Office of Research, Grants and Contracts
Standard Operating Procedures (SOP)

SOP Title	International Research with Human Subjects				
Date Last Revised		**Date Created**	08/02/2022	**Revision #**	1.0
SOP Number	27	**Required by**	☐OHRP ☐Funding Agency ☐OLAW		
Applicability	☐ RGC Internal	☒Researcher	☐Institutional		
Subgroup	☐ NKU Compliance	☒IRB	☐IACUC	☐IBC	

1.0 PURPOSE

The purpose of this internal regulation is to describe the parameters for Northern Kentucky University (NKU) researchers when recruiting participants or conducting study procedures outside of the United States.

2.0 GENERAL INFORMATION AND SCOPE

When research is conducted outside of the United States, investigators must comply with both the U.S. regulations and with the local policies and regulations governing the international research sites.

Depending on the international site, a local ethics committee review may or may not be required. It is the responsibility of the researcher to contact the appropriate entity who will make that determination and obtain written documentation that review is not required or provide documentation that a local ethics committee is not available. However, even if local ethics committee review is not required, additional documentation will be required to assess the cultural appropriateness of the proposed research and activities to be performed.

Based upon the study location and risk level, the IRB may require a local site collaborator and additional training.

3.0 PROCEDURES

A. STUDIES THAT ARE NO MORE THAN MINIMAL RISK (EXEMPT/EXPEDITED)

INTERNATIONAL REGULATIONS NOT REQUIRING LOCAL ETHICS REVIEW

Two documents are required for studies where international regulations do not require local ethics review:

1. Memo of Cultural Appropriateness
    a. Authored by an individual completely independent of your study who is highly familiar with the culture of the region where the research will be conducted.
    b. Required elements:
        i. Reference the title of the study displayed in the IRB application.

ii. Describe the expertise of the individual preparing the letter to address the local cultural and social norms.
iii. Confirm that they understand the intent of the research and activities to be performed.
iv. Confirm the planned study does not conflict with local and cultural norms.
v. Clearly state whether the individual perceives any compensation as appropriate, if applicable.
vi. The document is signed and dated.

2. Documentation that the local regulations do not require a local ethics review
    a. Provide direct references to the local regulations that state ethics review is not required, or
    b. Acknowledgement of Unregulated Research Activities letter confirming that local ethics review is not required
        i. Required elements:
            1. Provided on the official letterhead of the signatory.
            2. Document is signed and dated.
            3. Clearly state the planned research does not require local regulatory oversight.
            4. Confirm the Regulatory Official understands the intent of the research and activities to be performed.
            5. Reference the title of the study displayed in the IRB application.

INTERNATIONAL REGULATIONS REQUIRING LOCAL ETHICS REVIEW

Required document for studies where international regulations DO require local ethics review

1. Letter of approval from a local Ethics Committee
    a. Required elements:
        i. Reference the title of the study displayed in the IRB application.
        ii. Clearly state the research study was designated no more than minimal risk by the committee.
        iii. Clearly state the planned research was reviewed and approved.
        iv. Clearly state whether the individual perceives any compensation as appropriate, if applicable.
        v. The document is signed and dated.
        vi. The document is on the official letterhead of the signatory.

B. STUDIES THAT ARE MORE THAN MINIMAL (FULL/CONVENED REVIEW)

Studies that are designated as greater than minimal risk require a formal ethics review within the country where the research will be conducted. Not all countries have an ethics review committee and the oversight may be addressed by the Department of Ministries or other governmental entities. This is why

it is important to collaborate with local individuals early in the planning process so they can assist you in identifying the proper mechanism to obtain the approval.

1. Letter of Approval from an Ethics Committee
    a. Required elements:
        i. Reference the title of the study displayed in the IRB application
        ii. Clearly state the planned research was reviewed and approved
        iii. Clearly state whether the individual perceives any compensation as appropriate, if applicable.
        iv. The document is signed and dated
        v. The document is on the official letterhead of the signatory.

