

SUBJECT: Continuing Review of IRB Approved Studies		Policy Number: 10.3.14
	Effective Date: November 20, 2015	Renewal Date: November 20, 2018
	Supersedes: October 21, 2011 September 10, 2010	Page 1 of 6
	Responsible Authorities: Vice President, Research Institutional Review Board Director, Research Integrity	

I. Background

The following federal regulations require continuing review of applicable human subjects research studies:

- 45 CFR 46.103 (b)(4) and 21 CFR 56.108 state the regulations required of a continuing review process in order for an institution to receive federal funding.
- 45 CFR 46.109(e) and 21 CFR 56.109(f) require a continuing review to occur at least once per year.

II. Purpose

The purpose of this policy is to address the responsibilities of the FAU IRB and FAU Principal Investigators with respect to continuing review of approved, on-going human research activities.

III. General Statement

IRB review is a continuous process mandated by federal regulations. Continuing review is the ongoing monitoring mechanism by which the IRB ensures the continuing protection of subjects who participate in research. Sometimes actual risks can be better understood only after research has begun. Unexpected developments in a project or new findings can raise questions about the conduct of the research. At continuing review, the IRB can then reconsider its initial judgment. Additionally, changes in laws, regulations and guidance on human subject research can prompt the IRB to request modifications to already approved studies to ensure continued protection of human subjects.

IV. Policy

- The IRB will conduct continuing review of research at intervals appropriate to the degree of risk, but not less often than once a year. The Board will determine the appropriate review interval as follows:

- **If a study was initially reviewed at a full board meeting of the IRB, then continuing review will usually be by the full board.** The study may, however, become eligible for expedited review or be moved to exempt status as a result of any amendments.
- **A study previously reviewed by full board study may become eligible for expedited review if:**
 - a. The research is permanently closed to enrollment, all subjects have completed research-related interventions and the research remains active only for long-term follow-up subjects, or
 - b. No subjects have been enrolled and no additional risks have been identified, or
 - c. The remaining research activities are limited to data analysis.
- **Any approved study, whether expedited or full board, can be moved by the IRB to exempt status if the remaining research activities are limited to data analysis** and the investigator has recorded the data in such a way that the data are not identifiable and cannot be re-linked to personal identifiers. Research that is determined by the IRB to be exempt will no longer require annual review. PIs can request that the IRB reconsider a study's status.
- Upon review and approval of a proposed study, the IRB will set the continuing review expiration date as 365 days from the most recent approval date, unless it determines otherwise. The IRB may set a shorter continuing review if the IRB determines that a) The shorter review period will reduce possible risk to study subjects or is in the best interest of the subject, b) New information is likely to emerge that may alter the risk/benefit ratio.
- Continuing review of research must be substantive and meaningful. Each continuing review must ensure that the criteria for approval of research listed in 45 CFR 46.111 are still satisfied in order to re-approve the study. The IRB will also consider, at a minimum, unexpected results of ongoing research, unanticipated problems, the effects of the research project itself, regulatory changes and new knowledge gained.
- At continuing review, the IRB may elect to verify that no material changes have occurred since previous IRB review through an auditing mechanism. This may apply to a) randomly selected projects; b) complex projects involving unusual levels or types of risk to subjects; c) projects conducted by investigators who previously failed to comply with the HHS regulations or IRB requirements; and d) projects where concern about possible material changes occurring without IRB approval have been raised based upon information provided in continuing review reports, or from other sources.
- **Continuing review will be conducted by the convened IRB, with a recorded vote on each study, unless the research is otherwise appropriate for expedited review.**
- **No human subject research may be conducted without prior approval from the IRB.** A study that lapses past the annual review date is considered

to have an expired IRB approval. Therefore, all research must stop. Subjects may not be enrolled and no research data may be collected from currently enrolled subjects until the approval is re-instated. There is no provision for any “grace” or “extended approval” period. (45 CFR 46.109)

- **If a study has expired, the PI may appeal to the IRB for continued subject contact during the lapse.** Research procedures may only continue if, upon appeal, the IRB finds that it is in the best interests of individual subjects to continue participating in the research interventions or interactions.
- **All data collected and subjects enrolled during a lapse period, without special permission from the IRB, are considered unapproved research activities.** This is a reportable protocol violation and will be communicated to all applicable Federal, State, and University regulatory bodies, as required.
- Continuing review reminders are automatically issued by the Research Integrity Office in the Division of Research at specified intervals (60, 30 and 14 days). However, **the Principal Investigator is responsible for ensuring that the IRB receives the continuing review submission with sufficient time for review.** Late submissions cannot be guaranteed a timely review

V. Definitions

Approval Date: The date on which the IRB, through either an expedited procedure or full board review, determines that a research study continues to meet all of the criteria for IRB approval of research outlined in 45 CFR §46.111.

