



AIR UNIVERSITY

Research and Human Subjects Worksheet

Air University (AU) policy in compliance with Federal regulations requires the review of research activities for a determination of the involvement of human subjects. This includes activities conducted by AU Faculty, Staff and Students and by non-AU personnel.

The Primary/Principal Investigator/Researcher is to complete the Human Subjects Determination Worksheet and submit it to jendia.grissett@us.af.mil/ jendia.grissett@au.af.edu.

- This worksheet is a guide to help the investigator determine if the activity meets the definition of research and if the activity is human subject research and regulated by the Department of Health and Human Services (DHHS) and/ or Food and Drug Administration (FDA).
- Activities that meet the definition of human subject research will require submission to an Exempt Determination Officer or the appropriate IRB application at Air Force Research Laboratory (AFRL), the institution who supports AU through its IRB of Record.
- This worksheet will serve as a tool to assist the HRPP POC in providing the researcher with research guidance. This tool does not replace an official determination.

PRIMARY INVESTIGATOR/RESEARCHER:

RESEARCH PROJECT TITLE:

BRIEF SYNOPSIS OF THE RESEARCH:

Air University
Human Subjects Determination Worksheet

Review the following sections and questions to determine whether the activity is human subject research under 45 CFR 46. Your responses will be used to determine the appropriate approvals for your proposed research.

A. DEFINITION OF RESEARCH:

“Research” means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Does the activity meet the definition of “Research”? __ Yes __ No

If “Yes”, proceed to B. Definition of Human Subjects

If “No”, the activity is NOT a systematic investigation designed to develop or contribute to generalizable knowledge, the activity does not meet the definition of research under the DHHS regulations. However, it may meet the definition of human subject research under the FDA definition.

B. DEFINITION OF HUMAN SUBJECT

“Human Subject” means a living individual about whom an investigator conducting research obtains:

- (i) data through intervention or interaction with the individual, or
- (ii) identifiable private information.
 - *Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.*
 - *Interaction includes communication or interpersonal contact between investigator and subject.*
 - *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 (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.*

Does the activity involve a “Human Subject” under the definition provided? __ Yes __ No

If Yes,

- a. Does the activity involve at least one currently living subject? __ Yes __ No
If at least one of the subjects is living, the activity involves a “human subject” under the DHHS regulations. Proceed to number 2.
- b. Does the activity involve only dead/deceased subject? __ Yes __ No
*If none of the subjects are living, the activity **does not** involve a human subject under the DHHS or FDA regulations. The activity may require compliance with HIPAA.*

C. DEFINITION OF RESEARCH ACTIVITY INFORMATION

Indicate the type of information the activity will collect about the subjects

1. Does the activity involve obtaining data through interaction or intervention with the subjects?
[This activity includes interviews (in person or not), surveys, physical procedures, manipulations of the subject's environment, and any other direct contact or communication with a subject.]
 Yes No
2. Does the activity involve obtaining private identifiable information about the subject?
[This activity includes chart reviews, lab studies on tissue/specimens, using information from data or tissue repositories.]
 Yes No
3. Does the activity involve use of anonymized data, records, tissue or specimen obtained from a data repository and for which the investigator has no access to a code or link to re-identify the source of the data, records, tissue or specimen?
 Yes No
4. Does the activity involve the use of an FDA regulated product? [This includes drugs, medical devices, dietary supplements, etc.]
 Yes No

If you have indicated "Yes" on any of the above, the activity is collecting human subject research information under the DHHS regulations and requires you to contact AU's HRPP for further guidance. Please note that Item 3 may not result in HSR; however, a review of all the variables collected may be required to prevent indirect identifiers. Please contact AU's HRPP POC for further guidance.

D. DEFINITION OF SPECIAL POPULATIONS

Indicate if the activity will involve a protected/special population group under the DHHS regulations.

1. Does the activity involve adolescents as subjects? Yes No
2. Does the activity involve children as subjects? Yes No
3. Does the activity involve elderly as subjects? Yes No
4. Does the activity involve pregnant women as subjects? Yes No
5. Does the activity involve the economically challenged as subjects? Yes No
6. Does the activity involve the mentally challenged as subjects? Yes No
7. Does the activity involve the physically challenged as subjects? Yes No
8. Does the activity involve prisoners as subjects? Yes No

If you have indicated "Yes" on any item 1 through 8, the activity involves a special/protected population under the DHHS regulations and requires. Please contact AU's HRPP POC for further guidance.

E. ENGAGEMENT WITH RESEARCH

Indicate who will be engaged in the research.

1. AU is the sole DoD institution conducting the research? Yes No
2. AU and another DoD institution will be conducting the research? Yes No
3. AU and another non DoD institution will be conducting the research? Yes No
4. AU is supporting the research conducted by a non DoD institution? Yes No

If you have indicated "Yes" on item 3 or 4, the activity involves a non DoD institution and requires at minimum a HRPO review.

F. PRINCIPAL INVESTIGATOR CERTIFICATIONS/AGREEMENTS

1. PRINCIPAL INVESTIGATOR'S ASSURANCE

- A. I certify that all information provided in this application is complete and correct.

- B. I understand that, as Principal Investigator, I have ultimate responsibility for the conduct of this study, the ethical performance this project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by the approval entities. A determination to conduct research does not absolve investigators from ensuring the rights and welfare of human participants in research activities are protected and that the methods used to obtain consent are appropriate.
- C. I agree to comply with all Air University policies and procedures, as well as with all applicable federal, state, and local laws regarding the protection of human subjects, including, but not limited to the following:
 - a. Conducting the project by qualified personnel according to the approved protocol
 - b. Implementing no changes in the approved protocol or consent form without prior approval (except in an emergency, if necessary to safeguard the well-being of human subjects)
 - c. Obtaining the legally effective informed consent from each participant or their legally responsible representative prior to their participation in this project using only the approved, stamped consent form
 - d. Promptly reporting significant adverse events and/or effects to the approving IRB in writing within 5 working days of the occurrence.
 - e. Completing education on research with human subjects through CITI Program (Please go to www.citiprogram.org to complete human subjects training) and AU's Annual HRPP Training.
- D. By signing, I understand that no research activities will be conducted with human participants prior to obtaining the required approvals.

Principal Investigator (Please Print): _____

Principal Investigator's Signature: _____ Date: _____

2.

3. FACULTY SPONSOR (FOR STUDENTS)

- A. By my signature as sponsor on this research application, I certify that the student or guest investigator is knowledgeable about the regulations and policies governing research with human subjects and has sufficient training and experience to conduct this particular study in accord with the approved protocol.
- B. I certify that the project will be performed by qualified personnel according to the approved protocol using conventional or experimental methodology.
- C. I agree to meet with the investigator on a regular basis to monitor study progress.
- D. Should problems arise during the course of the study, I agree to be available, personally, to supervise the investigator in solving them.
- E. I assure that the investigator will promptly report significant adverse events and/or effects to the approving IRB in writing within 5 working days of the occurrence.
- F. If I will be unavailable, I will arrange for an alternate faculty sponsor to assume responsibility during my absence, and I will advise the Air University HRPP POC by letter of such arrangements.
- G. Prior to submission, I will have read the protocol submitted for this project for content, clarity, and methodology.

Faculty Sponsor (Please Print): _____

Faculty Sponsor's Signature: _____ Date: _____