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Subject: Procedure for Continuing Review of Research by the Expedited Procedure

Procedure

Investigator Responsibilities

The Investigator:

* Endeavors to submit continuing review application materials at least 30 days prior to expiration date to avoid a lapse for protocol if it was determined by the IRB to undergo continuing review to enhance the protection of research subjects;
* Submits with the Investigator’s Progress Report one copy of the following materials, if applicable:
  + [FOR200](http://www.uab.edu/research/administration/offices/IRB/Documents/200%20-%20hsp.docx) Human Subjects Protocol (HSP) application updated with any changes.
  + Completed [FOR225](http://www.uab.edu/research/administration/offices/IRB/Documents/225%20-%20ipr.docx) Investigator’s Progress Report (IPR). If the research is complete (i.e., no subjects having interventions or follow-up, no data acquisition, management or analysis, all reports completed), mark IPR as final;
  + Current informed consent document(s)—not required if study is closed to enrollment;
  + Addendum informed consent document(s) for currently enrolled participants, if applicable
  + Revised informed consent document(s) with changes highlighted, if applicable;
  + A “clean” copy of the informed consent document(s) to receive IRB approval stamp;
  + Updated funding application, if applicable.
* Ceases all research activities including stopping new enrollment, recruitment, advertisements, procedures on current participants, and collection of identifiable private information if the IRB has not reviewed and approved the research by the expiration date; makes a written request to the IRB for research activities to continue following expiration of IRB approval if there is an overriding safety concern or ethical issue present such that it is in the best interests of individual participants to continue participating in research interventions and interactions
* Submits an Expedited Status Update (ESU) for protocols not requiring annual continuing review.

OIRB Responsibilities

Administrative Staff:

* Sends a notice to investigators at least 2 months prior to expiration date of approval of protocol to submit either continuing review application or an expedited status update (ESU);
* Receives workflow assignment;
* Prepares list of protocols approved through the expedited review procedure for convened IRB confirmation.

Review Staff:

* Reviews submission to determine applicability and category of research satisfied for expedited review;
* Reviews expedited status update (ESU) which excludes;
  + (expedited review category 8(b)) Where no subjects have been enrolled and no additional risks have been identified; and
  + (expedited review category 9) Where (i) the research is not being conducted under an investigational new drug application or investigational device exemption, (ii) categories two (2) through eight (8) of the OHRP Expedited Review Categories (1998) do not apply, and (iii) the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.
* Generates report to Conflict of Interest Review Board for review, if applicable;
* Checks investigators’ and research personnel training status, if applicable;
* Generates expedited approval form, if applicable;
* Issues new approval to principal investigator, if applicable.

IRB Responsibilities

IRB Chair or designated experienced IRB reviewer:

* Receives the following information, as applicable:
  + Investigator’s Progress Report;
  + Informed consent document(s), if applicable;
  + Summaries of reportable problems (including adverse events) for determination as to unanticipated problems involving increased risks to subjects or others;
  + Preliminary research findings;
  + Manuscripts;
  + Abstracts;
  + DSMB or other monitoring reports;
  + Progress reports to and from sponsors.
* Uses the Criteria for Approval Tool ([GUI311](file:///T:/Forms/Internal%20Forms%20&%20Checklists/311%20-%20checklist-OIRB-expedited-continuing.doc)) to determine whether the materials are acceptable to undergo review and perform substantive review in accordance with the criteria in 45 CFR 46.111 and Subpart D, if applicable; and 21 CFR 56.111 and Subpart D, if applicable; and any other funding agency regulations, as applicable.
* Verifies research meets applicability criteria and categories of research for expedited review;
* Determines if the research meets the criteria for expedited status update (ESU);
* Determines if criteria for approval are met according to 45 CFR 46.111 and 45 CFR 46 Subpart D if applicable, and 21 CFR 56.111 if applicable, and 21 CFR Subpart D if applicable;
* Documents rationale for overriding the presumption that study on the HHS Secretary’s expedited review list involves greater than minimal risk;
* Refers protocol to convened IRB if the research cannot be approved with or without modifications to secure approval.

**Approved on January 21, 2019, by:**

Ferdinand Urthaler, MD

IRB Chair

Denise Ball

OIRB Interim Director