UNG UNIVERSITY of NORTH GEORGIA

Institutional Review Board (IRB)

IRB Guidelines 1.6

International and Cross-Cultural Research

Version 1.2: Created 4/23/2016

Overview

The Institutional Review Board (IRB) of the University of North Georgia is committed to protecting the people who participate in human subjects' research whether the work is conducted domestically or internationally. Under the Federal Wide Agreement (FWA) the University has with the federal Office of Human Research Protections (OHRP), it is obligated to follow all of the rules and regulations promulgated by OHRP. Both ethically and legally it is the responsibility of researchers to afford individuals who serve as international human subjects the same protections as they would for people in the United States. Individual countries or regions may have their own regulations that researchers need to know and MUST follow. To provide guidance for researchers in assessing their international research plan and for addressing specific questions relating to the IRB review of protocols involving study sites outside of the U.S.A, this document discusses the IRB institutional policies and offers links to additional resources.

Regulatory Authority: The Office of Human Research Protections states that the all Institutional Review Boards must have the proper information to assess the local research context of work that is being done internationally. Therefore, according to regulations:

1. IRBs must be capable of ensuring that (if applicable) (i) the selection of subjects is equitable; (ii) the privacy of subjects is protected and confidentiality of data is maintained; (iii) informed consent is appropriate; and (iv) adequate safeguards to protect the rights and welfare of vulnerable subjects have been put into place [45 CFR 46.111(a)(3),(a)(4),(a)(7),(b), and 46.116].
2. An IRB designated under an approved Federal Wide Assurance (like the IRB of the University of North Georgia) has a responsibility to ensure that its members possess sufficient knowledge of the local research context to satisfy these requirements. This responsibility endures regardless of the IRB's geographic location relative to the institution and the research. It is particularly critical where the research involves greater than minimal risk to subjects or vulnerable categories of subjects. To ensure that the IRB possesses sufficient knowledge of the local research context for international studies, may be accomplished in several ways (see discussion below).

Basic Terms and Definitions

The policy as well as definitions are informed by federal policy documents (e.g. 45 CFR 46, OHRP guidance letters), international agreements (e.g. the Belmont Report) and institutional best-practices of other US universities. These definitions will be applied to all international and cross-cultural research application UNLESS superseded by the authority of a local ethical review authority (i.e. a foreign IRB and/or its equivalent institutions).

International/Cross-Cultural Research: International research – as defined in this document – pertains to research conducted outside of the United States. For research with subpopulations of current or former US citizens living abroad (e.g. US citizens serving in the military overseas and/or expats), this policy may only apply to the extent that may affect local participants and/or may interfere with local customs and traditions. Please contact the IRB chair if in doubt.

No More Than Minimal Risks: The Common Rule §46.102(i) defines minimal risk as "*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." Risks, however, are not limited to psychological and physical risks alone but also include other forms of risks (e.g. social and economic risks to individuals such as stigmatization and risks to employability). For more discussion also see SACHRP Guidelines.

Documentation of Researchers' Familiarity with Local Research Context: To uphold the ethical standards of research in an international/cross-cultural setting, researchers are required to demonstrate an appropriate understanding of the local cultural context as well as its current social and political circumstances. Note: Researchers may demonstrate their familiarity by providing a basic description of the research context supported by relevant peer-reviewed research articles that offer specific insights into the current social, cultural and political context. It may also include investigators' previously published peer-reviewed papers or dissertations that are judged by the IRB to be applicable to the local context for the protocol being reviewed. Non-published, written materials provided by the investigator(s), however, cannot be the sole source.

Description of the Cultural Appropriateness of the Research Design: In addition to having an adequate understanding of the local research context, researchers also need to demonstrate the cultural appropriateness of the research design and its research protocols. In particular, researchers need to show how consent procedures, recruitment processes, negotiation of site access and protocols are culturally-sensitive and appropriate. Note: Researchers may support their description by providing relevant peer-reviewed articles that underscore the appropriateness of the research design. They may also include their own previously published peer-reviewed papers or dissertations (if judged by the IRB to be applicable to the local context). However, non-published, written materials provided by the investigator(s) cannot be the sole source of support.

