

Research Regulatory Oversight Office



Office of the Under Secretary of Defense (Personnel and Readiness)

Force Health Protection and Readiness Programs,
Office of the Assistant Secretary of Defense (Health Affairs)

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Research Regulatory Oversight Executive Summary



Human Research Protection Program

- Director, Defense Research and Engineering (DDR&E) has oversight responsibility for Human Research Protection Program (HRPP)
- September 13, 2004, Memorandum for Record re: "Findings of the HRPP Review of Under Secretary of Defense, Personnel and Readiness," USD(P&R)
- DDR&E designated the Office of the Under Secretary of Defense (Personnel and Readiness) as a component requiring its own Assurance granting and oversight program
- December 2, 2004, USD(P&R) delegated responsibility for issuing Assurances to the Assistant Secretary of Defense for Health Affairs (ASD (HA))
- December 7, 2004, ASD(HA) delegated responsibility to the Deputy Assistant Secretary of Defense for Force Health Protection and Readiness (DASD(F&P&R))
- DASD(FHP&R) is Component Designated Official (CDO)
- April 29, 2005, USD(P&R) Approved a Management Plan and established HRPP



Assurance



- Each institution engaged in research that is conducted or supported by a federal department or agency, must have an Assurance
- An Assurance:
 - documents the institution's commitment to comply with applicable laws, regulations, policies, and ethical guidelines
 - describes the institution's program for ensuring compliance with the above
 - identifies the Institutional Review Board(s), IRBs, used by the institution
- Conducted = Intramural
- Supported = Extramural



Institution (32 CFR 219)



- Institution means any public or private entity or agency
- For P&R, institution means any component organization as defined by USD (P&R)
- Most OUSD(P&R) institutions are established at the DASD or Department of Defense (DoD) Activity Director level
- The head of the institution is required to sign the Assurance and must be acquainted with the basics of the protection program



Engaged



- Supported by the institution (e.g., contracted, funded, material support)
- Conducted or directed by employees or agents (including contractors and subcontractors)
- Conducted by or under direction of an institution or facility



Research (32 Code of Federal Regulations 219)

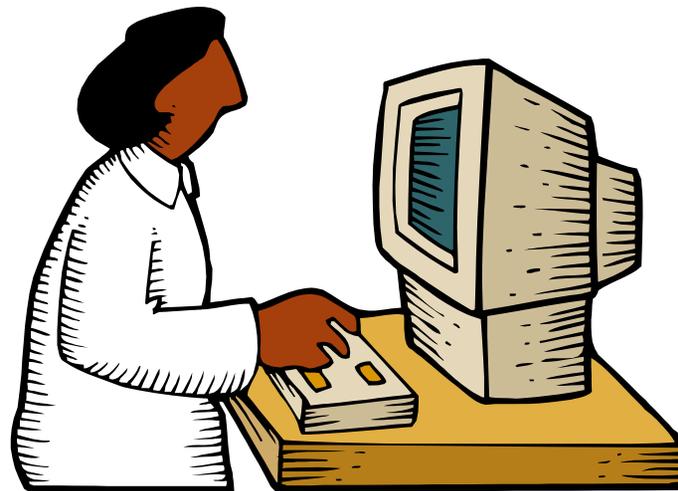


- A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge
- Systematic is hypothesis-driven with a research plan, data analysis, etc.
- Generalizable means the findings can be applied to other environments, people, or situations, or the results can be published in scientific or professional literature



Human Subject (32 Code of Federal Regulations 219)

- A living individual about whom an investigator conducting research, whether professional or student, obtains
 - data through intervention or interaction with the individual, or
 - identifiable private information





Human Subjects + Research

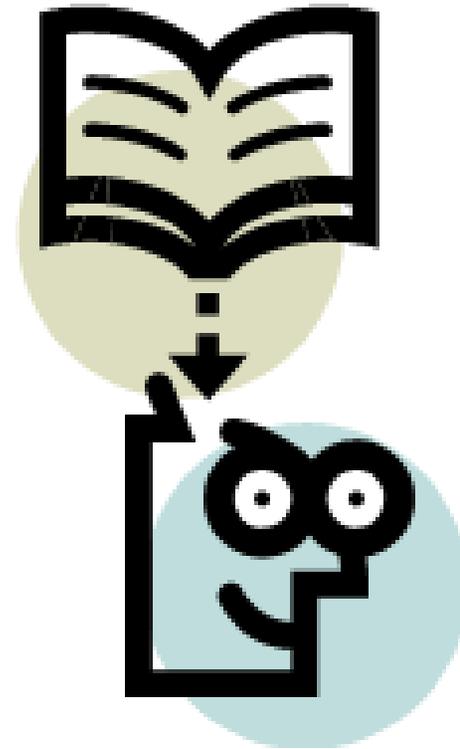


- Intervention includes manipulation of the subject or the subject's environment
- Interaction includes interviews, surveys, focus groups, etc.
- Identifiable private information research includes using existing data, micro-data files, data mining, etc.



