

BASIC INFORMATION FOR PROSPECTIVE INVESTIGATORS

ASSURANCE OF COMPLIANCE WITH POLICIES FOR THE PROTECTION OF HUMAN SUBJECTS

Federal regulations for the protection of human subjects require each institution that conducts research involving human subjects to describe, in detail, the procedures it will use to protect the rights and welfare of the human subjects. Each institution prepares a document that describes these procedures. The document is called an "Assurance of Compliance," commonly referred to as an "Assurance".

The NMCS D Federal Wide Assurance (FWA) is a public declaration by NMCS D that commits all NMCS D employees to comply with policies for the protection of human subjects before beginning any research and to continue compliance until completion.

The NMCS D FWA sets standards that meet both ethical and legal requirements. Failure to comply with the NMCS D FWA may constitute unethical behavior and violation of the law. Failure to comply can delay research, harm subjects, and generate sanctions against an investigator, the research program, NMCS D or the Navy.

The NMCS D Assurance applies to all research activities involving human subjects conducted by NMCS D personnel or supported by NMCS D contracts or other agreements, and requires that all NMCS D research activities involving human subjects follow the ethical principles of The Belmont Report and the legal requirements of applicable Federal Regulations (e.g. 32 CFR 219 and 45 CFR 46).

THE PRINCIPLES OF THE BELMONT REPORT GOVERN ALL RESEARCH SUPPORTED BY THE U.S. GOVERNMENT.

These principles are:

1. **Respect for Persons:** This principle acknowledges the dignity and freedom of every person. It requires obtaining informed consent from research subjects (or their legally authorized representatives).
2. **Beneficence:** This principle requires that researchers maximize benefits and minimize harms associated with research. Research related risks must be reasonable in light of expected benefits.
3. **Justice:** This principle requires equitable selection and recruitment and fair treatment of research subjects.

DEFINITION OF HUMAN SUBJECTS RESEARCH

Federal regulations and the FWA apply to research involving human subjects.

A **human subject** is a living individual about whom an investigator obtains either (1) data through intervention or interaction with the individual; or (2) identifiable private information.

Research means a systematic investigation designed to produce generalizable knowledge. Research may involve direct interactions or interventions with subjects, such as obtaining data by taking medical histories, obtaining blood samples, urine sampling, diagnostic procedures, or treating patients at least in part for the purpose of gaining generalizable information. Research may also involve indirect activities such as the analysis of specimens or data from people. Participation in these kinds of indirect activities, particularly if you plan to publish the results (or be a co-author), constitutes human subjects research.

The intent to publish the results of an activity nearly always means that it is research.

DUTIES OF THE PRINCIPAL INVESTIGATOR

The Principal Investigator:

- Designs the research study.
- Writes the protocol.
- Submits the protocol to the NMCS D Institutional Review board (IRB) for initial review and approval.
- Complies with all IRB decisions and stipulations.
- Is responsible for the conduct of the protocol, including rigorous adherence to sound scientific procedures and sound ethical principles.
- Submits all required forms / information to the IRB for its continuing review of the protocol.
- Reports promptly to the appropriate NMCS D IRB and others any unanticipated problems involving risks to subjects or others, or unexpected serious harm to subjects.
- Submits to the IRB proposed amendments to previously approved research.
- Complies with all requirements of the Food and Drug Administration when using investigational drugs, investigational devices, biologics, or other regulated test articles.

COLLABORATION IN RESEARCH

Special provisions must be made if you intend to collaborate in research involving human subjects at sites other than the NMCS D. These provisions are required because when you collaborate, you accept some measure of responsibility for protecting the rights and welfare of the human subjects involved.

What constitutes "collaboration" on the part of an NMCS D investigator? Collaboration exists if the NMCS D participant expects "something in return" as a result of having participated in a research activity. "Something in return" could include data, authorship on a publication, samples, or even patent rights. NMCS D views authorship as evidence of collaboration.

Collaborative activities may include but are not limited to:

- Collection of specimens.
- Visits to institutions to perform research activities or clinical research.
- Exchange of information containing personal identifiers.
- Preliminary data-collection activities involving human subjects.
- Substantive intellectual contributions to research techniques, protocol design, or interpretation of data.

Collaboration with researchers in human subjects research activities at other institutions is subject to the requirements of the NMCS D's Assurance. For example, collaborative research activities in which subjects are enrolled at a non-NMCS D site must meet high ethical standards similar to those required at the NMCS D. Before you begin the research, both you and your IRB must have documentation that your collaborator's IRB has reviewed and approved the protocol.