

Section XIII: Requirements for Concluding Projects that Involve Human Subjects

13.1 Concluding Projects

a. Federal regulations do not directly address when an IRB may or should close a project file. The institution must establish reasonable and consistent practices to define and manage project closures. In all case, however, the definitions adopted, the practices established, and the policies implemented must offer the greatest protection for the human subjects in the study and for the data generated during the study.

b. A human subject research project will remain in an “active” status as long as identifiable data collected in the study are being analyzed, since continuing oversight by the Academy’s IRB and the HRPP office are necessary to ensure that the appropriate confidentiality with respect to the data is being maintained.

1. After the data analysis has been completed, the principal investigator on the project must verify, via a project closure form, that the data (a) will remain de-identified and protected, and (b) will not be used for any purpose other than the one originally defined in the research protocol and approved by the Superintendent.

2. A project closure form must be received by the Academy’s HRPP office **within thirty days** after the data analysis has been completed. Oversight will continue until the Academy’s IRB reclassifies the project as “closed”, and until this reclassification is recorded in the Academy’s HRPP office.

3. A template for the closure form is available on the Academy’s IRB webpage. The required contents of the submission are incorporated into the on-line submission.

4. Project closure forms will be reviewed by the Academy’s IRB and the Academy’s HRPP office. If questions remain as to the use of the data, the status of the analysis, etc., the project closure form will not be accepted and the project will remain in an “active” status until all concerns are resolved.

5. Once a closure form has been accepted by the Academy’s IRB, a recommendation to close the project will be submitted to the Superintendent. If approved by the Superintendent, the principal investigator on the project will be notified by the Academy’s HRPP office and the project approval number will be entered into the “closed projects” records of the Academy’s IRB that are maintained in the HRPP office.

6. If, after a study has been closed, identifiable data are to be retained and if the data may subsequently be used for additional research studies beyond the original intent of the approved research project, then the data set will become part of the records maintained in the data repository of the Human Research Protection Program office at the Naval Academy. As such, the project data set is subject to the continued oversight of the Academy’s IRB and any future use must be monitored by the Academy’s HRPP office, reviewed by the Academy’s IRB, and subsequently approved by the Superintendent.

7. Although it is expected to be a rare case rather than the norm, as a condition of approval on the project, the Superintendent, acting on his own or on the recommendation of the Academy's IRB, may require that the data collected during the project be destroyed at the conclusion of the study due to the sensitive nature of the data and the potential harm to those subjects who participated in the study, should the data inadvertently be released.

c. The principal investigator for a research project is required to provide copies of all publications and/or presentations developed from the results of any approved research projects to the Academy's HRPP office. This submission requirement applies to "active" projects as well as to all "closed" projects.

d. The requirements and policies established at the Naval Academy for the closure of "active" projects apply to human subject research projects conducted at the Naval Academy Preparatory School.

e. In consultation with the Academy's HRPP office, retention of the data, transfer to a data repository, or data destruction will be recommended to the Superintendent, on a case-by-case basis, by the Academy's IRB, at the time of the initial approval of a protocol by the Superintendent.

f. Special approval and/or closure conditions may be recommended to the Superintendent by the Academy's IRB and/or by the Academy's HRPP office in the case of non-USNA investigators conducting human subject research on USNA midshipmen or on midshipman candidates at NAPS, or when data about USNA midshipmen or NAPS midshipman candidates have been collected and/or analyzed in the project.