Continuing Review

December 2018

Background:

Continuing review of research must be substantive and meaningful. In accordance with HHS regulations at 45 CFR 46.109(e), an IRB shall conduct continuing review of research requiring review by the convened IRB at intervals appropriate to the degree of risk, not less than once per year. Therefore, if research was initially approved by the convened Board, continuing review will normally be considered by the convened Board.

For minimal risk protocols approved under and “Expedited” category, in most instances the IRB will not require continuing review, but instead will require an every 3 year Status Report (see Investigator Guideline on Status Report.”

The IRB is responsible for conducting continuing review of ongoing research to ensure that the rights and welfare of human subjects are protected and to review the progress of the entire study. Protocols must continue to have ongoing IRB approval as long as the research continues to involve human subjects, even when research is permanently closed to the enrollment of new subjects, all subjects have completed all research-related interventions and only long term follow-up is being conducted or the only remaining activity is limited to data analysis of personally identifiable information.

1. Q: How often is a continuing review needed?

In compliance with the federal regulations, the UF IRB conducts continuing review of research at intervals appropriate to the degree of risk, but not less than once per year for expedited and full board studies. The continuing review date is calculated from the date that the convened IRB or Executive Reviewer (if reviewed under expedited procedures) approved the protocol or approved the protocol with explicit changes for the duration (e.g. 6 or 12 months) approved by the Board. In accordance with regulatory guidance, continuing reviews that are approved within 30 days before the prior IRB approval period expires may retain the anniversary date as the date by which the next continuing review must occur.

2. Q: Can the approval date be extended?

The regulations make no provision for any grace period extending the conduct of research beyond the expiration date of IRB approval. Therefore, continuing review and re-approval of research must occur on or before the date when IRB approval expires.

Investigators are required to submit a Continuing Review/Study Closure Report (CRR) on all Expedited and Full Board projects prior to the expiration date, even if the study is completed or the investigator has no intention of continuing the project. The “expiration date” that appears on correspondence from the IRB (e.g. approval and re-approval letters, expiration notices and expiration letter) is the first date that the research is no longer approved.

3. Q: Does the IRB notify investigators when a continuing review is due?

It is the Principal Investigator's responsibility to make sure that continuing reviews are submitted to the Institutional Review Board (IRB) for each active Expedited or Full Board protocol. It is strongly encourage that investigators submit the continuing review 6 weeks prior to the expiration date to avoid having the study expire.
As a service to Investigators, email notifications generated from myIRB at 90-, 45-, and 7 days prior to a study’s expiration. Another notification is sent on the day the study has expired. These notifications are tracked in the history log for the study, and the system lists all study personnel who were sent the notification.

4. **Q: What is required when submitting a Continuing Review?**

The investigator will be asked to upload the following documents as part of the submission of the continuing review: cumulative adverse event table, cumulative deviation tracking log, last signed informed consent (the last 3 signed consents for IRB-03) with subject/LAR name redacted, and any other information including, but not limited to Audit Reports, publications or meeting proceedings, and/or any other new findings/publications or information that relate to the risk/benefit ratio of the study should be submitted.

5. **Q: What happens if your study expires?**

If IRB approval expires, research activities including (1) the collection, use, or reporting of any data; (2) the performance of any study interventions, unless the IRB finds that it is in the best interests of individual subjects to continue participating in research interventions or interactions; (3) the enrollment or screening of any new subjects; and/or (4) receipt of any study funding must stop.

To determine if study subjects may continue receiving study interventions, the IRB Chair or designee, with the assistance of the investigator, will determine if the protocol is a therapeutic study, if any subjects are still undergoing therapeutic study interventions, and if there is a perceived risk to subjects if those therapeutic study interventions are stopped. The IRB Chair or designee will decide if those therapeutic study interventions may continue on those subjects involved. If the study is being conducted at the VAMC, the NF/SG Chief of Staff will be consulted. A decision must be made by the IRB Chair or designee within 2 working days.

There is no grace period extending approval for the conduct of research beyond the expiration date. Once a project expires, IRB review and re-approval must occur before re-initiation of research occurs. The Principal Investigator is given an additional 30 days from the expiration date to submit the Continuing Review/Study Closure Report. For any project that is allowed to expire and for which a Continuing Review or Study Closure is not received within 30 days of expiration, the project is permanently expired. To conduct further research on a project that has permanently expired, the PI must re-submit the project as a new study.

6. **Q: If my study was approved by full board will it always stay as a full board review?**

No. The IRB will move a protocol to “Expedited Review” status, based on information provided by the Principal Investigator who indicates that recruitment is complete and that all research activities have been completed on all study subjects, and only follow-up activities remain. Once under “Expedited Review” the protocol will no longer require continuing review unless the protocol is under FDA oversight or if the IRB otherwise requires a continuing review.

If the PI wishes to restart enrollment or initiate study related activities, then a revision must be submitted to the IRB to request study enrollment and provide the reason(s) for re-activating the research protocol. If the study was a full board study, the revision must be reviewed by the Full Board. The re-approval date for the revived research protocol will be determined by the Executive reviewer or Full Board, but will not exceed one year.