	<b>IRB SOP: Informed Consent Process for Human Subjects Research</b>		
	NUMBER	APPROVED BY	EFFECTIVE DATE
	HSR-410	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

This procedure established the process to obtain informed consent from participants, the legally authorized representatives of adults unable to consent, and/or the parents or guardians of children.

## Background

Federal regulations and the Campbell IRB require that Principal Investigators provide a process for obtaining subjects' consent prior to their involvement in human subjects research, unless the IRB has approved a waiver or alteration of the consent process. For Exempt (45 CFR 46.104) and Registration Projects the IRB may or may not require a consent process 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

**Assent:** an affirmative agreement to participate in research project. The failure to object should not, without an affirmative agreement, be construed as assent.

**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.


**Impartial witness:** An International Conference on Harmonization Guideline for Good Clinical Practice: A person, who is independent of the project, who cannot be unfairly influenced by people involved with the project, who attends the informed consent process if the subject or subject's legally acceptable representative cannot read, and who reads the consent form and any other written information supplied to the subjects'.

**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.


## Principal Investigator Responsibilities

It is the Principal Investigator's (PI's) responsibility to obtain legally effective and prospective informed consent from research subjects as required by institutional policy, tribal law passed by the official governing body of an American Indian or Alaska Native tribe and institutional policies.

## Procedures

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1. PIs must provide the information regarding the consenting process to the IRB for review.
  - A detailed description of the intended method for obtaining initial informed consent;
  - 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);
  - Assurance that the informed consent process is an ongoing exchange of information between the project team and the project participants throughout the course of a project. Informed consent is a continuous process of communication and acknowledgement over time, not just a signed document.
2. The consenting process may begin after the PI has provided the necessary information and documents to the Campbell IRB and received approval by the Campbell IRB. See IRB SOP: *Informed Consent Document for Human Subject Research*.
3. Any changes in the informed consent documents or process must be must submitted via an amendment to the Campbell IRB for review and approval prior to implementing the change.
4. The informed consent process must:
  - 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 project. This subsection must be organized and presented in a way that facilitates comprehension;
  - Occur in circumstances that minimize the possibility of coercion and undue influence;
  - Conducted in a private and quiet setting;
  - Obtained on the most current IRB approved consent form;
  - Utilize language to promote the subject’s understanding of the information;
  - Provide the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information;
  - Allow sufficient time for consideration of the information and decision regarding participation. In some cases, this may mean providing all the information and giving the prospective subject time to go home and continue the consent process on another day;
  - Not waive or appear to waive subjects’ rights; and
  - Include each of the required elements and applicable additional elements of informed consent describing the project and the nature of research participation as required by federal regulations, tribal laws, institutional policies and approved by the IRB;
  - Include a discussion regarding the use and retention of data, if they choose to withdraw from a project.
5. The consent form may be read to the subject, but it is not a requirement, unless the IRB has approved the use of a verbal consent process. The consent form should be used as a guide to the verbal explanation of the study and a meaningful exchange between the investigator and prospective subject. The consent form should not serve as a substitute for discussion.
6. For more than minimal risk studies, invite and encourage the subjects to take the written information home to consider the information and discuss the decision with family members and others before making a decision.

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7. Ask the subject questions to determine whether all of the following are true, and if not, either continue the explanation or determine that the subject is incapable of consent;
  - The subject understands the information provided.
  - The subject does not feel pressured by time or other factors to make a decision.
  - The subject understands that there is a voluntary choice to make.
  - The subject is capable of making and communicating an informed choice.
8. If the subject has questions about treatments or compensation for injury, provide factual information and avoid statements that imply that compensation or treatment is never available.
9. Once a subject indicates that he or she does not want to take part in the research project, this process stops.
10. In accordance with institutional policy research subjects must sign & date the informed consent document. A potential research subject's agreement to participate in a research project is documented by the subject indicating his/her approval by signing and dating the consent document which includes, where appropriate, the HIPAA authorization information unless the project has received approval for waiver of consent, documentation and/or HIPAA from the IRB.
  - If the subject is capable of written assent but not consent, the legally authorized representative must provide written consent. A signature line for the subject must also be included. See *IRB SOP: Use of Legally Authorized Representative (LAR)* and *IRB SOP: Research with Subjects Likely to Manifest or Develop Decreased Decisional Ability* for detailed information.
11. Provide a copy of the consent form to the participant/representative. Whenever possible provide the consent form to the subject in advance of the consent discussion.
12. In the event the consent process includes electronic consent document, electronic signatures are allowed for consent documentation. A written copy must be given to the person signing the electronic consent form.
13. If a waiver of documentation or waiver of informed consent process is requested and approved by the Campbell IRB, this SOP does not apply. Please refer to *IRB SOP: Waiver or Alteration of the Informed Consent Process* and *IRB SOP: Waiver or Alteration of the Documentation of Consent*.


