Happy Holidays Everyone! I would like to take this opportunity to introduce you to the UF IRB Quality Assurance Program. There are two coordinators, Allison Faunce and Sherri Mizrahy, whose responsibilities are to assess the research activities conducted through UF IRB-01, IRB-02, and IRB-03. We accomplish this through conducting random visits to researchers to review the research records, or we may be asked to investigate reports of significant non-compliance, or a researcher (or a member of the study team) may ask us to come out and help them prepare for an upcoming (FDA or sponsor) audit. We also assess how each of the IRBs is complying with the regulations.

Both Allison and I have been in our positions for over 2 years now. We have both conducted a number of random and for cause audits, and through compiling the findings for our administrators, there are some common findings. One of our goals for the coming year is to develop some educational presentations designed to help researchers stay within compliance after they have received IRB approval and are enrolling subjects, and these will be incorporated into the IRB Brown Bag lunch presentations. Another goal of ours is to hopefully be more visible to researchers and their study teams so that they will feel comfortable contacting us with questions, concerns or issues before they become major violations or safety concerns.

Allison and I look forward to working with you and hope that you will see the UF QA Program for more than just “auditors”, the QA Program should be seen as a resource for the research team in order to conduct research projects in accordance with the regulations and GCP (Good Clinical Practice) guidelines. The end result is subject protection, subject safety, and sound scientific outcomes which is what the University of Florida strives for through its research community. Please feel free to contact Allison or I with any questions or concerns you may have. At some point during 2013 and the years to come we may be contacting you to see how you are doing.

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Upcoming Educational Events

Sara Jo Nixon, Ph.D., IRB-01 Board Member and University of Florida Researcher will present the January 2013 Brown Bag. This will occur on the 16 January 2013 from noon until 1:30 p.m. in room 104 of the Broad Building.

Lisa Demanual from the VA will be presenting the February 2013 Brown Bag. The location and time are the same as January Brown Bag.

If there is a topic that you would like to see presented at an upcoming Brown Bag or would like to suggest a speaker, please send an e-mail to tiffany.danielle@ufl.edu. I would love to hear from you!

Upcoming Changes

IRB-01 will be accepting full Board and proposed new studies involving Banking via myIRB. Currently, Exempt, Expedited (not involving Banking), and Non-Human studies must be submitted via my IRB.

Of Interest.....

Rebecca Richie, IRB/CTSI Coordinator, is available to assist with proposed new studies. She can be reached at (352) 273-9603 or rlrichie@ufl.edu.

IRB forms frequently change. Always check the IRB website for additional information and updated forms at www.irb.ufl.edu.

Web based submission tracking is available at: http://irb.ufl.edu/webtrack.

IRB Training is NOW Mandatory!

Effective January 7, 2013, the IRB education requirements must be met in order for a protocol to be reviewed by IRB investigators, sub-investigators, research coordinators and any other study staff involved in the conduct of a human subject research study (i.e.: those previously listed in Addendum A).

Additional information is available at http://irb.ufl.edu/irb01/news.htm#training.