Institutional Review Boards' Monthly Newsletter

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Urgent Change to Studies Involving Banking

The Privacy Office and IRB have determined that our Banking Consent and storage of tissue Informed Consent addendum need to be revised to better comply with the HITECH ACT (a recent update to the HIPAA rule). In particular, after March 26th 2013 HITECH requires research Consent Forms to detail that researchers could potentially bill secondary researchers who receive banked data/tissue in order to recover their costs. As a result we have revised our banking consent form templates to include appropriate language. The language that has been added is as follows:

Your <tissue/data/tissue and data, whichever is appropriate> may be shared with other research centers or private companies, in which case the University of Florida may charge the research center or private company a fee in order to recover the University of Florida’s costs of sharing your <tissue/data/tissue and data>.

Even if you do not anticipate sharing your banked tissue or data in the future, ALL existing studies that meet the following two conditions MUST submit a revision by June 15th, 2013 to update their Informed Consent Forms into the current format: The two conditions are that the existing study is (1) a tissue and/or data bank and (2) you obtain Informed Consent from subjects either as a stand-alone consent form or the banking addendum.

In order to update your banking consent or banking addendum form, please submit a revision to delete certain language and add the new language above. The following is an example of what should be edited from the old banking informed consent template. The language that needs editing is right before the signature section:

<Name of PI or group> and/or <other named or class of individuals> will be allowed to collect, use and/or give out your tissue/data. They may give your tissue/data to other researchers whose research is approved by an Institutional Review Board (IRB) (An IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research). They may
also give your tissue/data to a study sponsor, the Food and Drug Administration, the Department of Health and Human Services, the Office of Human Research Protections, or other Government agencies. Your <tissue/data/tissue and data, whichever is appropriate> may be shared with other research centers or private companies, in which case the University of Florida may charge the research center or private company a fee in order to recover the university of Florida’s costs of sharing your <tissue/data/tissue and data>. There is a risk that information received by these authorized persons or agencies could then be passed on to others beyond your authorization and not covered by the law.

In general, presenting research results helps the career of a scientist. Therefore, the Principal Investigator may benefit if the results of this study are presented at scientific meetings or in scientific journals. Although your tissue or data will never be sold, it is possible that new treatments, medicines, therapies or products could be created from studies that use your tissue or data. If that happens, the Principal Investigator and the University of Florida could receive significant financial benefits. You will not be offered any payment or any other financial benefit.

This is an example of the edit for the banking addendum. The language that needs editing is currently right before the banking choices:

There will be no cost to you for any specimens collected and stored in the _____________ (type of specimen) specimen storage bank. Your tissue will be used only for research and will not be sold. Your <tissue/data/tissue and data, whichever is appropriate> may be shared with other research centers or private companies, in which case the University of Florida may charge the research center or private company a fee in order to recover the University of Florida’s costs of sharing your <tissue/data/tissue and data>. Some new products might be made because of the results of the research that uses your samples. These products might be sold sometime in the future, but, should this occur, you will not get paid.

For all new banking studies, you must download the new banking templates on the IRB website. The updated forms are available at the following links:

Banking consent template: Short ICF: Tissue/Data Banks conducted at UF/Shands Storage of tissue addendum: Storage of Tissue.
If you have any questions please contact the IRB at UFIRB-L@lists.ufl.edu. Please include the IRB number about the study in question.

**July full Board Meeting Date Changes**

Due to the July 4th holiday, IRB-01 has decided to reschedule the full Board meetings this July to the 2nd and 4th Wednesdays of the month. As a result the meeting dates and deadlines have changed. Please note this as you prepare to submit full Board items to IRB-01.

The updated meeting schedule and associated deadlines is available at: [http://irb.ufl.edu/irb01/deadlines.htm](http://irb.ufl.edu/irb01/deadlines.htm) (please be sure to refresh your browser. The old meeting dates are struck out on the current web page). Our current dates are:
Continuing Review Report and Deviation Table Change

IRB-01 has determined that the Cumulative Deviation Table submitted with Continuing Reviews needed to include not only minor deviations as it has in the past, but also major deviations. As a result the form has been updated to include all deviations along with a column to indicate if the deviation is major.

Please note that researchers will be required to include this new form with all Continuing Reviews submitted on or after June 1st, 2013.

Important note: IRB-01 is not applying this requirement retroactively, i.e. you do not have to list any major deviations that occurred prior to this requirement on June 1st, 2013. PIs must only include major deviations that occur on or after June 1st 2013 and after on the table. Minor deviations that occurred on or after January 1st, 2008 must still be listed.

The new form is available on our alphabetical listing of forms at: [http://irb.ufl.edu/irb01/forms1.htm](http://irb.ufl.edu/irb01/forms1.htm)

Upcoming Education!

Susan Blair, Privacy Officer, University of Florida, will be presenting the next Brown Bag on the HITECH changes to HIPAA affecting Human Subjects’ Research on the 12 June 2013 in room 104 of the Broad Building.

Please e-mail suggestions for future Brown Bags to tiffany.danielle@ufl.edu.