Policy Number: 16
Title: Human Subject Research/ Non-Human Subject Research Determination
Date of Last Revision: 06/16/08, 05/15/10, 06/01/10, 10/15/13, 01/28/15, 05/03/21, 03/11/22, 08/18/22

Policy:
It is the policy of the UC Irvine (UCI) Institutional Review Board (IRB) to assist in determining whether an activity meets the definition of human subject research.

I. Non-Human Subject Research Determinations
A. An investigator may self-determine that an activity does not represent human subject research.
B. The electronic IRB submission and management system allows for the investigator to self-determine whether the activity either:
   1. Meets the DHHS regulatory definitions of “research” that involves “humans subjects,”
   2. Meets the FDA regulatory definition of “clinical investigation,”
C. The investigator must submit the determination of non-human subject research in order to receive written confirmation which is provided via email from the electronic IRB submission and management system.
D. If the activity does not represent human subject research the activity does not require IRB approval and oversight.
E. HRP Staff will monitor the electronic IRB submission and management system by performing quarterly assurance to confirm that the activity qualifies as non-human subject research.

II. Non-Research Activities
A. Activities are not research if they do not involve a systematic approach involving a predetermined method or a plan for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing theory. A systematic approach incorporates collection of data, either quantitative or qualitative, or specimens; and analysis.
1. Examples of activities that would not normally be considered systematic investigations include, but are not limited to:
   a. Training activities (e.g., individuals being trained to perform a certain technique or therapy such as art therapy, psychoanalysis, oral history techniques); and
   b. Classroom activities involving human participants or human participant data where the objective of the activity is to teach proficiency in performing certain tasks or using specific tools or methods.
   c. Case reports or case series of three or less individuals.
2. Examples of systematic investigations include, but are not limited to:
   a. Observational studies;
   b. Interviews (including those that are open-ended) or survey studies;
   c. Group comparison studies;
   d. Test development;
e. Program evaluation; or  
f. Clinical investigations.

B. Activities are not research if they do not intend to contribute to generalizable knowledge or to draw general conclusions (i.e., knowledge gained from a study may be applied to populations beyond the specific study population), inform policy, or generalize findings.

1. Examples of activities that are typically not generalizable include:  
   a. Biographies and service or course evaluations, unless they can be generalized to other individuals;  
   b. Oral history activities in general which are solely designed to create a record of specific historic events;  
   c. Data collection for internal department, school, or other University administrative purposes (e.g., teaching evaluations, “customer service” surveys);  
   d. Classroom activities designed specifically for education or teaching purposes, where the data is collected from and about human subjects a part of a class exercise or assignment that is not intended for use outside of the classroom;  
   e. Quality Improvement activities designed to continuously improve the quality or performance of a department or program or health care; and  
   f. A Case Report or a write up of up to three patients. The Case Report or write up must specifically describe medical care (i.e., not research related care) and outcomes from treatment provided solely as part of the patient’s clinical care.

2. Thesis or dissertation projects conducted to meet the requirements of a graduate degree are usually considered generalizable and therefore, require IRB review and approval.

3. Refer to the 2018 revised Common Rule for examples of what does not meet the definition of ‘research.’

III. Department of Energy (DOE)  
A. For all DOE-funded, or DOE/Laboratory conducted research, consult with the applicable DOE IRB Manager/Administrator, who will help determine if the activity qualifies as human subject research. DOE has a distinct definition for “generalizable”:  

1. Information/research findings that are intended to be applied to populations or situations beyond that studied/will have meaning and impact outside of the single immediate activity itself.
IV. **Non-Human Subject**

A. Activities **do not involve** humans as participants if they **do not involve** the following definition:
   
   1. *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

B. Examples of activities that would **not normally involve** human subjects if the research is about things or expertise, rather than “about whom” (i.e., questions are not about the individual providing the information).

C. Per the Office of Human Research Protections (OHRP), the following definitions apply when considering private or identifiable information or biospecimens:
   
   1. *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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).
   
   2. *Identifiable private information* is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
   
   3. An *identifiable biospecimen* is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

D. Private or, “personal information” does not include publicly available information or lawfully obtained, truthful information that is a matter of public concern.

E. **Personal information may be defined as follows** (California Consumer Privacy Act of 2018): “Personal information” means information that identifies, relates to, describes, is reasonably capable of being associated with, or could reasonably be linked, directly or indirectly, with a particular consumer or household. Personal information includes, but is not limited to, the following if it identifies, relates to, describes, is reasonably capable of being associated with, or could be reasonably linked, directly or indirectly, with a particular consumer or household:
   
