



DON Human Research Protection Program

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# Department of the Navy Human Research Protection Program

**Research Involving Human Subjects**

August 2013



# Regulations



## DON Human Research Protection Program

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Four sources:

- 32 CFR 219 (Common Rule)
- DoDI 3216.02
- SECNAVINST 3900.39D
- 21 CFR 50 and 812 (FDA regulations)



# Regulations



## DON Human Research Protection Program

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32 CFR 219.101

To what does this policy apply?

- **All research involving human subjects** conducted, supported or otherwise subject to regulation by any federal department or agency
  - Includes research conducted by federal civilian employees or military personnel

AND

  - Research conducted, supported, or otherwise subject to regulation by the federal government outside the United States



# Regulations



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DoDI 3216.02

This instruction applies to:

- **All DoD-conducted or -supported research** involving human subjects...



# Regulations



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SECNAVINST 3900.39D

This instruction applies to:

- **All biomedical and social-behavioral research** involving human subjects
  - Conducted by Navy and Marine Corps activities or personnel
  - OR**
  - Involving naval military personnel and DON employees as research subjects
  - OR**
  - Supported by naval activities



# Definitions



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32 CFR 219.102 (d)

**Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge...**



# Definitions

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### 32 CFR 219.102 (f)

**Human subject** means a living individual about whom an investigator (whether professional or student) conducting research obtains:

(1) Data through intervention or interaction with the individual

**OR**

(2) Identifiable private information



# Definitions



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32 CFR 219.102 (f)

Intervention includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.



# Definitions



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32 CFR 219.102 (f)

Interaction includes communication or interpersonal contact between investigator and subject.



# Definitions

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### 32 CFR 219.102 (f)

“Private information” includes:

- Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place **AND**
- Information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public



# Definitions



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32 CFR 219.102 (f)

Private information must be individually identifiable in order for obtaining the information to constitute research involving human subjects.



# Definitions



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### DoDI 3216.02

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



# Definitions



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In addition to the 32 CFR 219 definition, the SECNAVINST 3900.39D adds:

Research includes, but is not limited to, any

- Project
- Task
- Test
- Pilot Study
- Experiment
- Investigation
- Study



# Definitions



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### SECNAVINST 3900.39D (con't)

- Clinical Study
- Clinical Investigation
- Clinical Trial
- Evaluation
- Developmental Effort
- Or similar undertaking

whether or not conducted or supported under a program that is officially considered research



# Definitions

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### 21 CFR 50.3 (Drugs)

(c) *Clinical investigation* means any experiment that involves a test article and one or more human subjects...

(g) *Human subject* means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control.

A subject may be either a healthy human or a patient.



# Definitions



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### 21 CFR 812.3 (Devices)

(p) A human subject is an individual on whom or on whose specimen an investigational device is used.



# Activities that are **NOT** Research Involving Humans Subjects under DoDI 3216.02



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- Force Health Protection:

Activities carried out solely for purposes of diagnosis, treatment, or prevention of injury and disease in Service members and other mission essential personnel



# Activities that are **NOT** Research Involving Humans Subjects under DoDI 3216.02



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- **Medical Treatment:**  
Authorized health and medical activities as part of the reasonable practice of medicine or other health professions undertaken for the sole purpose of patient treatment
- **Medical Quality Assurance:**  
Activities performed for the sole purpose of medical quality assurance



# Activities that are **NOT** Research Involving Humans Subjects under DoDI 3216.02



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- Operational Test and Evaluation\*:  
Activities performed solely for an Operational Test and Evaluation (OT&E) project where the activities and project meet the definition of OT&E [Section 139(a)(2)(A), of title 10, United States Code]
- \* (i) the field test, of any item of weapons, equipment, or munitions for the purpose of determining the effectiveness and suitability of their use in combat by typical military users and  
(ii) the evaluation of the results of such test



# Activities that are **NOT** Research Involving Humans Subjects under DoDI 3216.02



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- **Compliance Assessment:**

Activities performed solely for assessing compliance of individuals and organizations with requirements applicable to military, civilian, or contractor personnel or to organizational units

Includes such activities as occupational drug testing, occupational health and safety reviews, network monitoring, and monitoring for compliance with requirements for protection of classified information



# Activities that are **NOT** Research Involving Humans Subjects under DoDI 3216.02



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- Program Evaluation:

Activities\* designed solely to assess the performance of DoD programs where the results of the evaluation

- Are only for the use of Government officials responsible for the operation or oversight of the program being evaluated **and**
- Are not intended for generalized use beyond such program

\*(including program evaluation, customer satisfaction surveys, user surveys, outcome reviews, and other methods)



