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IRB InvestiGATOR

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Use of Current Forms is a Must!

Change is constant at the IRB. We continually seek better ways to implement federal policy and thus improve human subjects protection efforts at the University of Florida. These improvements sometimes result in IRB policy changes and revision of IRB forms.

New IRB forms are now announced in the IRB InvestiGATOR. We also update the IRB website to make new forms immediately available to all UF investigators. The IRB expects all research staff to begin using the new forms once they are introduced and made available. Please check the IRB website before you begin working on an IRB submission (adverse events, continuing reviews, new projects, and revisions). Make sure that you download the most recent version of the appropriate IRB form(s). There will come a time in the near future when the IRB will refuse to review material that is not submitted on the most recently created forms.

Match Grant Titles with Project Titles

Protocol titles and grant titles need to be the same in order for the Division of Sponsored Research (DSR) to determine that grant activities have IRB approval. DSR staff access the IRB database to verify IRB approval and use the grant title as a point of reference. Keep this in mind when choosing a title for your grant or protocol. When titles are different, one or the other will have to be revised to accommodate the disparity. Plan ahead to avoid potential funding problems and administrative delays.

IRB Education Opportunities

UF Policy on Tissue Storage & Tissue Banking

December 13, 2001

Please call 846-1494 to register.

When Investigators Leave UF

Any IRB project associated with a Principal Investigator (PI) who has left the University of Florida **cannot** continue without modification. These projects must be closed or a new PI must be assigned to take full responsibility for the project and the subjects enrolled in the project. If the study cannot be closed because of safety issues related to participant involvement, it is mandatory that a local, affiliated investigator be named as PI. The IRB considers a change in PI to be a *major revision*, usually requiring a full Board review before the change can be officially implemented.

A change in sub-investigators must also be reported to the IRB. It is the responsibility of the PI to notify the IRB when a sub-investigator is dropped from a study and when a new sub-investigator joins an IRB-approved project. Sub-investigator changes are considered *minor revisions*, but must also be approved before the change can be implemented.

Update on Continuing Review Policy Changes

Last month the IRB InvestiGATOR informed the research community about a new Continuing Review (CR) policy involving the inclusion of Informed Consent Forms (clean and signed) with every CR submission regardless of study status.

To further assure the protection of human subjects, **all** studies undergoing CR must include the Adverse Event Table – whether adverse events have occurred during the review period or not. Simply attach the Adverse Event Table to your CR submission and check the box that indicates “No Adverse Events Have Occurred.” In this way, the IRB (1) can be certain that no adverse events have occurred during the previous approval period and (2) can review adverse events from previous reporting periods.

Please distribute and post the IRB InvestiGATOR for those without access to the publication.