CAMPBELL UNIVERSITY	**IRB SOP:** Waiver or Alteration of the Informed Consent Process		
	NUMBER	APPROVED BY	EFFECTIVE DATE
	HSR-430	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

To establish the process for a Principal Investigator to request and obtain a waiver or alteration of the informed consent process by the IRB.

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) or Registration Projects the IRB may not require a Waiver or Alteration of the Consent Process based on the level of risk associated with the research activities and under which category the research is approved (e.g., exempt category #4 allows for the secondary use of previously collected data which was collected for non-research purposes, without a consent process). For further information see, *HRPP Policy: Registration Projects and FLEX Review*.

Definitions

None

Waiver or Alteration of Consent Process

1. The IRB may waive or alter the requirement for the Principal Investigator to obtain a potential subject's consent for participation. To approve such a waiver or alteration, the IRB must find and document within the *Research Plan*:
   - The project involves no more than minimal risk to the subjects;
   - The project could not practicably be carried out without the waiver or alteration;
   - If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
   - The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
   - Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

   The above waiver conditions must be met for research that involves the use of identifiable private information or identifiable biospecimens and the research could not be practicably carried out without using such information or biospecimens in an identifiable format;
2. When considering a waiver of the consent process for screening, recruiting, or determining eligibility of prospective subjects without the informed consent of the prospective subject or the subjects legally authorized representative, the IRB must find one of the following:

- The Principal Investigator, or their designee, will obtain information through oral or written communication with the prospective subject or legally authorized representative; or
- The Principal Investigator, or their designee, will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

3. When considering a waiver of the consent process for Public Demonstration Projects, the IRB must find:
   - The research is conducted by or subject to the approval of state or local government officials
   - The research or demonstration project is designed to study, evaluate, or otherwise examine:
     - Public benefit or service programs;
     - Procedures for obtaining benefits or services under those programs;
     - Possible changes in or alternatives to those programs or procedures; or
     - Possible changes in methods or levels of payment for benefits or services under those programs; and
     - The research cannot be practicably carried out without the waiver of alteration.

4. The IRB may not waive the consent process for any research to be conducted under DoD regulations where the research is classified or if subject meets the DoD definition of an experimental subject. Research involving an experimental subject is defined as: An activity, for research purposes, where there is an intervention or interaction with a human subject for the primary purpose of obtaining the effect of the intervention of interaction.
   - A waiver of the consent process for such DoD regulated research requires permission of the Secretary of Defense.
     - If a waiver of consent is granted, the Principal Investigator (PI) must identify their process to solicit and obtain consent from an experimental subject's legally authorized representative, and the PI must include a description regarding how the research will benefit the individual subject.
       - The convened IRB will make a final determination if research is intended to be beneficial to the individual experimental subject.
     - The Assistant Secretary of Defense for Research & Engineering may waive the requirement of consent when all of the following elements have been met:
       - The research is necessary to advance the development of a medical product for the Military Services.
       - The research might directly benefit the individual experimental subject.
       - The research is conducted in compliance with all other applicable laws and regulations.

   For additional information, see *IRB SOP: Research Involving Department of Defense Funding and/or Military Participants*.

5. For research subject to Department of Education regulations, the IRB will follow the requirements of the Family Educational Rights and Privacy Act (FERPA) when considering whether it may grant a disclosure to parental/student consent to release of records for research.
    - In addition, the PI must ensure the project complies with and follows the requirements set forth the Protection of Pupil Rights Amendment, for research seeking a disclosure of student information. For further guidance see, *IRB SOP: Use of CU Student Educational Records in Human Subjects Research*.

Principal Investigator Responsibilities and Procedures

1. Obtain and verify that you are using the most current IRB-approved version of the project specific informed consenting script and that the script language is understandable to the subject.
2. When possible provide a copy of the script to the subject
3. If consenting verbally, have a meaningful discussion about research participation with the subject. Begin with a concise and focused presentation of the key information that is most likely to assist the participant/representative to understand the reasons why one might or might not want to participate in the research. Explain the details in such a way that the subject understands what is would be like to take part in the research project. Check the subject understands all information, allow for a discussion, and allow ample of time for the prospective subject to decide on research participation.
4. If consenting electronically, give information on who to contact about questions before participating.
5. Once the subject indicates that he or she does not want to take part in the research project, this process stops.

References

45 CFR 46.104(d)(3) and (d)(4)
45 CFR 46.116(e)(f)(g)
34 CFR 99
HRPP Policy: Registration Projects and FLEX Review
IRB SOP: Research Involving Department of Defense Funding and/or Military Participants
IRB SOP: Use of Campbell University Student Educational Records in Human Subjects Research