Creighton UNIVERSITY
Institutional Review Board

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DOES MY PROJECT REQUIRE IRB REVIEW?

Not all research involving humans requires Creighton University (CU) IRB review. Only activities meeting the regulatory definitions of **(a)** "**research**" and **(b)** "**human subjects**" and where **(c)** CU is "**engaged**" in the conduct of human subjects research require CU IRB review and approval. Use this tool to help you determine whether IRB submission is needed. **Answer the questions in the order they appear**. **Do not submit this document to the IRB.**

Due to the potential consequences of not obtaining IRB review and Not Human Subjects Research (NHSR) confirmation, the investigator should choose to error on the side of caution and consult an IRB Administrator when it's uncertain whether the project is human subjects research or not. NOTE: The IRB does not provide confirmation of a NHSR project when it has already started or is complete.

SECTION 1: DETERMINATION OF "RESEARCH"

RESEARCH - "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

Activities 'designed to develop or contribute to generalizable knowledge' are those activities designed 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. The project may be "research" if it:

- intends to advance general knowledge in the academic, scientific, or professional community;
- is conducted using a research design that will lead to scientifically valid findings; or
- subjects are not expected to benefit personally from the knowledge gained.
- is being conducted to support a dissertation

NOT RESEARCH - projects may be systematic but "not research." Examples of "not research":

- Classroom projects solely to fulfill course requirements and the intention is to not share the results beyond the University community;
- Quality assurance activities designed to continuously improve the quality or performance of a department or program where it is not the intention to share the results beyond the project site;
- Most of the subjects who participate in the project are expected to benefit from the knowledge gained and the main goal of the project is to improve services;
- Oral history activities, in general, are designed to create a record of specific historical events and, as such, are not intended to contribute to generalizable knowledge. Only those oral history projects that conform to that regulatory definition of research need to submit for IRB review.
- Capstone projects which demonstrate a student's skill and knowledge with the intent to apply those skills towards solving a clinical problem.
- 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.
- 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. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including

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trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

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

Use the information above to answer the following questions.

1. Do the proposed activities involve a systematic approach? A "systematic" approach involves 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. **[__] YES [__] NO**

2. Is the intent of the proposed activities to *develop or contribute to generalizable (scholarly) knowledge*? **[__] YES [__] NO**

   If NO is selected for both questions above - STOP, this project is not research, therefore, IRB review is not required.
   If YES is selected for both questions above – continue to Section 2.

SECTION 2: DETERMINATION OF "HUMAN SUBJECT"

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*.

(1) 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.
(1) Interaction includes communication or interpersonal contact between researcher and subject.
(2) Identifiable includes where the identity of the subject is or may be ascertained by the researcher or associated with the information
(2) 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 or educational record information). Private information must be individually *identifiable*

* The information being obtained **must be about** the individual/subject; their opinions, characteristics, or behavior. **Solely** obtaining information, for example from an employer, how many employees they have or whether a specific HR policy exists would **not be about** the individual and therefore not meet the criteria for "human subject."

Use the definitions above to answer the following questions.

1. Are the human subjects *living individuals*? This applies to charts reviews and datasets. **[__] YES [__] NO**
If NO to 1, the criteria for human subject are not met. Go to Section 4.

2. Do the activities involve CU personnel directly obtaining information through *intervention*, *interaction* or *observations* about the individuals? E.g., interviews, surveys, sensors placed on the body, etc. Directly obtaining refers to firsthand collection and not analysis of existing data. **[__] YES [__] NO**

3. Do the activities involve CU personnel accessing *individually identifiable* (e.g., names, medical record numbers,

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social security numbers, study ID codes, etc.) **and** *private* information about living individuals? This applies to charts, records, datasets, and specimens. Even if you are not recording identifiers, if the source of the data contains identifiers, then mark this question as a "yes." **[__] YES [__] NO**

4. Do the activities involve CU personnel obtaining or receiving *individually identifiable* (e.g., study ID codes, names, medical record numbers, social security numbers, etc.) **and** *private* information about living individuals? This applies to charts, records, datasets, and specimens. **[__] YES [__] NO**

4a. If yes to #4, will the *data/specimens be coded* such that a link exists that could allow the source of the data/specimens to be re-identified (i.e., key available to decipher the code)? **[__] YES [__] NO**

4b. Is there a written agreement that prohibits the CU researcher and his/her research team from having access to the link, or the likelihood for the CU researcher to have access to the identifiers is extremely unlikely? **[__] YES [__] NO**

If 2-4 are YES, the criteria for human subject are met. Go to Section 3.