Review of Research Proposal by Qualified Cultural Consultant: The term "qualified consultant" refers to an individual (or IRB member) who has personal knowledge of the study site, such knowledge having been obtained through extended, direct experience with the subject population and their environment, who are, in the estimation of the IRB qualified to provide an informed and independent review. Qualified individuals may include, for example, a scholar, the author of a book, article (etc.), or someone who has traveled or lived within the country. The review procedure mirrors the one described under "Greater Than Minimal Risk" Research (see below). **Note:** To minimize conflicts of interest, the IRB of the University of North Georgia will not accept for consultants that fall into any of the following categories: (1) a friend of the investigator(s); (2) a collaborator on protocols or grants of the investigator(s); (3) anyone who has personal/professional ties with the protocol investigator(s) that precludes him or her (in the opinion of the IRB) from speaking independently and objectively about the research project; or (4) anyone who in the estimation of the IRB is not qualified to conduct the review.

Research Involving "No Greater Than Minimal Risk"

For studies involving "no greater than minimal risk" (those that fall into an exempt or expedited category), the IRB will employ one of *two basic approaches* to review and assess the ethical nature of international and cross-cultural research. *Independent of the particular review option, researchers are required to demonstrate an adequate familiarity with the local social, cultural and/or political research.* Hence, investigators are strongly encouraged to collaborate with an individual or organization with expertise in the region. This collaboration will greatly assist in identifying appropriate research sites, navigating the local regulations and policies, understanding culture, local infrastructure, overcoming language barriers & increasing community partnership. Based upon study location and risk level, the IRB may – on a case by case basis – require individual researcher to work with a local site collaborator. Note: Please also consult Flowchart 1.1 for further help.

Approach 1: Studies Requiring Foreign Institutional Oversight

The IRB of the University of North Georgia cannot supersede the authority of foreign ethical oversight mechanisms that are in place to protect populations. In cases where the principle investigator (PI) plans to work with populations that are subject to local IRBs (e.g. students at a foreign university) or local ethics committees/tribal councils their authority generally tends precedence. To address difficulties arising from different types of research and/or challenges to secure appropriate oversight, the IRB of the University of North Georgia will apply one of the following two options in its determination process. Important: It is the responsibility of the PI to become familiar with the local oversight mechanism in ALL international/cross-cultural settings.

Review Option 1

If institutional oversight is required by foreign local law, the PI will need to provide the following information and documentation to help the UNG IRB to make its determination:

1. a description of the cultural appropriateness of the research design
2. approval letter of the foreign ethical review board (and a translation if necessary)
3. additional application requirements (where appropriate)
    - documentation of site permissions and/or
    - contact information for local site collaborators.

Review Option 2

If foreign institutional oversight is required by local law or custom but the PI has been unable to secure the approval, the IRB of the University of North Georgia will require the following information and documentation to make its determination:

1. explanation as why PI was unable to secure an approval letter from a foreign oversight authority
2. a description of the cultural appropriateness of the research design
3. review of research proposal by qualified cultural consultant
4. additional application requirements (where appropriate)
    - documentation of site permissions and/or
    - contact information for local site collaborators.

Approach 2: Studies NOT Requiring Foreign Institutional Oversight

In cases where the research does not involve populations subject to oversight by local IRBs (e.g. students at a foreign university) or local ethics committees/tribal councils, the IRB of the University of North Georgia will use the following mechanism to make its determination. Whether option 1 or 2 will be applied will depend on a variety of factors (e.g. nature and risk of study, ability of researcher to demonstrate adequate familiarity with the local research contact etc.

Review Option 3

If foreign institutional oversight is NOT required by local law, the IRB of the University of North Georgia will require the following information and documentation to make its determination:

1. a description of the cultural appropriateness of the research design
2. additional application requirements (where appropriate)
    - documentation of site permissions and/or
    - contact information for local site collaborators.

