



DON Human Research Protection Program

# Department of the Navy Human Research Protection Program

## Policy and Regulations

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# Regulations and Guidance



## DON Human Research Protection Program

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Research personnel are required to follow ethical principles, federal regulations, DoD Instructions, and DON Instructions when conducting human subjects research:

- The Belmont Report
- 32 CFR 219 (Common Rule)
- 45 CFR 46, Subparts B, C, and D
- DoD INST 3216.02
- SECNAVINST 3900 series



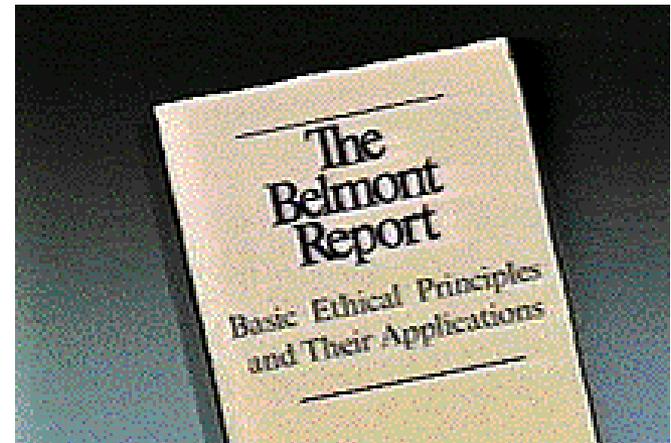
# The Belmont Report



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### 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





# 32 CFR 219.111(a) Criteria for IRB Review



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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



# Criteria #1 – Minimize Risks



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## Investigators should:

- Use the most appropriate research design
- Use sound scientific principles
- Use the appropriate sample size and provide justification
- Use standardized, accepted procedures – if possible use those procedures already being performed
- Use appropriate safety procedures
- Describe how risks are minimized; additional precautions, safeguards, or monitoring



## Criteria #2 – Risks Reasonable



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### Investigators should:

- Describe risk-harms - frequency, severity, and reversibility
- Provide justification for risks
- Provide context
- Describe any benefit to individual subject or state if there are no benefits
- Describe the importance of knowledge to DON population



# Criteria #3 – Subject Selection



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## Investigators should:

- Ensure research is consistent with mission and directly related to DON
- Describe how subjects are approached, selected, qualified, etc.
- Ensure there is no undue influence to participate
- Use command-specific guidance or standards, if they exist
- Explain unique requirements
- Provide a justification if using a “convenience” population



# Criteria #4 – Informed Consent



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## Investigators should:

- Describe the consent process
- Include all basic elements in the consent document
- Include all additional elements, as appropriate
- Request waiver or alteration of consent (if appropriate)



# Criteria #4 – Informed Consent



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## Investigators should:

- Provide clear information for subjects
- Provide a consent document appropriate for the study population (reading level, foreign language, etc)
- Not assume comprehension or understanding



# Criteria #5 – Informed Consent Documentation



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## Investigators should:

- Obtain signature of subject or legally authorized representative (LAR)
- Document consent in subject records (if appropriate)
- Request waiver of documentation of consent (if appropriate)



# Criteria #6 – Monitoring Data & Safety

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## Investigators should:

- Describe monitoring plan - Who is doing what, when, where, why, and how?
- Describe the qualifications of the research monitor, DSMB, etc
- Describe if this is standard practice or unique to this research (additional)
- Define thresholds
- Plan for unanticipated problems/adverse events and know requirements for reporting to IRB and others



# Criteria #7 – Privacy & Confidentiality

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## Investigators should:

- Recognize and disclose the extent of privacy/confidentiality especially when there is decreased or no privacy (small command, multiple roles)
- Describe plans for securing data
- Disclose planned access and sharing
- Describe actions to be taken to prevent inadvertent disclosure



# Additional Safeguards: 32 CFR 219.111(b)



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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
  - Mentally disabled
  - Educationally disadvantaged
  - Economically disadvantaged



# Additional Safeguards: 45 CFR 46



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- Subpart B – Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research
- Subpart C – Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects
- Subpart D – Additional Protections for Children Involved as Subjects in Research



# 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



# Prisoners



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- Broad definition of prisoner
- Different definition of minimal risk
- Research in four (4) allowed categories only:
  - Causes and effects of incarceration
  - Prisons as institutions/prisoners
  - Conditions affecting prisoners
  - Innovative and accepted practices to improve health and well being



# Research with Children



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- Risk / benefit assessment – 4 categories
  - Only 1 category of minimal risk
- Parental permission - Passive consent and 'opt out' not acceptable, applicability of 10 USC 980
- Child's assent – In general, 'No' means 'No'
- State laws – age of majority, emancipation



# DODI 3216.02



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- Pregnant women – requirements of 45 CFR 46 subpart B apply only to greater than minimal risk research
- Prisoners - Two additional categories
  - Epidemiological research
  - Exempt research categories, however, must be reviewed by full board
- Children - No additional stipulations
- Requirement for research monitor for greater than minimal risk research



# DODI 3216.02



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- Expanded expedited category 5
- Use of experimental subjects per 10 USC 980
  - Must obtain consent
  - LAR consent only acceptable if the research will be beneficial to the subject
- DoD personnel as subjects
  - Concerns regarding undue influence
- Compensation to subjects
- Provision for medical expenses if subjects are injured



# SECNAVINST 3900.39D



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- Requires education and training for all study personnel
- Identifies other groups of subjects warranting extra protections
  - Severely ill patients
  - Those in employer-subordinate status
  - Student-teacher
  - Supervisor-subordinate relationships
  - Deployed active duty personnel



# SECNAVINST 3900.39D



## DON Human Research Protection Program

- Survey research conducted outside the command typically requires review and approval per OPNAVINST 5300.8C
- Outlines responsibilities for different roles in human subject research
  - Surgeon General
  - Chief of Naval Research
  - Commanders, COs, and Officers in Charge
  - DON IRBs, Chairs and Vice Chairs
  - Principal Investigators



# Questions

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

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