

Utah Valley University
 Institutional Review Board
 Determination of Human Subject Worksheet

Instructions for faculty and staff: Complete this worksheet to determine whether your proposed research activity qualifies as research and/or involves the use of human participants. You are not required to submit the completed form to the IRB. Submitting to the IRB is optional. You may submit the completed form to the IRB if you would like consultation or assistance in making the determinations. For more information about the determination of human research please visit the IRB website at www.uvu.edu/irb.

Complete this section only if you are submitting this form for additional determination by the IRB	
PI Name:	Phone
School/College/Dept:	E-mail
Title of Project:	
Describe the proposed activity: Who or what do you propose to study (specimens, data, and/or individuals)? How do you plan to obtain the information? What do you plan to do with the information gathered?	

1. Determination of Research vs. Non-research

Review the DHHS definitions below and answer the questions to determine if your activity is research under DHHS regulations.

45 CFR 46.102(d): *Research* is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities meeting this definition constitute research, whether or not they are conducted or supported under a program which is considered research for other purposes.

Questions

1. Yes No Is the proposed activity a systematic investigation?
 Consider whether the data/specimens will be obtained in a systematic manner.

2. Yes No Is the proposed activity designed to develop or contribute to generalizable knowledge?
 Consider whether the data/specimen collection is intended for the purpose of contributing to generalizable knowledge.

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If you answered “Yes” to both questions the proposed activity is research under DHHS regulations. Continue to section 1.2 to determine whether the research involves human participants.

If you answered “No”, to one question the proposed activity is **not** research under DHHS regulations.

2. **Determination of Human Research**

Review the DHHS definitions below and answer the questions to determine if your research activity involves human participants under DHHS regulations.

Definitions

45 CFR 46.102(f): *Human participant* means a living individual about whom an investigator obtains: (1) data through intervention or interaction with the individual or (2) identifiable private information.

- a) *Intervention* includes both physical procedures by which data are gathered (for example: venipuncture) and manipulations of participant or the participant’s environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and participant.
- b) *Private information* includes information about behavior occurring 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).

Questions

1. Yes No Does the research involve obtaining information about living individuals? Consider whether the data/specimens will be obtained in a systematic manner.

If you answered “No” the research is **not** human research under DHHS regulations.

If you answered “Yes”, continue to question 2.

2. Yes No Does the research involve intervention or interaction with the individuals?

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If you answered "Yes" the research is human research under DHHS regulations. Your project meets the criteria for research involving human participants and you are required to submit an application to the IRB.

If you answered "No", continue to question 3.

3. Yes No Is the information individually identifiable?
Consider whether the identity of the participant will or may readily be ascertained by the investigator or associated with the information.

If you answered "No", the research is **not** human research under DHHS regulations

If you answered "Yes", continue to question 4.

4. Yes No Is the information private as defined in 45 CFR 46.102 (f) (2)?
Consider whether a) the research involves access to identifiable private information, b) whether the investigator will be obtaining data/specimens with identifiable private information, c) whether the data/specimens will be coded such that a link could allow the data/specimens to be re-identified, and d) whether the research involves access to or uses any of the following individually identifiable private information?

- Names
- Account numbers
- Certificate/license numbers
- Social security numbers
- Device identifiers and serial numbers
- Health plan beneficiary numbers
- Full-face photographic or comparable images
- Vehicle identifiers and serial numbers, including license plate numbers
- All elements of dates directly related to an individual, except year (of birth, admission)
- Fax numbers
- Telephone numbers
- Electronic mail addresses
- Medical record numbers
- Web Universal Resource Locators (URLs)
- Biometric identifiers, including finger and voiceprints
- Internet Protocol (IP) address numbers
- Any geographic subdivisions smaller than a state, except for the initial three digits of a ZIP code
- Any other unique identifying number, characteristic or code

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If you answered “No”, the proposed activity is not human research under DHHS regulations.

If you answered “Yes”, the research is human research under DHHS regulations. Your project meets the criteria for research involving human participants and you are required to submit an application to the IRB.