



DON Human Research Protection Program

# Department of the Navy Human Research Protection Program

**IRB Review of Research**

**March 2013**

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# Foundation for IRB Review



## DON Human Research Protection Program

IRBs use ethical principles, federal regulations, DoD Instructions, Navy Instructions, and other guidance:

- The Belmont Report
- 32 CFR 219
- 45 CFR 46, Subparts B, C, and D
- DoD INST 3216.02
- SECNAVINST 3900 series
- Other relevant guidance and instructions



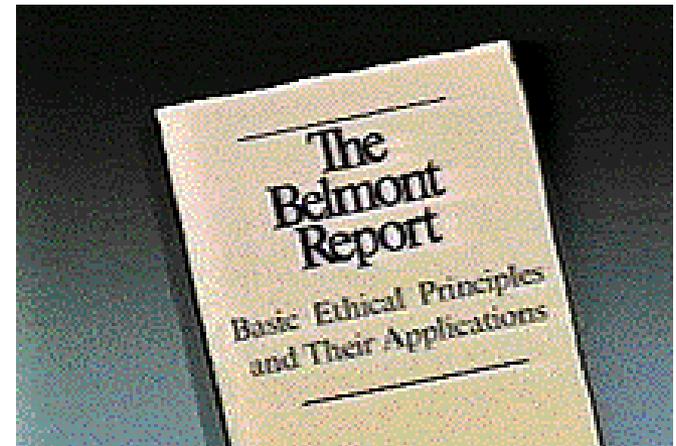
# The Belmont Report



## DON Human Research Protection Program

### Three Basic Ethical Principles:

- Respect for Persons
  - Individual autonomy
  - Protection of individuals with reduced autonomy
- Beneficence
  - Maximize benefits and minimize harms
- Justice
  - Equitable distribution of research burden and benefits





# Criteria for IRB Review



## DON Human Research Protection Program

1. Risks to subjects are minimized
2. Risks are reasonable in relation to anticipated benefits
3. Selection of subjects is equitable
4. Informed consent is sought from each subject
5. Informed consent is appropriately documented

When appropriate:

6. Data collection is monitored to ensure subject safety
7. Privacy and confidentiality of subjects is protected

Additional safeguards are included for vulnerable populations

32 CFR 219.111 (a) & (b)



# Criteria #1 – Minimize Risks



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- Use sound research design
- No unnecessary exposure to risk
- Use procedures already being performed
- Inform subjects about any reasonably foreseeable risks or discomforts that may result from the research; possibility of unforeseen risks during consent process

Belmont Principle – Beneficence

Informed Consent – Approval Criteria #4 & #5



# Criteria #1 – Minimize Risks

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### Investigators

- Proper research design; scientific review; sample size justification
- Use standardized, accepted procedures
- Equipment and safety procedures
- Describe how risks are minimized; additional precautions, safeguards, or monitoring

### IRB

- Consider scientific review; research protocol stands on its own merit; other models (no humans, animal model?)
- Recognize standards and departure from them
- Confirm or add methods to minimize risks; reduce those necessary to achieve objectives



# Criteria #2 – Risks Reasonable



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- Risks to subjects are reasonable in relation to anticipated benefits, if any, and importance of knowledge expected
- Risks & benefits resulting from research

Not long-range knowledge for policy



# Criteria #2 – Risks Reasonable



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### Investigators

- Describe risk-harms - frequency, severity, and reversibility
- Provide justification for risks
- Provide context; assess design
- Any benefit to individual subject? If not, say so
- Importance of knowledge to Navy – Marine Corps population

### IRB

- Consider relevant data, information, alternatives
- Gather information about research (use consultants, if needed)
- Determine if risks are justified
- Balance risk of harm to subjects with benefits from actual research
- With increased risk, emphasize voluntariness



# Criteria #3 – Subject Selection



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## Equitable subject selection

- Purpose of research relevant to subjects
- Research setting
- Concern for vulnerable, unique populations

Belmont Principles - Respect for Persons & Justice



# Criteria #3 – Subject Selection



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### Investigators

- Is research consistent with mission and directly related to Navy - Marines
- Describe how subjects are approached, selected, qualified etc.
- If there is command-specific guidance or standard, use it
- Explain unique requirements
- Justification for convenience population

### IRB

- Unique settings & subjects – address process, populations (military and civilian)
- Confirm if research is consistent with mission
- Recognize standards, SOPs & departures from them
- Require additional or other methods



# Criteria #4 – Informed Consent Process



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Informed consent from prospective subjects or legally authorized representative (LAR)

### Essential Elements:

- Information
  - Required elements and, when appropriate, additional elements and waivers
- Readability
- Voluntariness

Belmont Principles - Respect for Persons, Beneficence & Justice

Minimizing risks - Approval criteria #1



# Criteria #4 – Informed Consent Process



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### Investigators

- Clear information for subjects
- Describe consent process (various methods)
- Do not assume comprehension or understanding
- Address all appropriate 'elements' – clear and complete

### IRB

- What would a reasonable person want to know
- What do subjects really want to know
- Consent process – tailored to protocol
- Opportunity to say 'no' or to stop participation
- Assess comprehension or understanding ('testing')
- Consider allowed waivers to increase protection



# Criteria #5 – Informed Consent Document



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Informed consent will be documented

- Written consent document
- Short form + summary with witness
- Document informed consent process in research notes
- Waiver of signed consent, if criteria are met

Belmont Principles - Respect for Persons

Minimizing risks - Approval criteria #1



# Criteria #5 – Informed Consent Document



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### Investigators

- Consent document itself – complete? clear? readable?
- Consent documented in research/individual's records?
- ANY possibility of non-English as primary language for communication - any international subjects?

