UC IRVINE INSTITUTIONAL REVIEW BOARD
NON-HUMAN SUBJECT RESEARCH DETERMINATION FORM
HRP Version: July 2018

The UC Irvine IRB is required to review and approve all research involving human subjects. If an individual has questions about whether an activity is human research, please review the Activities that Require IRB Review web page. In addition, this form is intended to help you determine if your project requires IRB approval. If you require written documentation from the IRB Office, complete the entire form, and email the signed form and any relevant supporting documents (i.e., grant, protocol, consent forms) to the HRP staff at IRB@research.uci.edu. You should receive a response within 10 business days.

SECTION 1:
Determining whether an activity is human subjects research per DHHS Regulations (Parts A and B below)

PART A: DETERMINATION OF "RESEARCH"

45 CFR 46.102(d): ***Research*** - a ***systematic investigation***, including research development, testing and evaluation, ***designed to develop or contribute to generalizable knowledge***.

A ***systematic*** approach involves a predetermined system, method or a plan for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing theory. A systematic approach includes the collection of information and/or biospecimens, and analysis either quantitative or qualitative.

Activities ***designed to develop or contribute to generalizable knowledge*** are those activities designed to draw general conclusions, inform policy, or generalize outcomes beyond the specific group, entity, or institution (i.e., to elaborate, to be an important factor in identifying or expanding truths, facts, information that are universally applicable).

1. Does the proposed activity involve a ***systematic*** *approach*?
☐ **YES*** ☐ **NO**

2. Is the intent of the proposed activity to ***develop or contribute to generalizable knowledge***?
☐ **YES*** ☐ **NO**

***If YES to both 1 & 2, the activity constitutes research.**

PART B: DETERMINATION OF "HUMAN SUBJECT"

45 CFR 46.102(f): ***Human subject*** - a *living individual* about whom an investigator (whether faculty, student, or staff) conducting research obtains: **(1)** data through ***intervention*** *or* ***interaction*** with the individual; or **(2)** ***identifiable private information***.

Intervention includes both physical procedures by which information is 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 information). Private information must be individually identifiable.

Identifiable is where the identity of the subject is or may be ascertained by the researcher, or will be associated with the information. The research could involve the use of ***coded*** data/specimens.

Coded means a living individual's identifiable information such as name or social security number has

been replaced by a code, such as a number, letter, or combination thereof ***and*** there is a key to link the code to the identifiable information of that individual. *Coded data are considered identifiable under the Common Rule.*

Use the definitions above to answer the following questions.

1. Does the activity involve obtaining information about *living individuals* through ***intervention*** or ***interaction*** with the individuals?
☐ **YES*** ☐ **NO**

***If YES to #1, the activity involves human subjects.**

2. **If NO to #1,** does the activity involve obtaining protected health information (PHI) about deceased individuals?
☐ **YES*** ☐ **NO** ☐ **N/A**

***If YES, the following must be true:**
1) The use or disclosure is solely for research on the PHI of decedents; and
2) The PHI is necessary for research purposes.
3) If requested by the covered entity (UCI), the Lead Researcher will be required to provide documentation of the death of the individual(s).

3. Does the activity involve obtaining ***identifiable*** and ***private information*** about living individuals?
☐ **YES*** ☐ **NO**

***If YES to #3, the activity involves human subjects.**

4. Does the activity involve the use of ***coded*** private information/specimens?
☐ **YES*** ☐ **NO**

5. **If YES to #4**, the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information/specimens pertain because:

a. The holder of the key and investigator enter into an agreement prohibiting the release of the key to the investigator under any circumstances, until the individuals are deceased. **Provide a copy of this agreement (an informal email exchange is sufficient).** ***OR***
☐ **YES** ☐ **NO***

b. The investigator has documentation of written policies and operating procedures from a repository or data management center that prohibits the release of the key to the investigators under any circumstances, until the individuals are deceased. **Provide documentation of the written policies and operating procedures.** ***OR***
☐ **YES** ☐ **NO***

c. There are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased. **Provide documentation of the legal requirements.**
☐ **YES** ☐ **NO***

***If YES to 4, and NO to 5a, 5b, or 5c the activity involves human subjects.**

6. Were the information/specimens previously collected (or yet to be collected) specifically for the currently proposed project?
☐ **YES** ☐ **NO** ☐ **N/A**

SECTION 2:
Determining whether an activity is clinical investigation per FDA Regulations (Part C below)

PART C: DETERMINATION OF "HUMAN SUBJECT"

21 CFR 50.3(g): *Human subject* *- an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.*

Use the definition above to answer the following questions.

1. Does the activity involve human subjects as defined by FDA regulations?

a. An individual will be a recipient of any test article (i.e. drug, biologic, or medical device) or as a control.

☐ **YES*** ☐ **NO**

***If YES to #1a, the activity involves human subjects.**

b. An individual on whose specimen+ a medical device will be used (21 CFR 812.3(p)) *(i.e. In vitro diagnostic++ device)*

☐ **YES*** ☐ **NO**

***If YES to #1b, the activity involves human subjects.**

Note: The FDA regulations (21 CFR Parts 50 and 56) apply to all clinical investigations regulated by FDA, as well as other clinical investigations that support applications for research or marketing permits. Therefore, all studies of investigational IVDs that will support applications to FDA are subject to 21 CFR Parts 50 and 56, even if they are not subject to most requirements of 21 CFR Part 812. For more information see the FDA Guidance on **In Vitro Diagnostic Device Studies - FAQs**.

+ Specimen – including use of leftover specimens that are not individually identifiable (e.g., a remnant of a human specimen collected for routine clinical care or analysis that would otherwise have been discarded).

