Institutional Review Board Newsletter

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AHC IRB Website

2018 Annual Research Conference

The annual Adventist HealthCare Research Conference will be held on Friday, October 19, 2018 from 8:00 AM to 1:00 PM in the Sycamore/Birch conference room at Shady Grove Medical Center. Discussion topics include FDA common audit findings and prevention, research site best practices, and a parent's journey through pediatric organ donation and bio-specimen research.

The formal invitation will be sent out shortly. We hope to see you there!

Formalized IRB Reliance Approval Process

In accordance with the NIH Single IRB Review Policy effective January 25, 2018, the IRB Reliance Approval Process has been formalized. Revised documentation can be found on our website under IRB Submission Forms/IRB Reliance Approval Process and includes Principal Investigator Guidance, an abbreviated Site Protocol Application when relying on an outside reviewing IRB, the AHC Boilerplate Consent Language, and the Reliance Agreement template.

IRB Handbook transitioning into Research Policies

The IRB Handbook is transitioning into Adventist HealthCare Research policies. Please refer to the policies located in the Adventist HealthCare Policy Library on the intranet. For any policies that are not yet posted, please continue to refer to the IRB Handbook on our website.

Quality Improvement vs. Research Guidance

The IRB Office is frequently asked about the difference between human subjects research and Quality Improvement (QI) projects and would like to provide guidance on how to make this distinction. Please remember to contact the IRB Office to make the official research versus QI determination.

An activity is deemed human subjects research if it involves people or Protected Health Information, employs a systematic framework, and is intended to produce generalizable results for use outside of Adventist HealthCare.

QI projects, by contrast, focus on translating existing knowledge into clinical practice to improve the quality of a health care process, program, or system. QI projects apply existing knowledge to identify corrective actions and do not involve gathering private information or randomization. Some QI activities may qualify as research under the purview of the IRB if they meet the definition of human subjects research. Even though a QI project may not constitute human subjects research, its results may be used to inform future human subjects research.

Please contact the IRB Office with any questions or to make a human subjects research vs. QI project determination.

Updated Research Feasibility Checklist and Review Form

The Research Feasibility Checklist and Decision Form has been updated and can found on our website. Please utilize this document moving forward.

Revised Common Rule Implementation Delay

The effective date of the revised Common Rule has been delayed until July 19, 2018 to provide, “… regulated entities additional time to prepare to implement these revisions”.