Suspension and Termination of Research

A suspension of research activity may occur in response to reports of possible non-compliance or new information regarding risk to participants. This guidance clarifies the applicability of reporting requirements for suspensions and terminations of previously approved non-exempt research activities.

Suspension

A suspension occurs when a temporary hold is placed on non-exempt research that has been previously approved so that no new participants can be enrolled, no research interventions may occur (unless necessary for the safety and well-being of the enrolled participants), and no follow-up can be conducted unless it is in the best interest of the participant and approved by the IRB.

The IRB or person, or other entity ordering the suspension must:

- Consider actions to protect the rights and welfare of currently enrolled participants,
- Consider whether procedures for withdrawal of enrolled participants take into account their rights and welfare (e.g., making arrangements for medical care outside of a research study, transfer to another researcher and continuation in the research under independent monitoring).
- Consider informing current participants of the suspension, and
- Report any adverse events or outcomes to the IRB; if applicable.

Termination

A termination is the withdrawal of IRB approval or requirement to end all previously approved non-exempt research activity permanently. No new participants may be enrolled and no additional research interventions can occur. A research protocol is terminated:

- When a corrective action plan approved by the IRB has not been implemented; or
- When the IRB determines that it is in the best interest of the research participants.

Reporting Requirements

When the IRB committee or the IRB Chair makes a determination to suspend or terminate a study, this action must be reported to the Institutional Official and OHRP, and if applicable, the VA and/or FDA.

Expirations of IRB approval, administrative holds and suspensions by a non-IRB entity (principal investigator, study sponsor, Institutional Official, AVPR, DSMB or other administrative group) do not need to be reported.