CHAPMAN UNIVERSITY | INSTITUTIONAL REVIEW BOARD

Research Determination Form

The Chapman University IRB is required to review and approve all research involving human subjects. If an individual has questions about whether an activity is research, please contact the IRB staff. This form is intended to help you determine if your project requires IRB approval.

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 principal investigator's email address, send the form to irb@chapman.edu. If the project is student directed, a faculty advisor is required; s/he must be included on the email submission. For questions contact the IRB staff at irb@chapman.edu or call (714) 628-2833.

SECTION 1: DETERMINATION OF "HUMAN SUBJECTS RESEARCH"

PART A: 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: 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.

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. Submit a protocol to the IRB.**

2. Does the activity involve obtaining identifiable and private information about living individuals?

☐ Yes ☐ No

***If YES to #2, the activity involves human subjects. Submit a protocol to the IRB.**

3. Does the activity involve the use of coded private information/specimens?

☐ Yes ☐ No

If YES to #3, please indicate why the investigator cannot ascertain the identity of the individual(s) to whom the coded private information/specimens pertain:

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 3, and No to A, B, and C the activity involves human subjects, and IRB review is needed.**

4. Were the information/specimens previously collected (or yet to be collected) specifically for the currently proposed project?

☐ Yes ☐ No ☐ N/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

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

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 #2, 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 Chapman University?

☐ Yes ☐ No

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

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 Names

Proposal #(s)

Prime Awardee(s)

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

SECTION 4: CONTACT INFORMATION

Principal Investigator

PI Department

Phone

E-mail

SECTION 5: ACTIVITY INFORMATION

Category of Activity

- ☐ Purpose/Aim is Social Behavioral
- ☐ Purpose/Aim is Biomedical

1. Briefly describe the purpose of the proposed activity

2. Provide a brief description of the procedures

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

4. Were the 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.**

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

6. Explain how the information/specimens will be provided to the investigator.

7. Submit the survey or questions that will ask of individuals, if applicable.

☐ 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).

☐ N/A

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.

☐ N/A

SECTION 6: PRINCIPAL INVESTIGATOR SIGNATURE

(required only if hard copy is submitted to IRB staff)

PI Signature: _____ Date: _____

Faculty Sponsor's Signature: _____ Date: _____
(if applicable)

SECTION 7: DETERMINATION OF HUMAN SUBJECTS RESEARCH
FOR IRB AND IRB STAFF 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 Forms & Instructions page on the IRB web site. If you have questions or needs additional guidance on the IRB submission process, please contact IRB staff for guidance at irb@chapman.edu.

IRB Staff or Chair: _____ Date: _____