Procedure Title: International Research and Scholarly Activity

Associated Policy:	Human Research Protection Policy (OSA Policy 1.0)		
Responsible Unit:	Office of Scholarly Activity		
Created:	6.3.2020	**Executive Lead:**	Chief Research Officer
Effective:	06/30/2020	**Revision History:**	.00 – 6.03.2020; .01 – 3.21.2023
Approved by:	Research Committee and Department of Clinical Education		
Procedure Number:	119.01		
Key Words:	Belmont Report, International, International Research, Ethics Committee		
Purpose:	To meet the responsibilities for protecting human subjects as issued by the Office for Human Research Protections (OHRP) requirement for individuals involved in the conduct or review of human subjects research at institutions holding OHRP-approved Federal Wide Assurances (FWAs)		

Process:
This Standard Operating Procedure (SOP) serves to inform all agents, offices, departments, and affiliate sites of PNWU regarding conducting research and scholarly activity outside of the United States.

General Information:
Many countries outside the Unites States have research regulations and restrictions independent of the United States' regulations. International research must also be consistent with the principles in the Belmont Report and have protections equivalent to those afforded to subjects in the United States. For these reasons, international research and scholarly activity require additional oversight by the Office of Scholarly Activity and the PNWU Institutional Review Board. In most cases, it will require additional time to receive approval from the host country and the PNWU IRB.

Responsible Parties

The PNWU Institutional Review Board (IRB) is responsible for:

- Protecting the rights and welfare of human research participants.
- Being a steward of a research environment that promotes the responsible conduct of research.
- Considering the qualifications of the investigators and research staff to conduct the study outside the United States, including the study team's knowledge of relevant laws, regulations, guidance, and customs.
- Making determinations as to whether the consent process and consent documents are appropriate for the subject language, literacy level, and population, and that arrangements have been made to enable communication with the subjects throughout the study (e.g., to ask and answer questions).
- Making determinations as to whether the investigator has obtained the appropriate host country permissions to conduct research (e.g., IRB, local, tribal, institutional, governmental or ministerial).

- Ensuring mechanisms for communicating with the investigator and research staff are in place while they are conducting research in other countries.

The Office of Scholarly Activity (OSA) is responsible for:

- Supporting investigators in developing feasible research projects and scholarly activities.
- Providing investigators with access to domestic and international research regulations.
- Fostering a research environment that promotes the responsible conduct of research and scholarly activity.
- Monitoring compliance with this SOP.
- Posting this SOP for the PNWU community.

The Department of Clinical Education (ClinEd) is responsible for:

Approving Research Elective Rotation 701 and Global Health Rotation 703 requests and awarding credit for Research Elective Rotation 701 and Global Health Rotation 703.

The Investigator is responsible for:

- Providing information regarding their international research or scholarly activities to the Institutional Review Board and the Office of Scholarly Activity.
- Developing a relationship with a host agency/organization and securing a letter of support.
- Ensuring that the resources and facilities are appropriate for the nature of the research or scholarly activity.
- Understanding the research ethics of the host country (see HHS guidance on Social-Behavioral Research Standards).
- Obtaining all appropriate host country permissions to conduct research or scholarly activity (e.g., institutional, governmental, or ministerial, IRB, local, or tribal).
- Ensuring that the consent process and consent documents are appropriate for the subject language, literacy level, and population, and that arrangements have been made to enable communication with the subjects throughout the study (e.g., to ask and answer questions).
- Demonstrating understanding of the cultures, language, and religious norms in the country where the study will take place.
- Upholding human ethics and representing PNWU.
- Ensuring that there are mechanisms in place for communicating with the IRB when they are conducting research in other countries.

Definitions

Please reference the Glossary for complete definitions of the following terms and additional terms not listed.

- Ethics Committee
- Federalwide Assurance
- Generalizable Knowledge
- Institutional Review Board
- Systematic Review

Investigator Procedures:

1. Investigators planning to conduct research abroad must meet with the Office of Scholarly Activity to determine if the proposed project is research with human subjects.
    a. Projects that are considered research, per IRB Standard Operating Procedure 103 – Activities Subject to Human Protection, require review and approval by PNWU's IRB and review and approval with documentation by an IRB or Ethics Board in the destination country before the project begins. In some cases, it may be beneficial to work with a local university located in the destination country. It is recommended that you start working with the destination country well ahead of the time as it may take upwards of a year to receive the necessary approvals. The Office for Human Research Protections compiles laws and regulations on human subject protections for 133 countries. You can find the most current Edition of International Compilation of Human Research Protections here: https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html

2. All investigators must submit an application to the PNWU IRB for either:
    a. Request for Determination of Nonhuman Subjects Research
        i. This application is for projects that may involve human subjects but may not be systematic investigations or the information may not be generalizable. Most quality improvement projects and case studies meet these criteria. This form will allow the investigator to get a letter of determination from the IRB that may be helpful when publishing. Some publishers now ask for proof of IRB review. Contact the IRB Administrator if you require assistance in filling out this form.
    b. Request for Review and Approval of Human Subjects Research
        i. This application is for projects that are both systematic and generalizable and involve human subjects.

