

Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 127	
CHAPTER: Institutional Review Board	ISSUED: 6/2010	REVISED/REVIEWED: 11/2013
POLICY: Engaged in Research	PAGE 1 OF 8	

1. POLICY

This policy describes the process for determining whether Creighton University and/or the agents of Creighton University are engaged in human subjects research. Creighton University has adopted the [OHRP Guidance on Engagement of Institutions in Human Subjects Research](#), dated October 16, 2008, which has been modified specifically for use at Creighton University. Creighton University applies this guidance to all research to determine whether Creighton University or its agents are engaged in human subjects research.

2. DEFINITION OF A CREIGHTON UNIVERSITY AGENT:

- 2.1. An agent is defined as any Creighton University faculty, administrators, staff, students and other persons involved in the design, administration, financing, conduct or reporting of research or sponsored program activities at or through Creighton University, regardless of the source of funding.
- 2.2. All agents who are engaged in Human Subject Research shall have completed the appropriate human subjects protection education (see IRB policy 123, "[Human Subjects Research Education Program](#)")

3. CREIGHTON UNIVERSITY ENGAGED IN HUMAN SUBJECTS RESEARCH

- 3.1. In general, Creighton University is considered *engaged* in research when the involvement with the project includes any of the following:
 - 3.1.1. A Creighton University agent receives an award through a grant, contract, or cooperative agreement for the non-exempt human subjects research (i.e., awardee institutions), even when all activities involving human subjects are carried out by employees or agents of another institution.
 - 3.1.2. A Creighton University agent intervenes for research purposes with any human subjects of the research by performing invasive or noninvasive procedures. Examples of invasive or noninvasive procedures include drawing blood; collecting buccal mucosa cells using a cotton swab; administering individual or group counseling or psychotherapy; administering drugs or other treatments; surgically implanting medical devices; utilizing physical sensors; and utilizing other measurement procedures.

Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 127	
CHAPTER: Institutional Review Board	ISSUED: 6/2010	REVISED/REVIEWED: 11/2013
POLICY: Engaged in Research	PAGE 2 OF 8	

- 3.1.3. A Creighton University agent intervenes for research purposes with any human subject of the research by manipulating the environment. Examples of manipulating the environment include controlling environmental light, sound, or temperature; presenting sensory stimuli; and orchestrating environmental events or social interactions.
- 3.1.4. A Creighton University agent interacts for research purposes with any human subject of the research. Examples of interacting include engaging in protocol-dictated communication or interpersonal contact; asking someone to provide a specimen by voiding or spitting into a specimen container; and conducting research interviews or administering questionnaires.
- 3.1.5. A Creighton University agent obtains the informed consent of human subjects for the research.
- 3.1.6. A Creighton University agent **obtains** for research purposes identifiable private information or identifiable biological specimens **from any source** for the research. It is important to note that, in general, agents of the university who obtain identifiable private information or identifiable specimens for human subjects research are considered engaged in the research, even if the university's agents do not directly interact or intervene with human subjects. In general, obtaining identifiable private information or identifiable specimens includes, but is not limited to:
- 3.1.6.1. observing or recording private behavior;
 - 3.1.6.2. using, studying, or analyzing for research purposes identifiable private information or identifiable specimens provided by another institution; and
 - 3.1.6.3. using, studying, or analyzing for research purposes identifiable private information or identifiable specimens already in the possession of the investigators.

In general, private information or specimens are considered to be individually identifiable as defined in 45 CFR 46.102(f) when they can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.

Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 127	
CHAPTER: Institutional Review Board	ISSUED: 6/2010	REVISED/REVIEWED: 11/2013
POLICY: Engaged in Research	PAGE 3 OF 8	

4. CREIGHTON UNIVERSITY IS NOT ENGAGED IN HUMAN SUBJECTS RESEARCH

Creighton University would be considered **not** engaged human subjects research project (and, therefore, would not need IRB review) if the involvement of Creighton University agents in that project is **limited to one or more** of the following. The following are scenarios describing the types of university involvement that would make the university **not** engaged in human subjects research; there may be additional such scenarios:

- 4.1. Creighton University agents perform commercial or other services for investigators provided that **all** of the following conditions also are met:
 - 4.1.1. the services performed do not merit professional recognition or publication privileges;
 - 4.1.2. the services performed are typically performed by Creighton University for non-research purposes; and
 - 4.1.3. the Creighton University agents do not administer any study intervention being tested or evaluated under the protocol.

