Policy on Informed Consent

Effective date: 9/20/2019

I. Background
This policy outlines the regulatory requirements for obtaining informed, documented consent, and for when the informed consent process can be waived or altered.

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 (LAR): 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 non-research 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 Research: For exempt research that involves interaction with subjects (e.g., surveys, interviews, education research, computer games, etc.), researchers are expected, at minimum, to identify themselves and UCSC to subjects, state the purpose of the research, state what is expected of subjects who participate in the research, and describe the voluntary nature of the study.

b. Exempt Research with Limited IRB Review: When Limited IRB Review is required, researchers are also expected to inform subjects that researchers are collecting identifiable information about them; what risks are reasonably anticipated if this information were inadvertently disclosed; when identifiable information will be destroyed or that it will be retained indefinitely; and how identifiable information will be protected by researchers (e.g. encryption).

c. Non-exempt Research: Unless granted a consent waiver or alteration, researchers must obtain the informed and documented consent of their subjects or the subject’s LAR. Researchers must use the UCSC Informed Consent Template to ensure that all required elements of consent are present and that consent information is presented in a way that is consistent with HHS.
expectation that key information be “concise and focused.” In most cases, informed consent documents pertaining to minimal risk research should be no more than five pages. Absent an approved waiver or alteration, informed consent documents must include the following elements:

i. 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;

ii. A description of any reasonably foreseeable risks or discomforts to the subject;

iii. A description of any benefits to the subject or to others which may reasonably be expected from the research;

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

v. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

vi. 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;

vii. 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

viii. 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:

i. 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;

ii. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

iii. Any additional costs to the subject that may result from participation in the research;
iv. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

v. 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

vi. The approximate number of subjects involved in the study.

vii. 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;

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

ix. 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:

a. Both of the following are true:
   i. 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
   ii. The research could not practicably be carried out without the waiver or alteration; OR

b. ALL of the following are true:
   i. The research involves no more than minimal risk to the subjects;
   ii. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
   iii. The research could not practicably be carried out without the waiver or alteration; and
   iv. 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 that:

a. 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

b. 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

c. 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 showing all required elements and lines for wet signature, or else request the applicable consent waiver or alteration and demonstrate how the study satisfies the corresponding waiver criteria (see above).

b. IRB: The IRB will review the researcher’s justification for any consent waiver(s) and determine whether the applicable criteria are met. If met, the approval of the waiver will be documented and communicated to researchers in the IRB approval letter for the research. If not, the IRB or ORCA will explain why the study is not eligible for the waiver/alteration as proposed and give the researcher the opportunity to revise the protocol.

VII. Non English Speaking Subjects

a. The Principal Investigator is responsible for providing an accurate translation of the consent document in the subject’s language for non-English speaking subjects and providing such subjects with an opportunity to ask questions in their language. Researchers are required to affirm this in the application. Researchers must provide a copy of the translated consent form to the IRB by request only.

b. Since UCSC primarily conducts minimal risk social, behavioral, educational research, the UCSC IRB does not allow use of the “short form” consent document, which was meant for medical center settings.
VIII. Minors and Parent Permission
The age of majority varies depending on where the individual in question lives. In the State of California, anyone 17 years of age and younger is considered a minor. Minors, as defined by their state of residence, cannot give legally valid informed consent to participate in research except under certain conditions listed in the UCSC Policy on State and Local Laws. Under all other conditions, and in the absence of an approved consent waiver or alteration (see above), a parent or LAR must give their permission for the child to participate and their permission must be documented. Furthermore, the researcher must obtain the assent of any child over the age of 6 and submit an assent script with their protocol for this purpose.

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.

IX. Posting Clinical Trial Consent Documents
a. For clinical trials conducted or supported by a Common Rule department or agency (see https://www.hhs.gov/about/agencies/hhs-agencies-and-offices/index.html https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html), a copy of the IRB-approved consent form that was used to enroll subjects must be posted by the awardee or the federal department/agency conducting the trial on a publicly available federal website at clinicaltrials.gov or regulations.gov within 60 days after the last subject’s study visit.

X. Legally Authorized Representative (LAR)
a. Regulations require the informed consent of subjects or their LAR. When the LAR consents on behalf of a subject, this is called “surrogate consent.” See UCOP Guidance on Surrogate Consent for Research.
b. When proposing to obtain the consent of a LAR, researchers must describe how they intend to assess the subject’s capacity, or incapacity, to provide their own consent. If a subject does not want to participate and/or resists, they
must not be compelled to participate even if they are determined incapable of consenting for themself.

c. The LAR must abide by the researcher’s approved informed consent process and sign on the subject’s behalf unless a waiver of documentation is approved.

XI. Third Party Observation of Consent Process

a. The IRB may require that a third party observe the consent process to ensure that the process is properly carried out and documented, that the subject has adequate time to consider participation, that researchers have not coerced the subject to participate, and that what is stated to subjects is in a language they understand and matches the approved informed consent document.

b. The IRB may require third party observation for studies that are high risk, involve complicated procedures, involve vulnerable populations, involve researchers with limited experience with consenting subjects, or for other reasons at the IRB’s discretion.

XII. References

a. 45 CFR 46.116, 117, 46.408(c)

b. Stanford University HRPP Policy Manual