	University of North Carolina Wilmington Institutional Review Board	Standard Operating Procedure
	Expedited Review of Applications to Conduct Human Subjects Research	**#5.2**

The purpose of this SOP is to provide human subjects researchers with guidance on UNCW procedures for expedited review, and provide researchers with links and resources for more information on expedited review categories, as provided by the Office of Human Research Protections (OHRP).

I. General Requirements

As allowed in 45 CFR 46.110, the UNCW Institutional Review Board (IRB) may review certain categories of research using an expedited review procedure provided the expedited reviewer finds that the research involves no more than minimal risk to subjects. The UNCW IRB may also review minor changes to studies previously approved by the full board using an expedited review procedure. Expedited review means that one or more voting IRB members may conduct a thorough and rigorous review of an application to conduct human subjects research in lieu of the application being placed on an agenda for a full board meeting.

II. Scope

This SOP pertains to all human subject research applications submitted to the UNCW Institutional Review Board that does not qualify for exemption or require full board review.

III. Applicable Definitions

A. Minimal risk

The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

A. 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.

IV. Procedures

A. Authority to Conduct Expedited Reviews

1. UNCW IRB co-chairs may exercise all of the authorities of the full IRB when conducting expedited reviews of research, except that they may not disapprove research.

2. If an IRB co-chair us unable to approve an application to conduct human subjects research, the co-chair may seek consultation with others who have relevant expertise, such as other IRB members, other UNCW staff members, or external consultants.

3. If an IRB co-chair is still unable to approve a study, he or she will inform IRB staff and ask them to place the application on the agenda for the next full board meeting.

B. Expedited Review Considerations

1. Research categories included on the list provided by OHRP indicate that a type of research is merely eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

2. The categories in the OHRP list apply regardless of the age of subjects, except as noted.

3. Unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal, the expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably:

   a. place them at risk of criminal or civil liability, or

   b. be damaging to the subjects financial standing, employability, insurability, reputation, or be stigmatizing.

4. The expedited review procedure may not be used for classified research involving human subjects.

5. The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.

C. Research Categories

As identified by the U.S. Department of Health and Human Services, Office for Human Research Protections Guidance: https://www.hhs.gov/ohrp/regulations-

and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html

D. Application

Researchers planning to conduct human subjects research that qualifies for expedited review must submit applications to the IRB through the IRBIS system at least ten (10) days prior to the desired start date of their research.

E. 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. Notification of deficiencies typically occurs by IRB staff returning the application to the principal investigator (PI) with specific stipulations. PIs are strongly encouraged to comply with these recommendations to avoid delays in approval.

F. Approval Procedures

Within a reasonable timeframe after the PI responds to the stipulations, UNCW IRB staff will confirm that no further revisions are needed. If no further revisions are needed, IRB staff will forward a request to an IRB co-chair to conduct an expedited review of the application. If the co-chair approves the application, the co-chair will generate 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 (if applicable). PIs must use this stamped official copy of the consent and/or assent-permission form when distributing copies to subjects.

H. Continuing Review

IRB approval to conduct human subjects research 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.

V. References to Other Applicable SOPs

SOP Title	SOP #
Informed Consent	6.8

VI. Responsibilities

Title	Responsibility
IRB Co-chair	Responsible for reviewing studies that qualify for expedited review.
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.
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 Expedited Review Categories: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html
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