

Section IV: Selection of Research Subjects and Informed Consent

4.1 Definition of Informed Consent

As noted in Enclosure (2) and in Section II of this policies and procedures manual: “Informed consent” is “a person’s voluntary agreement, based upon an adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic or preventive procedure. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution or agents thereof from liability for negligence.”

4.2 Recruitment and Selection of Participants

a. As noted in reference (i) of Enclosure (1): Voluntary informed consent is a fundamental precept to ethical research with humans, and as such, it begins with subject recruitment. Every care must be taken to identify eligible participants for a research study, to educate the possible participants and their legal guardians (as appropriate) to the goals and methodologies of the study, and to allow each selected recruit the opportunity to refuse to participate in the study.

b. Each potential participant in human subject research must have sufficient information to make an informed decision about participating in the proposed study.

1. If a potential participant cannot physically, mentally or legally give informed consent for him or herself, the consent must be obtained in writing from the individual’s legal representative.

2. Informed consent must be obtained from each potential subject, unless the Academy’s IRB has waived the requirement of informed consent and/or the documentation of informed consent.

3. If a potential subject is a minor, the individual’s legal representative must provide informed consent, unless this required is waived by the Academy’s IRB, with justification.

4. Justification for waivers is described in section 116 (c) and (d) and section 117 (c) of reference (c) of Enclosure (1).

c. When the potential participant is a minor or when he/she is mentally incapacitated, the written permission (with signature and date) of the individual’s legal representative is required on the informed consent paperwork.

d. Emancipated Minors

1. Age seventeen (17) is the minimum age to join the military; nevertheless, a volunteer who is seventeen must have the written permission of a parent(s) or a legal guardian to enlist in military service. In Maryland, there is no specific law declaring a member of the military (including those at the service academies) emancipated from his or her parents. Once a minor reaches age 18 in Maryland, he/she is emancipated regardless of military status. Similar ambiguity exists in Rhode Island state law.

2. As a result of the lack of clarity in the federal and state laws, midshipmen at the Naval Academy (USNA) and midshipman candidates at the Naval Academy Preparatory School (NAPS) in Rhode Island who are under the age of 18, as well as visitors to USNA or to NAPS who are under the age of 18, may complete surveys and/or participate in research studies only after an informed consent form has been discussed with the legal guardians of the potential participant and the approving signatures of the guardian(s) have been obtained. All informed consent issues must be addressed before the minor may participate in the proposed activity.

e. Superior to Subordinate

Regardless of the risk level of the research, no superiors (civilian or military) may influence, in any manner, the decisions of their subordinates (civilian or military) whether to participate as research subjects in any research activity.

f. Active Duty Military Personnel

1. Active duty military personnel (including midshipmen at USNA and midshipman candidates at NAPS) serve in an environment where the ability to make a voluntary decision not to participate in a research effort could possibly be compromised. Potential participants cannot be required, compelled, ordered or coerced into participating in any form of research. This applies equally to assessment activities, surveys and focus groups. Participation cannot be mandated; nor may it be ordered by the chain-of-command within a military organization.

2. Actions such as requiring subjects to sign documents verifying participation or sanctioning penalties (to include administrative and/or conduct actions by superiors) for declining to participate in a research project, survey or focus group is strictly prohibited.

3. Subjects in a study, survey or focus group cannot be required, compelled, ordered or coerced into discussing the results of their participation in the research (such as revealing their responses on a survey) to anyone outside of those immediately responsible for the research protocol, survey or focus group.

4. When an individual informed consent form is required for participation in a research study, survey or focus group: Senior officers, non-commissioned officers and midshipmen superior to the potential participant may not present the informed consent paperwork to their

subordinates. In the case of senior to junior requests, the need for an informed consent must be presented by an independent person so as to avoid all appearances of chain-of-command pressure, direct or implied orders, etc.

g. Protected Classes of Research Subjects

1. Federal regulations provide higher standards of protection for individuals belonging to certain classes of research subjects. These include, but are not limited to, prisoners, pregnant women and their fetuses, the seriously ill, mentally or cognitively compromised adults, and minors under the age of eighteen.

2. Secretary of the Navy-level approval may be required on the proposed research when it involves any of the protected classes of human subjects. The Academy's Human Research Protection Program office will advise the principal investigator (PI) for the proposed project of the need for a Secretary of the Navy-level approval. The Director of the Academy's HRPP office (not the PI) will serve as the USNA point-of-contact to the appropriate Secretary of the Navy office to request the required approval.

