CAMPBELL UNIVERSITY	**IRB Guidance:** Informed Consents and Waivers

Requirements for Informed Consent Form

The requirements for the informed consent form differ for Registration/Exempt determined research and Expedited/Full approved research.

For Expedited/Full Review Approved Research

Before involving a human subject in expedited or full approved research, an investigator shall obtain the legally effective informed consent of the participant or the participant's legally authorized representative (LAR). Informed consent is to be obtained under circumstances that minimize the possibility of coercion or undue influence and that provide sufficient opportunity for the person to review, discuss and consider whether to participate.

Information must be provided in language understandable to the participant and/ or LAR. Potential participants must provide the information that a reasonable person would want to have in order to make an informed decision about whether to participate.

The informed consent process as a whole must present information in sufficient detail relating to the research and must be organized and present in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or LAR's understanding of the reasons why one might or might not want to participate.

The informed consent process and forms may not include exculpatory language through which an individual is made to waive or appear to waive any legal rights or release the investigators, institutions, or sponsors from liability for negligence.

For Registration/Exempt Review Determined Research

Before involving a human subject in registration or exempt research, it is ethically important in the responsible conduct of research to obtain the informed consent of potential participants. The informed consent process for registration and exempt research may not need to include all the required elements of informed consent in the Common Rule (45 CFR 45) regulations (as noted below), researcher should employ a consent process when interacting with participants even when conducting registration or exempt research. Understand the IRB will make the final determination on informed consent requirements.

Researchers are strongly encouraged to continue using the guidance information below and one of the IRB Informed Consent Form Templates. The Institutional Informed Consent Template should be used for projects that are not federally funded or do not require review under federal regulations (i.e. research in vulnerable populations would not meet this criteria). At minimum, the informed consent process for registration and exempt research should disclosure of the following to participants:

- That the activity involves research.
- A description of the procedures.
- That participation is voluntary

- Name and contact information of the Researcher and the IRB Office.

Key Information Summary

The informed consent form must begin with a concise and focused presentation of key information that is most likely to assist the prospective participant or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the consent process and form must be organized and presented in a way that facilitates comprehension. To accomplish this, a section is added at the beginning of the informed consent form or script that is used to facilitate this process.

How each Principal Investigator applies the key information requirement, and to what level of detail, is dependent on the complexity of the research involved. Federal regulations suggests the following elements be included as Key Information:

1. A statement that the project is research and participation is voluntary.
2. A summary of the research, including:
    - Purpose
    - Duration
    - List of procedures.
3. Reasonable, foreseeable risks and discomforts.
4. Reasonable, expected benefits.
5. Alternative procedures or courses of treatment, if applicable.

Elements of Informed Consent

In addition to the Key Elements, the informed consent process and form must contain basic elements of informed consent and additional elements, when applicable, to allow participants to make an informed decision about whether to participate.

Basic Elements

Basic elements must be included in the information provided to participants unless elements are waived by the IRB under specific conditions. The basic elements of informed consent are incorporated into the IRB consent form templates, excluding the following:

- Assent forms for 7 -10 years of age and 11-13 years of age,
- Verbal consent script,
- Online consent.

Please refer to IRB SOP: Informed Consent Documentation for Human Research Subjects for more information.

Additional Elements

When appropriate, additional elements of informed consent must be provided to participants and or LARs. Please refer to IRB SOP: Informed Consent Documentation for Human Research Subjects for more information.

Alterations

In some circumstances, the IRB may approve a consent procedure and form that omits some or alters some or all of the elements of informed consent. The specific conditions for a consent alteration can be found in the section below or in IRB SOP: Waiver or Alteration of Informed Consent Process.

Documentation Requirements

Informed consent must be documented by the use of written informed consent form approved by the IRB and signed (including electronic format) by the subject or the subject's LAR. A written copy shall be given to the person signing the form and sufficient time allowed to read or have the form read to them.

Waiver of Documentation of Informed Consent

Under specific conditions, the IRB may waive the requirement to obtain informed consent for research all together. The IRB will need to find and document that specific conditions have been met in order to grant a full waiver. More information on these conditions can be found in IRB SOP: Waiver or Alteration of Documentation of Consent.

Other Waivers and Exceptions to Informed Consent

Complete Waiver of Informed Consent Process

In some circumstances, the IRB may waive the requirement to obtain informed consent for research. The IRB will need to find and document that specific conditions have been met in order to grant a full waiver. More information on these conditions can be found in IRB SOP: Waiver or Alteration of Informed Consent Process.

Exception for Screening, Recruiting, or Determining Eligibility

An IRB may approve a research protocol in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining eligibility of prospective participants without the informed consent of the individual. The specific conditions can be found in IRB SOP: Waiver or Alteration of Informed Consent Process.

Waiver/Alteration for Public Benefit and Service Programs

The IRB may approve a waiver of the requirement to obtain informed consent or approve a consent procedure that omits or alters some or all of the elements of informed consent for public benefit and service programs conducted by or subject to the approval of State or local officials. More information on these conditions can be found in IRB SOP: Waiver or Alteration of Informed Consent Process.

Informed Consent Form Templates

The IRB has developed several Campbell University informed consent/assent form templates for use with adults and children. These templates incorporate the 2018 Common Rule (45 CFR 46) required and additional elements of informed consent.

The IRB has also developed other types of informed consent form and alternatives to the informed consent form.

All informed consent template documents are located in the **Information for Investigators: Consent Template Forms** area of the IRB website.