	University of North Carolina Wilmington Institutional Review Board	Standard Operating Procedure
	Research Conducted at non-UNCW Facilities or Institutions	**#6.4**

The purpose of this SOP is to clarify procedures when human subject research activities will be conducted at non-UNCW locations or will use populations under another entity's jurisdiction.

I. General Requirements

Researchers are required to provide documentation to the IRB that permission has been granted by a high level administrator at a non-UNCW organization when the researchers will be physically present to recruit or collect data on premises where the clients, patients, or students served at those organizations have a reasonable or regulatory expectation of privacy, including but not limited to nursing homes, rehabilitation or other medical clinics, public or private schools, or day care centers.

Researchers may need to obtain additional approvals from non-UNCW IRBs or from tribal governments if research subjects fall under the jurisdiction of another entity.

- Documentation of permission is not required when recruitment or data collection will take place at public locations such as community centers or public libraries.

- Documentation of permission is not required when researchers will recruit adult subjects who are employed at non-UNCW organizations by email, provided that their email addresses are publicly available (or otherwise known to the researcher) and the researcher will not thereafter collect data on the organization's premises.

- Documentation of permission may not be required when a UNCW researcher collaborates with a colleague employed by another organization with its own IRB. This situation is handled on a case-by-case basis and additional requirements are determined by a number of factors, including the level of "engagement" that UNCW has in the research activities and the other IRB's willingness to enter into a reliance agreement with UNCW's IRB. Researchers are encouraged to contact IRB staff so that they can determine how best to proceed.

II. Scope

This SOP pertains to all activities that meet the definition of human subjects research, regardless of review level.

III. Applicable Definitions

A. Educational Institution

For the purposes of this SOP, "educational institution" means a daycare center, preschool, elementary school, middle school, high school, college or university, whether publicly or privately funded.

B. Engagement in Research

Institutions are considered *engaged* in non-exempt human subjects research project when their employees or agents in that project:

1. receive an award through a grant, contract, or cooperative agreement even where all activities involving human subjects are carried out by employees or agents of another institution;
2. intervene or interact for research purposes with any human subjects of the research;
3. obtain for research purposes identifiable private information or identifiable biological specimens from any source, even if the institution's employees or agents do not directly interact or intervene with human subjects.

Institutions are not considered engaged in research if they are merely selected as a recruitment site, if their employees or agents inform or provide information to prospective subjects about the availability of research (unless it the information is part of the informed consent process), or if their employees or agents seek or obtain permission from prospective subjects for investigators to contact them.

IV. Procedures

A. Types of Permission Accepted

1. In General

Researchers must provide documentation that they have support and permission from a high-level administrator or applicable review board at the external organization to conduct the research activities. Researchers must abide by any special requirements identified in sections IV.B (Educational Institutions), IV.C (Medical Facilities), and IV.D (Tribal Populations) below. It must be clear from this documentation:

a. what role the administrator has at the organization;
b. how the IRB can contact this administrator if needed;
c. that the administrator is aware of the nature of the research (it is adequate to simply cite the principal investigator's name and title of the study); and
d. that the administrator supports the research.

2. Letters of Support

   The most common way for a researcher to provide documentation of permission is to ask an appropriate administrator to provide a Letter of Support. A researcher may upload a PDF copy of a Letter of Support to the Attachments section of his or her IRBIS application. In addition to the requirements in section IV.A.1 above, the Letter of Support must be written on the organization's letterhead and include the signature of the administrator.

3. Permission Sent By Email

   A researcher may upload emailed correspondence between the researcher and an appropriate, high-level administrator in lieu of submitting a Letter of Support, provided the researcher is able to upload a PDF copy of the correspondence to the Attachments section of his or her IRBIS application. In addition to the requirements in section IV.A.1 above, the original header of the email must be intact (From, Sent, To, Subject). (If using Outlook, open the email from the facility administrator, select File, select Print, change the printer setting to Adobe PDF, and save the copy where you can easily retrieve it when uploading as an attachment in IRBIS.)

B. Special Requirements for Educational Institutions

1. Family Education Rights and Privacy Act (FERPA)

   Researchers who hope to obtain student data from educational institutions must determine if the release of that data is allowed or prohibited under the U.S. Department of Education's Family Education Rights and Privacy Act (FERPA). Researchers may review the educational institution's FERPA policy to determine if any special procedures are required. If the UNCW IRB determines during the review process that a release of student information is subject to FERPA requirements, the IRB may require the researcher to obtain documentation from the educational institution that any release of student data will be done in accordance with FERPA.

