Institutional Review Board Newsletter

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AHC IRB Website

Research Study Summary added to Informed Consent Template

To maintain compliance with the Common Rule revisions, a research study summary has been added to the Informed Consent Form Template and will be required for all new studies effective January 2018. IRB approved studies actively enrolling new subjects are also encouraged to include the summary in their consent form.

The research study summary is a one-page synopsis included on the first page of the informed consent form that details the study purpose, procedures, duration, risks, and benefits.

The language and text should be easy to comprehend and should supply important information that will help prospective subjects make an informed decision as to whether or not to participate. Other elements, such as compensation or confidentiality information, may be included while maintaining the one page limit.

2017 Adventist HealthCare Research Conference Venue Change

The annual Adventist HealthCare Research Conference will be held on Friday, Oct. 20, from 8 a.m. – 1 p.m. in the Ladew Conference Room at Behavioral Health, 14915 Broschart Road, Suite 100, Rockville, MD 20850.

Discussion topics include FDA audit readiness, Common Rule revisions, emerging device research in soft tissue repair, and research participant experiences.

RSVP early as limited seating is available. We hope to see you there!

CV/CITI Training Documentation available in IRBANA

Training documentation (CV and CITI expiration date) on file with the IRB Office is accessible under your account profile in IRBANA.

Consolidated ROE Feasibility Checklist and Decision Form

The Research Operations Feasibility Checklist and Decision Form have been consolidated. The combined document continues to be located on the AHC IRB home page.

Revised AHC IRB Website Content and Layout

Please note that changes have been made to the AHC IRB Website to improve and streamline content and layout.

Updated IRB Fee Schedule: Addition of Site Closure Fee

The IRB Fee Schedule has been updated to include a fee for site closures to offset administrative processing costs. This fee change will only apply to new industry-sponsored studies.

Revised IRB Forms

In addition to the Informed Consent Form Template, the AHC Site Protocol Application and Amendment Request Form have been updated. Please use these documents for future submissions.