



RESEARCH/HUMAN SUBJECT DETERMINATION FORM

Project Title:

Form Instructions:

- Principal Investigators fill out sections 1-7. Attach all research instruments, e.g. survey or interview population and questions. Sign and forward the form to your project advisor (if you are a student/fellow) or your department chair (if you are faculty) for review.
- Project advisors/chairs review the form, sign, and forward to their department Exempt Determination Official or the USAWC Human Protection officer for official determination

Name of Principal Investigator (PI):

Email Address:

Name of Department Chair or equivalent (Project Adviser, if PI is a student):

Email Address:

Department or Organization:

This form is to help you and your department chair (or Project Adviser) to determine if your proposed study will require a review for the protection of human subjects. Three critical questions are addressed: Is your study "research," does it involve "human subjects" as defined in 32 CFR §219, and if it is human subject research, should be be exempt per 32 CFR §219.101(b)?

1. Provide a brief description of the study. Include the problem statement/topic background; what the study is about (purpose/subject under investigation); primary and secondary research questions; and a rationale for the proposed research.

2. Briefly describe the population, sample selection rationale, data collection and analysis method, and data storage plan.

3. Determination of "Research."

Research means "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge" [32 CFR §219.102 (d)].

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|---|-----|----|
| a. Is the activity a systematic investigation, including research development, testing and evaluation? | Yes | No |
| b. Is the activity designed to develop or contribute to generalizable knowledge? (Must have some form of theoretical component, e.g testing a theory or hypothesis) | Yes | No |

"Yes" answers to **both** 3.a. and 3.b. meets the definition of research. *If not both, project is not human subject research.*

4. Determination of "Human Subject."

A **human subject** is defined as "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" [32 CFR §219.102 (f)].

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|---|-----|----|
| a. Is the data being collected from a living individual? | Yes | No |
| b. Is the investigator obtaining the data through intervention or interaction with the individual? | Yes | No |
| <ul style="list-style-type: none">• Physical procedures performed on individuals• Manipulation of individuals• Manipulation of individuals' environments• Communication with individuals (i.e., interview, survey)• Interpersonal contact with individuals (i.e., direct observation) | | |
| c. Is the information that will be obtained private AND individually identifiable? | Yes | No |
| <ul style="list-style-type: none">• Private could be one of the following:<ul style="list-style-type: none">○ The information is about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place○ The individual has provided the information for a specific purpose and can reasonably expect that the information will not be made public (e.g., a medical record)• Individually identifiable could be one of the following:<ul style="list-style-type: none">○ The identity of the subject is or may readily be ascertained by the investigator○ The identity of the subject is or may readily be associated with the information | | |
| d. Is the information that will be obtained about a living individual? | Yes | No |

"Yes" answers to 4.a and 4.d, plus either 4.b or 4.c meets the definition of human subjects

5. It is the opinion of the Principal Investigator that the proposed research is Human Subject Research as defined in 32 CFR §219.102. (Meets definition of research + definition of human subject) Yes No

If the proposal meets the definition of Human Subject Research continue to Exemptions (section 6). Otherwise, sign at the bottom of page 3.

6. Exemptions per 32 CFR §219 101 (b). Complete for each exemption.

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|---|-----|----|
| (1). Is the research conducted in a <u>commonly accepted</u> educational setting involving <u>normal</u> educational practices and does not involve more than minimal levels of risk?
e.g. Research on accepted educational strategies or techniques
If yes, research is exempt, go to section 7. If no, continue to exemption (2). | Yes | No |
| (2). Does the research involve use of <u>educational tests, surveys, email questions, or interviews</u> ? If yes, continue below. If no, go to exemption (3). | Yes | No |
| a. Will the collected information be recorded in a way as to allow for identification of the subject? e.g. Research notes or publication
If yes, continue below. If no, research is exempt, go to section 7. | Yes | No |
| b. Would any disclosure of the subject's responses reasonably place the subject at more than minimal risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation?
If yes, research is not exempt and requires an IRB. If no, research is exempt, go to section 7. | Yes | No |

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|---|-----|----|
| <p>(3) Does the research involve educational tests, surveys, or interviews of elected or appointed public officials or candidates for office?
 Note: This exemption does not apply to General Officers, Flag Officers, or non-appointed SES
 If yes, research is exempt, go to section 7. If no, proceed to exemption (4).</p> | Yes | No |
| <p>(4) Does the research involve the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publically available or if the information is recorded in such a manner that subjects cannot be identified directly or indirectly through identifiers linked to the subjects?
 If yes, research is exempt, go to section 7. If no, proceed to exemption (5).</p> | Yes | No |
| <p>(5) Is the research conducted to evaluate a public service program and approved by head of a Federal Department or Agency?
 If yes, research is exempt, go to section 7. If no, proceed to exemption (6).</p> | Yes | No |
| <p>(6) Is the research conducted for taste and food quality evaluations?
 If yes, research is exempt, go to section 7. If no, proceed to section 7.</p> | Yes | No |

7. Researcher recommendation on exemptions

Per section 5, my research appears to meet the definition of human subject research IAW 32 CFR §219.102

After reviewing the exemptions in section 6, I believe my research:

is exempt per 32 CFR §219.101(b)

is NOT exempt per 32 CFR §219.101(b) and requires IRB review

Please sign below

 Signature of Principal Investigator (Required)

 Date

E-mail this form to your Project Adviser/Department Chair/Director for validation

I hereby confirm that I have read this application and my signature denotes the completeness and accuracy of the information provided.

 PRINT Name of Project Adviser, REQUIRED IF PI IS A STUDENT

 SIGNATURE of Project Adviser, REQUIRED IF PI IS A STUDENT

 Date

I hereby confirm that I have read this application and my signature denotes departmental/organization approval of this project. To the best of my knowledge, the information in the attached application relating to members of my department/organization is correct.

The investigator(s) who are members of my department/organization are qualified to perform the roles proposed for them in this application. Any novice researchers from my department/organization will be supervised by qualified investigators.

PRINT Name of Department Chair (or equivalent), REQUIRED

SIGNATURE of Department Chair (or equivalent), REQUIRED

Date

**Provide a signed and validated form to your department Exempt Determination Officer (EDO)
or the USAWC Human Protections Administrator (HPA)**

EDO/HPA Determination

I have reviewed the information provided and determine that the proposed study:

is human subject research

is NOT human subject research

is exempt under the provisions of 32 CFR §219.101(b), para:

is NOT exempt under the provisions of 32 CFR §219.101(b) and requires IRB review

PRINT Name of Determination Officer or Human Protections Administrator

SIGNATURE of Determination Officer or Human Protections Administrator

Date

EDO/HPA Justification or Comments on Determination