

## Non-Human Subjects Research Determination Form

The CSUSB IRB is required under federal regulations to review and approve all research involving human subjects. The following sections will help you independently determine whether your investigation is a case of **Human Subjects Research** or **Non-Human Subjects Research (NHSR)**.

- If your investigation meets the definition of human subjects research, you are required to submit a full IRB protocol for exempt, expedited, or full board review through the [online application](#) system.
- If the proposed activity does not meet the definition of human subjects research, your investigation does not need to be reviewed or approved by the IRB. However, if you need documentation from the CSUSB IRB stating that your activity is not research and/or does not involve human subjects, please submit an [online application](#) (see **Section 3** below for more details).

For further questions, please contact [irb@csusb.edu](mailto:irb@csusb.edu)

### **SECTION 1: DETERMINATION OF "HUMAN SUBJECTS RESEARCH":**

#### **PART A: RESEARCH**

First, determine if your investigation is a form of "research" under the definitions of PART A: 45 CFR 46.102:

**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).

**The following activities are deemed not to be research under the 2018 Common Requirements:**

(1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

(2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority.

(3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

(4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

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 and #2, the activity constitutes "research." Please continue to Part B to determine if this research involves human subjects.**

**\*If Yes to either #1 or #2, the activity may still constitute "research." Please continue to Part B to determine if this research involves human subjects**

**\*If No to both #1 and #2, the activity may not be "research." However, you should continue to make a determination in the following sections.**

## PART B: HUMAN SUBJECTS

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

**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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record).

**Identifiable private information (or biospecimen)** is private information/biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information/biospecimen.

**Coded data** 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 private information (if the investigator possess the key to identify a particular subject).

### Secondary Data Analysis

\* Publicly available datasets for secondary data analysis are not considered identifiable private information only when they fulfill both of the following conditions:

1. if the investigators do not hold the keys to identify particular subjects, and
2. if the investigators cannot readily pinpoint the identity of particular subjects through examining other demographic characteristics or variables in the data.

1. Does the activity involve obtaining pre-existing information or specimens about living individuals through intervention or interaction with the individuals?

Yes \_\_\_\_ No \_\_\_\_

2. Does the activity involve obtaining or the use of identifiable private information or specimens about living individuals? (see elaboration below)

Yes \_\_\_\_ No \_\_\_\_

When considering #2, please note that the following data arrangements are not considered identifiable private information/specimens and may qualify a NHR determination. **However, to obtain a letter of NHR determination, the IRB may require a copy or an email exchange on these arrangements. See **Section 3** below for detail if you need a letter.**

- 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.  
\* This may include publicly available data for secondary data analysis, such as the U.S. Census, General Social Survey (GSS), National Health Interview Survey (NHIS), American National Election Studies (ANES), etc. The investigators do not hold the keys to identify particular subjects and cannot otherwise pinpoint the identity of particular subjects by examining demographic characteristics or other variables.
- 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.  
\* This may include publicly available data for secondary data analysis from organizations such as the Inter-university Consortium for Political and Social Research (ICPSR).
- c. There are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased.
- d. The investigator obtains publicly available information from internet sources. The internet site has obtained permission from users to release their information. 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.)

**\*If Yes to #1 and/or #2, the activity involves human subjects in Part B. You are required to submit a full protocol to the IRB if you also answered Yes to #1 and/or #2 in Part A.**

## SECTION 2: DETERMINATION OF "HUMAN SUBJECT" PER FDA REGULATIONS:

**PART A: 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.

1. Does the activity involve individuals (healthy or patient) who will be a recipient of any test article (i.e., drug, biologic, or medical device)?  
Yes \_\_\_\_ No \_\_\_\_
2. Does the research involve 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 #1 and/or #2 in section 2, the activity involves human subjects. You are required to submit a full protocol to the IRB if you also answered Yes to #1 and/or #2 in Part A.**

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 - F\\*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: REQUESTING IRB DETERMINATION

You do not need to submit this information to IRB if you have determined independently that your research is Non-Human Subjects Research according to the above guidelines. This application only applies to one the following conditions:

- a. You need a letter from the CSUSB IRB indicating a Non-Human Subjects Research determination for your investigation. This letter may be presented for the purposes of grant applications, publications, thesis and dissertation completion; or
- b. You are uncertain whether your investigation is Non-Human Subjects Research and would like the CSUSB IRB to provide you a determination.

Please note, this is just a template and you need to submit all information below into the [online submission application](#) for the IRB to receive your NHSR application.

#### 1. Check a category relevant to the proposed activity or investigation

\_\_\_ Purpose/Aim is Social Behavioral

\_\_\_ Purpose/Aim is Biomedical

2. Briefly describe the purposes of the proposed activity or investigation. Discuss if your activity or investigation involves systematic approaches to anticipate generalizable knowledge.

3. Provide a brief description of the procedures of your activity or investigation. Discuss also if your activity or investigation involves intervention or interaction with living individuals.

4. Describe the subject population, sample, or the type of data/information/specimens involved in your activity or investigation.

5. If you did not or do not plan to collect individual information/specimens, were the obtained information/specimens originally collected solely for research purposes?  
Yes \_\_\_\_ No \_\_\_\_ N/A \_\_\_\_

**\*If YES to #4, the 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.**

6. Explain where and how you plan to obtain the information/specimens. Discuss if your activity or investigation involves identifiable private information. If applicable, please address your access to secondary data by means listed above (Part A #3, from a to d). The IRB may request documentation on your data access arrangements.

7. Submit other documents (e.g., examples of survey or questions, documentations of data access) that may help the IRB determine if your activity is Non-Human Subjects Research.