3. Proposed research efforts that will involve any of the protected populations must be discussed, in detail, with the Director of the Academy's Human Research Protection Program (HRPP) office before a research protocol is submitted to the Academy's IRB. Attention in the discussions should focus on the underlying reasons for the inclusion of participants in a protected population in the proposed project, how the data will be collected and stored, and the additional steps required of USNA to secure a Secretary of the Navy-level approval for projects that include members of a protected class of participants. The principal investigator for the research activity, as well as his/her USNA and non-USNA collaborators, are restricted from soliciting participants, distributing informed consent documents, or taking any other action to initiate the research until after the Academy's IRB and the Superintendent have recommended approval and written Secretary of the Navy-level approval of the project has been received by the Director of the Naval Academy's HRPP office.

4.3 "Research Fatigue"

a. Repetitive sampling of the same population results in "research fatigue". (An example would be repetitive surveys of all female midshipmen in a given class in the Brigade of Midshipmen at USNA.) Unless there is a clear and compelling reason to do otherwise, only random samples of participants can be used for research projects, surveys and focus groups. This is especially relevant when the potential respondents are midshipmen at USNA and/or midshipman candidates at NAPS.

b. Requests to deviate from a random sampling technique must be discussed, in detail, with the Director of Institutional Research before a research protocol is submitted to the Academy's IRB. Attention in the discussions should focus on the justifications for deviating from a random sampling of participants in the proposed project, and the impact on the proposed project if the request for a directed, rather than random, sampling technique is not approved.

c. The principal investigator for the research activity, as well as his/her USNA and non-USNA collaborators, are restricted from soliciting participants, distributing informed consent documents, or taking any other action to initiate the research until after the project has been reviewed and favorably recommended by the Academy's IRB and subsequently approved by the Academy's Superintendent.

4.4 Federal Limitations on the Use of Humans as Experimental Subjects

Per reference (f) of Enclosure (1): "Funds appropriated to the Department of Defense may not be used for research involving a human being as an experimental subject unless

- (1) the informed consent of the subject is obtained in advance; or
- (2) in the case of research intended to be beneficial to the subject, the informed consent of the subject or a legal representative of the subject is obtained in advance."

4.5 Follow-up after the Research Project Concludes

Depending on the nature of the research undertaken, ongoing discussion with and additional education of the human subjects who participated in a project may be necessary long after the original informed consent of the individual was obtained. It is the responsibility of the principal investigator (PI) on the research project to (1) continue after-project discussions with the study participants and (2) keep the Academy's IRB and the Academy's HRPP office advised of these discussions.

4.6 General Requirements for "Informed Consent" Documents

a. In accordance with reference (c) of Enclosure (1), the components of an "Informed Consent" document for research projects must include the following information. (A standardized template for an informed consent document is available from the Academy's IRB website.)

1. a full disclosure of the name(s) and contact information for the principal investigator (PI) and for the USNA and non-USNA sponsor(s) of the research project.
2. a full disclosure of the name(s) and contact information for the USNA and the non-USNA collaborator(s) on the research project.
3. a detailed explanation of the purposes of the research.
4. an expected time duration for persons who choose to participate in the research.
5. a summary of the procedures and methodologies to be followed in the project.

6. a detailed description of any procedure that is experimental in nature.
 7. a description of any foreseeable risks or discomforts, and the expected levels of these risks or discomforts, to persons participating in the research.
 8. a description of any benefits to the persons participating in the study or to others that may reasonably be expected from the research.
 9. a statement, if applicable, describing appropriate alternative procedures or courses of treatment that might be advantageous to the persons participating in the research.
 10. a statement regarding the anonymity or confidentiality of the persons participating in the study. If records identifying the human subjects will be maintained, the informed consent form must indicate the extent to which these records will be kept confidential, who will maintain the data, and who will have access to the raw data during the research and beyond.
 11. the contact information for the PI's immediate supervisor for relevant questions about the research practices proposed by the PI.
 12. the contact information for the Academy's HRPP office, in the event that the participants in the research project have questions about their rights and about any research-related injuries.
 13. a statement that participation in the proposed research, survey or study is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
 14. the reference tracking number assigned to the research project.
- b. Where appropriate, the human subjects participating in research may be provided with additional information such as the following. As a condition of approval for the study, the Superintendent may require the PI to provide some or all of the following to those persons choosing to participate in the study.
1. a statement that the particular treatment or procedure may involve unforeseeable risks to the persons participating in the research.
 2. a statement that outlines the anticipated circumstances under which the subject's participation may be terminated by the investigator without securing the subject's consent.
 3. a statement that outlines any additional costs to the subject that may result from his or her participation in the research.

4. a statement that explains the consequences that may result from a subject's decision to withdraw from the on-going research project.

5. a statement that explains the procedures for orderly termination of participation by the person.

6. a statement that significant findings developed during the course of the research may relate to the subject's willingness to continue participation; and

7. a statement that provides the approximate number of participants in the research.

