CAMPBELL UNIVERSITY	**IRB SOP:** Informed Consent Documentation for Human Subjects Research		
	NUMBER	APPROVED BY	EFFECTIVE DATE
	HSR-420	Miranda van Tilburg, PhD IRB Chair, IRB Office Campbell University	12/02/2020

Applies to Campbell faculty, faculty advisors, students and staff conducting or overseeing human subjects research.

Purpose

It is the Principal Investigator's responsibility to prepare an informed consent document which incorporates the required elements and applicable additional elements as required by the Federal regulations, tribal law passed by the official governing body of an American Indian or Alaska Native tribe and institutional policies. This procedure establishes the process to document the informed consent process in writing.

Background

Federal regulations require that subjects provide written consent prior to their involvement in human subjects research, unless the IRB has approved a waiver or alteration of the documentation of consent. For Exempt (45 CFR 46.104) and Registration Projects the IRB may or may not require subjects provide written consent prior to their involvement in human subjects research based on the level of risk associated with the research activities and under which category the research is approved. For further information see, *HRPP Policy: Registration Projects and FLEX Review*, *IRB SOP: Waiver or Alteration of the Documentation of Consent* and *IRB SOP: Waiver or Alteration of the Informed Consent Process*.

Definitions

Consent: refers to an explicit agreement to participate in a certain action, particularly and especially after thoughtful consideration.

Coercion: the use of force or intimidation to persuade someone to do something which they are unwilling to do.

Exculpatory language: language that waives or appears to waive any of the subject's legal rights or attempts to prospectively remove responsibility from the Sponsor or project team.

Reasonable Person: A phrase in law to denote a hypothetical person in society who exercises average care, skill, and judgment in conduct and who serves as a comparative standard by which to make a determination.

Undue Influence: (as a term in jurisprudence) is an equitable doctrine that involves one person taking advantage of a position of power over another person.

Principal Investigator Responsibilities and Procedures for IRB Submission

1. Principal Investigators (PIs) must provide a detailed description of the method for obtaining informed consent within the initial submission. The description should include the following information:

a. Who (by title) will conduct the consent process;
b. Where and when the process will take place;
c. The process that will be followed;
d. Steps taken to minimize the possibility of coercion or undue influence;
e. How much time the potential subject (or the subject's legally authorized representative) will have to consider whether or not to participate;
f. How it will be determined that the potential subject (or the subject's legally authorized representative) understands the information presented;

2. The informed consent document must:
    a. Begin with a concise and focused presentation of the "key information" that is most likely to assist a prospective subject in understanding the reasons why one might or might not want to participate in the research. This subsection must be organized and presented in a way that facilitates comprehension;
    b. Utilize language to promote the subject's understanding of the information;
        - The information provided in the informed consent documents must be in a language understandable to the subject (target population);
        - Technical and scientific terms should be adequately explained using common or lay terminology;
        - Generic names are preferable when describing pharmaceuticals unless the brand name is more commonly known and understood. Regardless of which name is preferred, it should be used consistently throughout the informed consent documents;
        - Devices and procedures should also be described consistently throughout the documents and explained in simple language;
    c. Provide the essential information a reasonable person would want to have. This information should be in sufficient detail and organized to facilitate the prospective subject's understanding. The information is aimed at helping to make an informed decision about whether to participate in research and provide an opportunity to discuss that information;
    d. Not waive or appear to waive subjects' rights; and
    e. Include each of the required elements and applicable additional elements of informed consent describing the research and the nature of research participation as required by institutional policy;
    f. It is generally recommended that consent documents be written at a sixth to eighth-grade reading level.
3. PIs are responsible for incorporating the required, and if applicable additional elements, of informed consent and HIPAA standards/FERPA language into each informed consent document for their research studies. PIs are required to use the Campbell IRB Consent Form Templates in their development of a consent form for use in research studies.
4. The consent document must include a provision for the research subject's dated signature.
    a. Additional signatures lines may be required per IRB policies or per a sponsor's protocol.

   b. If signature lines not identified per Campbell IRB informed consent templates are required, the PI and research team must contact the IRB prior to submitting the consent document.
5. The required elements of informed consent may not be omitted unless specifically waived by the IRB. In addition, there may not be discrepancies within the informed consent documents, the IRB application, the Sponsor's or Investigator's Protocol, the Investigator's Brochure, the grant and/or the contract regarding the purpose, foreseeable risks, and benefits of the research.
6. PIs must include all informed consent documents (full written documents, oral scripts, a list of talking points, videos, comprehension materials, any type of comprehension or assessment aids, and short forms) in their application for review and must receive approval by the Campbell IRB prior to use.
7. After receiving approval if the PI wishes to make any changes to the informed consent process or the documents; the PI must submit an amendment to the Campbell IRB for review and approval prior to implementing the change.

