Request for Determination of Non-Human Subject Research

(Federal regulations and USU policy require IRB review of all research involving human subjects. Some categories of research are difficult to discern as to whether they qualify as human subject research. Therefore, the IRB has established policies and procedures to assist in this determination).

1. Principal Investigator Information

<table>
<thead>
<tr>
<th>Name of Principal Investigator</th>
<th>College:</th>
<th>Department:</th>
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<tbody>
<tr>
<td>Phone:</td>
<td>Email:</td>
<td>UMC:</td>
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2. Study Information:

   A. Title:

   B. Give a brief summary of the project:

   C. Describe the subject population / type of data / specimens to be studied:

   D. Signatures:

      ______________________      ____________________
      Signature of PI (type name if sending by email)  Date

☐ Based on the information provided to USU’s IRB, it has been determined that this project does not qualify as human subject research as defined in 45 CFR 46.102(d) and (f) and is not subject to oversight by USU’s IRB.

☐ Based on the information provided to USU’s IRB, it has been determined that this research does qualify as human subject research and submission of an application for review by the IRB is required.

      ______________________      ____________________
      IRB Authorization     Date

3. Determination of ‘research.’

   45 CFR 46.102(d): 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.
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One of the following must be “no” to qualify as “non-research”:

A. Will the data/specimen(s) be obtained in a systematic manner?
   ☐ No  ☐ Yes

B. Will the intent of the data/specimen collection be for the purpose of contributing to generalizable knowledge?  ☐ No  ☐ Yes

Generalizable knowledge: is knowledge that is “expressed in theories, principles, and statements of relationships” that can be widely applied to our experiences. Generalizable knowledge is usually created to share with other people, such as through presentations and publications. Masters’ theses and Ph.D. dissertations are considered to present generalizable knowledge.

“Generalizable knowledge” would include one or more of the following concepts:
- The knowledge contributes to a theoretical framework of an established body of knowledge
- The primary beneficiaries of the research are other researchers, scholars and practitioners in the field of study
- Publication, presentation or other distribution of the results is intended to inform the field of study
- The results are expected to be generalized to a larger population beyond the site of data collection
- The results are intended to be replicated in other settings
- Web based publication for professional purposes

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4. Determination of “Human Subject”: 45 CFR 46.102(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. 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 be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

a. Does the research involve obtaining information about living individuals?
   ☐ No  ☐ Yes

If no, then research does not involve human subjects, no other information is required.
If yes, proceed to the following questions.
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All of the following must be “no” to qualify as “non-human subject”:

b. Does the study involve intervention or interaction with a “human subject”?
   □ No    □ Yes

c. Does the study involve access to identifiable information?
   □ No    □ Yes

d. Are data/specimens received by the investigator with identifiable private information?
   □ No    □ Yes

e. Are the data/specimen(s) coded such that a link exists that could allow the data/specimen(s) to be re-identified?
   □ No    □ Yes
   If “yes” is there a written agreement that prohibits the PI and his/her staff access to the link?
   □ No    □ Yes