Office for the Protection of Research Subjects

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Institutional Review Board
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Lapse in IRB Approval

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Approved by: Human Protections Administrator and Director of OPRS
AAHRPP Ref #: 122
AAHRPP Elements: II.2.D.2, II.2.E.2

POLICY:

I. Investigators, or other responsible parties, must file either a continuing review application or a final report in advance of the expiration date of IRB approval, when applicable.

II. UIC OPRS strongly recommends submitting the continuing review application or final report application 30-45 calendar days prior to the date of expiration while also taking into account the submission deadlines for the appropriate board meeting.

III. Department Heads, Unit Heads, and Faculty Sponsors are responsible for ensuring that PIs leaving UIC submit a *Final Report* form for each of their active protocols or transfer the responsibility to another qualified investigator to serve as PI by submitting an amendment form. For additional information, please refer to the UIC HSPP policies *Final Report of Research Activities* and *Managing Research Prior to Departure, Sabbatical, Medical Leave, or Other Absence*.

IV. Lapse in IRB approval represents a failure to obtain approval of a final report or obtaining continuing review approval prior to the expiration date assigned by the IRB.

V. After expiration of IRB approval, all research activities must stop, including any research related interventions, recruitment, data collection, data sharing/reporting and analysis of data, and no new subjects may be enrolled. In addition, the investigator's IRB privileges will be suspended.

VI. The institution has the authority to suspend or revoke the investigator's privileges to conduct human subjects research due to a lapse in IRB approval.

VII. If the research is closed due to lapse in IRB approval, a new submission is required to re-open it.

VIII. After the IRB approval for a study has lapsed, any follow-up interventions or interactions with some or all subjects during a lapse require the submission of a request to the IRB for a protocol exception. Refer to UIC HSPP policy *Protocol Exceptions* for additional information.

IX. Lapses in IRB approval are not considered by OHRP to be a suspension or termination of IRB approval. However, the UIC HSPP policy considers the lapses to

represent non-compliance with the requirements of the IRB and are handled according to the UIC HSPP policy and procedure, *Handling Complaints and Allegations of Potential Non-Compliance with Human Subject Protection Regulations*, including consideration of whether the non-compliance is serious and/or continuing as defined within the policy.

Please note that repeated lapses and/or continuation of research activities during a lapse without an approved exception may represent serious and/or continuing non-compliance and, therefore, be subject to the IRB reporting requirements.

X. IRB members, OPRS staff, and OVCR staff may use the most effective means of communication necessary with respect to contacting investigators as to lapse in IRB approval on an as-needed basis. Documentation of oral and written communications must be filed in the protocol file.

PROCEDURE:

I. **Lapse in IRB Approval: Preventative Measures.** The OPRS utilizes several measures to notify the PI of continuing review for previously approved human subjects research in the following manner:
   A. Approval letters to investigators include a link to "Investigator Responsibilities" which reminds investigators that they are responsible for ensuring that a continuing review application or a final report is submitted to OPRS prior to the expiration date to prevent a lapse of IRB approval.
   B. As a courtesy, investigators receive reminders from OPRS at approximately 90, 60, and 30 days prior to the expiration of the approval period. This is accomplished as the RiSC database management software has a mechanism for the OPRS staff to monitor the status of the board's protocols on a weekly or bi-weekly basis.

II. **Lapse in IRB Approval: Procedures on the Expiration Date.**
   A. If the investigator has not submitted and obtained continuing review approval or approval of a final report by the protocol's expiration date, IRB approval lapses.
   B. The investigator is notified of the lapse in IRB approval via the *Notice of Expiration of IRB Approval* letter which is sent by email. The letter is copied to the Academic Department or Unit Head, Faculty Sponsor (if applicable), other relevant UIC oversight committees (e.g., investigational drug service, radiation safety, cancer center), OSP, sponsor, and the UIC OPRS protocol file.
   C. Consequences of the lapse are that:
      1. All research activities must stop, including new subject recruitment, enrollment; research interventions and interactions, data sharing/reporting, and data collection and analysis;
      2. The investigator's IRB privileges are suspended; and
      3. Procedures to close the research are initiated per Section III of this policy and procedure.

D. The lapse represents non-compliance and is referred to the IRB according to the UIC HSPP policy, *Handling Complaints and Allegations of Potential Non-Compliance with Human Subject Protection Regulations* for consideration of whether the non-compliance is serious or continuing.
    1. Specifically, the IRB Chair or designee makes a determination of whether the lapse represents possible serious or continuing non-compliance.
    2. If the Chair or designee determines that the lapse represents possible serious or continuing non-compliance, it is referred to the convened IRB for a final determination.
    3. The compliance determination is communicated to the investigator. Serious and/or continuing noncompliance is reported to applicable parties in accordance with the UIC HSPP policy, *Reporting of Unanticipated problems, Suspensions, Terminations, and Non-Compliance*.

