Policy on Informed Consent

Effective date: 12/14/2018

I. Background
UCSC Researchers are expected to communicate with subjects throughout the entire study period. This policy outlines the regulatory requirements for obtaining informed, documented consent, and times when researchers can request waived consent processes for non-exempt research.

For exempt interactive research (e.g., surveys, interviews, education research, computer games, etc.), UCSC generally expects some minimal consent process to meet the ethical principles of the Belmont Report.

II. Definitions
a. Informed Consent: Agreement to participate in research expressed by an individual (or his/her legally authorized representative) authorized under applicable law to make such decisions, based on sufficient information (e.g., regarding possible risks and benefits of the research) and adequate opportunity to consider voluntary participation. Also: legally effective informed consent.

b. Legally Authorized Representative: an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the nonresearch context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research. See UCOP Guidance on Surrogate Consent for Research

III. General Requirements for Informed Consent
a. Exempt For exempt interactive research (e.g., surveys, interviews, education research, computer games, etc.), researchers should at minimum identify themselves and UCSC, state the purpose of the research, what is expected of them, and describe voluntary nature of the study.

b. Non-exempt Unless granted a waiver of consent, researchers must obtain informed, documented consent of their subjects or the subject’s legally authorized representative for non-exempt research. Use the UCSC Informed Consent Template to ensure all elements of consent are present. While DHHS expects key information be concise and upfront, most
minimal risk research informed consent documents should be rather brief in entirety (e.g., no more than a few pages) and satisfy the concise requirements. Please ensure the following elements are in your document:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

(7) A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;

(8) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and

(9) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

IV. Waiver or Alteration of Consent
An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and
(2) The research could not practicably be carried out without the waiver or alteration.

OR

An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

The informed consent requirements are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

V. Waiver of Documentation of Consent

An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or

(3) Subjects are members of a distinct cultural group or community for whom signing documents is not the norm, provided that the research presents no more than minimal risk of harm to subjects and there is an
appropriate alternative method for documenting that informed consent was obtained.

VI. Researcher and IRB Responsibilities
   a. Researchers: The researcher must either submit an informed consent document with all required elements or request a waiver or alteration of consent with justification (e.g., to withhold purpose for deception, or no consent obtained for secondary data analysis, etc.). Also, the informed consent should have signature lines or the researcher requests a waiver of documentation of consent.
   b. IRB: The IRB will review the researcher’s justification for the waivers and determine whether they are met. If met, the IRB will include approval for the waiver as part of the approval of the study. If not met, the IRB will inform the researcher to revise the protocol.

VII. Minors and Parent Permission
Minors cannot give legally informed consent for themselves (age varies depending where the minor lives; in California it is 17 and younger). This means the parent must provide permission for the child unless waived. Also, if a child is above age 6, the researcher should obtain assent of the child and provide an assent script with their materials.

In addition to the provisions for waiver contained in 45 CFR 46.116 of subpart A, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in Subpart A of this part and paragraph (b) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with federal, state, or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

VIII. Posting Clinical Trial Consent Documents
   a. For clinical trials conducted or supported by a Common Rule department or agency, a copy of the IRB-approved consent form that was used to enroll subjects must be posted by the awardee or the federal dep’t/agency conducting the trial on a publicly available federal website at clinicaltrials.gov or regulations.gov as a consent form repository. Post within 60 days after last subject study visit.
IX. Legally Authorized Representative
   b. Researchers should describe plan to assess capacity for subject to provide their own consent based on populations that may require LAR consent. If the subject does not want to participate and resists, they should be excluded.

X. References
   45 CFR 46.116, 117, 46.408(c)