A myIRB CONVERSION GUIDE

1. Converting the existing paper study in myIRB is mandatory for actively accruing projects: If accrual is slow or you don’t think that you can complete the research study, then submit a study closure.

2. All studies except for retrospective chart reviews; studies in longitudinal status; studies closed to enrollment, no interventions; studies in data analysis only; and studies anticipated to close in the upcoming year do not need to be converted at this time. If you have questions, please contact the IRB-01 office at (352) 273-9600.

3. It is highly recommended that you start the conversion process 45-90 days before study expiration to prevent the existing paper study from expiring. Before you begin, please review the conversion instructions on the IRB-01 website at http://irb.ufl.edu/irb01/forms/converting-paper-studies-to-myirb.html

4. The myIRB conversion study will be an electronic version of the existing paper study as it is currently being run. It will be reviewed as a new study and may need to be brought up-to-date to IRB-01’s current acceptability standards. Once you create the study in myIRB please remember the following:

   - The new study will need to account for changes in staff, study site, current procedures, etc.; however, this is not a revision. Please do not attach a paper revision form and do not submit tracked change versions of your protocol and ICF.

   - Please attach clean, unstamped versions of your recruitment materials and ICFs as MS Word documents so they may receive an approval stamp for the myIRB conversion study. Please do not attach forms that were approved for the existing paper study or indicate that you will use recruitment materials previously approved for the existing study on the Recruitment Methods SmartForm.

   - Additional documents such as phone scripts and a Waiver of Documentation of Informed Consent to collect PHI during a phone screen, etc. may be needed.

   - Updated ancillary reviews from RAC, HURRC, and COI may be also be required.

5. After creating the new study in myIRB, Investigators MUST do the following:
• Indicate that the submission is a conversion on the *Legacy Determination* SmartForm.

• Provide the correct existing paper study # in Q1.0 of the *Legacy Paper Conversion* SmartForm.

• Appropriately indicate what is being submitted (i.e., same protocol, without changes; main study separated from a bank; making protocol and/or administrative changes; etc.)

• If you make protocol and/or administrative changes, please describe them in Q2.1 of the *Legacy Paper Conversion* SmartForm.

• Please attach the appropriate, completed and signed Continuing Review Report for the study (i.e., Tissue/Data Bank CR for banking-only studies). Please do not attach the IRB approval letter for last year’s continuing review.

• Please attach the cumulative AE and deviation tracking logs with all previously reported events logged on the tables, the last signed ICF with the subject’s name redacted, publications, and DSMB report.

• Submit the study for review. Deadlines will still apply for Full Board studies.

• Email notifications will be sent to the PI (and Coordinator) if changes are needed.

• Once approved, the approval letter will indicate approval for the myIRB study AND indicate the paper study has been converted. All future submissions MUST be submitted in myIRB.

*NOTE: Revisions in paper will not be accepted by the IRB office while the conversion is in process.*

1. Effective in February 2017 (an exact date will be provided in the January 2017 newsletter), all new studies in the pre-submission state and created prior to January 1st 2016 will be administratively withdrawn from the system. 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 initially added to the study may no longer be affiliated with UF.
   • The attached protocol and consents may not be current which will result in regulatory non-compliance.

This clean-up will occur annually. No other project types will be affected at this time.

2. Please note that the IRB receives many calls asking about training statuses for study staff to determine myIRB registration status. Please try adding the relevant person to a study (this might require creating a new study or using an existing study in pre-submission).
   • If the person’s name is not appearing on the drop-down menu in Q 6.0 of the *Study Title and Staff* SmartForm, the person is not registered in myIRB.
   • To check on an individual training status, please click on the hyperlinked name of the person added in Q 6.0 of the *Study Title and Staff* SmartForm and go to their myIRB registration page.
To check training status for all study staff, please go the **Researcher Training Summary** SmartForm.

3. Since July 2014, all studies involving human subject compensation are required to go through the Human Subject Payment (HSP) system. Unfortunately, the HSP system was not designed to update the study number once an existing paper study is converted to myIRB. As a result, researchers must submit a new request to HSP and get departmental approval. Once approved, you must then pick up all new cash, receipts, and debit cards – and then close-out the old one. Please contact the HSP Program by email at Treasury-HSP@admin.ufl.edu or by phone at (352) 392-9057 for more information.

**Holiday Humor**

“I FEEL LIKE NOBODY REALLY LIKES ME…”

“FRUITCAKE.”

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**Office Closed**

This is a friendly reminder that all UF IRB offices will be closed from 12/26/2016 – 1/2/2017. Normal business hours will resume on Tuesday, January 3rd.

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**IRB Education Opportunities**

**January Brown Bag Series**

Broad Building, Room 104
Noon – 1:30 PM
January 11, 2017

“CT.Gov and the Final Rule – An Update”
Elizabeh Piantadosi, BS, RN
Regulatory Research Analyst III
University of Florida
College of Medicine
Research Administration and Compliance

**Objectives:**

1. Describe registration requirements for clinical trials as of 2007
2. Describe NIH requirements on dissemination of NIH-funded clinical trials information.
3. Describe clarifications in federal regulations regarding registration of clinical trials to be effective in January 2017.
4. Describe UF ClinicalTrials.gov’s roles and responsibilities to the institution and the study teams and vice versa.
5. Describe tips for a successful submission within the protocol registration and results system (PRS)

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**To all of you, Happy Holidays and Best Wishes**