	University of North Carolina Wilmington Institutional Review Board	Standard Operating Procedure
	Full Board Review of Applications to Conduct Human Subjects Research	#5.3

The purpose of this SOP is to provide human subjects researchers with guidance on and clarify review procedures for human subjects research applications that require full board review.

I. General Requirements

Pursuant to 45 CFR 46.109, the UNCW Institutional Review Board (IRB) is responsible for reviewing research conducted by UNCW faculty, staff, or students (or researchers from other institutions who are using UNCW faculty, staff or students as subjects). Research projects that involve more than minimal risk to human subjects or involve certain populations are reviewed at a convened meeting of at least a quorum of IRB members.

II. Scope

This SOP pertains only to those research projects that meet the definition of human subjects research identified in 45 CFR §46.102 and that do not qualify for exemption or review under the expedited review procedures.

III. Applicable Definitions

A. Deception

Knowingly providing false information to research subjects or intentionally misleading research subjects about some key aspect of the research.

B. Incomplete disclosure

Withholding information about the specific purpose, nature, or other aspect of a research study from research subjects.

C. Minimal Risk

The probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

D. Prisoners

Any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of

statutes or commitment procedures, which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

IV. Procedures

A. Research Requiring Full Board Review

Depending on the nature of the research methods, subjects and other conditions, research requiring full board review may include, but is not limited to:

1. Studies involving more than a minimal risk of the following factors that would exceed what one would experience in everyday life even after reasonable and appropriate protections are implemented:
   a. Invasion of privacy and/or breach of confidentiality;
   b. Physical discomfort, injury and/or pain, and/or side-effects from medications or other substances;
   c. Psychological and/or emotional distress, including embarrassment, which may be the result of deception of the subjects, or other methods designed to intentionally invoke feelings of aggression, stress, anxiety, anger, rejection or other negative response;
   d. Loss of professional and/or social reputation, income, employment and/or insurability
   e. Disclosures of illegal activity and/or negligence
2. Other research involving more than one of the above risks, even if the magnitude of each risk is minimal;
3. Research involving certain vulnerable populations, such as prisoners, subjects who have diminished capacity to consent, or other research that an IRB co-chair is unable to approve by the expedited review process.

B. Application

A researcher who is planning to conduct human subjects research that is subject to full board review must submit an application to the IRB through the IRBIS system by the deadline posted on the Human Subjects Research website for the meeting during which the researcher desires review.

C. Initial Review

Within a reasonable timeframe after receipt, which may vary depending on volume of submissions, UNCW IRB staff will conduct initial reviews of applications submitted to the IRB to identify if any deficiencies exist that would prevent approval upon further review. Principal investigators are strongly encouraged to comply with these recommendations to avoid delays in approval.

D. Attendance at Full Board Meeting

Principal investigators and/or faculty advisors may be asked to attend the full board meeting when their submission is under review. Researchers are strongly encouraged to attend full board meetings to respond to IRB member questions. This helps expedite the approval process.

E. Post-Review Procedures

Within a reasonable timeframe after full board review, UNCW IRB staff will notify the principal investigator of any revisions needed to secure approval. Notification typically occurs by returning the application to the PI with specific stipulations entered to indicate where revisions are needed.

F. Approval Procedures

Within a reasonable timeframe after the PI responds to the stipulations, an IRB co-chair or designate will confirm that no further revisions are needed. If no further revisions are needed, an IRB co-chair approves the application by generating an approval notification through the IRBIS system.

G. Post-Approval Procedures

If the study involved the use of an informed consent and/or assent-permission form, IRB staff will send an official, approved version of the consent and/or assent-permission form to the PI of the study. This official version will include a "stamp" and expiration date. PIs must use this stamped official copy of the consent and/or assent-permission form when distributing copies to subjects.

H. Continuing Review

Full board approval generally expires one year from the approval date, unless the IRB determines that an approval period of less than one year is required due to the risks of the research or some other factor. Prior to the expiration date the researcher must submit a form in IRBIS to either renew the study or close the study. Although periodic reminder notices regarding expiration of IRB approval are issued from the IRBIS system, it is the responsibility of the researcher to monitor this expiration date and to maintain compliance of the study.

II. References to Other Applicable SOPs

Name	**SOP #**
Use of Deception in Human Subjects Research	6.6
Informed Consent	6.8

III. Responsibilities

Title	Responsibility
IRB Co-chair	Responsible for facilitating full board meetings and verifying that any revisions required by the committee were made prior to granting approval.
IRB staff	Responsible for conducting initial reviews of applications that require full board review, notifying principal investigators on any deficiencies in the application, placing an application on a full board agenda, informing principal investigators of meeting dates, times and locations, and ensuring the principal investigator receives an official "stamped" copy of any consent and/or assent permission form approved by the IRB.
Principal Investigator	Responsible for submitting applications to conduct human subjects research to the IRB prior to initiating activities, ensuring all members of the research team have documentation of required training, representing proposed activities accurately and thoroughly, distributing to subjects only the official "stamped" copy of any consent and/or assent/permission form approved by the IRB, and otherwise conducting research in accordance with methods and procedures identified in the approved application.

IV. Resources

A. UNCW IRB Website: http://uncw.edu/sparc/integrity/irb.html
B. U.S. Department of Health & Human Services, Office of Human Research Protections website: https://www.hhs.gov/ohrp/
C. 45 CFR 46 ("Common Rule"): https://www.ecfr.gov/cgi-bin/text-idx?SID=75addf8360492a28075e3a218631fcdc&pitd=20180719&node=pt45.1.46&rgn=div5
D. Belmont Report: https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html