++In vitro diagnostic products are those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae.

SECTION 3: FUNDING

1. Will the activities be supported by Federal funding (e.g., NIH, NSF, DoE, DoD) that is awarded directly to UCI?

☐ **YES*** ☐ **NO**

***If YES to #1, provide a copy of the Human Subjects portion of the grant.**

2. FUNDING SOURCE:

☐	Grant/Subaward *(provide details below)*
☐	Contract/Subcontract *(provide details below)*
☐	Department or campus funds (includes department support, unrestricted funds, start-up funds, personal funds, campus program awards, etc.)
☐	Non-cash support from manufacturer/sponsor (e.g., free drug, device, research materials)
☐	Subject/subject's insurance/third party payer
☐	Student project that will incur no costs

Sponsor Name(s): **<Type Here>**

SPA Proposal #(s): **<Type Here>** Prime Awardee(s): **<Type Here>**

NOTE: If UCI is the prime recipient of a Federal award (e.g., NIH, NFS, DoE, and DoD) through a grant, contract, or cooperative agreement, however a non-UCI entity will carry out the non-exempt human subject research activities, OHRP considers UCI engaged in human subjects research and UCI IRB Approval is required.

SECTION 4: HUMAN SUBJECTS RESEARCH DETERMINATION

If the proposed activity does not meet the definition of human subjects research you are not required to submit this form. If you require a written determination, submit this completed form as follows:

From the lead researcher's UCI email address, send the form to IRB@research.uci.edu. If the lead researcher is a student, a faculty sponsor is required; s/he must be included on the email submission. Alternatively, you may send a copy by campus mail to the UCI HRP, Office of Research, 141 Innovation Drive, Suite 250, Irvine, CA 92697 (Zot Code 7600). For questions contact the HRP staff at IRB@research.uci.edu.

SECTION 5: CONTACT INFORMATION

1. UCI LEAD RESEARCHER (LR):	
2. LR DEPARTMENT:	
3. LR PHONE NUMBER:	**4. LR E-MAIL ADDRESS:**
5. UCI FACULTY SPONSOR (FS – *if required*):	
6. FS PHONE NUMBER:	**7. FS E-MAIL ADDRESS:**
8. ADMINISTRATIVE CONTACT (AC – *if applicable*):	
9. AC PHONE NUMBER:	**10. AC E-MAIL ADDRESS:**
11. ACTIVITY TITLE (*if applicable*):	

12. CATEGORY OF ACTIVITY:

☐ **Purpose/Aim is *Social Behavioral.***

☐ **Purpose/Aim is *Biomedical.***

SECTION 6: ACTIVITY INFORMATION

1. Describe the **purpose** of the proposed activity.

<Type Here>

2. Provide a brief description of the **procedures**.

<Type Here>

3. Describe the **subject** population, or the **type** of information/specimens to be studied.

<Type Here>

4. Were the information/specimens **originally collected solely for research purposes?**

☐ **YES*** ☐ **NO** ☐ **N/A**

***If YES to #4,** the UCI IRB *may* request a copy of the IRB Approval Letter and Consent Form from the original study. This documentation will be reviewed to confirm that use of the information/specimens conforms to the informed consent form.

5. Explain where the information/specimens were collected/obtained (i.e. identify source of data/specimens).

☐ **Not Applicable – *Activity does not involve the use of data/specimens.***

☐ **UCIMC Pathology – *UCI IRB Approved Pathology Research Bio-repository will be used.***

☐ **UCIMC Medical Records – *Identify the access point(s) below (e.g. QUEST, CoPath, OnCore,***

etc.).

AND/OR

<Type Here>

6. Explain how the information/specimens will be provided to the investigator (e.g. investigator will ask the UCIMC Medical Records Department to provide de-identified data; the investigator will be provided an already existing, de-identified data set, etc.).

<Type Here>

OR ☐ **N/A**

7. Submit the survey or questions that will ask of individuals, if applicable. (*Note: The proposed activity cannot meet the definition of research).*

OR ☐ **N/A**

8. Provide a **separate list** of the **data points, variables, and/or information** that will be collected and/or analyzed (i.e. data abstraction form).

OR ☐ **N/A**

Notes:

- Access is limited to the items included in the list. The HRP must be notified of any additions to the list.
- The list will be reviewed to confirm that no private identifiable information (i.e. 18 PHI Identifiers) will be obtained. If the list includes any private identifiable information, **the activity involves human subjects.**

9. If the activity involves **collection of information from internet sources**, please review the internet site's privacy statement. The internet site may prohibit use of their information or may require their written permission prior to use. **Provide a copy of the privacy statement**.

OR ☐ **N/A**

SECTION 7: LEAD RESEARCHER & FACULTY SPONSOR SIGNATURE(S)

(required only if hard copy submitted to HRP Office)

Lead Researcher's Signature	Date
Faculty Sponsor's Signature (if applicable)	Date

SECTION 8: UCI DETERMINATION OF HUMAN SUBJECTS RESEARCH

FOR HRP STAFF AND IRB ONLY – researchers do not complete this section.

☐ The proposed activity as described **DOES NOT** constitute human subjects research. IRB review is not required. This determination only applies to the activities described in this request. If there are any changes that may alter this determination the investigator may request another written determination.

☐ The proposed activity as described **constitutes human subjects research**. Submission of an IRB Application **IS REQUIRED**. IRB Approval must be obtained before the research can begin. Please complete and submit an IRB Application with the appropriate protocol narrative. **All forms are available on the Applications & Forms web page under IRB forms**. If you have questions or needs additional guidance on the IRB submission process, please contact HRP staff for guidance at irb@research.uci.edu**.**

HRP Staff or IRB Chair	Date