

IRB Administrative Closure Guidance

What is an Administrative Closure?

If the IRB approval for your research study has lapsed (expired), regulations and BRI policy do not allow researchers to continue to engage in that research until IRB approval has been restored. [OHRP guidance](#) If this occurs, the IRB will “Administratively Close” your study until such time approval can be reestablished. *Enrollment of new subjects cannot occur after the expiration of IRB approval.* The regulations make no provision for any grace period extending the conduct of research beyond the expiration date of IRB approval.

- **For studies when a Continuing Review Progress Report (CR) has undergone IRB review** prior to its expiration date, *if all contingencies requested by the IRB are not submitted and approved (signed off by the IRB Chair) by the expiration date, research must stop.* All contingencies must be resolved and the Chair sign off before you may continue research.
- **For active, enrolling studies:** This means an *immediate hold* would be put on new accrual. In addition, if there are previously enrolled participants still receiving research interventions, all research activities, including data collection/analysis, would immediately need to cease. Exceptions may be considered by the IRB when stopping the study would **not** be in the best interests of the individual participants.
- **For studies closed to accrual with participants still receiving research interventions or interactions:** This means all research activities would *immediately need to cease*. Exceptions may be considered by the IRB for previously enrolled participants, when discontinuance would **not** be in the best interests of such individuals.
- **For Cooperative or NCI CIRB-reviewed studies:** Since the IRB of record is not BRI IRB for these studies, after *60 days past* the reviewing IRB’s expiration approval date, the above situations will apply for administratively closing out the study. (This allows sufficient time to gather the reviewing IRB’s final approval documents).
- **For all other studies:** This means that all study activities would need to cease.

In each case above, IRB approval would be granted upon receipt of the Continuing Review documents, an explanation of why the lapse occurred, reassurance by the PI no study activity occurred during the lapse, and final BRI IRB Chair sign-off.

What are the consequences of allowing your study to lapse?

- IRB staff will notify the study coordinator and the principal investigator of the administrative closure via “high priority” IRB Expiration e-mail notice.
- The notice will be copied to the IRB Manager, Unit Manager, Unit Director, IRB Chair and the Administrative Director of Clinical Research. It will include the statement that **no** future IRB approval for any new or continuing studies will be granted until the outstanding information is received. Until this is done, the restriction will not be lifted. If the investigator does not wish to re-activate the study, he/she **must** submit a final Closure Report Form to the IRB office.

- If IRB approval has been lapsed for **6 months (180 days)** or more, and the IRB has not received a Status Report requesting renewal of approval or a request to close the research study, the IRB will close the study permanently (unless there are subject safety and welfare concerns).
 - A Closure Letter will be mailed to the researcher and other institutional personnel (see reporting below) as well as sent as an email attachment.
 - The date of administrative closure will be the date the study expired.
 - A study Closure Report Form will still be requested of the research.

Reporting

- The IRB Administrative Closure Letter will be sent to the following entities:
 - The Principal Investigator.
 - Study Coordinator.
 - Unit Manager.
 - Unit Director.
 - IRB Chair.
 - IRB Manager.
 - Staff within the Regulatory Compliance and Education Department.
 - Administrative Director of Clinical Research.
 - Other parties deemed pertinent.

NOTE: For WIRB-reviewed studies: Follow WIRB's instructions (correspondence directed to the PI in the case of expiration).

• **What is BRI IRB's responsibility?**

- The IRB is responsible for communicating in a timely manner with researchers about IRB questions or decisions, including deadlines for receiving the researcher's response.

• **What are the Researcher's responsibilities?**

- The researcher is responsible for maintaining current IRB approval on all on-going research studies.
- The researcher is responsible for responding to written (printed or email) IRB correspondence, result letters, and requests within the time frame specified by the IRB.

• **How Does BRI IRB Staff Help to Avoid this Situation?**

- 11-month review cycles, instead of 12 (this helps to avoid lapses in CR approval dates).
- CR reminder notices sent 3+ months in advance of IRB expiration.
- Reminder calls and emails for CR submission deadlines.
- Overdue notices sent for CRs not received on deadline.
- Extensive pre-screening by IRB Coordinators to get things fixed prior to IRB review, to the extent possible.
- CR "result letters" (Full review studies) and screening "result requests" (non-Full review studies) to be distributed ASAP via e-mail.

• **How Can You Help to Avoid this Situation?**

- Pay attention to deadlines.
- Respond to result letters/screening requests ASAP, always keeping in mind your IRB expiration date.
- Coordinators and PIs should at all times have a running list of all active studies and expiration dates (you may request this list from the IRB at any time).

Please contact the IRB Manager, at (206) 341-0787 if you have questions.