



DON Human Research Protection Program

Department of the Navy Human Research Protection Program

Roles and Responsibilities of Principal
Investigators

May 2013



DON Human Research Protection Program

HISTORY AND REGULATIONS



US Historical Underpinnings



DON Human Research Protection Program

- Tuskegee Experiment
 - Began in 1930 as a Public Health Service study of untreated syphilis
 - 400 African-American men with syphilis and 200 without, participated in this study (none were told they were infected)
 - Recruited without informed consent and were misinformed of some of the study procedures
 - Although a cure was found in the 1940's:
 - Study continued as planned
 - Participants were not informed or treated



US Historical Underpinnings



DON Human Research Protection Program

- Tuskegee study became public in 1972 through an Associated Press news article resulting in:
 - Congressional advisory panel provided policy recommendations to ensure that such maltreatment would not happen again
 - Recommended the establishment of a permanent body with the authority to regulate all federally supported research involving human subjects



Legislative and Executive Action



DON Human Research Protection Program

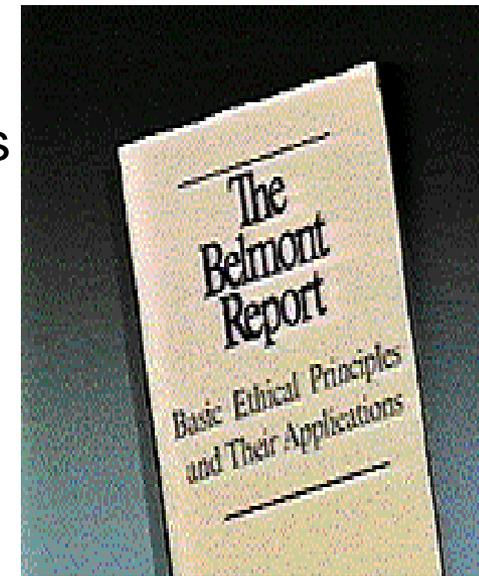
- 1974: National Research Act passed and signed
- 1979: National commission for the Protection of Human Subjects of Biomedical and Behavioral Research established by Congress



The Belmont Report

DON Human Research Protection Program

- Commission identified basic principles for guiding the involvement of human subjects in research
 - Respect for Persons
 - Autonomy/Informed Consent
 - Additional protections for vulnerable subjects
 - Beneficence
 - Good research design
 - Competent investigators
 - Favorable risk/benefit analysis
 - Justice
 - Equitable selection of subjects
 - Appropriate inclusion and exclusion criteria





Regulations and Policies



DON Human Research Protection Program

DON human subject research is governed by Federal, DoD and DON policies:

- **10 USC 980**: Limitation on Use of Humans as Experimental Subjects
- **DoD Instruction 3216.02**: Protection of Human Subjects and Adherence to Ethical Standards in DoD Supported Research
- **SECNAVINST 3900.39D**: Human Research Protection Program



Regulations and Policies



DON Human Research Protection Program

- **32 CFR 219:** DoD's implementation of 45 CFR 46, Subpart A
- **45 CFR 46 Subpart B:** Additional Protections for Pregnant Women, Human Fetuses, and Neonates Involved in Research
- **45 CFR 46 Subpart C:** Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects
- **45 CFR 46 Subpart D:** Additional Protections for Children Involved as Subjects in Research



DON Human Research Protection Program

DEFINITIONS



Definitions

DON Human Research Protection Program

- Research
 - “...a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” [32 CFR 219.102(d)]
- Human subject
 - “...a living individual about whom an investigator (whether professional or student) conducting research obtains
 - Data through interventions or interaction with the individual, or
 - Identifiable private information.” [32 CFR 219.102(f)]



Definitions

DON Human Research Protection Program

- Research Involving Human Subjects
 - Activities that include *both* a systematic investigation designed to develop or contribute to generalizable knowledge, AND
 - involve a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or identifiable private information.

--DoDI 3216.02



DON Human Research Protection Program

PRINCIPAL INVESTIGATOR RESPONSIBILITIES PER SECNAVINST 3900.39D



DON Human Research Protection Program

1. Must be current federal employees

- Uniformed or civilian, staff, or trainee **OR** covered under the Intergovernmental Personnel Act (IPA), **OR** a consultant consistent with requirements at 5 USC 3109
- AND**, must be assigned to or employed by a specific command.
- Status as a contractor or federal retiree alone is not sufficient to qualify individuals as principal investigators for such research.



Principal Investigator Responsibilities



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2. Complete and document initial and continuing research ethics and human subjects protections training.

- All personnel involved in reviewing, approving, supporting, conducting, managing, or overseeing research involving human subjects must complete initial and ongoing training...
- PIs may access the online Collaborative Institutional Training Initiative (CITI) Program to meet the training requirements. This online training can be found at <https://www.citiprogram.org>.



Principal Investigator Responsibilities



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3. Obtain written determination of whether the proposed activity is research with human subjects or the research meets criteria for exemption.

- Activities that do not qualify as research, activities that do not involve human subjects **AND** exemption determinations...will be determined by IRB Chairs, IRB Vice chairs, designated IRB administrators, or designated officials of the HRPP.
- Investigators may not make these determinations.



Principal Investigator Responsibilities



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- 4. Obtain institutional approval prior to conducting or continuing research.**
 - Scientific review is required.
 - IRB review and recommendation for approval
 - The IRB will determine if the review will be by expedited procedures or by full board.
 - The PI's CO is the approval authority and this may not be delegated.



Principal Investigator Responsibilities



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5. Obtain institutional approval prior to implementing proposed amendments to approved research.

- All amendments require IRB review and Command approval.
- Includes amendments to exempt research.
- IRB review of amendments may be done by expedited procedures or by full board depending on the amendment.



Principal Investigator Responsibilities



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- 6. Notify the IRB in writing of unanticipated problems involving risks to subjects or others; serious adverse events; serious or continuing noncompliance with the human subjects protection regulations and IRB requirements; and protocol deviations**
 - An unanticipated problems involving risks to subjects or others (UPIRTSO) is unexpected, related or possibly related to the research, and suggests greater risk than previously known.
 - An adverse event is any unfavorable and unintended occurrence associated with the conduct of a research project.



Principal Investigator Responsibilities



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6. (Continued)

- Serious noncompliance is the failure...to act in accordance with (federal, DoD and DON regulations, instructions, and policies) such that the failure could adversely affect subjects;
- A protocol deviation is any departure from the approved research plan (including the protocol, the recruitment plan, etc).



Principal Investigator Responsibilities



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- 7. Obtain informed consent from research subjects or their legally authorized representatives and provide them a copy of the completed informed consent document prior to the start of research, unless a waiver of the documentation is approved by the institution.**
 - Voluntary informed consent is fundamental to ethical research with humans.
 - Informed consent includes a thorough discussion with prospective subjects and/or their legally authorized representatives and continues for at least the duration of the research.
 - Depending on the research, ongoing discussions and education of subjects may continue long after the original informed consent is obtained.



Contacts

DON Human Research Protection Program

Please contact DON HRPP with any follow-up questions or concerns.

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