The following are some examples, assuming the services described would not merit professional recognition or publication privileges:

- The laboratory whose employees perform routine serum chemistry analyses of blood samples for investigators as a commercial service.
 - The hospital whose employees obtain blood through a blood draw or collect urine and provide such specimens to investigators as a service.
 - The radiology employees perform chest x-rays and send the results to investigators as a service.
- 4.2. Creighton University is not a research site and the Creighton University agents provide clinical trial-related medical services that are dictated by the protocol and would typically be performed as part of routine clinical monitoring and/or follow-up of subjects enrolled at a study site by clinical trial investigators (e.g., medical history, physical examination, assessment of adverse events, blood test, chest X-ray, or CT scan) provided that **all** of the following conditions also are met:

Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 127	
CHAPTER: Institutional Review Board	ISSUED: 6/2010	REVISED/REVIEWED: 11/2013
POLICY: Engaged in Research	PAGE 4 OF 8	

- 4.2.1. the Creighton University agents **do not** administer the study interventions being tested or evaluated under the protocol;
- 4.2.2. the clinical trial-related medical services are typically provided by Creighton University for clinical purposes;
- 4.2.3. the Creighton University agents do not enroll subjects or obtain the informed consent of any subject for participation in the research; and
- 4.2.4. the investigators from an institution engaged in the research retain responsibility for:
 - 4.2.4.1. overseeing protocol-related activities; and
 - 4.2.4.2. ensuring appropriate arrangements are made for reporting protocol-related data to investigators at an engaged institution, including the reporting of safety monitoring data and adverse events as required under the IRB-approved protocol.
- 4.3. Creighton University is not initially selected as a research site whose agents administer the study interventions being tested or evaluated under the protocol limited to a one-time or short-term basis (e.g., an oncologist at the institution administers chemotherapy to a research subject as part of a clinical trial because the subject unexpectedly goes out of town, or is unexpectedly hospitalized), provided that **all** of the following conditions also are met:
 - 4.3.1. an investigator from the institution engaged in the research determines that it would be in the subject's best interest to receive the study interventions being tested or evaluated under the protocol;
 - 4.3.2. the Creighton University agents do not enroll subjects or obtain the informed consent of any subject for participation in the research;
 - 4.3.3. the investigators from the institution engaged in the research retain responsibility for:
 - 4.3.3.1. overseeing protocol-related activities;
 - 4.3.3.2. ensuring the study interventions are administered in accordance with the IRB-approved protocol;

Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 127	
CHAPTER: Institutional Review Board	ISSUED: 6/2010	REVISED/REVIEWED: 11/2013
POLICY: Engaged in Research	PAGE 5 OF 8	

- 4.3.3.3. ensuring appropriate arrangements are made for reporting protocol-related data to investigators at the engaged institution, including the reporting of safety monitoring data and adverse events as required under the IRB-approved protocol; **and**
- 4.3.3.4. informing an IRB designated on the engaged institution's FWA that study interventions being tested or evaluated under the protocol have been administered at an institution **not** selected as a research site.

4.4. Creighton University agents may inform prospective subjects about the availability of the research by:

- 4.4.1. providing prospective subjects with information about the research (which may include a copy of the relevant informed consent document and other IRB-approved materials) but do not obtain subjects' consent for the research or act as representatives of the investigators;
- 4.4.2. providing prospective subjects with information about contacting investigators for information or enrollment; and/or
- 4.4.3. seeking or obtaining the prospective subjects' permission for investigators to contact them.

