

## Fundamental Premise

The U.S. Naval Academy subscribes to the highest levels of ethical practice, based on the three main principals of the Belmont Report.

**Respect for Persons:** The Naval Academy recognizes the personal dignity and autonomy of individuals. Human subjects must be allowed to enter into a research project voluntarily and with adequate information to make an informed decision.

**Beneficence:** The Naval Academy recognizes its responsibility to protect persons by maximizing the anticipated benefits with an activity while minimizing potential harm.

**Justice:** The Naval Academy recognizes its obligation to monitor that all investigators ensure no one group is either consistently selected to participate, or consistently deprived of the opportunity to do so.

### INSTITUTIONAL REVIEW BOARD (IRB)

The Superintendent appoints a group of scientists, engineers and non-scientists to protect the rights and welfare of human subjects (YOU!). The IRB reviews and recommends approval for all human subject research at USNA.



The Human Research Protection Program (HRPP) is responsible for the management and safeguarding of all human subject research institutional records.

We recognize the need for appropriate additional protections for Midshipmen involved in human subject research who are likely to be vulnerable to coercion or undue influence.

The HRPP Office encourages and promotes communication first between the investigator and research subjects.

You may contact this office at any time to:

- ◆ Obtain answers about your specific rights
- ◆ Express concerns about a project/study
- ◆ Discuss issues about the research with someone not involved in the protocol



Human Research Protection Program

United States Naval Academy  
589 McNair Road  
Annapolis, MD 21402  
Mail Stop 10M

Phone: 410-293-2533  
Fax: 410-293-2507  
E-mail: HRPPoffice@usna.edu

## USNA Human Research Participant Rights



*Midshipmen guidance  
for making an informed  
decision about  
participating in human  
subject research.*

United States Naval Academy HRPP  
Nimitz Library Building G-10  
410-293-2533

## Definitions to Know

**Research: A systematic investigation designed to develop or contribute to generalizable knowledge.**

- ⇒ Research projects ask a question, state a method to seek an answer or solution, recruit subjects, and share the results with the public.
- ⇒ Research can take the form of a project, pilot study, experiment, survey, evaluation, development study, clinical study, investigation, questionnaire, focus group, etc.

**Assessment: Evaluation of a program, course or initiative for internal purposes.**

- ⇒ Surveys, studies or questionnaires are often used to determine value or effectiveness within the USNA.
- ⇒ This is NOT considered to be research and can be mandatory for Midshipmen.

**Undue Influence or Coercion: Using excessive or inappropriate rewards, exerting pressure based on relationship, or threatening harm in order to gain participation of a subordinate.**

- ⇒ Investigators cannot use rank or the student/teacher relationship as an influence when recruiting Midshipmen for research.

**Incentives: Rewards offered in exchange for subject participation in research.**

- ⇒ Midshipmen cannot receive cash payments.
- ⇒ With Superintendent approval, rewards such as Mid Store cards, extra credit, time off, etc. can be authorized under specific conditions.

## The Informed Consent Process

Investigators must provide a verbal or written explanation of the project to include:

- \* That the study is for research purposes
- \* Participation is strictly VOLUNTARY
- \* Description of the activity involved
- \* Time commitment for participants
- \* Any anticipated risks or discomfort
- \* Benefits to the research subject, if any
- \* Whether the activity is experimental
- \* Age of subjects (excludes under 18)
- \* Discussion about the extent of confidentiality of the records to identify the subjects
- \* Incentives offered to participate
- \* Participants can OPT OUT of a study at any time during the process without penalty
- \* Whom to contact on the investigative team for questions about the project
- \* Referral for treatment or other concerns should an unanticipated problem arise
- \* Contact information for the HRPP Office

## Inquiring Minds Want to Know

If you want clarification or more information about a project at ANY time in the process, don't hesitate to speak up.

**Midshipmen Can Ask Questions!**

## Midshipmen Rights in Research

### PARTICIPATION IS VOLUNTARY

You must agree to take a survey or take part in any research activity. And you can decide to withdraw from a study at any time, without penalty.

You should not feel pressure, obligation or coercion to be a research subject.

### SEEK FIRST TO UNDERSTAND

Make sure you are given adequate information, the procedure is clearly stated, and any concerns are addressed by the investigator. Receive a copy of the Informed Consent or an information sheet.



*Midshipmen can make a difference in research!*