



Human Research Protection Program Executive Summary

Caroline Miner

HRP Program Manager for the
OUSD (Personnel and Readiness) HRPP



Background

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



Assurance

- Any institution engaged in federally funded or sponsored research involving human subjects, 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



Institution (32 CFR 219)

- Institution means any public or private entity or agency
- For P&R, institution means any component organization as defined by P&R
- The head of the institution is required to sign the Assurance and to be acquainted with the basics of the protection program



Engaged

- Sponsored by the institution
- Conducted or directed by employees or agents (including contractors and subcontractors)
- Conducted by or under direction of an institution facility
- Institution releases non-public information to identify or recruit subjects or releases identifiable data for the research



Research (32 CFR 219)

- A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge
- Systematic means it is hypothesis driven with a research plan, data analysis, etc
- Generalizable means applying the findings to other environments, people or situations or publishing the results



Human Subject (32 CFR 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 includes research using micro-data files, data mining, etc.



Summary

- Institutions engaged in human subjects research must have an Assurance
- 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 or implement a program for assuring compliance with the requirements



USD(P&R) Assurances

- USD(P&R) Assurances may be tailored to fit the needs of the component:
 - Single Project Assurance (SPA)
 - Multiple Project Assurance (MPA)
- Assurances are signed by an Institutional Official (IO)
- Assurances identify the Institutional Review Board(s) for the institution or the project(s)



Single Project Assurance

- Covers a single research project for three years or until the end of the project, whichever is first
- Appropriate for institutions engaged in human subjects research less than once every three years
- Greater oversight responsibility falls onto the Component Designated Official's (CDO's) Oversight Office



Multiple Project Assurance

- Covers all research conducted or sponsored by the institution for three years
- Appropriate for institutions regularly engaged in human subjects research
- Greater oversight responsibility falls onto the institution
 - Institution designates an Exempt Determination Official (EDO) and a Deputy EDO (when appropriate) to oversee research reviews and coordinate oversight activities
 - Institution develops and follows written procedures



Exempt Determination Official (EDO)

- An individual identified by the MPA institution
 - 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
- EDO is local representative for the CDO
 - Responsible for local oversight



Deputy EDO

- The EDO needs a deputy EDO if the institution processes more than a handful of reviews annually
 - 2006 Component Review Finding
- For purposes of continuity and to ensure each institution functions independently
- Deputy EDO should have a similar level of training as the EDO



Institutional Official (IO)

- The IO is the individual who signs the Assurance for the institution. The IO and other executives of the institution have certain responsibilities
 - Acting for and obligating the institution
 - Setting the tone and providing guidance
 - Providing resources for the HRPP
 - Ensuring researchers fulfill their responsibilities
 - Supporting the EDO
 - Establishing effective institutional procedures
- IOs are the primary contact if adverse situations arise within their institutions



Component Designated Oversight Office

- 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

- The EDO is the cornerstone of the USD(P&R) Human Research Protection Program (HRPP)
- The EDO must have the support of the IO in order to be effective
- Activities that seem to involve human subjects research should be forwarded to the EDO for review and determination
- The EDO and IO are responsible for ensuring all activities receive required review and approval
- The effectiveness of the process will be evaluated at least annually by the CDO's Oversight Office



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
 - Belmont Report codified into regulation
 - 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 | Regulation

- Respect for Persons
 - Extra protection when reduced autonomy
- Beneficence: Maximize benefit and minimize harm
- Justice: equitable distribution of research burdens and benefits
- Informed consent
 - Additional regs active duty, children, etc.
- Risk/benefit analysis for each project
 - Privacy / confidentiality protections
- Equitable selection of subjects



Laws, Regulations & 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 3216.2
 - Summarizes additional DoD requirements



Commensurability

- Low risk and procedures within allowed category
- Minimal risk and procedures within allowed category
- Greater than minimal risk or procedures not allowed for expedited
- Potentially exempt from the regulation (EDO review)
- Expedited Review by one or more members of an IRB
- Review by a convened IRB



Institutional Review Board (IRB)