4.7 Waiver of the Documentation of Informed Consent

a. Per reference (b) of Enclosure (1), there are situations whereby the Naval Academy's Institutional Review Board (IRB) may recommend and the Superintendent may approve a consent procedure which does not include, or which alters, some or all of the elements described in Section 4.6, or may waive the requirements to obtain documented informed consent, by individuals, provided any one of the following applies and is recorded.

1. The research involves no more than minimal risk to the subjects.

2. The waiver or alteration of the consent procedure will not adversely affect the rights and welfare of the human subjects.

3. The research could not practically be carried out without the waiver or alteration.

4. The research does not involve members of a protected class of research subjects.

b. Wherever appropriate, the human subjects in a study will be provided with pertinent information after their participation.

c. The Academy's Superintendent, acting on a positive recommendation of the Academy's IRB, is the only person or entity at the Naval Academy who can grant waivers or approve alterations to the requirements for written documentation of informed consent.

d. In the event the research involves members of a protected class of research subjects (See Section 4.2(g) above.), the Director of the Academy's HRPP will coordinate the efforts to obtain all required Secretary of the Navy-level approvals for the research. Any waiver of the documentation of informed consent by members of a protected class of research subjects can only be approved at the Secretary of the Navy-level, when the project itself is approved.

e. A waiver of the documentation of *individual* informed consent does not reduce in any way the responsibility of the principal investigator to convey (orally or in writing) to the human subjects participating in a research project all of the elements of informed consent disclosure that are normally found in a written and signed form.

4.8 Waiver of Informed Consent

a. If the principal investigator believes a research project requires a waiver of informed consent by the proposed project participants, the Superintendent (via the Academy's IRB) must be petitioned for a waiver of informed consent as part of the proposal submission to the Academy's IRB. The specific justification for each waiver of informed consent must be recorded in the minutes of the Academy's IRB meeting held to discuss the proposed project. The Superintendent can favorably endorse a request for waiver of informed consent, but he/she cannot approve such a request.

b. Per reference (i) of Enclosure (1), all waivers of informed consent that involve USNA personnel and/or projects conducted at USNA with non-USNA personnel must be approved by the Secretary of the Navy. A record of the Academy's IRB recommendation to the Academy's Superintendent and a record of the Superintendent's favorable endorsement of the recommendation must be sent to the Secretary of the Navy as part of the supporting documentation forwarded with the request for a waiver of informed consent. The Academy's HRPP office is responsible for the logistics associated with submitting the request for the waiver approval to the Secretary of the Navy. The Secretary's decision on the request for a waiver of informed consent must be included in the Academy's IRB records retained on the project.

c. No activities on a proposed project may begin until the informed consent waiver has been granted by the Secretary of the Navy, written notification has been received by the Academy's HRPP office from the Secretary, and the principal investigator has been advised of the favorable decision by the Secretary of the Navy.

4.9 Informed Consent vs Assent

a. Per reference (b) of Enclosure (1):

1. *Children* are "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted".
2. *Assent* means "a child's affirmative agreement to participate in research". A child's failure to object should not, absent affirmative agreement, be construed by anyone directly or indirectly involved with the research, as assent.
3. *Permission* means "the agreement to participate" by the parent(s) or guardian(s) for his/her (their) child or ward.
4. *Parent* means "a child's biological or adoptive parent", and *guardian* means "an individual who is authorized under applicable state or local law to consent on behalf of the child to general medical care".

- b. As noted in the definition of *assent*, a child's passive resignation to submit to an intervention, a procedure, or involvement in a project cannot not be considered assent. Federal regulations do not specify an age at which informed assent of the child should be possible. It is expected that the assent process should be considered whenever children are to be participants in a research activity. Therefore, the Academy's IRB is granted considerable discretion in determining whether a child is capable of assenting to his/her participation in a project. In addition, the Academy's IRB is granted the authority to determine whether and how a child's assent is documented, who explains the project and the assent process to the child, who is present (or not present, such as the child's parent) during the discussion on assent, etc.
- c. As a matter of practice, every effort should be made by the researchers to conduct projects that involve children capable of assent before enrolling those less able to assent.
- d. If a parent (or guardian) provides an affirmative informed consent for the child, but the child does not assent to participate in the project, then the child's declination of participation outweighs the parent's desire and permission for the child to participate.
- e. Questions about "assent" should be addressed to the Academy's HRPP office.

4.10 Legal Effectiveness of Informed Consent

The informed consent and documentation requirements for informed consent in this policies and procedures manual are not intended to preempt any applicable federal, state, or local laws which require additional information be disclosed for informed consent to be legally effective.