An example of this would be a clinician who provides patients with literature about a research study at another institution, including a copy of the informed consent document, and obtains permission from the patient to provide the patient's name and telephone number to investigators.

- 4.5. Institutions (e.g., schools, nursing homes, businesses) permit use of their facilities for intervention or interaction with subjects by investigators from another institution. Examples would be a school that permits investigators from another institution to conduct or distribute a research survey in the classroom, or a business that permits investigators from another institution to recruit research subjects or to draw a blood sample at the work site for research purposes.
- 4.6. Creighton University agents **release** to investigators at another institution identifiable private information or identifiable biological specimens pertaining to the subjects of the research. Note that in some cases the institution releasing identifiable private information or identifiable biological specimens may have institutional requirements that would need to be satisfied before the information

Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 127	
CHAPTER: Institutional Review Board	ISSUED: 6/2010	REVISED/REVIEWED: 11/2013
POLICY: Engaged in Research	PAGE 6 OF 8	

or specimens may be released, and/or may need to comply with other applicable regulations or laws. In addition, if the identifiable private information or identifiable biological specimens to be released were collected for another research study covered by 45 CFR part 46, the institution releasing such information or specimens should:

- 4.6.1. ensure that the release would not violate the informed consent provided by the subjects to whom the information or biological specimens pertain (under 45 CFR 46.116), or
- 4.6.2. if informed consent was waived by the IRB, ensure that the release would be consistent with the IRB's determinations that permitted a waiver of informed consent under 45 CFR 46.116 (c) or (d).

Examples of institutions that might release identifiable private information or identifiable biological specimens to investigators at another institution include:

- schools that release identifiable student test scores;
- an HHS agency that releases identifiable records about its beneficiaries; and
- medical centers that release identifiable human biological specimens.

Note that, if Creighton University agents **obtain** the identifiable private information or identifiable biological specimens from a releasing institution, Creighton University would be engaged in human subjects research.

4.7. Creighton University agents may use de-identified data:

- 4.7.1. obtain from another institution involved in the research coded private information or human biological specimens that retains a link to individually identifying information (such as name or Social Security number); and
- 4.7.2. are unable to readily ascertain the identity of the subjects to whom the coded information or specimens pertain because, for example:
 - 4.7.2.1. the institution's employees or agents and the holder of the key must enter into an agreement prohibiting the release of the key to the those employees or agents under any circumstances;

Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 127	
CHAPTER: Institutional Review Board	ISSUED: 6/2010	REVISED/REVIEWED: 11/2013
POLICY: Engaged in Research	PAGE 7 OF 8	

- 4.7.2.2. the releasing institution has IRB-approved written policies and operating procedures applicable to the research project that prohibit the release of the key to the institution's employees or agents under any circumstances; or
- 4.7.2.3. there are other legal requirements prohibiting the release of the key to the institution's employees or agents.

For purposes of this document, *coded* means that:

- identifying information (such as name or Social Security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, and/or combination thereof (i.e., the code); and
 - a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.
- 4.8. Creighton University agents access or utilize individually identifiable private information **only** while visiting an institution that is engaged in the research, provided their research activities are overseen by the IRB of the institution that is engaged in the research.
- 4.9. Creighton University agents access or review identifiable private information for purposes of study auditing (e.g., a government agency or private company that will have access to individually identifiable study data for auditing purposes).
- 4.10. Creighton University agents receive identifiable private information for purposes of satisfying U.S. Food and Drug Administration reporting requirements.
- 4.11. Creighton University agents author a paper, journal article, or presentation describing a human subjects research study.

Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 127	
CHAPTER: Institutional Review Board	ISSUED: 6/2010	REVISED/REVIEWED: 11/2013
POLICY: Engaged in Research	PAGE 8 OF 8	

5. COOPERATIVE RESEARCH

- 5.1. Creighton University may enter into agreements with other institutions if the Creighton University agent is conducting his/her research at another institution that has a registered Federal-wide Assurance (FWA) and an institutional registered Institutional Review Board (IRB)
- 5.2. See IRB Policy 115, "[External Studies](#)."