IRB SOP 505
Study Completion, Suspension or Termination

Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the procedures for study completion, closure or termination.

Scope

The SOP applies to all human research projects submitted to the IRB.

Definitions

Administrative Hold: An administrative hold is a voluntary action by an investigator to temporarily or permanently stop some or all approved research activities and are not considered suspensions or terminations. Protocols on administrative hold remain open and require continuing review.

Administrative Closure: This is an administrative status whereby a previously approved protocol's expiration date has passed and an investigator has not submitted a renewal, or the investigator has submitted a study closure request. The IRB assumes that no human subject

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- Transferring participants to another investigator
- Making arrangements for clinical care outside the research
- Allowing continuation of some research activities under the supervision of an independent monitor
- Requiring or permitting follow-up of participants for safety reasons
- Requiring unanticipated problems or outcomes to be reported to the IRB and the sponsor
- Notification of current participants
- Notification of former participants

8.0 Expiration of Approval Period

Once the approval period for a given study has expired prior to the renewal of approval by the IRB, it is considered a lapsed study and all research-related procedures must cease, except where doing so would jeopardize the welfare of the human subjects.

IRBNet generates a notice of expiration electronically to the investigator and all personnel with full access to the project, indicating that continuation of research studies is a violation of federal regulations, however if the subjects would be harmed by halting the activities permission must be obtained by the IRB to continue research study related activities.

If the Investigator fails to submit the materials for continuing review within two weeks following the expiration date, then the lapsed study will be classified as administratively expired. If the investigator submits the materials for continuing review within two weeks following the expiration date, the IRB will conduct continuing review (if applicable) and reactivate the protocol. This reactivation establishes a new approval period that is not retroactive to the prior date of expiration. If the investigator desires to continue a study that has lapsed for greater than two weeks, then the investigator must submit a new application for re-review by the IRB, and must receive IRB approval before resuming research under the protocol.

9.0 Reinstatement of a Project

To reinstate a project that has been suspended, the investigator must satisfactorily resolve any pending issues required by the IRB. To reinstate a project that has been terminated, the investigator must submit the project to the IRB as a new application and past issues must be resolved to the satisfaction of the IRB.

Regulated Documentation
21 CFR 56.113; 45 CFR 46.113

University Related Documents
IRB Study Closure Form (IRBNet Forms and Templates)

HISTORY

Effective Date:
Revisions: October, 2018