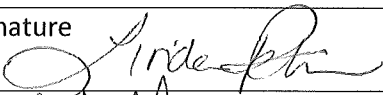





Standard Operating Procedures		
<b>SOP #408.6 Revision 6</b>	<b>TITLE: Expiration of IRB Approval</b>	Effective Date: 1/1/2017
Approved By: OIRB Director	Signature 	Date 1/9/2017
Approved By: IRB Chair	Signature 	Date 1/9/2017

**PURPOSE**

The purpose of this policy is to describe what occurs when a Principal Investigator (PI) does not obtain final IRB approval for continuation or closure of a study prior to the expiration date.

**REVISIONS FROM PREVIOUS VERSION**

Update policy to eliminate 10 day grace period; require training after 2<sup>nd</sup> occurrence; change title of SOP

**POLICY**

The PI must submit an application for continuing review or closure at least 30 days in advance of the expiration date. The expiration date is the last date that the protocol is approved (i.e. IRB approval expires at midnight on the expiration date). If the PI fails to do so, and IRB approval expires, all human research activities must stop. No human research activities may take place after the expiration date unless the IRB finds it is in the best interest of individual participants to continue participation in research interventions or interactions.

*Definitions*

*Noncompliance* includes failure to comply with federal regulations and guidance if applicable, or the requirements and determinations of the IRB. Failure to have a study approved or closed prior to the IRB approval expiration date is considered noncompliance.

**RESPONSIBILITIES**

Execution of SOP: Researchers, IRB Chair(s), IRB, OIRB.

**PROCEDURE**

- OIRB staff sends email notification to the PI to inform that all research activity must cease as of the IRB approval expiration date. Additionally, the OIRB will instruct the PI to notify the Sponsor, if any, of the lapse immediately and copies of these communications need to be submitted to the OIRB.
- All research activities (including recruitment, enrollment, treatments, follow-up, and data collection/analysis) must cease when a study approval period has expired. The PI must immediately submit a written request to continue interventions for any research participants for whom



discontinuation of the research would cause harm and continuation in the research would be in the best interest of the individual participant.

3. The IRB Chair or Vice Chair will determine if the subject(s) may continue in the research and this determination may be reviewed through an administrative process. Requests to allow continued participation should be submitted via appropriate submission processes (containing the signature of the PI). The OIRB will notify the PI and/or other key personnel of the decision and will provide further instructions as applicable.
4. Upon expiration, the OIRB will assign the study for "Noncompliance Review" to an IRB Chair or OIRB Director (IRB alternate) and the study will be administratively closed and status will be changed to "closed-expired." The IRB Chair(s) or OIRB Director has the right to assign the study to a Full Board review if he or she decides it is necessary. The OIRB will notify the PI of any decisions.
5. For studies that are greater than minimal risk, the IRB may decide that additional reviews and determinations are required.
6. In the event of a lapse of IRB approval for a funded study, OIRB staff will notify the Office of Contract & Grant Accounting.
7. If appropriate documentation is submitted and approved within six months and there are no contingencies that present more than minimal risk to the study participants, the study may be reactivated. After 6 months of expired status, the PI is unable to reactivate the study; a new project must be submitted.
8. If noncompliance issues have not been resolved, including but not limited to having a study with expired status, the OIRB will not process amendment submissions or accept new studies from that PI until those issues have been resolved.
9. With a second occurrence of any study expiration under the PI, the PI will be notified in writing that this is a second occurrence of noncompliance with regard to study expirations and a mandatory training with the OIRB will be required.
10. With the third or greater occurrence of expiration under a PI after the date of first implementation of this policy (6/1/2015), a fully convened IRB review will be conducted to determine if the noncompliance is actionable. Possible actions that can be taken by the IRB include, but are not limited to, reporting to the IO, PI meeting with IRB chairs, notification sent to department chair or center director, limitation on number of active studies under that PI. The PI, department chair and others, as applicable, will be notified of the committee determination.

#### REFERENCES

- 45 CFR 46.109(e)
- 21 CFR 56.109(f)