

Section XVIII: Research Collaborations

18.1 General Information: Research Collaborations on Projects Involving Human Subjects and/or the Data about Human Subjects

- a. Per reference (i) of Enclosure (1), collaborative research projects are those that involve more than one institution, command, etc. Department of the Navy (DoN) commands and activities may collaborate with each other, with other DoD agencies, with non-defense agencies, and/or with non-federal institutions. Any research grants, contracts, cooperative agreements, Cooperative Research and Development Agreements (CRADAs), or other transactions must include the additional DoD and DoN requirements for the protection of human subjects in the research.
- b. Per reference (i) of Enclosure (1): When a collaborative research effort is being developed, regardless of the identities of the human subject populations, an appropriate written agreement shall be established between the collaborators. This agreement must include a Statement of Work (SoW) that delineates the project goals and the assignment of responsibilities to each collaborator. The agreement must describe all of the following:
- the goals and methodologies of the proposed research,
 - the specific roles and responsibilities of each institution,
 - the responsibility for scientific merit and IRB review,
 - the proposed process for the recruitment of human subjects,
 - the proposed procedures for obtaining informed consent from the participants,
 - the proposed provisions for project oversight and ongoing monitoring,
 - the training requirements for each collaborator, as required by each researcher's home institution,
 - the reporting requirements for each collaborating institution,
 - the plan for safeguarding the data during and after the project,
 - the plan for documentation retention,
 - the plan for compliance for the entire research project.

While the descriptions of each these items within the agreement can be relatively brief, it is important to recognize that inclusion of each item in the agreement is a requirement.

- c. In collaborative research projects, each institution is responsible for safeguarding the rights and welfares of the human subjects and for protecting the data collected about the participants. Each research partner must comply with the IRB policies of their home institution as well as with the IRB policies, procedures and instructions of the collaborating partner. The policies and procedures defined in this document apply to all research studies conducted at, on behalf of, or in collaboration with the U.S. Naval Academy.

d. The IRB of the institution of the principal investigator is designated as the “primary IRB” in the review and approval process. The “primary IRB” must ensure that the investigators at all of the partner institutions on a collaborative project comply with applicable federal, state and local laws, as well as with all applicable DoD/DoN regulations and institution instructions. In all cases, the laws, regulations, instructions and IRB policies that offer the greatest protection for the human subjects participating in the project shall prevail.

e. Per reference (i) of Enclosure (1), non-federal collaborators must obtain a DoD Navy Addendum to their Federal Wide Assurance (FWA). Information on how this addendum can be obtained is available from the Academy’s HRPP office.

18.2 Collaborative Projects that Involve USNA Populations as the Human Subjects

a. Using a USNA population group (or subset thereof) as human subjects or using data about a USNA population in a collaborative project will not be permitted unless there is a clear and demonstrated benefit to the Naval Academy, to the Department of Defense, and/or to the Department of the Navy, and with minimal potential risk or harm to the USNA human subjects.

b. Decisions on the benefits of a proposed study may be made by the Director of the USNA HRPP office, by the USNA Academic Dean and Provost, by the NAPS Academic Dean, by the Director of Institutional Research office, by a Division Director or by a member of the Senior Leadership Team (SLT), as appropriate to the project content, the project participants and the identity of the USNA collaborator(s). In some cases, the only person who can make the decision on the benefits of a project involving USNA human subjects and/or the data about them is the Naval Academy Superintendent. The identity of the benefits decision-maker on a proposed study will be determined on a case-by-case basis. A request for an evaluation by the Academy’s IRB of a collaborative study that involves the Naval Academy and/or a USNA population group (or subset thereof) cannot be made until the benefits review has been completed and a permission to proceed with the protocol submission has been obtained. Additional guidance on this “benefits evaluation” requirement can be obtained from the Academy’s HRPP office.

c. Each collaborative research project that involves a USNA population group (or any subset thereof), as defined in Section 1.6 of this policy document, must be reviewed by the Academy’s IRB and approved by the Superintendent before the project can commence.

d. **Deferring IRB approval to a collaborating institution is not permitted if USNA populations or the data about them are directly or indirectly involved in the project or study.**

e. Persons not employed at the Naval Academy who wish to conduct research on or about a USNA population group (or subset thereof) as defined in Section 1.6 of this policies and procedures manual must partner on the project with a USNA faculty member, NAPS faculty member, USNA staff collaborator or NAPS staff collaborator before the proposed project will be considered for review by the Academy's IRB and subsequent approval by the Academy's Superintendent. The USNA project partner must:

1. serve as the USNA point-of-contact on the project;
 2. coordinate the preparation of all submissions and responses to the Academy's IRB;
 3. coordinate the human subject research training of all non-USNA collaborators;
 4. maintain copies of all required records and files associated with the project;
 5. assist the external collaborators as their institution prepares additional paperwork required to pursue the project, such as preparing an application for a DoD Navy Addendum to the institution's FWA (if required), etc.
 6. ensure that all federal regulations, DoD, DoN, SECNAV instructions, and USNA policies and procedures that apply to human subject research projects are adhered to by the external researchers.
 7. understand that being a research "partner" requires an active involvement in the project by the USNA investigator, and cannot be agreed to "in-name only" so that the external researcher has access to a USNA population that he/she would not otherwise have in the project;
- and** 8. accept the legal and ethical responsibilities associated with being involved in the project.

f. The department or office of the principal investigator (or point-of-contact) at USNA is responsible for ensuring that collaborative research activities that involve USNA human subjects or the data about human subjects have been reviewed via the Academy's IRB process described in this policies and procedures manual and the notification of the Superintendent's approval of the project has been obtained in writing prior to any activity on the project.

g. The department or office of the principal investigator (or point-of-contact) at USNA is responsible for ensuring that appropriate protections for the USNA human subjects of a collaborative research protocol are in place within the Naval Academy department or office in the event that the proposed project is approved by the Superintendent.

h. The department or office of the principal investigator (or point-of-contact) at USNA is responsible for ensuring that appropriate protections are in place within the Naval Academy department or office for the data collected about USNA human subjects during an approved project. This includes protections while the data are collected and provisions for the safeguarding of the data once it has been collected. Particular attention must be paid to the secure storage of the data and the restrictions in access to the data by anyone other than the collaborating investigators.

18.3 Collaborative Projects that Involve Non-USNA Populations as the Human Subjects

a. In collaborative research projects, each institution is responsible for safeguarding the rights and welfares of the human subjects and for protecting the data collected about the participants. Each research partner must comply with the IRB policies of their home institution as well as with the IRB policies, procedures and instructions of the collaborating partner. The policies and procedures defined in this document apply to all research studies conducted at, on behalf of, or in collaboration with the U.S. Naval Academy.

b. Collaborative research projects that involve a non-USNA population and/or data about a non-USNA population, but involve USNA personnel as research collaborators must be reviewed by the Academy's IRB and approved by the Superintendent before the Academy personnel can become involved in the human subject research aspects of the project.

A deferral of the IRB approval to the collaborating institution is not permitted, however, a simplified review and protocol submission to the Academy's IRB may be possible so as to avoid duplication of effort. As a minimum, the Academy's HRPP office must:

1. verify that the collaborator's institution holds a valid DoD, DoN or other federal assurance or a DoD Navy Addendum to a Federal Wide Assurance;
 2. ensure that an "evaluation of scientific merit" has been completed;
 3. have on file the DoN training certificates of the non-USNA collaborators.
- and
4. have a copy of the IRB review and approval of the project by each of the collaborating institutions.

c. Guidance on the possibility of the USNA collaborator submitting a simplified research protocol, on a collaborative project that does not involve any USNA populations (or subsets thereof) as the human subject in the project and does not require any data about USNA populations, and only involves USNA personnel as project collaborators, is available from the Academy's HRPP office.

18.4 Conditions of Approval for All Projects

- a. As a condition of approval to conduct the collaborative research with USNA populations, each of the investigators must agree to adhere, in general, to all USNA policies and regulations, and in particular, to the Human Research Protection Program (HRPP) policies defined in this policies and procedures manual.
- b. The Academy's IRB must confirm that all research collaborators (as institutions and as investigators) hold current Assurance approvals prior to recruiting and enrolling human subjects in the research study. This requirement applies to all academic personnel, Naval personnel, subcontractors and sub-grantees, etc., who may participate in the project. The type and approval authority of an Assurance, along with the institution's identification information, must be recorded in the Academy's IRB records for the protocol.

18.5 Recordkeeping

- a. It is the responsibility of each of the collaborating investigators and the Academy's HRPP office to record the Assurance identification information, date of issue, and approval authority for each participating institution on the project. Documentation of a DoD Navy Addendum for a non-federal collaborator must also be recorded by each participating institution.
- b. The tracking number and approval number assigned to a research protocol during the Academy's IRB process must be recorded on all files maintained on an approved study by the PI for the project and by the Academy's HRPP office. (Additional information about these numbers is available in Section VIII of this policies and procedures manual.)
- c. 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.