

Section VIII: Administrative Issues

8.1 Records Maintenance and Retention

Organizationally, the Naval Academy's Human Research Protection Program (HRPP) office is the custodian of the records for the USNA Human Research Protection Program and for the Academy's IRB. Items on file include, but are not limited to, human subject research protocols; document tracking numbers; proposal approval numbers; informed consent documentation; records and reports on continuing and concluding projects; minutes of all meetings; records of the Academy's IRB review outcomes and recommendations to the Superintendent with respect to approval on protocol submissions; records of delivery, attendance and content of education briefs; and training certification records; as well as any other documentation required by law, by regulation or by instruction.

a. Minutes and documentation of the Academy's IRB meetings, correspondence of the Academy's HRPP office and of the Academy's IRB, records of the Superintendent's approve/not approve decisions on projects, and any conditions or restrictions on a project associated with the Superintendent's approval are maintained in the HRPP office.

1. Complete records and minutes of all of the Academy's IRB convened meetings (including when, where, attendance, summaries of discussions on proposals, approve/not approve recommendations to the Superintendent, approval decisions on proposed research protocols, and other related agenda items of the Academy's IRB), as well as all correspondence related to the administrative functions of the Academy's IRB will be preserved and catalogued by the Academy's HRPP office.

2. Complete records of all correspondence (in all formats) with principal investigators and others associated with or knowledgeable about a human subject research project protocol, copies of research protocols and supporting materials on a human subject research project, as well as all other types of documents and materials associated with the position of "Chair of the IRB" must be maintained by the individual serving in the position. At the conclusion of his/her tenure as the Chair of the IRB, all records and files must be transferred to the Academy's HRPP office.

3. Records of all proposal submissions (electronic and hardcopy), whether or not the project is ultimately approved by the Superintendent, will be maintained by the Academy's HRPP office.

b. Proposal Tracking Numbers

Each research proposal submitted for review via the Academy's IRB process will be issued a tracking number. This number will appear on all documentation, consent forms, title pages (for on-line surveys), invitation e-mails (for e-mail surveys), evaluations of scientific merit, addenda or amendments to the original research proposal, continuing and concluding project reports, etc. A database, searchable by tracking number, of all research protocols proposed at the Naval Academy or at the Naval Academy Preparatory School (NAPS) and submitted for review via the Academy's IRB process will be maintained in the HRPP office. The approve/not approve recommendation of the Academy's IRB and the Superintendent's decision will be recorded as one segment of the project record in the database.

c. Approval Numbers

Each research proposal recommended for approval to the Superintendent via the Academy's IRB process will be issued an approval number once the project has been approved by the Superintendent. This number will appear on all documentation, consent forms, title pages (for on-line surveys), invitation e-mails (for e-mail surveys), addenda or amendments to the original research proposal, continuing and concluding project reports, etc. A database, searchable by approval number, will be maintained by the Academy's HRPP office.

d. Approval to Begin the Research

The principal investigator (PI) will be notified of the Superintendent's decision with respect to approval and of the project approval number, in writing, by the Academy's HRPP office. The PI may begin data collection activity / analysis on the project, solicit human subject participants, distribute informed consent forms to the human subject participants selected for the study, etc., after he/she has been notified of the approval number assigned to the project.

e. Recordkeeping on Human Subject Research Projects

1. All records pertaining to a research protocol must be retained by the project PI during the course of the research activity as well as for three (3) years after the conclusion of the research. (See Section XIII of this policies and procedures manual for more information on the requirements for concluding projects that involve human subjects and/or the data about them.)

2. Applicable records that must be retained by the principal investigator include, but are not limited to: training documents for each investigator and for all key research personnel (USNA and non-USNA); research protocols with supporting documentation; the template and completed informed consent documents; progress reports on the status of the research; reports of any research-relevant injuries to project participants and subsequent treatment of the project subjects; reports of any adverse events and how they were resolved; copies of all publications and presentations resulting from the research; and correspondence concerning the use of human subjects or the data about human subjects in the research.

3. Records and reports submitted to the Academy's HRPP office will be retained in perpetuity as part of the data repository in the HRPP office.

4. The Academy's IRB may recommend or the Superintendent may independently decide that, as a condition of approval for the protocol, the data collected during a project must be destroyed at the conclusion of the study. In this case, that data (in all formats) must be destroyed.

(a) Only the data should be destroyed. The Academy's HRPP office will assist the principal investigator with the destruction, and the Academy's HRPP will document in the project records that the requirements to destroy all originals and copies of the data (in all formats) have been met.

(b) All records (exclusive of the data) about the project must be retained by the principal investigator for three (3) years after the conclusion of the research and after the project records being classified as "closed" by the Academy's IRB.

(c) Records and reports submitted to the Academy's HRPP office will be retained in perpetuity.

5. Guidance on the DoN-HRPP documentation requirements for a project, the format required for all supporting information on a project, which persons and offices are required to keep files, how long records and informed consent forms must be kept, what information must be retained by the Academy's HRPP office, what information must be sent to DoN-HRPP, etc., is available on the Academy's IRB website.