Adverse Event Reporting Policy Changes

IRB-01 approved to change the policy for reporting deaths at the 1/7/2015 meeting for Full Board Protocols.

- **Previous policy**: All local deaths and non-local deaths (study related or not) are considered Serious AND Unexpected and should be reported within five working days of discovery using the Serious and Unexpected AE Reporting Form.

- **New policy**: IRB-01 considers all local deaths and non-local deaths considered by the local PI or project Study Chair to be related or possibly related to study participation to be Serious AND Unexpected, even if it is a possible outcome of disease progression. All local deaths and non-local deaths considered related or possibly related on Full Board protocols must be reported within five working days of discovery, even if the PI considers the local death to be unrelated to the study. A non-local death considered to be unrelated can be reported at the time of continuing review on the Cumulative AE Tracking Log.

- The IRB-01 Policy & Procedures Manual, the Definitions for Adverse Event (AE) Reporting, the Adverse Event Evaluation & Reporting Guide, and the Serious and Unexpected AE Reporting Form will be appropriately updated and uploaded onto the IRB-01 website soon.

Revising ICF Attachments in myIRB

- Within the ‘Edit Modified Study’, click on the ‘Upload Informed Consent Documents’ smart form.

- Upload the ICF attachment, save it to your computer, make strike-through/underline changes and save the document.

- Go back to ‘Edit Modified Study’, click on the ‘Upload Informed Consent Documents’ smart form and click the UPDATE button to attach the revised, track changed document (a clean copy is not required; the submission will be sent back by office staff if a tracked version is not attached).

- Click the ADD button if you are adding an entirely different ICF.

- **DO NOT DELETE** your ICF in a revision **UNLESS** you attached your document incorrectly (e.g., attached an advertisement instead of an ICF) and want to correct and upload again; if you click DELETE before you upload and UPDATE a revised ICF, the ICF version you want to revise will disappear from the document history.

HIPAA for Researchers Training

The beginning of a new year means it is time to renew the “HIPAA for Researchers Training”. This training must be renewed annually. ALL individuals involved in research are required to update this training in the myUFL portal (log into myUFL > My Self Service > Training and Development > myTraining link) before it expires on February 28, 2015.

- Please note expiration of this training will prevent you from being able to “Agree to Participate” and submit a study in myIRB EVEN if you have previously done so.
IRB Education Opportunities

Brown Bags for February and March 2015 TBD.