Continuing Review: A regularly scheduled review of a continuing research project. The goals of continuing reviews are to ensure that the risk/benefit ratio is still acceptable, that the measures taken to safeguard subjects are adequate, that the approved protocol is followed, that the project reflects any changes that have been made in the regulations for human subjects research since the last approval, and that all of the criteria for IRB approval of research are still satisfied.

Expiration Date: The date when IRB approval expires. The IRB approval expires at 12 a.m. the same day as the approval day, the anniversary date. For example, if the IRB approval date is February 14, 2015, the expiration date is February 14, 2016 at 12 a.m. Continuation of research must be evaluated, reviewed, and approved prior to this date in order to avoid expiration of IRB approval.

Expired: Status in which a study is no longer considered to have IRB approval.

IRB Approved Research: Research that the IRB, through either an expedited procedure or full board review, has determined that all of the §46.111 criteria for IRB approval of research have been satisfied.

Lapse: An accidental or temporary halt of an expired study.

Research-Related Intervention: An activity that is required as part of the IRB approved protocol. The intervention occurs as a contribution to research results or is a follow-up to already approved research activities.

VI. Accountability

The Principal Investigator (PI) will be responsible for:

- Monitoring when a continuing review is due for each research study in which he/she serves as PI.
- Submitting a Continuing Review Form to the IRB:
 - **If re-approval is desired**, the PI must submit the continuing review form and related documentation *30 days prior* to the expiration date. Applications submitted after the 30 day deadline cannot be guaranteed IRB review prior to expiration of the study. This is especially true for studies requiring full board review.
 - If re-approval **is not** desired, the PI should submit a request for closure. If this application is not submitted before the expiration date, the study will be considered expired. Research Integrity will close the study in accordance with IRB policy for closure of studies.
 - Applications must be submitted through IRBNet with all appropriate documentation.

The Institutional Review Board will be responsible for:

- Determining the appropriate level of IRB review for a continuing study.
- Considering whether a study submitted for continuing review, whether full-board or expedited, continues to fulfill the criteria for approval of research outlined in 45 CFR 46.111.
- Requesting additional precautions, if warranted, and reassessing special requirements it had previously imposed on the research protocol.
- Establishing the Continuing Review Date (Expiration Date).
- Abstaining from continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

The Research Integrity office will be responsible for:

- Ensuring that reminders are issued automatically to the PI via IRBNet 60, 30, and 14 day intervals prior to the study's expiration date.
- Reviewing incoming requests for continuing review and facilitating the review process in accordance with internal SOPs.
- Closing the study file in accordance with the IRB policy for closure of studies.

VII. Procedures

- The PI should submit the Continuing Review form via IRBNet 30 days prior to the study expiration date. At a minimum, include in the submission:
 - The Continuing Review Form completed in its entirety, with detailed and accurate accounting of number of subjects approved, enrolled, withdrawn, etc.
 - Clean, un-stamped copies of approved consents, assents, verbal scripts or advertisements that were used in the past year, and will be used in the upcoming year.
 - The Protocol Amendment Form and any revised study documents, *if changes to the original protocol are proposed for the upcoming year*.

- The IRB maintains fixed anniversary dates for the expiration of IRB approvals, approval may occur within 30 days prior to the expiration.
- ***If the continuing review is submitted 30 days prior to expiration***, the PI may continue research under the current IRB approval until the expiration date. The IRB will make every effort to review the submission within 30 days to avoid study lapse.
- ***If the continuing review is submitted less than 30 days prior to expiration***, the PI may continue research under previous IRB approval until the study reaches its expiration date. The PI should include a note indicating his intent to cease data collection should the study expire before the IRB can approve the study's continuation.
- ***If the continuing review is submitted after the expiration date***, the PI should include a memo to the IRB with a detailed explanation of the cause of the lapse and a plan to avoid future lapses. The IRB will only consider this option for studies where 30 days or less have passed since study expiration.
- ***If re-approval is not desired, the PI should submit a request for closure***. The PI will receive an acknowledgment from the IRB regarding the study closure. If this request is not submitted before the expiration date, the study will be considered expired and the file will be closed.

VIII. Policy Renewal Date

11/20/2018

IX. References

45 CFR 46.103(b) (4)
 21 CFR 56.108
 45 CFR 46.115
 21 CFR 56.107(e)
 45 CFR 46.109(e)
 21 CFR 56.109(f)

Office of Human Research Protection (OHRP) Guidance on Continuing Review, January 15, 2007.

OHRP Draft Guidance on IRB Continuing Review of Research, November 6, 2009.

POLICY APPROVAL

Initiating Authority

Signature:

Date:

Name: Daniel C. Flynn, Ph.D., Vice President for Research

Executed signature pages are available in the Initiating Authority Office(s)