

The USU IRB is always willing to keep a protocol open that a researcher would like to maintain as open. Its practice is to *offer* the ability to close a protocol if IRB staff discover that it *can* be closed. When can a protocol be closed? Review the information below to find out:

Intervention Research

Before a protocol can be closed for research that involved an intervention, the analyses must be complete (to the point of being able to assess the outcomes, not necessarily to the standard of publication). The research team must have determined that there are at least null findings, but certainly not negative outcomes. If there were negative outcomes, the research team has a responsibility to contact participants about those findings if there is any increased risk of harm to the participants as a result of their participation, or if they simply said they would do so. Null results do not necessarily mean participants should be contacted.

As a general rule, identifiers should be destroyed. This includes audio and video recordings, stills, and anything else that was disclosed as an identifier when the research was approved. It *is* possible that a protocol can be closed without the identifiers being destroyed. The Common Rule only requires that the identifiers not be “used, analyzed, or studied” any further. If the research team wishes to close a protocol but retain identifiers, two things should be true: 1) the informed consent document should state that the identifiers will be retained; and 2) the IRB should get confirmation from the PI that they understand that any further use, analysis, or study of that data will require a new protocol.¹ The USU IRB does not reopen closed protocols.

Thus, if a Status Report for a project involving intervention research has not disclosed the research findings, it cannot be closed. If there seem to still be plans for use, study, or analysis of identifiers, the protocol cannot be closed. Otherwise, it can be closed (assuming no deviations, UAPs, or noncompliance issues are pending).

Non-Intervention Research

*If the protocol does **not** involve an intervention as a part of its procedures*, and the identifiers have been destroyed, that protocol is appropriate for closure (again, assuming no deviations, UAPs, or noncompliance issues are pending).

Thesis, Dissertation, and Funded Projects

Because a third party generally has some say in how these projects are conducted, these types of protocols should not be closed until that third party has signed off on the work that is completed. For example, a student may have completed data collection in a project that does not involve an intervention, and destroyed identifying information. At the defense, a committee member might ask that student to supplement that data; if a protocol were already closed, this would require that student to file a new protocol. In another case, identifiers that are properly retained (not being used, analyzed, or studied) might become something the student would need to go back and do additional coding/analysis for. These items are so common that the USU IRB does not close thesis or dissertation projects unless the defense has already successfully occurred.

Funded projects carry the same caveat; a sponsor might want additional analyses run, or more data collected. While the USU IRB can close a protocol before the award has been closed out, it is a best practice to first close out the awards with the sponsor. If the sponsor is a federal agency, the USU IRB must also be sure that it has reviewed the Data Management Plan. In order to properly close a federally funded protocol, the IRB must ensure that the DMP has been followed and is executed, or in the process of being executed.

¹ Generally speaking, whether there are interventions or not, the USU IRB will keep protocols open until the timeframe has passed where the study team told the participants the identifiers would be destroyed. While federal regulations might permit a study to be closed earlier than that, the IRB’s responsibility is primarily to the participants. In an effort to ensure that commitments made to participants are being followed through, the USU IRB will nearly always require a protocol to remain open while identifiers are retained. Movement from that position is an exception made on a case-by-case basis.