Summary of Regulations

- Institutions conducting or supporting human subjects research must have an Assurance
- The USD(P&R) has the authority to issue DoD Assurances
- That authority has been delegated to the Component Designated Official (CDO): DASD(FHP&R)
- Assured institutions must have a human research protection program for assuring compliance with the requirements, including a designated Program Manager





USD(P&R) Assurances

- Assurances define the authorities and responsibilities of the Institutional Official (IO), the researchers, and the Institutional Review Board (IRB)
- Assurances are signed by the IO and the IRB chair(s) when applicable
- Assurance covers all research conducted or sponsored by the institution for three years
- The IOs designate individuals for the following responsibilities:
 - Program Manager to oversee research reviews and coordinate oversight activities
 - Exempt Determination Official (EDO) to determine which activities meet the regulatory definition of research and, if so, whether they meet the regulatory requirements for exemption from IRB review
 - Secondary Review Official (SRO) to serve as the Human Research Protection Official (HRPO) as required by the Defense Federal Acquisition Regulation for contracted research
- Institution develops and follows written procedures



Institutional Official

- The Institutional Official (IO) is the individual who signs the Assurance for the institution. The IO and other executives of the institution have certain responsibilities:
 - Act for and obligate the institution
 - Set the tone and provide guidance
 - Provide resources for the HRPP
 - Ensure researchers fulfill their responsibilities
 - Support the EDO and SRO
 - Establish effective institutional procedures
- IOs are the primary contact for:
 - resolution of unanticipated problems involving subjects or others,
 - continuing or significant noncompliance,
 - research misconduct, or
 - other adverse situations that may arise within their institutions



Exempt Determination Official

- An individual identified by the Institutional Official
 - Knowledgeable about research
 - No vested interest in the research
 - Sufficient stature and authority
- EDOs determine what level and type of review each project needs and document the decision
- EDOs begin as EDO-in-training. Once proficient, they may make independent determinations.
- Proficiency is determined by the Component Designated Official's program manager
- EDO derives authorities and responsibilities from both the IO and the CDO
- EDO is usually the Program Manager for the Institution's Human Research Protection Program



Secondary Review Official

- An individual identified by the Institutional Official
 - Subject matter expert on research regulations as applicable within the institutional environment
- Unlike EDOs, SROs must be fully proficient prior to appointment.
- Proficiency is determined by the CDO's program manager.
- SROs perform the Human Research Protection Official (HRPO) reviews required by the Defense Federal Acquisition Regulation for any research activity involving human subjects.
- SRO has authorities and responsibilities from both the IO and the CDO and is responsible to both for regulatory oversight of research conducted under contract or grant



Component Designated Official's Headquarters Office

- CDO HQ Office is Responsible for:
 - Training IOs, EDOs, and Researchers
 - Establishing overarching policies and procedures
 - Conducting secondary, headquarters level, reviews of research as needed
 - Responding to noncompliance issues
 - Conducting Assurance Compliance Reviews
 - Coordinating P&R response during our annual component review



Summary of Institutional Requirements

- The EDO and SRO are the cornerstone of the USD(P&R) Human Research Protection Program (HRPP)
- The EDO/SRO must have the support of the IO to be effective
- Activities that seem to involve human subjects research should be forwarded to the EDO for review and determination
- The EDO, SRO, and IO are responsible for ensuring all activities receive required review and approval
- The effectiveness of the process will be evaluated periodically by the CDO



Overview of the Federal Requirements

- Two key ideas permeate the laws, regulations, and policies
 - Ethical guidelines must apply when humans are used as subjects in research
 - Commensurability
 - Level of risk to the subject commensurate with potential benefit to the subject
 - Level of review and oversight commensurate with the level of risk associated with the research



Code of Ethics

- National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research report, "Ethical Principles and Guidelines for the Protection of Human Subjects of Research," April 18, 1979
 - Became known as the "Belmont Report"
 - Identified three ethical principles that should be applied to all research involving human subjects
 - The three principles were codified into regulation in 1991



Ethical Principles Applied to the Regulations

Ethical Principals	Regulation
<p>Respect for Persons: Extra protection when individuals have reduced autonomy</p>	<p>Informed consent: Additional regulations for active duty participants, children, etc.</p>
<p>Beneficence: Maximize benefit and minimize harm</p>	<p>Risk/benefit analysis for each project: Privacy / confidentiality protections</p>
<p>Justice: Equitable distribution of research burdens and benefits</p>	<p>Equitable: Selection of subjects is fair and equitable</p>



Laws, Regulations and Policies

- 32 CFR 219
 - Known as the “Common Rule” because the identical regulation was adopted by 18 Federal Departments and agencies
- 10 USC 980
 - Provides additional requirements for obtaining informed consent
- DoDD 3216.02
 - Summarizes additional DoD requirements



Institutional Review Board

- A Board of at least five people constituted as required by regulation
 - Appropriate expertise to evaluate the research
 - Scientific and non-scientific members
 - Community representatives
 - Diversity of race, gender, and cultural background
- IRB may approve, disapprove, or require modification to proposed research
- An IO or other institutional executives (e.g., Commanding Officer) may disapprove an IRB approved study, but may not reverse IRB disapproval



Shared Reviews

- When multiple institutions are engaged in a single project involving human subjects research, each institution must certify that the study has been reviewed by an IRB listed in the Assurance
- Those institutions may elect to rely on a single IRB, thus reducing duplication and facilitating the review process
- Such agreements must be documented in writing and signed by the IO or designee



Federal Requirements Summary

- EDO reviews research protocols to determine if human subjects research is exempt from the regulation. If exempt, then the human subjects review process stops.
- If not exempt, then it is forwarded to an IRB identified in the Assurance for review, either expedited or convened.



Protecting Human Subjects – A Shared Responsibility





Contact Information

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