E. When the investigator feels it is in the best interest of a subject to continue research activities during the lapse, a request to continue the subject should be submitted to the IRB using the UIC OPRS *Protocol Exception* form. Refer to UIC HSPP policy *Protocol Exceptions* for additional information.

F. The department head has a direct responsibility to monitor individuals in their department and to ensure that continuity exists with the research, including the submission and approval of a continuing review or final report. If an investigator is no longer at UIC or able to fulfill the role of principal investigator, it the responsibility of the department head to ensure that a new principal investigator is assigned and approved by the IRB.

III. Lapse in IRB Approval: Procedures After the Expiration Date

A. If the investigator does not obtain IRB approval of a continuing review or a final report **within 28 calendar days** after the expiration date or the research will be administratively closed due to lapse.
    1. The 28-day period does not constitute an extension of the IRB approval period. The period is meant to allow for continuing review or final report submissions that may be in process to be completed before procedures to close the research protocol are initiated. Research activities must be stopped during this period.

B. **Twenty-eight (28) Calendar Days after the Date of IRB Expiration.**
    1. If the investigator has not obtained IRB approval of a continuing review or final report by 28 calendar days after the expiration date, **the research is closed by the IRB** unless the IRB chair has decided it is in the best interest of individual subjects for research interactions or interventions to continue.
    2. The IRB/OPRS sends a closure letter via email to the investigator and department head. Copies of this communication are provided to the HPA, Faculty Sponsor (if applicable), other relevant UIC oversight committees (e.g., investigational drug service, radiation safety, cancer center), OSP, sponsor, and the UIC OPRS protocol file.

3. For greater than minimal risk research, the IRB makes a compliance determination and decides whether the failure to respond to the lapse notice represents serious or continuing noncompliance. The compliance determination is communicated to the investigator. Serious or continuing noncompliance is reported to applicable parties in accordance with the UIC policy *Reporting of Unanticipated problems, Suspensions, Terminations, and Non-Compliance*.
4. Copies of the study closure letter to the investigator are forwarded to the Institutional Official.
5. UIC OPRS will notify the Office of Sponsored Programs (OSP) of the lapse in IRB approval if the study was funded.

C. The investigator must destroy the data, or a data security plan must be provided for data that will be retained; security must be at a level proportionate to the disposition of data, in accordance with the policy *Final Report of Research Activities*.
D. Investigators who have not corrected the lapse in protocol approval before 28 days will have their research privileges suspended until further notice. The investigator must submit a *Final Report of Research Activities* form before their privileges can be reinstated.
E. If the investigator has submitted a continuing review or final report before the expiration date and/or the investigator demonstrates a good faith effort in working toward obtaining IRB approval of the continuing review or final report, the IRB Chair or designee may at their discretion postpone the closure of the study. The chair must document in writing his or her decision to extend the time to closure. The IRB Assistant Director or IRB Coordinator must ensure that documentation of the above decision is filed appropriately.

REFERENCES:

21 CFR 56.108(b)(2)
45 CFR 46.108(a)(4)
OHRP Guidance on Reporting Incidents to OHRP

REVISION LOG:

Version (#, date)	Replaces (#, date)	Summary of changes
1.1, 11/05/08	1.0, 10/01/08	Clarifies the procedures for lapses in approval
1.2, 03/28/09	1.1, 11/05/09	Clarification of the procedure for closing research for lapses in IRB approval
2.0, 10/05/09	1.2, 03/28/09	Significant changes to the time period and general procedures for closing research for lapses in IRB approval. Re-structuring and re-drafting of the procedure portion.
3.0, 07/28/2015	2.0, 10/05/09	Significant changes were made to the policy to limit it to Lapse in IRB Approval. Final Report of IRB Activities for Study Closure. Information regarding withdrawal of research

		and final report of IRB activities for study closure was removed and added to other policies. Removal of JBVAMC. Inclusion of CHAIRb.
3.1, 10/13/2015	3.0, 07/28/2015	Editorial revisions.
3.2, 01/05/16	3.1, 10/13/15	Addition of CHAIRb specific language.
3.3, 02/14/17	3.2, 01/05/16	Editorial revisions and addition of hyperlinks.
3.4, 05/22/17	3.3, 02/14/17	Inclusion of additional requirements for VA sites under Research Reviewed by CHAIRb.
3.5, 03/02/21	3.4, 05/22/17	Removal of LMS training and CHAIRb specific language; Removing 14 day post lapse procedures, and updating of links.