U.S. Army War College
Human Subject Research Determination Form

Form Instructions:

1. Principal Investigators (PIs) fill out administrative data and sections 1-7
2. Electronically sign the form.
3. Email the form and all survey or interview questions to your project adviser (if you are a student) or department chair (if you are faculty) for review and official determination.

Project Title:

Name of Principal Investigator (PI):

Email Address:

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

Department or Organization:

This form will help you and your department chair (or project adviser) determine if your proposed study will require IRB 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 plan, method of analysis, and data storage plan.

3. **Does your project involve testing a generalizable theory or principle?** A generalizable theory is designed to be replicated under certain conditions and can apply to populations other then the one studied. Note: Program evaluation efforts, policy reviews, literature reviews, case studies, and historical descriptions are typically NOT generalizable. Yes ◯ No ◯

If yes, briefly describe your theory or principle, replicable in other similar situations:

4. Determination of the legal definition of research. "Research" means a systematition, designed to develop or contribute to generalizable knowledge [32 CFR §219.102 (d)].

a. Is the activity a systematic investigation, including research development, testing and evaluation? Yes ◯ No ◯

b. Is the activity designed to contribute to generalizable knowledge? (see section 3 above) Yes ◯ No ◯

"Yes" answers to 4a and 4b meet the definition of research. Continue with form.
If not both, STOP. Your project does not meet the regulatory definition of research.
Go to part 8, annotate such, sign, and forward for review.

5.. 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)].

a. Is the data being collected ***from*** a living individual? Yes ◯ No ◯

b. Is the data being collected ***about*** a living individual? Note: Policy evaluations typically are not about a living individual unless the question focuses on how the policy affects that person Yes ◯ No ◯

c. Is the investigator obtaining the data through intervention or interaction with the individual? Yes ◯ No ◯

- Physical procedures performed on individuals
- Manipulation of individuals
- Manipulation of individuals' environments
- Communication with individuals (e.g., interview, survey, email, phone call)
- Interpersonal contact with individuals (i.e., direct observation)

d. Is the information that will be obtained private ***AND*** individually identifiable? Yes ◯ No ◯

- **Private** could be one of the following:
  - 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:
  - The identity of the subject is or may readily be ascertained by looking at the research data or notes
  - The identity of the subject is or may readily be associated within the published report (body or citations)

"Yes" answers to 5.a **and** 5b. plus **either** 5.c or 5.d meets the definition of human subjects

e. Considering 5a. through 5d., my project includes the regulatory definition of "human subjects." (Yes to 5a and 5b, plus ***either*** 5c or 5d) Yes ◯ No ◯

6. It is the opinion of the Principal Investigator that the proposed research is Human Subject Research as defined in 32 CFR §219.102. (Meets both the definition of "research" (4a and 4b) + definition of "human subject" (5e) Yes ◯ No ◯

If "YES", continue to next section (section 7) to see if your project is exempt. If "NO", go to section 8

7. Exemptions per 32 CFR §219 101 (b).

(1). Is the research conducted in a commonly accepted educational setting involving normal educational practices and does not involve more than minimal levels of risk? Yes ◯ No ◯
e.g. Research on accepted educational strategies or techniques
If yes, research is exempt, go to section 8. If no,continue to exemption (2).

(2). Does the research involve use of educational tests, surveys, email questions, or interviews? 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 Yes ◯ No ◯
If yes, continue below. If no, research is exempt, go to section 8.

b. Would any disclosure of the subject's responses reasonable place the subject at more then minimal risk of criminal or civil liability or be damaging to the subject's financial standing, employability, ore reputation? Yes ◯ No ◯
If yes, research is not exempt and requires an IRB. If no, research is exempt, go to section 8.

(3). Does the research involve educational tests, surveys, or interviews of elected or appointed public officials or candidates for office? Yes ◯ No ◯
Note: This exemption does not apply to General Officers, Flag Officers, or non-appointed SES
If yes, research is exempt, go to section 8. If no, proceed to exemption (4).

(4) Does the research involve the collection or study of existing data, documents, records, pathological speciments, 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? Yes ◯ No ◯
If yes, research is exempt, go to section 8. If no, proceed to exemption (5).

(5) Is the research conducted to evaluate a public service program and approved by head of a Federal Department or Agency? Yes ◯ No ◯
If yes, research is exempt, go to section 8. If no, proceed to exemption (6).

(6) Is the research conducted for taste and food quality evaluations? If yes, research is exempt, go to section 8. If no, proceed to section 8. Yes ◯ No ◯

8. Researcher recommendation

Based on the above, I believe my project:

- ◯ Does not meet the legal definition of "research"(section 3)
- ◯ Does not meet the legal definition of "human subject research" [section 6]
- ◯ Is human subject research, but is exempt per 32 CFR §219.101(b) [exempt per section 7]
- ◯ Is non-exempt human subject research and requires IRB review [does not match any exemption category in section 7]

Please electronically sign below

_____ _____

Signature of Principal Investigator (Required) Date

By signing, the PI agrees to follow the principles of respect for persons, beneficence, and justice. Additionally, the PI agrees that he/she has no conflict of interest and will obtain written informed consent for all projects determined to be non-exempt human subjects research or research that includes more than minimal risk.

Email this form, along with a copy of all survey or interview questions, to your project advisor or department chair for review and processing**

Project Advisor Review (for student projects)

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

Name of Project Advisor

_____ _____

Electronic Signature of Project Adviser Date

Department Chair Review (for faculty projects)

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.

_____

Name of Department Chair (or equivalent)

_____ _____

Electronic Signature of Department Chair (or equivalent) Date

Following review, the PA or Department Chair emails the form and a copy of all survey or interview questions to the department Exemption Determination Official or the Office of Institutional Assessment for formal determination.

EDO/HPA Determination

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

- ◯ **is NOT research**
- ◯ **is human subject research**
- ◯ is research, but **NOT human subject research**
- ◯ **is exempt** under the provisions of 32 CFR §219.101(b), para:
- ◯ **is NOT** exempt under under the provisions of 32 CFR §219.101(b) and requires IRB review
- ◯ requires written informed consent from all participants (non-exempt research or research that involves more than minimal risk)
- ◯ does NOT require written informed consent (not human subjects research or exempt human subject research)

_____

Name of Determination Officer or Human Protections Administrator

_____ _____

Electronic Signature of Determination Officer or Human Protections Administrator Date

By signing, the EDO indicates that there is sufficient information to make an informed determination and that the EDO does not have a conflict of interest in this project

EDO/HPA Justification or Comments on Determination

**** Items required for determination:** Determination form with all signatures, copies of all survey and interview questions, plus any other correspondance that may assist in final determination.

Note: the USAWC HPA will keep a record copy of this form and all related materials on file for at least three years.