



## IRB GUIDANCE: IRB Review of Research - Project Closed to Accrual, in Data Analysis Only, or Terminated (Closed)

The DHHS regulations govern research during all phases, including development, testing, and analysis. [45 CFR 46.102(d).] Human subject involvement may change as research moves from one phase to the next. The testing phase may include:

- active enrollment and study intervention;
- closing a study to accrual, but continuing active study intervention in enrolled subjects; or
- only following subjects who have completed the active study intervention.

Then research moves to the analysis phase, which involves evaluation of the data collected and manuscript writing, and no continued subject intervention or follow up.

### Does the IRB review process change, depending upon the phase of the project?

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The IRB review process may change, depending upon the phase of the project. Research that initially required a convened review process because the research procedures involved more than minimal risk may undergo an expedited review process for the continuing review if the testing/intervention phase is truly complete, and the investigator is only following the participants using minimal risk procedures or completing data analysis with identifiable data.

Please note: if the follow up procedures are more than minimal risk, such as any procedures that involve radiation exposure (chest x-ray, DEXA, etc.), the IRB will continue to review the protocol at a convened meeting.

### What is the difference between research that is “closed to accrual” and research that is “terminated”?

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“Closed to accrual” merely means that no additional subjects will be enrolled in the study. Study activity is ongoing and may include intervention or interaction with subjects, continued use of a drug or device, and/or data analysis. “Termination” or closed means that ALL study activity has ceased – whether because the sponsor has decided that it may not continue, the investigator chooses not to continue the research, or the study activity and data analysis are complete.

### What impact does closing research to accrual have on IRB review?

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If the study is closed to accrual, an updated consent form need not be submitted to the IRB for continuing review UNLESS new information becomes available that would require modification of the information in the most recently approved consent form for re-consent of enrolled participants. However, all other reporting requirements must be met, just as they are during the subject accrual phase. For example, Continuing Review Applications must be submitted to the IRB and must include information about the subjects in the study, and Problem Reports of unanticipated problems involving risk to subjects or others must be submitted in accordance with IRB guidance. [Refer to: HRPP Policy 901 - Reporting Unanticipated Problems.](#)

### **Is a continuing review application required if research is in the evaluation, manuscript writing, or data analysis-only stage?**

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A continuing review application is required so long as the research uses identifiable data, thus posing a risk of breach of confidentiality to the participants. If the investigator is not using identifiable data, the protocol can be closed and no further IRB oversight is required.

### **Is submission of a termination/closure report required when study activity stops?**

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Yes. The PI must submit a Final Report to close out a study so that the IRB is informed of the reasons for a closure and has a summary of the progress of the research activity. If a study approval lapses and the IRB administratively terminates a research application, the PI must still submit a final report to the IRB.

### **What happens if a sponsor suspends or terminates a study before the proposed completion date?**

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If research is terminated by a sponsor, the PI must inform both the reviewing IRB and, if the project is funded, the Office of Sponsored Programs.

### **What happens if an investigator suspends or terminates a study before the research study is completed?**

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The PI must notify the IRB if he/she closes or suspends a research project. For projects that are funded, the PI must notify the funding agency. Letters of notification to sponsors must be co-signed by an Institutional official from the Office of Sponsored Programs before they are sent to the funding agency.

### **How should a PI notify the IRB that the research activity has been completed?**

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When the investigator is no longer using identifiable data as part of the research activity, the PI should submit to the IRB the Continuing Review/Final Report Form through the IRBNet system.

### **What should happen to the research records?**

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Once the study is closed, records related to IRB operations (as well as research related records) must be retained for at least three years. [Refer to: HRPP Policy 301, section 3.20 – General Policies and Procedures.](#)

### **What happens if an investigator would like to initiate a research project using data from a study that has been terminated?**

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An investigator may submit a New Research Application to initiate research using identifiable data from a closed study. A closed study may not be “resurrected” under its former IRB protocol number or IRBNet number, but the new research application may reference the terminated study’s database.

For additional guidance and information, contact University of Denver Office of Research Integrity & Education at (303) 871-2121 or at: [IRBAdmin@du.edu](mailto:IRBAdmin@du.edu).