From the Assistant Director:

Happy New Year everyone! 2016 was a year of a lot of changes within the IRB office and for researchers submitting to the IRB Office. 2017 promises to keep the changes going starting with mandatory conversion of eligible paper studies in to myIRB, getting all UF IRBs fully integrated in myIRB, applying for AAHRPP accreditation, implementation of GCP training, and last but not least Single IRB requests.

I want to thank the research community for enduring the changes as they come, as challenging as they are for us; I recognize that these changes can be equally as challenging for you. My hope is for all of us to continue to work together, using your feedback to modify, tweak, and edit as we go. I will never forget to acknowledge the great IRB team I work with. I have a great deal of appreciation and gratitude for the staff in the IRB and IT development Offices for their help, support, and commitment toward implementing the changes we’ve had, if it weren’t for them, none of this would be possible.

We are looking forward to a productive 2017, and as always, we are here to assist with your research needs.

With sincere appreciation,
Sherri Mizrahy

1. As mentioned in last month’s newsletter, all new studies in the pre-submission state that were created prior to January 1st 2016 will be administratively withdrawn from the system effective February 16, 2017. This clean-up occurs annually. No other project types will be affected at this time.

Once studies are administratively withdrawn they will disappear from the system; however, you can copy the study if you intend to come back to it. You must copy the study PRIOR to February 16! Please refer to page 53 of the myIRB Researcher Manual for more information.

2. On December 21, 2016, IRB-01 updated the default informed consent Costs and Subject Injury language to be used for studies that are NOT reviewed by the Research Administration and Compliance (RAC) Office.

To see the new default language, please go to http://irb.ufl.edu/irb01/forms/forms6.html and scroll/click on:
**“Question 14. If you choose to take part in this study, will it cost you anything?”** (Costs Language)

**“Question 16. What if you are injured because of the study?”** (Subject Injury Language)

For any study RAC does review, the RAC office will continue to provide Costs and Subject Injury language for Questions 14 & 16 via the RAC Financial Language Assessment (FLA).

*Reminder*: If a RAC FLA has been issued for a study, the study team must ensure that the final approved consent has the RAC FLA language inserted into Questions 14 & 16.*

**Requested Review Type Reminder**

When submitting a study to access existing data/medical records or specimens, please select Retrospective Data/Chart Review as the requested review type in myIRB rather than selecting a request for Exempt or Expedited review. Yes, a retrospective data/specimen review can be reviewed as exempt or expedited; however, this determination is made based on your responses and branching of questions within the submission. Please refer to the Selecting the Requested Review Type link for more information.

**HIPAA for Researchers Training** is due to expire on 2/28/2017. Please renew your training prior to the expiration date to avoid the crisis of not being able to submit your study. New study submissions and revisions to add study staff can only be submitted if all study staff have “Agreed to Participate”. This activity can only be completed if all of the IRB-01 mandatory training is up-to-date.

**IRB Education Opportunities**

**February Brown Bag Series**

Broad Building, Room 104
Noon – 1:30 PM
February 8, 2017

**Single IRB Review: UF’s Process**

Sherri Mizrahy RN, MSN, Assistant Director, IRBs

**Objectives:**

Upon completion of this activity, participants should be able to:

- differentiate between Ceded review, IRB of Record, Overall PI, site PI
- identify policies and procedures to request UF IRB be the IRB of Record or Cede Review to another IRB
- describe the role of the PI and coordinator when UF is the IRB of record
- describe the role of PI and coordinator when UF is ceding review to another IRB
- differentiate between SUS (State University System), OneFlorida, and single IRBs

**RSVP:** Ivana Simic, IRB Educator

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**Thank you for your patience**