- A Board of at least five people which has been 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 executive may disapprove an IRB approved study, but may not reverse IRB disapproval



Shared Reviews

- When multiple institutions are engaged in a single human subjects research project, 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

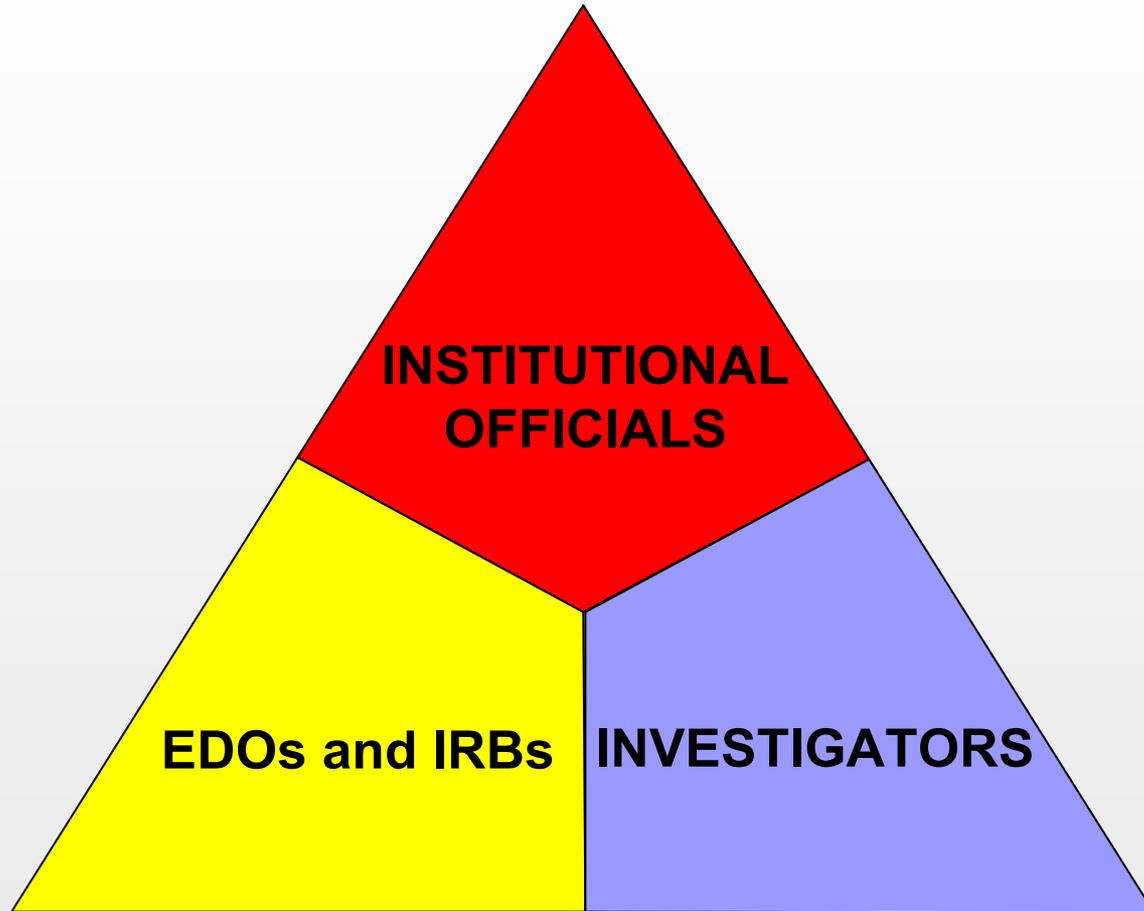


Summary

- 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 provided for in the Assurance for review, either expedited or convened



Protecting Human Subjects – A Shared Responsibility





Contact Information

Caroline Miner

Program Manager

Human Research Protection Program (HRPP)
for the OUSD (Personnel and Readiness)
Force Health, Protection & Readiness Programs

5113 Leesburg Pike

Skyline 4, Suite 403

(703) 575-2677

Fax (703) 824-4216

Caroline.Miner@tma.osd.mil