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Flowchart 1.1

International and Cross-Cultural Research

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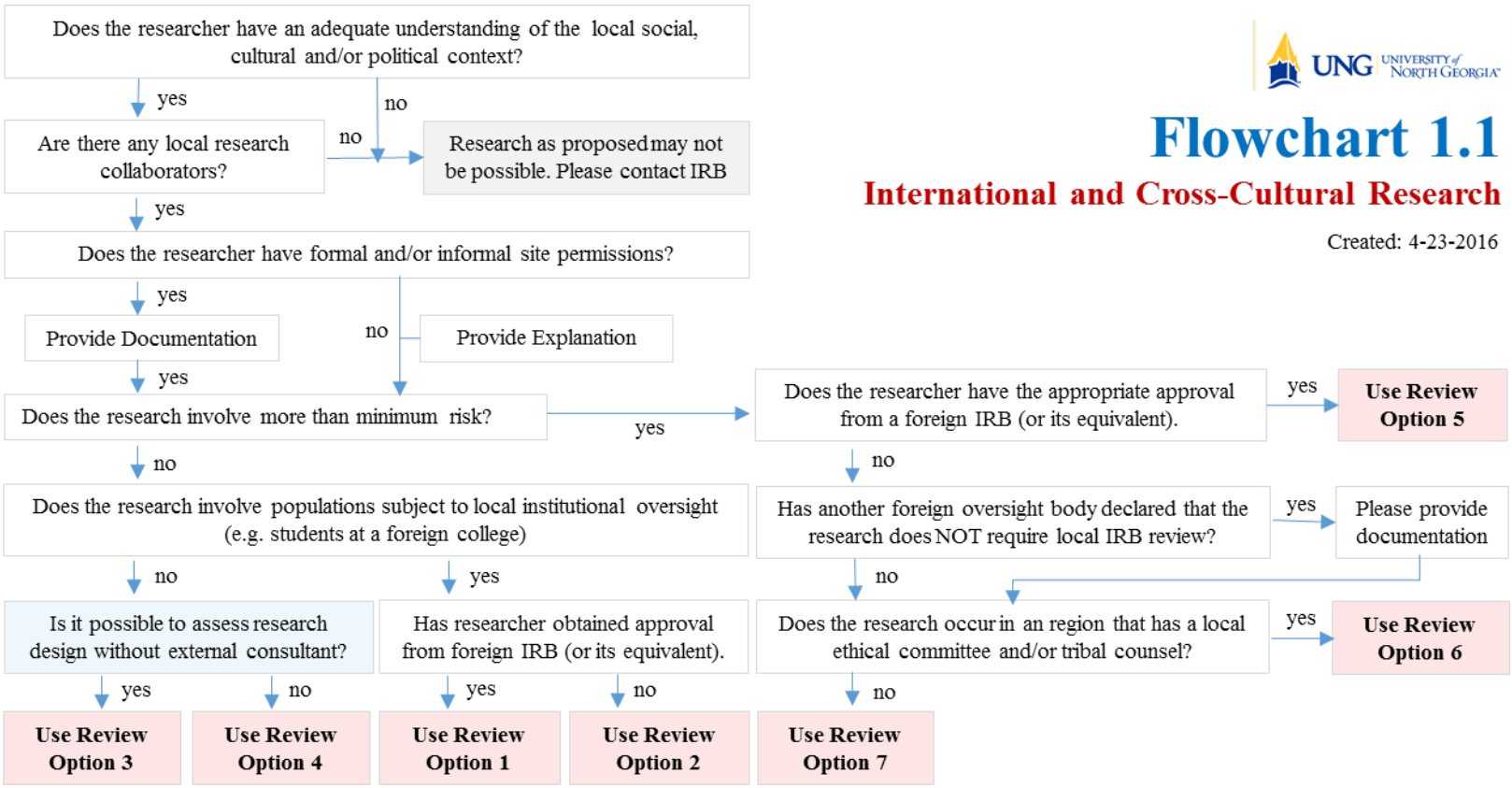

Review Option 4

In cases where the nature and risk of the research warrants an extra layer of protection and/or where the researchers familiarity with the local cultural context is limited, the researcher will be asked to provide the following information and documentation to the UNG IRB to make its determination:

1. a description of the cultural appropriateness of the research design
2. review of research proposal by qualified cultural consultant
3. additional application requirements (where appropriate)
    - documentation of site permissions and/or
    - contact information for local site collaborators

Research Involving "Greater Than Minimal Risk"

