

IRB ADMINISTRATIVE CLOSURE GUIDANCE

WHAT IS AN ADMINISTRATIVE CLOSURE?

If the IRB approval for a research study lapses (expires), federal regulations and BRI policy do not allow researchers to continue ongoing research for the project until IRB approval has been restored.

If this occurs, the IRB will “Administratively Close” the study until such time it can be re-opened or the study is formally closed out. **Enrollment of new subjects may not occur if IRB approval has expired.** The regulations make no provision for any grace period extending the conduct of research beyond the expiration date of IRB approval. [OHRP Guidance](#)

The following scenarios describe BRI IRB’s internal procedures for the ongoing compliance of federal regulations in regard to Continuing Review (CR) of research:

- **Studies having undergone Continuing Review at a convened IRB prior to its expiration date:**

Studies may be approved as submitted or approved with contingencies at an IRB meeting. If all contingencies requested by the IRB are not submitted and approved (*signed off by the IRB Chair*) by the previously established expiration date, *the study will not expire*. However, accrual must stop until all contingencies have been resolved for the study and the IRB Chair has signed-off. [OHRP Guidance](#)

- **Enrolling studies NOT having undergone Continuing Review prior to expiration:**

An **immediate hold** would be put on new accrual. In addition, if there are previously enrolled subjects 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 subject. [OHRP Guidance](#)

- **Studies closed to accrual; subjects still receiving intervention or interaction NOT having undergone Continuing Review prior to expiration:**

All research activities would **immediately need to cease**. Exceptions may be considered by the IRB for previously enrolled subjects, when discontinuance would **not** be in the best interests of such individuals.

- **Cooperative or NCI CIRB-reviewed studies going through Continuing Review:**

Since the IRBs of record for these studies are not BRI IRB, these studies will only expire locally **60 days past** the reviewing IRB’s expiration approval date. The above situations will apply for administratively closing out the study. (This allows time to gather the reviewing IRB’s final approval documents). [OHRP Guidance](#)

In each case above, if the study was “Administratively Closed”, it may be re-opened. IRB approval will 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 WILL HAPPEN IF A STUDY IS ADMINISTRATIVELY CLOSED?

- IRB staff will notify the study coordinator and the principal investigator of the administrative closure via “high priority” IRB Expiration e-mail notice. As well, a hard copy will be signed by the IRB Chair and distributed to all parties. The date of administrative closure will cite the date the study expired.
- 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 approvals for any new or continuing studies will be granted until the outstanding information is received**”. This restriction will not be lifted until a CR has been received or the PI submits a final Closure Report Form to the IRB office.

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

Reporting

- The initial IRB Administrative and Final Closure letter will be sent to the following people:
 - 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/Quorum reviewed studies: See WIRB/Quorum instructions directed to the PI in the case of expiration.

WHAT IS THE RESPONSIBILITY OF BRI IRB FOR CONTINUING REVIEW?

- 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.
- They are also responsible to report to OHRP any "*serious or continuing noncompliance*" with the federal regulations for the conduct of research. [45 CFR 46.103\(b\)\(5\)](#) [45 CFR 46.113](#)

WHAT ARE THE RESEARCHER'S RESPONSIBILITIES?

- The researcher is responsible for maintaining current IRB approval on all on-going research studies. [OHRP Guidance](#)
- The researcher is responsible for responding to all IRB correspondence, result letters, and requests within the time frame specified by the IRB.

HOW DOES BRI IRB STAFF HELP TO AVOID ADMINISTRATIVE CLOSURES?

- 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 study expiration.
- Reminder calls and emails for CR submission deadlines.
- Overdue notices sent for CRs not received by the deadline.
- Extensive pre-screening by IRB Coordinators to get things fixed prior to IRB review, to the extent possible.

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) 342-6916 if you have questions.