Campbell University Institutional Review Board
P.O. Box 1090, Buies Creek, NC 27506
Telephone: (910) 893-7780
Fax: (910) 893-1943
Campbell University FWA00008608
CUIRB-IRB00009201

Frequently Asked Questions

What does "informed consent" mean? What are the essential components?

Fully informing participants of the risks, benefits, and procedures involved in a study is a standard requirement in research with human participants. Ethically and legally, consent is not considered to be "informed unless the investigator discloses all the facts, risks, and discomforts that might be expected to influence an individual's decision to willingly participate in a research protocol. This applies to ALL types of research.

Are there different types of informed consent? What are they?

The informed consent process can take on various forms:

- A signed informed consent is the standard expectation in research with human participants. This is in the form of a document with the elements of informed consent, signed and dated by the participant and kept as a record by the researcher.
- In research with children (individuals under 18 years old), assent of the child and parental permission are standard requirements.
- In some circumstances, investigators can seek alternatives to standard informed consent procedures, such as:
    - A waiver of using a signed consent form (e.g., giving participants an information sheet but not collecting signatures)
    - A waiver of written consent (e.g., using oral consent procedures)
    - A waiver of some or all of the elements of informed consent (e.g., in research that involves deception)
    - A waiver of written consent for recruitment or preparatory research (see NOTE).

Contact the IRB office if you are unsure of the consenting process your research project will require.

What do the terms "consent" and "assent" mean? Aren't they the same thing?

Both consent and assent involve informing potential participants about the research and its risk and benefits, and documenting their understanding and agreement to participate.

The reason the different terms are used has to do with the age of the participants. In research involving **adults, "consent"** is obtained from individuals to participate in the project. In research involving minors, a parent must give permission to allow the child to participate in the research, and **children** who are able to understand information about participation are asked to **"assent"** or agree to participate as well.

Do I always have to obtain the informed consent of research participants?

In general, yes, but there are some limited exceptions. The expectation that the informed consent of research participants be obtained is based upon the Belmont principle of respect for persons, and regarded as extremely important in conducting ethical research. The IRB has the authority to waiver some or all of the federal requirements for informed consent in certain extenuating circumstances. A request for waiver of informed consent must be specifically justified by the researcher in the proposal to the IRB.

What is a "waiver of documentation" of informed consent?

A waiver of documentation of informed consent is a request whereby a signed consent document is not required. Consent will still be obtained from participants; however, they are not required to sign the consent form. There are only two circumstances when the IRB may waive the requirement to obtain a signed consent document:

1) The only record linking the research participant and the research would be the consent document AND the principal risk would be potential harm resulting from a breach of confidentiality (participant must be asked if he/she want documentation) OR
2) The research present no more than minimal risk of harm to participants and involves no procedure for which written consent is normally required outside of the research context (for example, no risk surveys or interviews).

What is a "waiver of informed consent (process)? How is it different from a "waiver of documentation?

A waiver of informed consent (process) could:

1) alter some or all of the required elements of informed consent OR
2) completely waive the requirement to obtain and informed consent (process).

The IRB may approve a consent procedure which does not include or alters some or all of the required elements of informed consent provided all of the following are TRUE:

- The research involves no more than minimum risk
- The waiver of informed consent will not adversely affect the rights and welfare of the subjects
- It is not practicable to conduct the research with the waiver or alteration
- Whenever appropriate, participants will be provided with additional pertinent information after their participation.

NOTE: A waiver of informed consent (process) may be obtained for recruitment or preparatory research purposes, allowing access by the investigator to potential participant's records to obtain information regarding eligibility criteria for a research project. In many situations the investigator will also request a waiver of HIPAA authorization for recruitment.