4.11 Including "Informed Consent" Documents in the Academy's IRB Protocol Submissions

- a. Templates of the proposed informed consent documents for a proposed project must be included in all protocol packages submitted to the Academy's IRB. (A standardized template for an informed consent document is available from the Academy's IRB website.)
- b. Depending on the roles of the human subjects in the proposed project and the nature of the research, additional information beyond the minimum outlined in Section 4.6(a) above may be appropriate on an informed consent form.
- c. Informed consent documents for the proposed research must be clearly written and in sufficiently understandable language to allow the potential participant (or his/her legal guardian) to make an informed decision on involvement. To the maximum extent possible, the informed consent form should be written in non-technical language that is understandable to a non-expert in the research field. As appropriate to the project description and, in particular, to the participant's role in the research, all scientific, technical, and/or medical terms must be clearly defined in the research protocol and on the consent form.

d. Once a protocol involving human subject research or the data about human subjects has been recommended for approval by the Academy's IRB and subsequently approved by the Academy's Superintendent, written informed consent must be sought from each prospective subject in the research or from the subject's legal representative, unless this requirement is waived, with justification, by the Academy's IRB. (See Section 4.2 (b) for more information on waiver justifications.)

e. As noted in Section 4.2(f.4) above, the need for an informed consent must be presented by an independent entity so as to avoid even the appearance of chain-of-command pressure, direct or implied orders, etc. The person/office responsible for presenting and collecting the informed consent forms to the potential research or survey participants will be determined as part of the Academy's IRB review of the research protocol.

f. Informed consent of each participant in the research project must be appropriately documented. Informed consent documents will be maintained as part of the file on the research project by the Academy's HRPP office.

4.12 Deception

a. Deception involves withholding information from subjects that might affect their decision to participate in the research. Principal investigators must respect an individual's right, based on full and open information, to make a decision about his/her participation in a proposed research project. Withholding information violates the fundamental ethical principle of autonomy.

b. There are certain types of research that would be impossible without some degree of deception (*e.g.*, fields such as social psychology). In these limited cases, deception is acceptable under federal regulations as long as appropriate protections are provided and the need for the deception is validated by the Academy's IRB and subsequently approved by the Superintendent before any participants are solicited, informed consent documents are distributed, or data collection activity begins on the project.

c. The Principal Investigator (PI) for a project must make a sufficiently strong case to the Academy's IRB before the use of deception will be approved in a proposed research project. In turn, the Academy's IRB must favorably recommend and the Superintendent must approve the planned deception, in writing, before the research project may begin.

d. Deception occurs in varying degrees of severity, with the severity progressively increasing, in order, below.

1. Incomplete disclosure: In this most benign form of deception, subjects in a research effort are told the truth in what they are told, but they are not told the whole truth. (*i.e.*, They are provided limited, but truthful, information.) The only information that is typically withheld in this scenario is the experimental hypothesis. This is done to ensure that the subjects participating in the project provide unbiased responses.

2. Deception as to the purpose of the experiment: The human subjects in the research protocol are knowingly misled with respect to the overall purpose of the experiment and/or with respect to some specific aspect(s) of the research protocol.

3. Deception about the status of other individuals: This deception may be one of two types. (a) Persons thought to be other subjects in the research are in fact not participants in the effort. These individuals are referred to as “confederates”. (b) Persons assumed to be outside of the experiment are in fact participating in the experiment.

4. Deception about their own status: This form of deception occurs when participants are not even aware that they are subjects in a research effort until after the experiment has concluded. This is the most severe form of deception.

e. Should deception be required and subsequently approved for a research project that involves human subjects, the Academy’s IRB and Superintendent endorse the following principles of best practice in studies requiring deception.

1. Deception must not be employed if there is an alternate methodology to allow for an investigation of the research question without resorting to the planned deception.

2. Incomplete disclosure, to protect the research hypothesis, may be considered by the Academy’s IRB and the Superintendent to be acceptable as long as every project / experiment involving the deception includes the following provisions:

(a) The informed consent document must advise potential research subjects that they are not receiving all of the relevant information prior to the project, but that they will be fully informed of all of the withheld information at the conclusion of the project. Language such as: “We cannot explain all of the details of the experiment to you at this time, but the details will be explained fully at the conclusion of the experiment.” are recommended for inclusion in the informed consent document(s).

(b) Subjects who choose to participate in the project must receive a thorough debriefing at the conclusion of the experiment or project. This debriefing, conducted by the Principal Investigator, must include a disclosure of the deception and an explanation of why it was necessary. At least one member of the Academy’s IRB must be present for this debriefing.

(c) As part of the methodology of the study, a complete debriefing script should be reviewed and approved by the Academy’s IRB and by the Director of the Academy’s HRPP office prior to any data collection activity on the project.

(d) To restore a subject’s autonomy and control (*i.e.*, to restore the person’s right to decide on participation based on full information), experimenters must, at the conclusion of the debriefing, offer the subject the opportunity to withhold the use of his or her data if he/she is in any way unhappy with or concerned about the deception.