Required Elements

The required elements of consent to be included in each informed consent document are:

- A concise and focused presentation of the "key information" that is most likely to assist a prospective subject in understanding the reasons why one might or might not want to participate in the research. This subsection must be organized and presented in a way that facilitates comprehension.
- A clear statement that the project involves "research". If the word "study" is used, it should say "research study";
- Information that a "reasonable person" would want to have in order to make an informed decision and subjects must be provided an opportunity to discuss that information;
- Information organized and presented in sufficient detail to facilitate understanding of the reasons why one might or might not want to participate
- An explanation of the purposes of the research;
- The expected duration of the subject's participation;
- A complete description of the procedures to be followed, and identification of procedures that are experimental and performed solely for the purposes of research;
- A description of the reasonably foreseeable risks and discomforts;
- A description of any benefits to the subject or others that may reasonably be expected from the research;
- A disclosure of appropriate alternative procedures or courses of treatment that might be advantageous to the subject;
- When the research involves the collection of identifiable private information or identifiable biospecimens, the one of the following statements must be included:
    - "Once all personal identification is removed from your health [and/or biospecimens] information, the information [and/or biospecimens] [may/may be]

used for future research or distributed to another investigator for future research without additional informed consent from you or your legally authorized representative."

- "[If identifiers are removed from your identifiable private information,] the information [may/may not] be used for future research or distributed to another investigator for future research without additional informed consent from you or your legally authorized representative."

- A description of the extent to which confidentiality of records identifying the subject and privacy will be maintained
- 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;
- An explanation of whom to contact for answers to pertinent questions about the research (e.g., Investigator), the research subjects' rights (e.g., IRB Office), and whom to contact in the event of a research-related injury; and
- 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

The informed consent document should, where appropriate, include the following additional elements:

- A statement that 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;
- A statement indicating whether clinically relevant results, including individual research results, will be disclosed to subjects, and if disclosed under what conditions;
- A statement about whether the research project will or might include whole genome sequencing;
- For women of child bearing potential, a statement that the particular treatment or procedure may involve risks to the subject (or the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
- Anticipated circumstances under which the subject's participation may be terminated by the PI without regard to the subject's consent;
- If there is the potential that costs of research procedures will not be paid by the sponsor or the subject's insurance, a description of any additional costs to the subject that may result from participation in the research;
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

- 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;
- The approximate number of subjects involved in the project;
- The Campbell IRB may require that information, in addition to that required by institutional policy, be given to research subjects when in its judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

Department of Defense (DoD)

In addition to the required elements and any applicable additional elements, consent forms for research funded or supported by the Department of Defense must include:

- A statement that the DoD or a DoD organization is funding the research project.
- A statement that representatives of the DoD are authorized to review research records.
- A statement as to whether any compensation, and/or whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained.

Department of Justice (DOJ)

In addition to the required elements and any applicable additional elements, consent forms for research supported by the Department of Justice must include the following statements:

- The name of the funding agency
- A statement describing the extent to which confidentiality of records identifying the subject will be maintained.
- Confidentiality may only be broken if the subject reports immediate harm to participants or others. The participant must be informed about any disclosure and the risk of harms from the disclosure.
- PIs do not have to report child abuse unless the participant signs another consent form allowing the child abuse reporting.
- In studies supported by the NIJ, the subjects must be informed that private, identifiable information will be kept confidential and will only be used for research and statistical purposes. If the identity of the individual cannot be maintained the participants must be explicitly notified.

Department of Energy (DOE)

In addition to the required elements and any applicable additional elements, consent forms for research supported by the Department of Justice must include the following statements:

- The identity of the sponsoring agency, unless the sponsor requests that it not be done, because:
- Doing so could compromise intelligence sources or methods;

- the research involves no more than minimal risk to the participants;
- the IRB determines that by not disclosing the identity, the investigators will not adversely affect the participants.

- A statement that the project is classified and what it means for the purposes of the research.

Procedures for Documenting Consent

1. If the consent process will be documented in writing with the consent form:
   a) Verify that the consent form is in language understandable to the subject.
   b) Have the following individuals personally print their name on the consent form:
      - Participant/Legally Authorized Representative;
   c) Have the following individuals personally sign and date the consent form:
   d) Participant/Legally Authorized Representative; if the IRB required written documentation of assent, have the minor/child sign and date the consent/assent form and have the Parent/Guardian of the minor/child sign and date on the appropriate line. (For children under the age of 14, the age appropriate IRB assent form template should be used to obtain the child's signature and date and the Parent/Guarding of the minor child should sign the consent/assent form. Have the person obtaining consent personally print their name, sign and date the consent form, if applicable or required.
   e) If an impartial witness was part of the consent process;
      - Print the name of the impartial witness on the consent form.
      - Have the impartial witness personally sign and date the consent form to attest that the information in the consent form and any other information provided was accurately explained to, and apparently understood by, the participant, and that consent and assent, if applicable was freely given.
   f) Provide subjects with the opportunity to receive copies of the signed and dated consent form. This may be accomplished by making a photocopy or by having the above individuals sign and date two copies of the consent form.
   g) If the requirement for written documentation of the consent process has been waived by the IRB and the IRB determined that the subject had to be offered the opportunity to document his or her consent in writing, offer the subject the option to document his or her consent in writing. See below for further information.
      - If the subject declines, take no further actions.
      - If the subject accepts, follow the process to document consent in writing with the informed consent form.
   h) Place the signed and dated forms in the subject's binder or with research documentation in a secured manner. Signed consent forms should not be kept with other data to protect confidentiality.

References

45 CFR 46.104(d)(3) and 45 CFR 46.104(d)(4)
45 CFR 46.117
HRPP Policy: Registration Projects and FLEX Review
IRB SOP: Waiver or Alteration of the Documentation of Consent
IRB SOP: Waiver or Alteration of the Informed Consent Process