   1. Real name
   2. Alias
   3. Postal address
   4. Unique personal identifier
   5. Online identifier
   6. Internet Protocol (IP) address numbers
   7. Email address
   8. Account name
   9. Social security number
   10. Driver’s license number
   11. Passport number
   12. Other similar identifiers may include (see ‘22’ below):
      a) Telephone numbers;
      b) Fax numbers;
      c) Medical record numbers;
d) Health plan beneficiary numbers;
e) Account numbers;
f) Certificate/license numbers;
g) Vehicle identifiers and serial numbers, including license plate numbers;
h) Device identifiers and serial numbers;
13. Commercial information, including records of personal property, products or services purchased, obtained, or considered, or other purchasing or consuming histories or tendencies.
14. Biometric information
15. Internet or other electronic network activity information, including, but not limited to, browsing history, search history, and information regarding a consumer’s interaction with an internet website application, or advertisement
16. Geolocation data
17. Audio, electronic, visual, thermal, olfactory, or similar information
18. Professional or employment-related information
19. Education information, defined as information that is not publicly available personally identifiable information as defined in the Family Educational Rights and Privacy Act (20 U.S.C. Sec. 1232g; 34 C.F.R. Part 99).
20. Inferences drawn from any of the information identified in this subdivision to create a profile about a consumer reflecting the consumer’s preferences, characteristics, psychological trends, predispositions, behavior, attitudes, intelligence, abilities, and aptitudes.
21. Sensitive personal information
22. Any personal information described in subdivision (e) of Section 1798.80 as follows: Signature, physical characteristics or description, state identification card number, insurance policy number, education, bank account number, credit card number, debit card number, and other financial information, medical information, and health insurance information.
23. Characteristics of protected classifications under California or federal law.

F. Specimens/data that are received by the Investigator as de-identified (i.e., stripped of all identifiers as noted above).

G. When the Investigator receives private information or specimens with no code or link that would allow an Investigator to establish identity, this would not involve human subjects. For example, a publicly available, unidentifiable, non-linked dataset qualifies as not involving human subjects.

V. A. The Investigator may receive coded private information or specimens and qualify for non-human subject if the following conditions are met:
1. The code is not derived or related to the HIPAA identifiers that must be stripped from the PHI (e.g., patient MR# + last 4 digits of individuals Social Security Number);
2. The private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; and
3. The Investigator cannot readily ascertain the identity of the individuals to whom the coded private information or specimens pertain, because:
   a. The key to decipher the code is destroyed before the research begins;
   b. The Investigator and the holder of the key enter into an agreement prohibiting the release of the key to the Investigator under any circumstances, until the individuals are deceased;
   c. The private information is received from an IRB-approved repository or data management center that includes written operating procedures that prohibit the release of the key to the Investigator under any circumstances, until the individuals are deceased; or
   d. There are other legal requirements prohibiting the release of the key to the Investigator until the individuals are deceased.

B. An activity only involving analysis of a Limited Data Set (LDS) (a set of data that lacks 16 of the 18 identifiers itemized by the privacy rule) provided by a third party would not involve human subjects. A LDS may contain dates and certain geographic information associated with an individual that would be absent of identifiable information. Information provided by a third party may include the following:
   a. 5-digit zip code (4-digit extension is not allowed)
   b. Full dates of birth or death
   c. Full date(s) of service (admission and discharge)
   d. Geographic subdivision (other than street address)

C. A cadaver is not considered to be a human subject.

D. Notable exception to non-human subject: In-vitro Device (IVD) studies using human tissue specimens while exempt from most provisions of 21 CFR part 812(c)(3), qualify as clinical investigations and are therefore subject to FDA 21 CFR parts 50 and 56, even if the clinical investigation involves de-identified, leftover tissue specimens.

VI. Amendments
Changes that might disqualify the activity from its “Non-Human Subject Research” status should be reported to the IRB for review and verification prior to implementation.

VII. All “Non-Human Subject Research” is subject to applicable institutional policies and procedures.

References:
45 CFR 46
21 CFR 50
21 CFR 56
21 CFR 812
32 CFR 219 (DoD)
28 CFR 512 (DOJ)
OHRP Guidance on Research Involving Coded Private Information or Biological Specimens, August 10, 2004
https://science.osti.gov/ber/human-subjects/About/Researchers/Frequently-Asked-Questions
HRP Policy # 2
California Civ. Code Section 1798.140(v)(1)
California Civ. Code Section 1798.80
Procedure Number: 16.A
Title: Procedure Human Subject Research/Non-Human Subject Research Determination

Procedure:
This procedure provides guidance for the determination of non-human subject or non-research projects.

I. Investigator Responsibilities
A. Investigators should review the non-human subject research confirmation module in the electronic IRB submission and management system. The portal is located on the HRPP website. To receive an email of confirmation, the Investigator must submit the non-human subject confirmation module.
B. Investigators must inform the HRP staff or the IRB of any proposed changes that might disqualify an activity from its “non-human subject research” status.

II. HRP Staff
A. Under the EQUIP program or as requested by HRP Senior Management, the IRB Chair or designee, HRP Staff will monitor the electronic IRB submission and management system by performing quarterly assurance to confirm that the sampled activities qualify as non-human subject research.
B. Where activities do not qualify as non-human subject research, HRP Staff will provide follow up in accordance with HRP Policy.