For studies involving "greater than minimal risk" (those that fall into a full review category), the IRB will employ one of *two basic approaches* to review and assess the ethical nature of international and cross-cultural research. *Independent of the particular review option, researchers are required to demonstrate an adequate familiarity with the local social, cultural and/or political research.* Researchers are advised that not all countries have an ethics review committee and the oversight may be addressed by the Department of Ministries or other governmental entities. Investigators are thus strongly encouraged to collaborate with an individual or organization with expertise in the region. This collaboration will greatly assist in identifying appropriate research sites, navigating the local regulations and policies, understanding culture, local infrastructure, and overcoming language barriers. Local collaborations can also assist in identifying the proper mechanism to obtain the approval. Based upon study location and the specific risk level, the IRB may require a local site collaborator. Please also consult Flowchart 1.1 for further help. Important: It is the responsibility of the PI to become familiar with the country and region-specific ethical requirements. For further information on ethical oversight in other countries please consult: HHS' Compilation of Standards or NIH ClinRegs (Online database of country-specific clinical research regulatory information)

Approach 1: Foreign IRB Review (DEFAULT)

If the country in which the research will take place has an IRB (or an equivalent), the research protocol needs to be approved by the foreign IRB (or its equivalent). Note that this type of review becomes especially important if the UNG researcher (a) collaborates with researchers from a foreign institution (e.g. university, hospital) or (b) seeks to do research with populations subject to institutional rules and regulations (e.g. students at a foreign university, soldiers in a foreign army, patients in a foreign hospital).

Review Option 5

To make its determination, the IRB of the University of North Georgia only requires a regular IRB application (e.g. see Form 1.1.) but the following information and documents:

1. approval letter of the foreign ethical review board (and a translation if necessary)
2. a description of the cultural appropriateness of the research design
3. additional application requirements (where appropriate)
    - documentation of site permissions and/or
    - contact information for local site collaborators.

Approach 2: Alternative Procedures

Only in cases where it is impossible to have the study reviewed by a foreign IRB (or its equivalent), the IRB of the University of North Georgia will entertain the application of the mechanisms below. Justified exception, for example, include situations where the PI can document that the country and/or region in which the research takes place does not have an IRB (or its equivalent) and/or that s/he has made reasonable efforts to secure ethical oversight in this places (but was unable to do so). To guarantee the appropriateness

of the review, the IRB – in consultation with the investigator – will determine which approach is the most appropriate given the nature of the research and the context in which it will be conducted.

Review Option 6

In cases where IRB review (or its equivalent) is impossible to obtain, the researcher may want to try to see if a local ethics committee and/or tribal council located in the region where the research takes place can conduct a qualified review of the proposed research. If the local ethics committee and/or tribal council agrees, it will be asked to conduct a confidential review. Based on the review it will then need to assess as to whether, in their judgement, the research is both culturally appropriate and by local ethical standards appropriate. While maintaining final discretion to determine what information is necessary for it to review a protocol, the IRB will take under advisement any concerns the investigator may have about confidential, proprietary or other sensitive issues relating to his/her research. If option 6 applies, the researcher will need to submit the following information and documentation to the IRB of the University of North Georgia.

1. explanation as to why researcher was unable to have a foreign IRB review the research proposal
2. a description of the cultural appropriateness of the research design
3. review letter from local ethics committee or tribal council (and translation if needed)
4. additional application requirements (where appropriate)
    - documentation of site permissions and/or
    - contact information for local site collaborators.

Review Option 7

In the rare cases where neither an IRB approval or review by local ethics committee and/or tribal council can be secured (or has been deemed inappropriate due to worries about increasing risks for participants), the IRB of the University of North Georgia will require the following information and documentation to make its determination:

1. explanation as why PI was unable to secure an approval letter from a foreign oversight authority
2. a description of the cultural appropriateness of the research design
3. review of research proposal by qualified cultural consultant
4. additional application requirements (where appropriate)
    - documentation of site permissions and/or
    - contact information for local site collaborators.

References

The policy was guided by information found in the following documents.

- OHRP's Useful International Research Links [Department of Health and Human Services]
- https://orra.rutgers.edu/international-research [Rutgers University]
- http://research.uga.edu/docs/policies/compliance/hso/PP_International_Research.pdf [University of Georgia]
- http://www.irb.wisc.edu/documents/Guidelines_-_International_Research.pdf [University of Wisconsin-Madison]
- http://osp.ua.edu/site/NewIRBdocs/74%20%20G%20%20International%20Research%20Final%201-24-2012.pdf [University of Alabama]
- https://sbsirb.uchicago.edu/page/international-research [University of Chicago]
  http://www.irb.pitt.edu/node/297 [University of Pittsburg]

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