Review of Adverse Events

Adverse Event Report Forms and Protocol Deviation Report Forms are reviewed by the IRB Chair, Vice Chair, or a designated IRB member. Anticipated Adverse Events, Protocol Deviations, and reports of Noncompliance will be reviewed by the IRB Chair or a designee of the Chair within 14 working days of receipt of the report. If it is determined that the event did not represent an unanticipated problem involving risks to participants or others, a letter of acknowledgement is sent to the PI, and the report is filed.

If an Adverse Event, Unanticipated Problem, or Noncompliance is serious, related and unanticipated, or continuing, the IRB Chair or designated IRB member(s) will review the report within 14 working days of receipt of the report, and determine whether the event requires review by the full board. All reports requiring full board review will be placed on the agenda for the next fully convened meeting of the IRB. If necessary, an emergency meeting may be called. IRB members will be provided with a copy of the report and all supporting documentation to review. Pending review by the full board, the IRB Chair and reviewing member(s) will determine whether immediate action, such as suspension of new enrollment or termination, is warranted.

The IRB votes on whether the event is an Unanticipated, Serious or Related Adverse Event or Protocol Deviation, or Serious or Continuing Noncompliance involving risks to participants or others, and the determination of the IRB is recorded in the minutes. If the IRB determines that an event is an Unanticipated Adverse Event involving risks to participants or others, the procedures outlined in the section of the Foundation’s IRB Policies and Procedures entitled “Reporting of IRB Findings to Federal Agencies” will be followed, and the IRB will consider taking the following actions:

1. No action;
2. Modification of the research protocol;
3. Modification of the information disclosed during the consent process;
4. Additional information provided to past participants;
5. Notification of current participants (required when such information may relate to participants’ willingness to continue to take part in the research);
6. Requirement that current participants re-consent to participation;
7. Modification of the continuing review schedule;
8. Monitoring of the research;
9. Monitoring of the consent;
10. Suspension or termination of the research;
If no action is required, a letter of acknowledgement will be sent to the PI, and a copy of the letter filed in the protocol file. If the IRB takes any actions or imposes any requirements, the actions and requirements are documented in the minutes and in a letter to the PI.

**Suspensions and Terminations**

A Suspension of previously approved research is defined as a temporary hold on any or all research activity associated with a study, or a permanent stop to some portion of a previously approve research activity. For example, a hold placed on additional recruitment pending clarification of an adverse event would be considered a suspension of approval. Suspended protocols remain open and require continuing review.

Termination of previously approved research is defined as a permanent withdrawal of study approval that requires all study related activity to cease.

In the event of an unanticipated problem, serious or continuing noncompliance, or a suspension or termination of approval, the IRB may require corrective or disciplinary action including, but not limited to, the following:

- a modification of the protocol or information disclosed in the informed consent document and process;
- information be provided to past participants;
- current participants be informed if the information may relate to their willingness to participate;
- re-consenting of currently enrolled participants;
- more frequent continuing review
- requiring additional education;
- barring an investigator from conducting human participant research.

**Suspension or Termination of IRB Approval**

The Chair, convened IRB, may suspend a study. The authority to suspend studies cannot be delegated to other individual members of the IRB, except the Vice Chair. The convened IRB may terminate a study.

Reasons for imposing a suspension or termination include, but are not limited to, learning of 1) previously unanticipated risks to participants, 2) findings of serious or continuing noncompliance, or 3) findings from the continuing review or internal monitoring process. The IRB or IO may also seek advice from other institutional areas (e.g., legal counsel) in determining whether to impose a suspension or termination of IRB approval. In addition, when imposing a suspension or termination, the IRB or IO will give consideration to the impact that the suspension or termination may have on participant safety and/or welfare. Consideration will include, but is not limited to:

- whether participation can be stopped safely;
• whether participants should be transferred to another physician for clinical care, if applicable;
• whether participants can be kept on study under the same PI;
• if kept on study under the same PI, whether additional monitoring is required;
• whether participants can be kept on study under another PI.

In the event of a suspension or termination of approval, the IRB or person imposing the suspension or termination will inform the investigator in writing. If immediate action is required, the person imposing the suspension or termination may give the directive verbally to the PI and the letter will follow. Letters to the PI should be sent within 14 working days of the effective date of suspension or termination. Such letters will include:

• the effective date of suspension or termination;
• if notification was initially done verbally the letter will reference the date of verbal notification;
• the reason for the suspension or termination;
• for suspension, identification of the research activity, in whole or in part, that must stop;
• any corrective action or clarification that must occur;
• if the reason for suspension may bear on the participant’s decision to continue participation, a directive that currently enrolled participants be informed of the suspension;
• for terminations, a directive that all currently enrolled participants be informed of the termination;
• if applicable, a directive of how to deal with any currently enrolled participants; and
• a direction to the PI regarding to whom to submit responses.

The person or board imposing the suspension or termination will send a copy of the letter to:

• IRB Chair and Vice Chair;
• The IO; and, if applicable
• Office for Sponsored Programs;

If an activity for which a suspension or termination has been imposed must continue, e.g., a research related treatment because it is in the best interest of the participant, the investigator must write a letter to the IRB Chair. The letter shall include:

• a justification as to why continuation is in the best interest of the participant;
• a request for approval for continuation of the specific activity either until the suspension is lifted or until alternate arrangements can be made for the participant;
• for terminations, confirmation that alternate arrangements are actively being sought and provide the anticipated time frame by which the arrangements should be finalized;
• confirmation that the investigator will inform participants that the study has been suspended or terminated but that permission for the activity has been obtained;
• confirmation that the investigator will direct participants to continue to report adverse events or unanticipated problems;
• confirmation that the investigator will continue to report all activity in accordance with policy.
Lifting a Suspension

Only the IRB Chair or Vice Chair can lift a suspension using either the expedited review process or full board review.

- that was imposed by the IO, providing the documentation noted above is received; or
- that was imposed by the convened board when the board specifically delegates to the chair the authority to lift the suspension;
- otherwise, the convened IRB will determine whether to lift a suspension.

The IRB will send written notification to the PI when the suspension is lifted. The letter will be prepared and reviewed by the Chair, or Vice Chair and sent out.