IRB Newsletter

February 2019

University of Florida Institutional Review Board, http://irb.ufl.edu/
IRB-01: (352) 273-9600. ufirb-l@lists.ufl.edu
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IRB Policy and Guideline Changes

Due to the new Common Rule changes that went into effect on 01/21/2019, some of our policies and Investigator Guidelines have been updated.

Policies:

- HRP-001 - Definitions
- HRP-004 - Implementation of the 2018 Common Rule
- HRP-022 - Expiration Date of IRB Approvals
- HRP -190 - Discretionary Policy

Investigator Guidelines:

- Continuing Review
- Expedited Submissions
- Informed Consents
- Status Report

Please contact the IRB office at (352) 273-9600 if you have any questions.

Revision Tips

To decrease review time and to prevent the revision being returned to you, please include the following in your submission:

- **Question 1.0 of the Revision SmartForm**: Please provide an overview of all of the proposed changes to the protocol, consent forms, recruitment materials, study questionnaires, study staff, SmartForm pages, etc. and provide a list of any revised IRB-approved documents being attached to the modified study in myIRB.
  - We recommend that you specify the sections of the attachments (protocol, ICF, advertisements, etc.) and individual SmartForm pages that will be changed.
  - We also recommend that you ensure that every modified document is uploaded as a track changes version and has a date in the file name to identify the document as “new”.

- **Question 2.0 of the Revision SmartForm**: It is critically important to include the scientific, editorial or other justification/purpose for each change. Also, if the revision is due to newly identified risks or impact on prospect for benefit, you should discuss the plans (if any) for informing current and former subjects.
  - The justification should include the effect changes have on the likelihood for harm and prospects for benefit (if any) to subjects and any impact on risk-benefit assessment.
*Please note that providing the same answer for Q1.0 and Q2.0 does not appropriately provide the reviewers with the necessary information, and the submission will be returned to you.*

- **Adding or uploading documents (ICFs):** If you are modifying the current ICF, please click the *UPDATE* button to attach the revised version showing tracked changes. If you are adding a second form (i.e., patient vs. controls ICF), please click on the *ADD* button to attach the new form.

For additional revision guidance, please refer to pages 42-53 of the myIRB Researcher Manual.

### Annual myIRB Cleanup
Effective **February 21, 2019**, all new studies in the pre-submission state and created prior to January 1st 2018 will be administratively withdrawn from the system if not submitted. The administrative withdrawal is required for the following reasons:

- Studies sitting in pre-submission for over a year will not have any system updates incorporated within the SmartForms.
- These studies are included in metrics reporting.
- The study staff listed on the study may no longer be accurate.
- Attached documents such as protocols and ICFs may not be current which could result in regulatory non-compliance.

This annual cleanup only affects new study submissions at this time. Please note that unlike previous years, the copy study option is unavailable due to the recent Common Rule change upgrades to the system.

### New IRB-01 Staff
The IRB-01 office is excited to announce that Jamie Mayfield was promoted from an IRB-01 Editor to the UF IRB Educator on Friday, February 1st, 2019, and Margaret Hamer, who has worked for over 10 years as a clinical coordinator in the Department of Ophthalmology, will start on Friday, February 22, 2019 as a Research Regulatory Analyst III (QA/Pre-reviewer). Please join us in welcoming these ladies to the IRB!

### Education
**UF IRB Brown Bag Series**
**Advertising through the CTSI Recruitment Center’s UF Studies Facebook page**

February 13th 2019, 12-1:00 P.M.
Shepard Broad Building, room 104

**Presented by**
Deaven Hough, CTSI Communications Specialist

**Program Description**
1. Providing a deeper look at using UF Studies to advertise and if you would benefit from social media Recruitment.
2. The process for using UF Studies.
3. Strategies for creating Facebook advertising plans.
4. Launching and monitoring a Facebook ad campaign.
5. Additional recruitment methods to optimize enrollment.

For additional information, or to RSVP, contact Jamie Mayfield at 352-273-6093 or e-mail jmayfield@ufl.edu.