Adventist HealthCare

Institutional Review Board Newsletter

June 2019

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Contact Us

- Elizabeth Carroll, IRB Administrator
- Maria Halaguena, IRB Coordinator
- 301- 315-3400
- IRB@AdventistHealthCare.com
- IRBManager Website
- Adventist HealthCare IRB Website
- Adventist HealthCare Research Policies

IRBManager Updates

Ongoing updates have been made to IRBManager since the system went live in April 2019. We appreciate your feedback as we strive to make IRBManager as comprehensive and user-friendly as possible. Updates include:

- Confirmation emails post-investigator signoff and post-IRB Office receipt
- Reminder emails for pending submissions
- Separated attestation emails to avoid confusion
- Clearly labelled automated emails

Please contact the IRB Office with any questions or if you would like to schedule a time to meet in-person or via Skype to review the IRBManager submission process.

NEW Biostatistician Resources

We have expert biostatistical resources to meet your research needs. This is fee for service coordinated through the IRB Office and charged to your respective department. Contact us for more information.

Single IRB Compliance with SMART IRB

Adventist HealthCare has joined SMART IRB, an NIH-funded platform designed to harmonize single IRB (sIRB) review, which is required for all NIH-funded multi-site studies and will be required for all federally funded multi-site studies in 2020. Almost 600 institutions currently participate in this initiative. If you plan to conduct human subjects research and are collaborating with a participating institution, please contact the IRB Office for next steps.

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2019 Research Conference Information

The 2019 Research Conference will be held on Friday, October 1 from 8:00 AM – 1:00 PM in the Sycamore/Birch Conference rooms at Shady Grove Medical Center.

Current investigators will showcase their research and Dr. Stephen Thomas, one of the nation's leading scholars in the effort to eliminate racial and ethnic health disparities, will discuss the role of research in health equity. A representative from the Food and Drug Administration will highlight Principal Investigator Responsibilities in Clinical Trials and a patient will share her story and discuss the importance of research.

To register or for more information, contact the IRB Office. We hope to see you there!

Policy Update: Use of the Short Form

Federal regulations require that informed consent information be presented in a language understandable to the subject. If the anticipated subject population is fluent in English and a potential non-English speaking subject is identified, the IRB may approve the use of a short form. Per revised policy, use of the short form is limited to 2 instances or 20% of the anticipated study enrollment, whichever is greater. Once this level is reached, then translation of the informed consent form will be required by the IRB.

Revised Consent Template Available

The revised Research Informed Consent Form Template is available on our website. Subject initials are no longer required on each page to reduce administrative burden while continuing to protect human subjects.

ROE: Department Chair Sign-off

ROE (Research Operations Evaluation) now requires department chair sign-off for all non-Center for Cardiac and Vascular Research studies prior to submission to ensure leadership transparency and engagement. The revised ROE checklist is located on our website.