Institutional Review Board Newsletter

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AHC IRB Website

In an effort to formalize information dissemination from the IRB office to the AHC research community, a newsletter will be sent out periodically highlighting any changes in regulations, policies, or procedures and providing helpful reminders and resources.

Creation of the IRB Email Address

The IRB now has its own email address to ensure timely response to inquiries. Please email IRB@adventisthealthcare.com with any questions, comments, or concerns. Outgoing correspondence will also be sent from IRB@adventisthealthcare.com.

2017 IRB Meeting Dates and Deadlines

The 2017 IRB Meeting Schedules/Submission Deadlines document can be found on our website under IRB Program Details - IRB Meeting Schedules/Submission Deadlines

Adventist HealthCare Federalwide Assurance

The Adventist HealthCare federalwide assurance number for the protection of human subjects now incorporates all of the entities (FWA00000969). Please update your regulatory files accordingly.

Updated Adventist HealthCare OHRP IRB Registration Number

Shady Grove Adventist IRB and Washington Adventist IRB merged earlier this year to become Adventist HealthCare IRB (IRB00001655). Please ensure that your regulatory documentation reflects this change.

Revised IRB Outcome Letter Templates

The AHC Site Protocol Application and Guidelines documents have been revised to be more concise and comprehensive. Please utilize the application when completing new study submissions. The revised site protocol application and guidelines documents can be

found on our website under IRB Handbook - Policies / Forms / Templates.

Approval Letter Sent Directly to Principal Investigators

As the Principal Investigator (PI) is ultimately responsible for the rights, safety, and welfare of research subjects, the PI will now be emailed directly with IRB approval letters and corresponding documentation. Additional requested contacts will be carbon copied on this correspondence. For more information about Principal Investigator responsibilities, please see FDA guidance at http://www.fda.gov/downloads/Drugs/.../Guidances/UCM187772.pdf.

Subject-Facing Study Materials (Beyond the Informed Consent Form) Will No Longer Receive an IRB Approval Stamp

In an effort to streamline our processes and reduce administrative burden, subject-facing IRB approved materials beyond from the informed consent form, such as recruitment materials and surveys, will no longer receive an IRB approval stamp.

Automated Continuing Review Expiration Notifications in IRBANA

To facilitate compliance with continuing review regulations, automatic notifications will be sent from IRBANA regarding notice of continuing review starting at 120 days prior to expiration.

Continuing review materials must be submitted at least 45 days prior to the expiration date. No further study activities are authorized once the study has expired, including long-term follow-up, long-term data collection, and data analysis.