2. School Districts with Research Review Boards

   a. In General

      Certain school districts in this region require researchers to obtain approval through a Research Review Board or undergo some other district-level approval prior to conducting the activities. When a district requires advance approval, they generally review research requests from a different perspective from that of the IRB. School districts typically consider how intrusive the research is to the teachers and the classroom, how much effort will be required of teachers, if and how the information gained by the

research will benefit the school district, and what the impact will be, if any, on the school or district office staff.

The UNCW IRB cannot advise researchers on individual district requirements. Researchers should contact district offices as early as possible in their planning process to determine what the requirements are for obtaining permission to conduct research in the desired school district(s).

b. Accepted Documentation

A researcher must upload to the Attachments section of their IRBIS application documentation that they have obtained district-level approval (consistent with sections IV.A.1 and IV.A.2 or 3 above) to conduct human subjects research from the district Research Review Board.

3. Universities and Colleges

a. In General

Most universities and some colleges have their own IRBs. Requirements among IRBs vary regarding external researchers who would like to recruit subjects from their populations or conduct research on their premises. Differences in requirements also occur depending on whether the UNCW researcher is collaborating with a researcher at the other institution.

b. Research Collaborations between UNCW Researchers and non-UNCW Researchers

When a UNCW researcher is collaborating on human subjects research with a colleague from another university or college with its own IRB, the IRB encourages both researchers to contact their home IRBs for guidance prior to duplicating application efforts. Depending on the circumstances, the two institutions may be able to agree that one of the IRBs will conduct the review of the study so that the review is as efficient as possible. This may be the best approach when both institutions determine that they are “engaged” in the research, based on the activities conducted by their respective employees. Usually, the IRB at the principal investigator’s institution will conduct a review on behalf of all other engaged institutions. When this agreement is reached, the principal investigator completes the application on behalf of the research team.

c. Non-collaborative Research Conducted at Other Universities by UNCW Researchers

When a UNCW researcher plans to recruit subjects from other universities or colleges, and is not collaborating with colleagues at the other locations, the researcher should plan to submit an application through the UNCW IRBIS

system, and contact the non-UNCW IRBs to determine their requirements, if any. Some IRBs require researchers to provide documentation of IRB approval from the principal investigator's home institution, while other IRBs require researchers to submit applications through their IRB for additional approval.

If another university's IRB requires documentation of UNCW IRB approval before it will provide its own approval to conduct the research, the researcher should notify the UNCW IRB. Once all aspects of an application are acceptable, other than providing documentation or permission from the non-UNCW IRBs, the UNCW IRB can issue a conditional approval letter to the researcher.

d. Accepted Documentation

A researcher who wishes to access another university's population must abide by the requirements established by that university's IRB. Once approval from the university's IRB is obtained, the researcher must upload it to the Attachments section of their IRBIS application.

4. Other Educational Institutions

Researchers who plan to conduct human subjects research at educational institutions that do not have Research Review Boards or IRBs must upload to the Attachments section of their IRBIS application documentation that they have obtained approval (consistent with sections IV.A.1 and IV.A.2 or 3 above) to conduct human subjects research from the highest level administrator of the organization, such as the president or superintendent.

C. Special Requirements for Medical Facilities with Their Own IRBs

Researchers who intend to conduct research at medical facilities that have their own IRBs should first consult with the UNCW IRB to determine if application through the UNCW IRB is necessary. It is possible that the medical facility's IRB will require the researcher to apply for approval through its IRB, and the UNCW IRB can likely arrange to defer to the IRB review conducted by the medical facility's IRB.

Specifically, the New Hanover Regional Medical Center's IRB has jurisdiction for all research conducted at its medical center or any satellite facility or clinic owned by the organization. UNCW's IRB has a standing agreement with the NHRMC IRB to defer to any review it conducts of research conducted by UNCW researchers.

D. Special Requirements for Tribal Populations

The UNCW IRB recognizes and respects the sovereignty of tribal nations to determine when research may be conducted with their people. When proposing to work within tribal boundaries, researchers must obtain permission from tribal governments (or

those designated by tribal authorities) to conduct research on reservations. This usually requires permission from the tribal chairperson or a tribal resolution approved by a convened tribal council.

IV. References to Other Applicable SOPs

V. Responsibilities

Title	Responsibility
IRB Staff	Responsible for confirming that the researcher has submitted an acceptable letter of support or other authorization meeting the requirements of this SOP for studies that are subject to the requirement.
Principal Investigator	Responsible for obtaining and uploading an acceptable letter of support or other authorization meeting the requirements of this SOP for studies that are subject to the requirement.

VI. 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
E. U.S. Department of Education, Family Educational Rights and Privacy Act (FERPA) Guidance: https://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html
F. U.S. Department of Health & Human Services, Office of Human Research Protections, Engagement of Institutions in Human Subjects Research Guidance: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html