UNIVERSITY OF Cincinnati

Human Research Protection Program Procedure

REVIEW OF CONTINUING REVIEW SUBMISSIONS BY THE INSTITUTIONAL REVIEW BOARD

DESCRIPTION

The IRB conducts continuing review of human subject research at intervals appropriate to the degree of risk, but not less than once per year according to federal regulations. Documentation for continuing review purposes may be requested from the Principal Investigator earlier than the scheduled interval at the discretion of the IRB. If continuing review and re-approval does not occur before the expiration date of IRB approval, all research-related activity must cease unless the IRB finds that it is in the best interests of individual subjects to continue participating in the research interventions or interactions.

Continuing review is allowed to stop only when:

- The research is permanently closed to the enrollment of new participants;
- All participants have completed all research-related interventions; and
- Collection and analysis of private identifiable information has been completed.

DEFINITIONS

- "Continuing review" is interchangeable with "progress report". Both terms refer to periodic review of human participant research. The review interval is determined by the IRB at the time of initial approval or continuing review re-approval. The expiration date is the first day the protocol is no longer considered an approved study by the IRB.

RESPONSIBILITY

It is the investigator's responsibility to submit required continuing review documentation far enough in advance of the IRB approval expiration date to allow substantive review by the IRB and resolution of any questions prior to the expiration date.
The investigator is also responsible for providing all documentation requested by the IRB for continuing review purposes.

- The HRPP staff are responsible for reviewing submitted documentation to assure completeness, requesting any missing or additional documentation from the researcher, and providing the documentation for review to the IRB Chair or designee and the IRB members (for full board review).
- IRB Chair or designee is responsible for providing IRB members adequate submission review training and ongoing guidance and for selecting a primary or secondary reviewer with relevant expertise to perform reviews and make necessary recommendations on approval decisions by the IRB. If a reviewer cannot be selected with relevant expertise to perform the

review, the IRB Chair or designee shall defer review to a consultant with the relevant expertise as necessary.

- The IRB Chair or designee and the HRPP staff are responsible to check each item on the agenda to determine whether a consultant is needed for additional expertise, such as scientific or scholarly expertise in a particular field, expertise regarding the local context or knowledge, or experience with working with vulnerable populations.
- The IRB Chair or primary and secondary reviewers are responsible for substantive review of the research with particular attention to adverse or unanticipated events and recent findings that may impact participants' willingness to continue in the research to assure approval criteria are met.
- The IRB members are responsible for reviewing all provided materials in enough depth to be prepared to discuss the information at the convened meeting.
- The IRB Director or designee is responsible for establishing and implementing processes for making research renewal decisions.
- The IRB and HRPP staffs are responsible for the timely and thorough review of the continuing review submission, communicating to the Investigator any needed changes, as well as reviewing and taking action prior to the approval expiration date.
- The Investigator is responsible for submitting a copy of the last informed consent documents (ICDs) consent form/assent form at the time of continuing review.
- The IRB is responsible for verifying that the correct ICDs are being used.

PROCESS

Continuing review of research is conducted at intervals appropriate to the degree of risk to the participant, but not less than once per year. Research must be reviewed and approved on or before the one year anniversary date of the previous IRB review date.

The anniversary date is determined at the initial review depending on the level of risk. At the time of approval, the research project is given an approval-through date. Investigators or qualified designees are required to submit continuing review records before the expiration date of the study or as specified by the IRB, but at least once per year.

When the Progress Report is received, it is reviewed for completeness and type of review. If additional information is needed by the IRB Chair or designee or IRB members, is requested and obtained from the investigator or other source.
Documentation required by the IRB provides sufficient information for the IRB Chair or designee and the IRB members (for full board review) to determine that the research still meets all criteria for approval. Consent forms signed by participants, with the participant's name masked to protect confidentiality, are required to document the use of the approved version.

Adverse event and unanticipated problem reports and interim findings (for example, reports generated by the data safety monitoring board/committee, adverse events, current literature, and other sources) are required to assess whether or not the current risk/benefit ratio is still acceptable, whether or not new information needs to be conveyed to participants, and/or if a segment of the population may be bearing an undue burden of research risk or being denied access to promising therapy.

EXPIRATION OF IRB APPROVAL

Federal regulations do not allow for a grace period or extension for the approval period. If the Progress Report form is not reviewed and approved by the end of the approval period, the Investigator may not continue enrollment or other research activity. The Investigator is responsible for notifying the IRB if there is a need to continue medical treatment of current participants for their safety and well-being.

If continuing review and re-approval does not occur before the expiration date of IRB approval, all research-related activity must cease unless the IRB finds that it is in the best interests of individual subjects to continue participating in the research interventions or interactions. The IRB Chair or designee will determine if subjects in an expired study may continue participating in the research interventions or interactions. Enrollment of new subjects cannot occur after the expiration of IRB approval. When continuing review of a research protocol does not occur prior to the end of the approval period specified by the IRB, IRB approval expires automatically. Such expiration of IRB approval does not need to be reported to OHRP as a suspension of IRB approval under HHS regulations. (OHRP Guidance January 15, 2007)

The expiration date is the first day the protocol is no longer considered an approved study by the IRB. If, after expiration of IRB approval, the IRB approves resumption of the study, the approval and expiration dates will be determined as for initial approvals.

The IRB may conduct continuing review earlier than the established review interval if the IRB becomes concerned that conditions for approval may be compromised or that there may be unexpected serious harm to subjects or at the request of a third party. 45 CFR 46.113. The investigator will receive written notification that continuing review will be conducted.

IRB approval may be withdrawn at any time if the IRB becomes aware that the conditions for approval are not being met. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and other appropriate entities. 45 CFR 46.113, 21 CFR 56.113. The

investigator and other appropriate entities will receive written notification that IRB approval has been withdrawn.

Applicable Regulations and Documents:
45CFR46.109(e)
21CFR56.109(f)
45CFR46.113
21CFR56.113
21CFR 812.62-812.64
OHRP Guidance on Continuing Review (January 15, 2007)
Policy II.06 *IRB Review of Reportable Events*
Policy III.01 *Review by the Institutional Review Board*
Policy III.09 *Continuing Review by the IRB*
Procedure 307 *IRB Review of Research at a Convened Meeting*
Procedure 320 *Review of Reportable Events*

Adoption Date:	Created by:	Date of Revision:	Revised By:	Summary of Revision:
03/05	AAHRPP committee	11/05	AAHRPP committee	Procedure Title Change, add text relating to social/behavioral IRB
		11/06	AAHRPP committee	Expand text in Medical IRB continuing review forms *Section II*
		7/09	J. Gerlach	Extensive revisions to remove redundant text and combine Procedures 315 Continuing Review Submissions for Medical and Behavioral Sciences IRBs and 317 Review of Continuing Review Submissions by the Institutional Review Board-Social and Behavioral Sciences into this Procedure
	AAHRPP committee	10-2009	AAHRPP committee	Description of when continuing review is allowed to stop
		10-2010	J.Gerlach	Added reference to 21 CFR 812.
		11/2011	J. Osborne	Added text regarding subjects continuing participation after expiration on page 6.
		06/2014	A. Braggs-Brown	Revised to reflect organizational changes.

Date Adopted June 2014 Signature signed copy on file