## **ADDITIONAL CONSIDERATIONS WHEN OBTAINING INFORMED CONSENT**

### **Research involves Adult Subjects with Decreased Decisional Ability**

The PI will provide a description of the project population and the consenting/assenting process in the submission. See *IRB SOP: Research with Subjects Likely to Manifest or Develop Decreased Decisional Ability* and *IRB SOP: Use of Legally Authorized Representative (LAR)* for detailed information.

### **Consent for Subjects Who Demonstrate Limited Literacy**

If the PI unexpectedly determines that a prospective subject demonstrates limited or a lack of literacy when discussing the project, the PI should:

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1. Identify a literate adult person to work with the prospective subject and to serve as a witness to the consenting process.
  - a. The Individual may not be a part of the project team,
  - b. The individual may be a family member.
2. Read and explain the entire consent to the subject or their legally authorized representative,
  - a. Obtain the subject or their legally authorized representative's informed consent
  - b. After the subject or the subject's legally authorized representative have provided written informed consent (dated signature), obtain the witness's dated signature
  - c. Provide a copy of the signed informed consent document to the subject for future reference
  - d. Highlight the name and contact information in the informed consent document of a project team member who can be contacted at any time for information or help.
  - e. Document the process in their project/study records. If an Investigator plans to recruit and enroll more than 1-2 subjects who may have limited or a lack of literacy, the Investigator must develop and describe in the protocol submission their consent process for this subject population.

#### **Consent for Subjects with Limited or No English Proficiency**

- The PI must include additional safeguards when consenting individuals with no or limited English proficiency in accordance with the *IRB SOP: Recruitment and Enrollment of Non-English or Limited English Proficient Subjects*.
- Guidance regarding the use of the Short Form or Translated Consent Documents is included in the *IRB SOP: Recruitment and Enrollment of Non-English or Limited English Proficient Subjects*.

#### **Participants who cannot give consent or those with decreased decisional capacity**


Additional safeguards must be in place when obtaining consent for research involving children, fetuses, neonates, prisoners, adults with diminished decisional ability and those who are economically or educationally disadvantaged. Additional guidance can be found in *IRB SOP: Research with Subjects Likely to Manifest or Develop Decreased Decisional Ability*.

#### **Consent for minors/children**

The IRB must have specifically approved the protocol to allow the enrollment of children. Permission is obtained from both parents unless:

- One parent is deceased, unknown, incompetent, not reasonably available;
- Only one parent has legal responsibility for the care and custody of the child; or
- The IRB has specifically approved the protocol to allow the permission of one parent regardless of the status of the second parent.

In the absence of a parent, permission may be obtained from an individual authorized to consent under applicable law on behalf of a child to general medical care. Additional guidance can be found in *IRB SOP: Research Involving Minor/Children*.

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### Prohibited Elements

Initial and ongoing consent discussions must not include:

- Unproven claims of effectiveness or certainty of benefit, either implicit or explicit,
- Any exculpatory language through which the subject is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the Investigator, the sponsor, or its agents from liability for negligence.

### Consent Monitoring

The IRB has the authority under institutional policy to observe or have a third party observe the consent process and the research. In order to ensure that the consent process is appropriate and the approved process is being followed, the IRB may determine that special monitoring of the process must occur. Such monitoring may be particularly needed for the IRB to meet its responsibilities to ensure human subject protections for research project that:

- Involves a vulnerable population,
- Involves use of a risky and innovative procedure,
- Is conducted by an inexperienced investigator and/or project team,
- Is a project about which the IRB has concerns that the consent process is not being properly conducted,
- Routine auditing purposes.

### References

45 CFR 46.116

21 CFR 50.20, 50.23

*IRB SOP: Recruitment and Enrollment of Non-English or Limited English Proficient Subjects*

*IRB SOP: Research Involving Minor/Children*

*IRB SOP: Research with Subjects Likely to Manifest or Develop Decreased Decisional Ability*

*IRB SOP: Use of Legally Authorized Representative (LAR)*

*IRB SOP: Waiver or Alteration of the Informed Consent Process*

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