	University of North Carolina Wilmington Institutional Review Board	Standard Operating Procedure
	Informed Consent	**#6.8**

The purpose of this SOP is to describe requirements for researchers to obtain informed consent from human research subjects.

I. General Requirements

Researchers must obtain consent from human subjects in accordance with 45 CFR 46.116 (a.k.a. the "Common Rule").

II. Scope

This SOP pertains to all human subjects research projects that do not qualify for exemption as allowed by 45 CFR 46.101 or as determined by the UNCW IRB.

III. Applicable definitions

A. Assent

A child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

B. Guardian

An individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

C. Informed Consent

An active and ongoing process by which a researcher:

1. Discloses to potential research subjects information needed for them to make an informed decision about participating in a research study;
2. Promotes the voluntariness of the decision to participate or not in the research study;
3. Ensures that a subject understands the information that has been disclosed, and;
4. Obtains documentation of agreement, usually on a written form.

D. Legally Authorized Representative (LAR)

An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

E. Minors (Children)

Persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. North Carolina law defines a minor as a person under age 18.

F. Parent

A child's biological or adoptive parent.

G. Permission

The agreement of parent(s) or guardian to the participation of their child or ward in research.

IV. Procedures

A. General

1. Informed consent/assent/permission forms must be written in a manner that is understandable to the subject and/or legally authorized representative (LAR) based on age, education level, developmental level and maturity.

2. Researchers may submit for approval by the IRB:
   a. An consent form based on a UNCW Informed Consent Form Template and/or Assent/Permission Form Template (available on the IRB website)
   b. An alternate consent format, provided the researcher also submit to the IRB a completed UNCW Informed Consent Checklist (available on the IRB website) to demonstrate that all required elements of informed consent were included.

3. Once approved by the IRB, informed consent/assent/permission documents are stamped, initialed and dated with an expiration date (when applicable).

4. IRB staff email a PDF copy of the official stamped and approved copy of the consent/assent/permission form to the principal investigator of the research study and uploads a PDF copy of the form into the IRBIS application.

5. Researchers must use the approved document when obtaining consent from subjects/LARs.

6. Researchers must give a copy of the approved consent form (unsigned) to each participant/LAR for his/her records, unless the need to waive this requirement is sufficiently justified by the researcher and approved by the IRB.

7. Researchers must inform subjects/LARs if there are any changes or new information available that may alter the subject's willingness to participate in the project.

B. Assent and Permission Requirements for Research Involving Minors

1. Permission from Parent or Guardian

A parent or guardian must give permission for a minor to participate in research unless in rare circumstances this requirement is specifically waived by the IRB in accordance with 45 CFR §46.408(c). The IRB has the authority to require researchers to obtain permission from both parents of a subject if the situation warrants this approach.

2. Assent from Minors

Minors must assent to participate in the research beginning at age 5 unless the IRB finds the subjects are unable to do so due to a disability or other factor. When minors are younger than age 5, researchers may request on the application to conduct human subjects research an alteration of the standard process as described below to seek permission from a parent/guardian without obtaining assent from minors.

3. Waiving Parental Permission Requirement for University Students

Researchers conducting research on UNCW students may request that the IRB waive the parental permission requirement for minors who are enrolled as regular UNCW students and have not yet reached the age of 18. Researchers should refer to the instructions provided in section D below. This option is not allowable for Isaac Bear Early College students, as they are not regularly enrolled as UNCW students.

4. Documentation of Assent/Permission

The standard assent/permission process is to provide parents/guardians with a permission form and minors with an assent form. Researchers may use a combined assent/permission form with two signature sections or use two separate forms. Researchers must justify deviations from the standard process on the application to conduct human subjects research.

5. Assent Variations Due to Age of Subject

a. Assent forms or assent sections on permission forms must be written in language appropriate to the age and maturity of the subjects.
b. Obtaining assent and documenting assent are two separate processes.
    i. When minors age 5-6 are involved in research, the IRB views verbal agreement as sufficient. Researchers must request an alteration of the standard process for documenting assent on the application to conduct human subjects research and must submit the assent script that will be read to subjects to the IRB for approval.
    ii. When minors age 7 and over are involved in the research, researchers must follow the standard process unless this requirement is specifically waived by the IRB.

C. Informed Consent in Languages other than English

If a researcher will use an informed consent document written in a language other than English, the researcher must submit to the IRB copies of the document in the foreign language along with an English translation. The IRB may seek guidance from an appropriate consultant to confirm that the translation accurately captures the nuances of the consent message.

D. Waivers of the Consent/Assent/Permission Requirement

1. General Requirements

Under 45 CFR 46.116(e) the IRB may waive the requirement for obtaining informed consent or approve a consent procedure that leaves out or alters some or all of the elements of informed consent, provided that the IRB finds and documents that all of the following four criteria are met:

a. the research involves no more than minimal risk to the subjects;
b. the waiver or alteration will not adversely affect the rights and welfare of the subjects;
c. the research could not practicably be carried out without the waiver or alteration; and,
d. whenever appropriate, the subjects will be provided with additional pertinent information after participation.

2. Procedures for Requesting Waivers for 17-Year Old UNCW students

Researchers who are conducting research on UNCW students whose population may include regularly enrolled students who have not yet reached the age of 18 may request a waiver of the parental permission

requirement pursuant to 45 CFR 46.408 and 45 CFR 46.116(e). Researchers should provide sufficient justification for this waiver (i.e. regularly enrolled college students are expected to be treated and conduct themselves as adults, and it would be inconsistent with the Belmont Report to disrespect this population by either omitting them from the study or seeking their parent's permission for their participation).

V. References to Other Applicable SOPs

SOP Title	SOP #
Exempt Review of Research	5.1
Expedited Review of Research	5.2
Full Board Review of Research	5.3
Training Requirements	6.1
Use of Deception in Research	6.6

VI. Responsibilities

Title	Responsibility
IRB Co-chair	Responsible for reviewing non-exempt application to conduct human subjects research, including review of consent/assent/permission forms to ensure that the process, forms and documentation are consistent with UNCW policy, SOPs and 45 CRF §46.116, §46.117, and §46.408, as applicable.
IRB Staff	Responsible for conducting initial reviews of new applications, including an initial review of any consent/assent/permission forms to ensure they include all required elements of informed consent and are consistent with UNCW policies and SOPs, and providing guidance to researchers on informed consent requirements.
Principal Investigator	Responsible for submitting applications to conduct human subjects research to the IRB, including consent/assent/permission forms as appropriate, and a completed Informed Consent Checklist if an alternate consent format is used. Responsible for conducting an active informed consent process that meets the requirements of UNCW policy, SOPs, and 45 CRF §46.116, §46.117, and §46.408, as applicable.

VII. Resources

A. U.S. Department of Health & Human Services, Office of Human Research Protections Informed Consent FAQs: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html.

B. UNCW IRB Website: http://uncw.edu/sparc/integrity/irb.html

C. U.S. Department of Health & Human Services, Office of Human Research Protections website: https://www.hhs.gov/ohrp/

D. 45 CFR 46 ("Common Rule"): https://www.ecfr.gov/cgi-bin/text-idx?SID=75addf8360492a28075e3a218631fcdc&pitd=20180719&node=pt45.1.46&rgn=div5

E. Belmont Report: https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html