C. LOCATING FOREIGN ETHICS COMMITTEES

U.S. FEDERALLY FUNDED RESEARCH STUDIES

Research studies supported by U.S. Federal funds are required to undergo foreign IRB review by an ethics committee that holds a Federal Wide Assurance (FWA).

Investigators of U.S. Federally funded research studies can search the OHRP "Database for Registered IORGs and IRBs, Approved FWAs and for Documents Received by OHRP in the Last 60 days" to locate foreign IRBs that hold an FWA:

- http://ohrp.cit.nih.gov/search/fwasearch.aspx?styp=bsc
- Press the "Advanced Search" link
- Select the appropriate country & Search

NON – U.S. FEDERALLY FUNDED RESEARCH STUDIES

Investigators of Non-Federally funded research studies can search the OHRP "Database for Registered IORGs and IRBs, Approved FWAs and for Documents Received by OHRP in the Last 60 days" to locate a foreign oversight body:

- http://ohrp.cit.nih.gov/search/irbsearch.aspx?styp=bsc
- Press the "Advanced Search" link
- Select the appropriate country & Search

D. SUMMARY OF REQUIRED DOCUMENTS BY REVIEW TYPE

Documentation	Exempt	Expedited	Full/Convened Board
Foreign IRB or Ethical Approval	If required by foreign regulation	If required by foreign regulation	Required

Memo of Cultural Appropriateness	Required, if foreign IRB/ethics approval is not required	Required, if foreign IRB/ethical approval is not required	Not required
Acknowledgement of Unregulated Research Activities	Required, if foreign IRB/ethics approval is not required	Required, if foreign IRB/ethical approval is not required	Not required
Site Permission	Required	Required	Required
Translated Documents	Required	Required	Required
Back Translations	Not required	Not required	Required
Translator Certification	Does not require certified translator	Does not require certified translator	Required a certified translator

E. INTERNATIONAL RESEARCH UTILIZING GRANT FUNDS

If the research is grant-funded, additional procedures are required including submitting an ad hoc Financial Conflict of Interest/Foreign Interest disclosure in Mentor COI. Contact compliance@nku.edu for more informatni.

4.0 REFERENCES

There is a high level of variability in the procedural details across international research regulations. However, the majority of foreign regulations are based upon the foundational ethical guidelines provided within the International Conference of Harmonization (ICH) and the Council for International Organizations of Medical Sciences (CIOMS).
International Conference of Harmonization
(ICH): http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html

Council for International Organizations of Medical Sciences
(CIOMS): http://www.cioms.ch/publications/layout_guide2002.pdf

Investigators can begin to educate themselves about applicable foreign research regulations, by specific country, using the resources below:

- Office of Human Research Protections (OHRP) "International Compilation of Human Research Standards for Social-Behavioral Research": http://www.hhs.gov/ohrp/international/index.html
-
- Harvard School of Public Health Research Ethics Guidelines International Online Navigation Map (REGION): http://www.hsph.harvard.edu/region-map/

4.0 DEFINITIONS

Cultural appropriateness: Sensitivity and awareness of how other ethnic, racial, and/or linguistic groups differ from one's own. Sensitivity can be manifested through knowledge of different languages or manners of speech, norms, and mores, religious beliefs and practices, family structures and dynamics, community decision-making patterns, and class consciousness and socioeconomic realities.

Ethics committee: a committee that has been formally designated to approve, monitor and review biomedical and behavioral research involving humans. May also be referred to as an Institutional Review Board (IRB), an Independent Ethics Committee (IEC), an Ethical Review Board (ERB) or Research Ethics Board (REB)

Greater than minimal risk: the research involves more than minimal risk to subjects.

Minimal risk: the probability and magnitude of physical or psychological harm anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life, or in routine medical, dental, or psychological examinations.

Approvals

Title	Approved	Date Approved	Not Applicable
Manager of Research Compliance	☒	08/02/2022	☐
Chair	☒	08/02/2022	☐
Institutional Official	☒	08/11/2022	☐

Revisions

Title	Approved	Date Approved	N/A	Summary
Manager of Research Compliance	☐		☐	
IACUC Chair	☐		☐	
Institutional Official	☐		☐	