| | University of North Carolina Wilmington<br>Institutional Review Board | Standard Operating Procedure |
|---|---|---|
| | International Research | #6.5 |

The purpose of this SOP is to describe the review process and requirements for research that will be conducted by UNCW researchers outside of the United States.

## I. General Requirements

The Institutional Review Board (IRB) will review human subjects research studies involving subjects enrolled at international sites by UNCW researchers to ensure that (1) the research complies with all federal regulations and UNCW IRB policy and procedures and (2) that local regulations governing human involvement in research are adequate to ensure proper protections for subjects. When the IRB determines that the research is exempt from the requirements of 45 CFR 46, the investigators are responsible for ensuring that research complies with local regulations and requirements.

## II. Scope

These policies and procedures apply to all human subjects research submitted to the IRB that is being conducted by UNCW researchers at an international location.

## III. Applicable Definitions

A. Ethics Committee

A group of persons who have knowledge about the local laws and/or traditions/customs who are also responsible for ensuring the safety of subjects in proposed research projects.

B. Personal Data

Under the General Data Protection Regulation (GDPR), personal data means any information relating to an identified or identifiable natural person ('data subject').

An identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

## IV. Procedures

A. Local Ethics Requirements

In addition to the usual requirements for approval for research involving human subjects as outlined in SOPs 5.1, 5.2 and 5.3, when UNCW researchers will conduct or supervise research conducted outside the United States, the IRB staff will refer to the International Compilation of Human Research Protections website for the applicable country or countries to determine local requirements, if any, and will consider the following:

1. The experience of the UNCW investigator in working in this area or region and the investigator's knowledge of the area or region as it relates to the research.
2. The appropriateness of the provisions for the UNCW researcher to ensure ongoing review and approval from the UNCW IRB.
3. The appropriateness of the provisions for reporting unanticipated problems involving risks to subjects or others, complaints and non-compliance to the UNCW IRB.
4. A process for obtaining consent that is appropriate given the local laws/customs/traditions.
5. Documentation of local IRB or Ethics Committee review and approval. When applicable, there will be appropriate coordination and communication between the UNCW IRB and the local Research Ethics Committee.

B. European Union General Data Protection Regulations (GDPR)

Researchers planning to conduct human subjects research that involves obtaining or collecting identifiable data from subjects in Europe may be subject to additional requirements to ensure compliance with the GDPR, which went into effect on May 25, 2018. These regulations pertain to how "personal data" must be obtained, stored and destroyed.

1. The regulations <u>do not apply</u> to anonymous studies.
2. The regulations <u>do not apply</u> to European citizens who are physically in the U.S. (but they may begin to apply if a researcher continues to monitor European subjects after returning to Europe).
3. The regulations <u>do</u> apply to subjects who are physically in Europe, even though the researcher is collecting data remotely from the U.S.
4. The IRB may require researchers to alter the usual consent requirements to ensure compliance with the GDPR.
5. Data subjects have the right under the GDPR to have their data erased ("right to be forgotten") that researchers must take into consideration.
6. Researchers are encouraged to contact the Research Integrity Office prior to designing research that is subject to the GDPR.

## V. References to Other Applicable SOPs

| SOP Title | SOP # |
|---|---|
| Determinations of Exemption | 5.1 |
| Expedited Review of Research | 5.2 |
| Full Board Review of Research | 5.3 |
| Identification and Reporting of Adverse Events and Unanticipated Problems | 6.7 |
| Informed Consent | 6.8 |

## VI. Responsibilities

| Title | Responsibility |
|---|---|
| IRB Co-chair | Responsible for reviewing submissions eligible for expedited review or selecting a designee and ensuring that local requirements for human subjects research are met. |
| IRB Staff | Responsible for processing and assisting the IRB reviewer with studies being conducted internationally. |
| Principal Investigator | Responsible for ascertaining and complying with all local requirements for the protection of human subjects research and for providing the IRB with relevant contact information, letters of support or other documentation to demonstrate that local requirements are met. |

## 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 Guidance on International Research: https://www.hhs.gov/ohrp/international/
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. International Compilation of Human Research Protections: https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html
F. GDPR: https://gdpr-info.eu/