Notification of IRB Decisions

Investigators will be notified in writing by the IRB Chair of the IRB's decision of approval, disapproval, or requested revisions for all initial submissions, continuing reviews, revisions, and reactivations.

If the IRB requires revision(s) to a submission, the investigator will be notified in writing listing the revision(s) and a date for submission of the corrections for review The IRB will determine if the revisions may be approved by the IRB Chair on behalf of the board. Substantive revisions to the research plan, such as major changes to enrollment, inclusion/exclusion criteria, or scientific design may require full board review. These revisions should be completed and submitted within 30 days.

The investigator will be notified in writing of the IRB Chair's approval of the revisions or the request for additional revisions or clarifications. Once IRB-required revisions are complete, an approval letter to the investigator will be sent along with the approved consent document and Authorization to Release Health Information (HIPAA) form. The consent form and the authorization form will be stamped with the approval date, expiration date, and signature of the Human Protections Administrator (HPA). The investigator will be instructed that only these stamped documents that have been stamped are valid to use for consenting subjects.

The notification letter will include:

- the date of review and/or the date of the IRB meeting
- study materials reviewed
- if the review was full board, expedited, or exempt; or, if the research was determine to be not human subjects research
- the IRB decision or determination
- if revisions are required, a description of the required revisions and, if applicable, the basis for requiring the revisions
- if disapproved, the reasons for disapproval
- the process for questions or concerns regarding the IRB decision

If the IRB decides to disapprove a study, a statement for the reasons for disapproval will be included in the correspondence. The investigator may respond in writing to any decision and any responses will be reviewed by the IRB at the next convened meeting. The IRB decision letter will include a phone number for any questions.

The investigators will be notified in writing of the IRB's acknowledgement of terminations, terminations at site, protocol deviations, unanticipated problems, adverse events, and adverse events / unanticipated problems / protocol deviations requiring revisions to the protocol and/or informed consent. The sponsor of the research and any applicable institution administration may also be notified in writing conveying the decisions of the IRB. Investigators and required federal agencies (FDA and OHRP, when necessary) will be notified in writing by the IRB Chair of

terminations/suspensions of IRB approval, serious or recurring noncompliance, and serious unanticipated problems involving risks to subjects.

Notification of approval period and continuing review dates for full board and expedited studies (when applicable)

The investigator will be notified in writing of the approval of the research study with or without required IRB revisions. The start date of the approval period for full board studies will be the date of the IRB meeting in which the study was approved, if no revisions were required. For studies approved by the full board with required revisions, the approval date will be the date that the revisions were approved (either by the full board or the IRB Chair). The expiration date for studies with requested revisions will remain as 3 months, 6 months, or 1 year from the IRB meeting date in which the study was conditionally approved.

For other studies approved via expedited review for which continuing review is required and the rationale is documented, the approval date will be the date the IRB Chair approved the study on behalf of the IRB. This letter will also contain the deadline date that the research must be submitted for continuing review. For a study approved for one year, the study will expire on the one-year anniversary date on which the study was initially approved.

For subsequent continuing reviews, expedited or full board, the study must be reviewed and approved by the one-year anniversary date of the last approval. For studies approved for six months or three months, the continuing review date will be calculated from the date of the IRB meeting at which the study was approved. The continuing review deadline date for all studies will be included in correspondence from the IRB Chair.

The expiration date is the first date that the research study is not approved, (i. e., the first date outside the approval duration). For example, if a study is approved (either via expedited or full board review) on September 1 for one year, the study will expire on September 1 of the following year, and must be reviewed and approved no later than September 1 of that year. On September 2, the study will be outside the approval duration and the study no long has IRB approval.

As a courtesy, the HPA will also notify investigators via email three months in advance of any upcoming continuing review deadline date with a contact number for any questions or concerns. The investigator will also be reminded in the approval letter that no changes to the protocol may be implemented without prior IRB review and approval. The Research and Development Committee will also be notified of any approved research studies at their convened meetings.

Appealing an IRB decision

If an investigator wishes to appeal the IRB's decision to disapprove a submitted protocol, the investigator may petition the IRB in writing explaining:

a). which elements of the protocol have been amended,

b). which elements of the protocol the investigator feels were misunderstood by the IRB, and/or
c). interpretive errors the investigator feels were made by reviewers.
An IRB subcommittee appointed by the IRB Chair will review this petition and (a) uphold the decision of disapproval, (b) present the new information to the IRB with suggestions about interpretation and application, or (c) offer suggestions to the investigator of changes that might be made in the research or its documentation that would make it acceptable. This appointed subcommittee does not have the authority to reverse the decision of the IRB. The IRB will review the subcommittee's suggestions at the next convened meeting