3. All research and scholarly activity abroad require a letter of support from the hosting organization in the destination country.
    a. Required elements:
        i. Written on letterhead of the hosting organization.
        ii. Title of the project.
        iii. Name(s) of investigators involved.
        iv. Confirms the hosting organization understands and supports the intent of the research or scholarly activities to be performed.
        v. Confirms that the investigator(s) from PNWU are appropriate for the role and will have adequate support.
        vi. Documents whether the project needs IRB/ethics board review in the destination country and which IRB in the destination country will be reviewing the project.
        vii. Document is signed and dated.

4. All PNWU investigators and members of the study team conducting research or scholarly activity abroad must complete CITI training, including the module on international research before IRB approval will be granted.
    a. Contact the Office of Scholarly Activity if you need help locating this module.
    b. Locals in the destination country who assist with logistics like securing lodging or translating AND who have no vested interest in the outcomes of the study are not considered members of the study team and do not need to complete CITI training.
    c. In rare cases CITI Training from other institutions may be considered at the approval of the Institutional Official (IO) or designee.

i. Collaborating investigators from external R1 institutions will be required to submit a copy of a current curriculum vita (CV) and current human protections training. Training must have been completed in the last four years. The CV and training information will be reviewed by the IRB Chair to ensure that training is appropriate, the investigator resides at an R1 university, and that the investigator is qualified to serve in the requested role. If approved by the IRB Chair, the IRB Administrator will request approval from the IO or his/her designee. Collaborating investigators must maintain current training throughout the period of the study.

5. The PI and research team members conducting international research shall include relevant local context information in their IRB applications. Local context should be evaluated for each location of the research. This includes, but is not limited to, the following:
    a. Cities, regions, countries where research will be conducted.
    b. Scientific/ethical justification for conducting the research in an international setting.
    c. Economic status of the country/community.
    d. Current events or sociopolitical environment in the country that may impact research conduct or alter the risks or benefits to subjects.
    e. Societal and cultural beliefs in the country that may impact research conduct or alter the risks or benefits to subjects.
    f. The role of women and children in the society, including their autonomy and legal capacity to make decisions.
    g. Literacy rate of the potential subject population.
    h. Languages and dialects of the potential subject population.
    i. Involvement of organizations, community leaders, or experts in engaging the subject population or conducting the research.
    j. Description of the research team's knowledge of, or experience in, the host country.
    k. Relevance of the research to the area's health, economic, educational, or other needs.
    l. Distribution of risks and current and future benefits.
    m. Any proposed incentives for research subjects including:
        i. Description of the incentive (e.g., food item, payment, gifts, etc.)
        ii. Value in US currency and host country currency
        iii. When incentive(s) will be given during the study (e.g., at study completion)
        iv. Whether the incentive could pose undue influence
    n. A description of how you will keep the study data secure.
    o. Approval from the host country's IRB/Ethics Committee **OR** documentation from the host country's IRB/Ethics Committee that approval is not necessary for the proposed research.

6. The investigator is responsible for creating a plan for data security and storage before leaving for the destination country.
    a. Make sure your laptop is encrypted before leaving.
    b. Some countries have restrictions on the collection and use of identifiable data or bringing identifiable data into/out of the country.
        i. Data export laws may affect your research in countries with which the US has embargoes or trade restrictions, such as Cuba and Iran.
        ii. The European Union's General Data Protection Regulation (GDPR) is the strictest security and privacy law worldwide. The GDPR applies to all personal data collected in EU and non-EU European Economic Area (EEA) countries which include: Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Iceland, Liechtenstein and Norway. You can find more information about the GDPR here: https://gdpr.eu/tag/gdpr/

7. Students hoping to conduct research or scholarly activities abroad are encouraged to work under a primary investigator who has already started a project.

   The Office of Scholarly Activity suggests the following research or scholarly activities as feasible projects for a two- or four-week rotation elective:
   - Case study or case series of four cases or fewer
   - Literature review
   - Qualitative interviews of healthcare providers
   - A quality improvement project selected by the host organization
   - Working on a small component of a larger project with a principal investigator

8. Please contact the Office of Scholarly Activity if your project is federally conducted or federally-supported research. Federally conducted or supported research can only be conducted if the foreign institution or site holds a Federalwide Assurance with the Office of Human Research Protections (OHRP) and if an IRB Authorization Agreement is in place. Investigators are encouraged to start planning very early as this may take additional time.

References:

1. The Office for Human Research Protections, International Compilation of Human Research Protections https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html
2. Department of Health and Human Services (DHHS) Regulations (45 CFR 46 Subparts A, B, C, and D) http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html
3. University of Pittsburg Human Protections Office https://www.irb.pitt.edu/node/297
4. Fordham University Office of Research Guidelines and Procedures. https://www.fordham.edu/info/24327/guidelines_and_procedures/10345/irb_guidelines_on_international_research
5. Department of Health and Human Services Social Behavioral Research Standards. https://www.hhs.gov/ohrp/international/social-behavioral-research-standards/index.html
6. The Belmont Report. https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html

Revision History:

Version/ Effective Date	Author	Section Changed & Reason for Revision
.00 / 06-30-2020	L. Lamb	Original SOP
.01 / 3-24-2023	C. Case	Minor grammatical changes; Added Global Health Elective 703 to the Department of Clinical Education responsibilities; Revised the CITI training language to match SOP 101 Training Requirements; Removed reference to the L: Drive location in the footer as all SOPs are now stored in the IRB electronic management system.

Appendices: None