# Activities that are **NOT** Research Involving Humans Subjects under DoDI 3216.02



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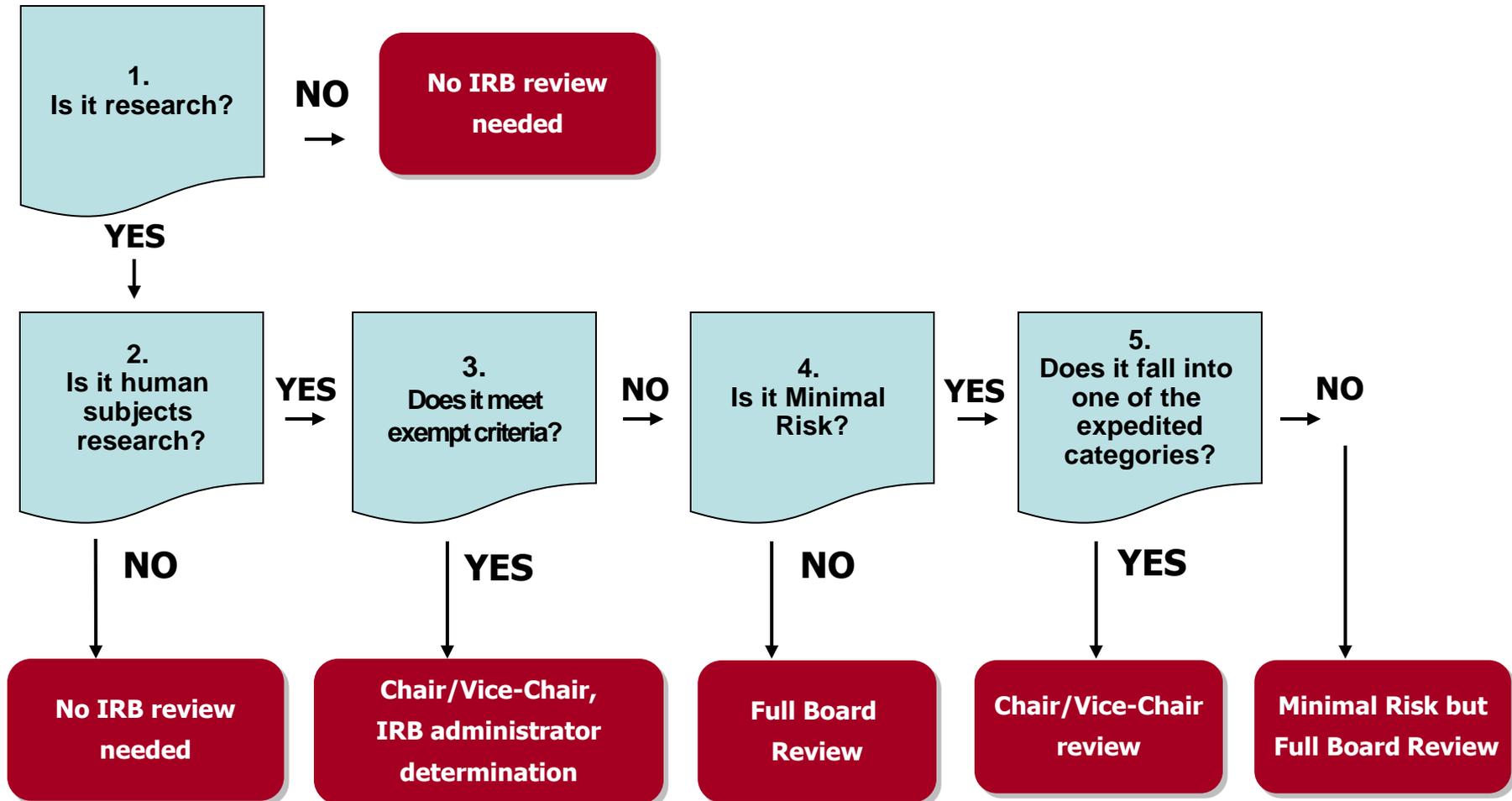
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- Intelligence Activities:  
Survey, interview, or surveillance activities and related analyses performed solely for authorized foreign intelligence collection purposes



# IRB Review Decision Tree

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# 1. Is it Research?



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Is the activity:

- A systematic investigation?
- Designed to contribute to generalizable knowledge?



## 2. Is it Human Subjects Research?



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Does the research involve:

- Obtaining private, individually identifiable information about a living individual?

**OR**

- Obtaining data through intervention or interaction with the individual?



### 3. Does it Meet Exempt Criteria?



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- Does the research activity/activities meet one or more of the six Exempt categories (as outlined in 32CFR219)?
- Principal Investigators cannot make exemption determination.



## 4. Is it Minimal Risk?

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32 CFR 219.102(i) & 21 CFR 56.102(i):

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and among themselves than those ordinarily encountered:

- In daily life

**OR**

- During the performance of routine physical or psychological examinations or tests



## 4. Is it Minimal Risk?

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- Minimal risk is based on the “average” person on an “average” day.
- Minimal risk does not include the inherent risks certain categories of human subjects face in their everyday life.



## 4. Is it Minimal Risk?

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#### Example:

If the research will involve asking a diver during a routine (already scheduled) dive to test a new fin, the IRB does NOT consider the dive in determining risk.

However, if the research will involve asking a diver to make an additional dive to test a new fin, the IRB DOES consider the dive in determining risk.



## 5. Does it Fall into One of the Expedited Categories?



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- Proposed research involves only activities as described in Federal Register: November 9, 1998 (Volume 63, Number 216)
- The categories in the list apply regardless of age, except as noted (such as for Category 2)
- DoDI3216.02 alters Category 5 to include materials previously collected for ANY purpose (Federal Register allows for only those collected for non-research purposes)



# Contacts

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

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