	University of North Carolina Wilmington Institutional Review Board	Standard Operating Procedure
	Exemption Determinations on Human Subjects Research	**#5.1**

The purpose of this SOP is to clarify review procedures for applications that involve low risk human subjects research and may qualify for a determination of exemption as allowed by 45 CFR 46.

I. General Requirements

All research using human subjects must be reviewed by the University of North Carolina Wilmington (UNCW) Institutional Review Board (IRB). Certain categories of human subject research are exempt from Common Rule [45 CFR 46] in that IRB approval, full research consent, and other requirements are not applicable. Thus, determinations of exemption are granted rather than approved. However, this research is not exempt from ethical considerations, such as honoring the principles described in the Belmont Report. Human subjects research qualifying for exemption must still be conducted in an ethical manner, in a manner consistent with sound research practices, and in accordance with UNCW policies and SOPs. Specifically, exempt research fulfills the organization's ethical standards, such as:

- The research holds no more than minimal risk to subjects.
- Selection of subjects is equitable.
- If there is recording of identifiable information, there are adequate provisions to maintain the confidentiality of the data.
- There are adequate provisions to maintain the privacy interests of subjects.

Individuals involved in making determinations of exemptions for a proposed human subjects research project cannot be involved in the proposed research. Reviewers must not have any apparent or perceived conflict of interest.

II. Scope

A. This SOP pertains only to those research projects that meet the definition of human subjects research identified in 45 CFR §46.102.

B. This SOP pertains to human subjects research that meets the criteria set forth in 45 CFR §46.101.

C. Student research that is not designed to yield generalizable knowledge does not meet the definition of research with human subjects and does not require IRB review. However, this research must be conducted in a responsible manner, be reviewed by the advising/responsible faculty member, and have sufficient oversight, particularly if conducted off campus. More information about activities that do not meet the IRB definition of research is provided in the ***Activities Not Requiring IRB Review Procedures*** (SOP #1.1).

III. Applicable Definitions

A. Conflict of Interest

As stated in UNCW policy 03.230 Conflict of Interest or Commitment III.A., *Conflict of Interest* relates to situations in which financial or other personal considerations, circumstances, or relationships may compromise, may involve the potential for compromising, or may have the appearance of compromising a Covered Employee's objectivity in fulfilling their University duties or responsibilities, including research, service and teaching activities and administrative duties.

B. Deception

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

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. 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. In North Carolina, the legal age for consent is 18 years.

E. 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. Applications requesting determinations of exemption in accordance with 45 CFR 46 are subject to initial review for completeness and appropriateness of methods and procedures by IRB staff.

B. An IRB co-chair or designee will review for determination of exemption.

C. Certain types of human subjects research do not qualify for exemptions, such as certain studies involving minors, studies involving the use of deception, and any study involving prisoners.

D. Researchers must conduct exempt studies in accordance with the methods and procedures detailed in the exempted application reviewed by the IRB.

E. If an exempt study involves the use of a consent and/or assent-permission form, IRB staff will send the principal investigator of the study an official, approved copy of the consent and/or assent-permission form. The official, approved version will include an IRB "stamp." Researchers must use this official version when distributing copies to subjects.

F. Researchers must submit requests to modify exempt studies prior to making any changes to the methods and procedures reviewed by the IRB, as changes to an exempted study may render it no longer exempt.

G. Exempt determinations do not have a termination date.

H. Researchers are not required to annually renew studies that have been determined to qualify for exemption.

I. Researchers must notify the IRB when an exempt research project is complete so that the organization can maintain an accurate database of active research.

V. References to Other Applicable SOPs

SOP Title	SOP #
Activities Not Requiring IRB Review	1.1
Online Research	6.2
Anonymous Surveys/Questionnaires	6.3

VI. Responsibilities

Title	Responsibility
IRB Co-chair	Responsible for designating IRB staff with the authority to make determinations of exemption. The IRB has designated the research compliance manager to make determinations of exemptions.
IRB Staff	Responsible for conducting initial reviews of all applications and appropriately referring applications for a determination of exemption, expedited review, or full board review. Responsible for notifying principal investigators on any deficiencies in the application that would prevent approval upon further review, and ensuring the principal investigator receives an official "stamped" copy of any consent and/or assent permission form approved by the IRB.
Research Compliance	Responsible for conducting secondary reviews of

Manager (RCM)	applications that appear to qualify for exemption. Upon confirming that the application is complete and methods and procedures are appropriate, the RCM may grant an exemption.
Principal Investigator (PI)	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.

VII. 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.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html
D. Belmont Report: https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html