



## TIPS ON TOPICS

The IRB Office has a new Location. We are now located at 3702 Spectrum Blvd., UTA Suite 155. Our mailing address remains the same.

USF IRB Consents and Research Authorizations can now be combined. See our website for the revised template. More about this in our next issue.

Check the IRB Website for the new IRB application forms and consent/assent templates.

## Special points of interest:

- A glossary of terms is under development that will assist research personnel in defining technical, medical and regulatory terms to use in informed consent documents. If you have suggestions for words or definitions you would like to see included in this glossary, please contact Brenda Best at 813-974-9343.

## FDA-Prompted IRB Changes Impact Principal Investigators

USF IRB recently underwent a Food and Drug Administration Site Visit. During this visit, a number of recommendations were made by the FDA Inspector.

Effective immediately are some of the changes to IRB policies and procedures that will directly impact Principal Investigators conducting human research:

- Principal Investigators now have **30 days** in which to respond to requests from the IRB. In some cases that time may be reduced, based on the impact of that request on the well-being of research participants,

The reason this recommendation is being implemented is that IRBs make requests based on participant safety and rights. If the IRB believes that a change or additional information is necessary to ensure

participant well-being, it is reasonable that the change needs to be implemented as quickly as possible.

- Failure to submit an annual progress report (which includes Final Reviews) will result in the suspension of the Principal Investigator's ability to submit any new applications for consideration by the IRB.

The reason this recommendation is being implemented is that the IRB is required by federal regulations to review research at an interval appropriate to the level of risk of the research but not less frequently than once every 365 days. Progress reports allow the IRB to evaluate whether research participants are being adequately protected and that all available information which might impact their willingness to continue participation has been provided to them in a

timely fashion. The Principal Investigator is responsible for requesting continuing IRB approval at a frequency determined by the IRB. Should that approval expire, the research and all procedures associated with that research must cease immediately.

The Division of Research Integrity and Compliance send reminder notices to PI's to ensure that there is appropriate time for the PI to complete a Continuation or Final Review Report. This information must be reviewed by the IRB regardless of whether the period since last IRB review was the first year of a study or the last.

To help investigators realize the importance of submitting this information, even in the last period of the research, the Continuation Review Report and Final Review Report will be combined and renamed the **IRB Progress Report Form**.

## Principal Investigators Signature on IRB Submissions

The recent FDA Inspection of USF IRB records revealed that the IRB was reviewing materials that had been submitted without Principal Investigator's (PIs) signatures.

FDA questioned how the USF IRBs could be sure that the PI was aware of the information in the submission if there was no signature from the PI attesting to the validity of that infor-

mation. The USF IRB felt that this was a valid concern. As a result, effective immediately, all submissions to the IRB will require the submission be presented under the signature of the Principal Investigator. Electronic submissions or responses to the IRB must be presented from the PI's e-mail address.

Certainly, research personnel

can continue to process and prepare IRB submissions, However, those submissions will not be accepted unless the Principal Investigator signs the documents.

This requirement includes PI responses and submissions of initial reviews, modification requests, IRB Progress Reports and Information reports.