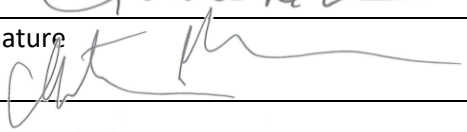
OFFICE OF THE INSTITUTIONAL REVIEW BOARD

Standard Operating Procedures		
SOP #408.7 Revision 7	**TITLE: Expiration of IRB Approval**	Effective Date: 2/23/2018
Approved By: OIRB Director	Signature 	Date 3/1/2018
Approved By: IRB Chair	Signature 	Date 3/1/2018

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 project prior to the expiration date.

REVISIONS FROM PREVIOUS VERSION

Update requirements related to required compliance training

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 project approved or closed prior to the IRB approval expiration date is considered noncompliance.

PROCEDURE

1. IRBNet automatically sends email notification to the PI to inform that all research activity must cease as of the IRB approval expiration date.
2. All research activities (including recruitment, enrollment, treatments, follow-up, and data collection/analysis) must cease when the IRB 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 participant(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 project for "Noncompliance Review" by OIRB staff and the project will be administratively closed and status will be changed to "closed-expired." The OIRB staff have the right to assign the project to IRB Chair(s) or OIRB Director or for review at a convened meeting as they deem necessary. The OIRB will notify the PI of any decisions.
5. For projects that are greater than minimal risk, the IRB may decide that additional reviews and determinations are required.
6. In the event that IRB approval expires 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 participants, the project may be reactivated. After 6 months of expired status, the PI is unable to reactivate the project; 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 projects from that PI until those issues have been resolved.
9. With a second occurrence of any project expiration under the PI, the PI will be notified in writing that this is a second occurrence of noncompliance with regard to expirations and a mandatory training with the OIRB will be required. The training requirement will be noted in an IRB letter. The training must be completed by the end of the following month or a process hold will be put on any new submissions by the PI.
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 Institutional Official, 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)