SECTION 3: DETERMINATION OF "ENGAGED"

CU Auspices: CU personnel (student, faculty, or staff) who: (1) act on behalf of the institution; (2) exercise institutional authority or responsibility; or (3) perform institutionally designated activities.

Non-CU researchers wishing to conduct human subjects research using CU personnel as subjects or its facilities are not considered to be engaged. This document is for the determination of CU IRB review only and you are expected to obtain other permission as necessary. For example, the CU IRB does not have authority to grant the release or use of CU listservs, equipment, or facilities.

ENGAGED	NOT ENGAGED
CU is considered to be engaged in human subjects research if CU or CU personnel are involved in **any** the following activities under CU auspices: • direct awardee of a federal grant, award, or contract; • obtaining informed consent; • performing invasive or noninvasive procedures with subjects; • intervening for research purposes with any subjects by manipulating the environment; • interacting for research purposes with any subject; (e.g., conducting research interviews or administering questionnaires); or • obtaining private identifiable information.	CU is considered to not be engaged in human subjects research if CU or CU personnel are **solely** involved in the following activities: • performing commercial/service where: (a) the services performed do not merit professional recognition or publication privileges; (b) the services performed are typically performed by those institutions for non-research purposes; and (c) the institution's employees or agents do not administer any study intervention being tested or evaluated under the protocol; • inform (e.g., provide a copy of informed consent document, information about contacting the investigator, seek or obtain the prospective subjects' permission for investigators to contact them) prospective subjects about the availability of the research but do not obtain subjects' consent for the research or act as representatives of the investigators; or • release of identifiable private information/specimens pertaining to the subjects of the research.

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Use the information above to answer the following question.

1. Is CU **engaged** in human subjects research? **[__] YES [__] NO**
   If YES or NO, please explain why CU **IS** or is **NOT** engaged in human subjects research:

2. Is any non-CU IRB involved in reviewing this project? **[__] YES [__] NO**
   If YES, please explain which IRB(s) and the status of IRB approval(s):

SECTION 4: IS YOUR PROTOCOL HUMAN SUBJECTS RESEARCH AND CU IS ENGAGED?

When the project is Human Subjects Research and CU is Engaged
If based on your responses in Section 1 the activities constitute research; **and** per your responses in Section 2 the activities involve human subjects; **and** per your responses in Section 3 CU is engaged, please use InfoEd to complete an initial submission for IRB review. InfoEd guides and templates are available on the IRB website. If you have questions, contact the IRB office at irb@creighton.edu**.**

When the project is research that doesn't involve human subjects (NHSR)
If based on your responses in Section 2, CU is **not engaged** in **human subjects research**, you are **not required** to submit for IRB review. If you would like confirmation and documentation from the IRB staff that your proposed activities do not constitute CU being engaged in human subjects research (e.g. for instance, if requested by the sponsor a collaborator, or journal), please complete a Not Human Subjects Research (NHSR) initial submission in InfoEd for IRB administrative review and attach a completed proposal, using the CU *NHSR Proposal Template,* located on the IRB website.

When the project is Quality Improvement (NHSR)
If in Section 1: Q1 = YES and Q2 = NO, and if in Section 2: Q1 = YES, this project may be Quality Improvement (NHSR). Quality Improvement projects do not require IRB review. If you would like confirmation and documentation from the IRB staff that your proposed activities do not constitute CU being engaged in human subjects research (e.g. for instance, if requested by the sponsor a collaborator, or if it's anticipated a journal will make this request), please complete a Quality Improvement (NHSR) initial submission in InfoEd for IRB administrative review and attach a completed proposal. For additional information on QI vs Human Subjects Research, see resources on the Guidance for Investigators webpage.