### IRB

- Verify consent document complete, clear, readable
- Verify documentation methods or determine waiver
- Verify international subjects
- Translation & back translation
- Standard format – or NOT
- Additional requirement



# Criteria #6 – Monitoring Data & Safety



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When appropriate, research **plan** to monitor the data to ensure the safety of subjects

- Research Monitor\* – required for greater than minimal risk
- IRB may require for other research

Belmont Principle - Beneficence

\*DoDI 3216.02, Enclosure 3, #8



# Criteria #6 – Monitoring Data & Safety



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### Investigators

- Describe monitoring **plan**
- Who is doing what, when, where, why, and how?
- Investigator &/or research team, Independent team, Data Monitoring Safety Board (DSMB)?
- Is this SOP or unique to this research (additional)
- Thresholds - defined
- Required reporting to IRB and others

### IRB

- Assess adequacy of monitoring plan
- Is there SOP? Is this a departure? Or unique to research protocol?
- Additional monitoring needed?
- Continuing review frequency (short duration)
- Plan for unanticipated problems/adverse events
- Required reporting
- Assess qualifications of monitor



# Criteria #7 – Privacy & Confidentiality



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When appropriate, provisions to protect privacy of subject & confidentiality of data

- What is privacy?
- Reasonable expectation of privacy?
- What is confidentiality? Anonymity?
- Use of SSN (DODI 1000.30)

Belmont Principle - Respect for Persons



# Criteria #7 – Privacy & Confidentiality



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### Investigators

- Recognize and disclose especially when there is decreased or no privacy – small command, multiple roles
- Describe plans, if any, for securing data
- Disclosure: planned access and sharing, inadvertent disclosure, & connection to consent document

### IRB

- Assess extent of privacy, if any
- Assess plans for security and confidentiality
- Agreements about data
- SOP for dealing with inadvertent disclosure
- What about 'incidental findings' on subjects (test pilots)
- Use of medical data and records for other purposes



# Review Criteria – Additional Safeguards



## DON Human Research Protection Program

32 CFR 219.111(b) When some or all subjects vulnerable to coercion or undue influence, include additional safeguards to protect subjects.

- Specifically defined populations:
  - Pregnant Women, fetuses, neonates
  - Prisoners
  - Children
- Specifically prescribed protections

DoDI 3216.02, Enclosure 3, #7 mandates DHHS 45 CFR 46 Subparts B, C, & D



# Review Criteria – Additional Safeguards



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32 CFR 219.111(b) continued...

No specific definitions and no proscribed protections

- Mentally disabled
- Educationally disadvantaged
- Economically disadvantaged



# Educationally & Economically Disadvantaged



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- No specifically identified protections
- Issues of literacy
  - Alternative methods for consent
  - Witnesses
- Undue influence & coercion
  - Compensation
- ‘Over studied’ or convenient sample



# Pregnant Women, Fetuses & Neonates



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- Exemptions may apply
- Direct benefit to woman
- Direct benefit to fetus
- Pregnant woman's consent
- Father's consent
- Applies only to greater than minimal risk research

DHHS 45 CFR 46, Subpart B

DoDI 3216.02, Enclosure 3, #7a



# Prisoners



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- Broad definition of prisoner
- Different definition of minimal risk
- IRB must have prisoner or rep as member
- IRB must certify seven (7) additional 'findings'
- Research in four (4) allowed categories only:
  - Causes & effects of incarceration
  - Prisons as institutions/prisoners
  - Conditions affecting prisoners
  - Innovative & accepted practices to improve health & well being



# Prisoners



## DON Human Research Protection Program

- Two additional categories<sup>1</sup>
  - Epidemiological research
  - Exempt research categories, however, must be reviewed by full board
- Expedited review not allowed
- UNSECNAV approval authority<sup>2</sup> - No local approval

<sup>1</sup>DoDI 3216.02, Enclosure 3, #7

<sup>2</sup>SECNAVINST 3900.39D, 7a(2)(b)

DHHS 45 CFR 46, Subpart C



# Research with Captured or Detained Personnel



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- Research involving prisoners of war is prohibited
- Research involving captured or detained personnel is prohibited

DoDI 3216.02, Enclosure 3, #7c  
SECNAVINST 3900.39D, para 6a(8)



# Research with Children



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- Risk / benefit assessment – 4 categories
  - Only 1 category of minimal risk
- Parental permission - Passive consent & 'opt out' not acceptable, applicability of 10 USC 980

Child's assent – 'No' means 'No'

- State laws – age of majority, emancipation

DHHS 45 CFR 46, Subpart D



# DoD Personnel as Subjects



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- Undue influence – coercion\*
- Recruitment
- Saying 'no'
- Research monitors
- Direct benefit\*\*
- Force Health Readiness\*\*

\*DoDI 3216.02, Enclosure 3, #7e

\*\*10 USC 980



# Voluntariness and Undue Influence



## DON Human Research Protection Program

Regardless of the risk level of the research, no superiors (civilian supervisors, officers, and non-commissioned officers [NCOs]) shall influence the decisions of their subordinates (e.g. junior enlisted personnel) whether to participate as research subjects.

For research involving Service members as human subjects that has been determined to be greater than minimal risk and when recruitment occurs in a group setting, the IRB shall appoint an ombudsman.

DoDI 3216.02, Enclosure 3, #7e  
SECNAVINST 3900.39D, para 6a(6)



# Questions

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

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