBs that clinical trials involving adolescents must be found to meet the provisions of 21 CFR 50, subpart D, "Additional Safeguards for Children in Clinical Investigations" and concludes, "Enrollment of appropriately selected adolescents in relevant adult oncology trials with appropriate dose considerations and adequate safety monitoring is justified given the severe and life-threatening nature of their disease."

The guidance will serve as a reference to the IRB when reviewing oncology clinical trials involving adolescents in the future.

The FDA Draft Guidance Considerations for the Inclusion of Adolescent Patients in Adult Oncology Clinical Trials can be reviewed here: https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm609513.pdf.