Research Protocol Template Tips:

You may use the sponsor’s Protocol or the CTSI Protocol, if available. However, if you need to write your own Protocol please go to the IRB-01 website for the Protocol Template which is found at http://irb.ufl.edu/docs/frm-prot.doc. You may also find a sample Protocol with helpful information to consider when writing your Protocol at http://irb.ufl.edu/docs/frm-prothiddentext.pdf. Protocol template guidelines are available at http://irb.ufl.edu/docs/prot%20template%20guidelines%20v03.01.04.doc. The contents (including the title) of the Protocol must be consistent with your SmartForm responses, Consent document, flyers, advertisements, and any other study documents.

Once the study has been approved and enrollment begins it is common to find that things may not flow or work as well as anticipated. You may need to:

1. Re-review the Protocol and other study documents
2. Submit a revision to the IRB for changes that need to be made.

Remember your Protocol is telling the IRB how you are conducting your study. Any changes you make in study conduct without IRB approval is considered a deviation and the consequences may be significant.

The Boot Camp is back! Mark your calendars now! It will be held June 13, 2014 from noon – 3 p.m. in room C1-11 of the Communicore Building. I will be reviewing the different types of proposed new studies, how to submit a proposed new study in myIRB, how to submit a revision is myIRB, how to submit a reportable event in myIRB, how to close/renew a study in myIRB, and how to respond to IRB correspondence.

Please RSVP to tiffany.danielle@ufl.edu by June 11, 2014. There is limited seating.

The May Brown Bag will be presented by Dr. Cathy Striley. Details will be forthcoming via the listserv.