**Issuing Department:** Human Subjects Protection Program (HSPP)
**Policy Number:** 2011-009.13
**Policy Title:** Institutional Review Board – Lapse in IRB Approval

## *Purpose*

The purpose of this policy is to describe what occurs when a Principal Investigator does not obtain final IRB approval for continuation of a study prior to the end of the approval cycle.

## *Definitions*

See policy 2011-007.0 for definition of:

IRB Approval | Suspension | Termination

## *Policy*

The Principal Investigator (PI) retains the responsibility for submitting requests for continuation. If a PI does not obtain final continuing approval from the IRB by the end of day through which approval is valid, a lapse in approval will occur (e.g. research valid through 5/1/17 could not be conducted on 5/2/17). With one exception as described below, once a lapse occurs all research related activity, including analysis of identifiable data, must stop until such time as final approval for continuation is granted.

For studies requiring full board review, if review does not occur by the next convened meeting and the PI has not expressed an intention to obtain continuing approval, the study is administratively closed by the IRB. For studies for which continuing approval is sought, the IRB will retain the anniversary date by which continuing review must occur (i.e. the review interval will be more frequent than annually).

For studies requiring expedited review, if review has not been obtained within 30 days after the expiration date, and the PI has not expressed an intention to obtain continuing approval, the study is administratively closed by the IRB staff. For studies for which continuing approval is ultimately obtained the approval interval will be for 364 days from the date of approval unless specified otherwise by the reviewer. Anniversary dates are not maintained for expedited reviews.

If a request for continuation is approved contingent, and a PI does not respond to contingencies for approval for continuation within a reasonable time frame after a lapse (e.g. 30 days), the IRB may administratively close the study.

An administrative study closure is not considered a suspension or termination that is reportable to institutional officials or agency heads.

The exception to conducting activity during a lapse is if continuation of an activity is required during a lapse in approval due to it being in the best interest of the subject. In such cases the PI must submit a written request to continue the activity to the Chair explaining why the activity is in the best interest of the subject, and obtain the approval from the Chair, to continue the activity. The IRB Chair reserves the right to grant or deny permission to continue an activity.

## *Procedure*

**Notification of Lapse:**

The electronic IRB system will generate automatic reminder notifications to the PI to request continuing review. If approval for continuation is not obtained prior to the expiration of the current approval cycle, the system will automatically change the study status to Lapsed and generate a Lapse In Approval Notification. The Regulatory Specialist will verify that the PI was included as a recipient of the Lapse Notification, and if not will forward the message to the PI through Outlook as well as through Study Correspondence.

**Permission to Continue Activity:**

If during the lapsed period the PI needs to continue an activity due to it being in the best interest of the subject the PI must submit a written request for permission for continuation of specific activity(ies), explaining why the continuation of the activity is in the best interest of the subject; and confirming that approval for continuation is actively being sought.

The IRB Chair will decide whether to grant approval for such requests and designated Regulatory Specialist will communicate the decision back to the PI.

The preferred method of communication for this to occur is for the PI to submit a request for addendum/modification in IRIS and attach the memo to the request. If the PI communicates outside of IRIS (e.g. by e-mail with attached memo) the Regulatory Specialist will ensure that communications are uploaded to the Study Management, Review Board Internal Documents section of IRIS and the PI is responsible for keeping documentation of the correspondence with the study file.

**Tracking Lapse Status:**

Designated IRB staff will use the system generated lapsed status to track studies and determine whether continuing approval has been requested/obtained within the required time frame. For studies for which approval for continuation is not sought (i.e. by the next convened board meeting for studies requiring full board review, or by 30 days after expiration for expedited studies) IRB staff will administratively close the study and send a written notification to the Principal Investigator of the administrative closure. For lapsed studies for which a response to contingencies has not been received within a reasonable time frame (e.g. 30 days) the Regulatory Specialist may administratively close the study and send written notification to the PI. Prior to closure the RS will issue a final request for responses within iRIS to the PI and study contacts and the PI will be given one week to respond.

## *Related Policies*

2011-007.0 – Definitions Applied to Policies
2011-009.3 – Institutional Review Board – Expedited Reviews
2011-009.5 – Institutional Review Board – Review by Convened Board
2011-009.10 – Institutional Review Board – More Frequent Review

## *Basis*

45 CFR 46
21 CFR 56

***Document Attributes***

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***Richard H. Simon*** ***15 June 2017***

**Richard Simon, MD** **Date**

**Director Human Subjects Protection Program**