3.11 Possible IRB Actions

The IRB or reviewer(s) may arrive at the following decisions:

- Approval (or “Approve” or “Approved”) – see Section 3.10.1;
- Deferred with Minor Modifications—see Section 3.10.2;
- Deferred with Major Modifications—see Section 3.10.3;
- Disapproval (or (“Disapprove” or “Disapproved”)—see Section 3.10.4;
- Approval in Principal—see Section 3.10.5;
- Suspension or Termination—see Section 3.11.1; and
- Investigator Hold—see Section 3.11.12.

The following Sections provide clarification with respect to each of these decision options.

3.11.1 Approval:

Approval – the study is approved as submitted.

Approved (or “Approved,” “Approval,” or “IRB Approval”): means the determination by the IRB that the investigation and Protocol, as submitted, has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and other institutional and Federal regulations. The Research may begin as of the IRB approval date. [DHHS 45 CFR §46.102(h); FDA 21 CFR §56.103(m)]. IRB Approval letters are generated by IRBNet.

NOTE: if there are any pending approvals from any other institutions or other research oversight committees, the research cannot commence until all such approvals have been obtained, and the PI is to provide to the Tulane IRB via IRBNet a copy of all approval letters as received. This includes Tulane Institutional Biosafety approval (when applicable), Tulane Radiation Safety Committee approval (when applicable), and any other committee approval required by the University. Language to this effect is included on approval letters, and the PI is to comply with the language on said approval letters.

3.11.2 Deferred with Minor Modifications:

3.11.2.1 Definitions

Deferred with Minor Modification: is a situation where the IRB cannot approve the Research as submitted or where the Proposal and/or Consent Form Templates (TU Forms 402; 403; and 407) require minor revisions (e.g., wording changes, with replacement language provided). For Protocols reviewed at a Convened IRB Meeting, the needed revisions are agreed upon at the IRB meeting. For Protocols submitted Expedited Review, the needed revisions are designated by the reviewer(s). None of the required modifications can be related to the regulatory criteria for approval. These revisions are presented to the PI for incorporation by simple concurrence. Revisions must be made exactly as designated by the IRB or reviewer(s).

In order to receive approval for a Protocol Deferred with Minor Modifications:

- For Protocols reviewed by the Convened IRB, the PI’s response is provided to the IRB Chair, and/or a designee of the IRB Chair for review. The reviewer(s) may approve the study upon receipt and approval of the revisions without further action by the IRB.
For Protocols initially submitted for Expedited Review, the PI’s response is provided to the IRB Chair and/or designee for re-review.

Approval of the Protocol application will not be granted and an approval letter will not be issued until all deficiencies, if any, are corrected to the satisfaction of the IRB or the reviewer(s).

The outcome of the IRB’s deliberations or reviewer(s) findings is communicated to the PI in writing. The PI may not proceed with the Research until receipt of notice of IRB/reviewer(s) approval of the Research.

The IRB’s determination concerning the revision will be documented in the minutes of the next regularly scheduled IRB meeting and in the study record.

IRB Deferred with Minor Modification letters are generated by IRBNet.

NOTE: For Full IRB review or Convened IRB review, the expiration date for the Protocol is calculated based on the date of the last Convened IRB Meeting and NOT on the final approval date.

3.11.3 Deferred with Major Modifications:

3.11.3.1 Definitions

Deferred with Major Modification: is a situation where the IRB cannot approve the Research as submitted because (1) the Protocol and/or Consent Form Templates (TU Forms 402; 403; and 407) require major modification or clarification; or (2) insufficient information is provided to adequately judge the Protocol application (e.g., the risks and benefits cannot be assessed with the information provided). IRB approval of the proposed Research must not occur until subsequent review of the material the PI submitted by the convened IRB or the expedited reviewer(s).

3.11.3.2 Policy

This IRB action is taken if major modification or clarification is required, or insufficient information is provided to adequately judge the Protocol application (e.g., the risks and benefits cannot be assessed with the information provided). IRB approval of the proposed Research must not occur until subsequent review of the material the PI submitted by the Convened IRB or the expedited reviewer(s).

For Proposals initially submitted for Convened IRB Review, in order to receive approval for a Protocol Deferred with Major Modifications, the Investigator’s response must be submitted for review at a subsequent, convened meeting of the IRB. The HRPO provides the IRB with the PI’s response, the revised Proposal and the previously submitted Proposal. The item is placed on the agenda for re-review at the next meeting.

IRB approval of the Proposal will not be granted and an approval letter will not be issued until all deficiencies, if any, are corrected to the satisfaction of the IRB or the reviewer(s).

The IRB’s determination concerning the subsequent amended Proposal will be documented in the minutes of the IRB meeting or in the study record. The outcome of the IRB’s deliberations will be communicated to the PI in writing through a letter via IRBNet.
3.11.3.3 Time Limit for Submitting Requested Changes for New Research Protocol Application Deferrals (Minor or Major Modifications)

NOTE: Failure to submit a response to IRB stipulated changes or inquiries related to deferred Protocols within 90 days of the IRB date of determination will result in administrative closure of the IRB file. The PI will receive notification of the closure of the IRB file, including an explanation for this action. An extension beyond 90 days may be granted by the IRB if sufficient cause is provided by the PI.

3.11.4 Disapproved

The IRB action of Disapproved means that it cannot approve the Protocol as written. The IRB has determined that the Research cannot (1) be conducted on Institutional or TUHC premises, or other facilities; (2) cannot involve University or TUHC patients; (3) be conducted on or by Institutional employees or Institutional Agents; and/or be conducted under the auspices of Tulane’s IRB. Written notice of Disapproval will be issued by the IRB through IRBNet.

3.11.5 Approved in Principle

**Approved in Principle** is IRB approval, as requested by a Sponsor, without the IRB having reviewed all of the study procedures and consent documents. [DHHS 45 CFR §46.118].

There are two circumstances in which the IRB may grant approval required by a sponsoring agency without having reviewed all of the study procedures and consent documents. [45 CFR §46.118] One is if study procedures are to be developed during the course of the Research, but Human Subject approval is required by the sponsoring agency. The other is if the involvement of Human Subjects depends on the outcomes of work with animal subjects. The IRB may then grant approval without having reviewed the undeveloped recruitment, consent, and intervention materials. However, if the Proposal is funded, the PI must submit such materials for approval at least 60 days before recruiting Human Subjects into the study, or into any pilot studies or pre-tests. Approval in Principle is granted to satisfy sponsoring agency requirements or to allow Investigators to have access to funding to begin aspects of the project that do not involve Human Subjects. Approval in Principle may be done via Expedited Review.