GLOBAL ALLIANCE
for Behavioral Health and Social Justice

Guidelines for Conducting Global Research: Global Alliance Perspective

As a long-standing interdisciplinary organization whose goal is to promote mental health and well-being for all globally and across the lifespan, the Global Alliance for Behavioral Health and Social Justice (GA) is committed to supporting research endeavors at the local and global levels that have the goals of improving care, adhering to strict research protocols, and respecting and empowering research participants. We embrace our social responsibility to all people, to the advancement of science, and the use of evidence-based treatment interventions. This document will include guidelines that should be reviewed by all researchers including US- based and foreign researchers conducting studies in the U.S. and abroad prior to engaging in all types of inquiry in low, middle, and high resourced communities.

Research / inquiry is a practice that seeks to gather information about a topic of interest in order to answer an unknown question, better understand processes, explore variations, advance knowledge, and develop treatment models that are grounded in the needs, practices and desires of the people it aims to serve. As a global organization committed to social justice and human rights, we support research that:

1. Ensures the protection of human subjects.
2. Respects the right of individuals to choose to participate in research.
3. Is transparent and respectful.
4. Partners with communities where the research will be conducted.
5. Prioritizes community-based participatory research processes and strategies.
6. Disseminates findings back to the community of interest and to the larger scientific community in the form of peer-reviewed papers, oral presentations, contributions to local and popular magazines, radio discussions and posters.
7. Evaluates the impact of the research process using feedback from the participants, participating organizations and agencies, after the research has been conducted.

Examples from history and some contemporary events have shown that individuals who participate in research can potentially be at risk for harm. It is particularly true about vulnerable populations including individuals with mental health conditions. These individuals are at higher risk for harm due to various factors, such as limited capacity to understand the consequences of participation in research, institutionalization, limited mental health literacy and social stigma that can lead to discrimination, among other factors. Therefore, for US-based investigators engaging in investigator-initiated research or global partner-initiated research as well as for foreign researchers conducting studies in the U.S., it is essential to assess the risk to such individuals and examine the adequacy of protections against that risk.

Protection of Human Subjects

When conducting research internationally, particularly research involving mental health issues, it is essential that the protection of human subjects is in place and is appropriate for the site where the research occurs and the individuals who are involved. In recent years, promotion of international research on mental health led to the need for developing basic guidelines and/or recommendations regarding the protection of human subjects that researchers should consider while conducting studies outside of the US. The following recommendations were developed by

the GA for investigators to consider when planning to and when conducting international studies on mental health.

Institutional Review Board (IRB)

International research must be approved by the local IRB or its equivalent. If there is no established IRB locally, researchers should work with local non-governmental organizations (NGO) and community leaders to ensure that the project is compliant with the local laws and is consistent with legal requirements. Given the sensitive nature of mental health and substance use conditions, it is essential to learn about local laws and legal provisions related to behavioral health issues in order to ensure that the project does not jeopardize the well-being of the participants and is in keeping with the values, goals and mission of the local international organizations, universities, and community.

Local culture and language

One of the three basic ethical principles established by the Belmont Report (1979) is respect for persons. This principle includes awareness of local ethnic/racial and cultural norms, and conformity with the local religious beliefs and practices. Therefore, the research project including its design, measures, and data collection method should be feasible and appropriate in the context of the political climate, beliefs related to mental illness and its treatment, as well as the comfort level of the participants. Respect for persons should also include either researchers' knowledge of local language and linguistic proficiency or active collaboration with local individuals who can ensure effective communication and the use of adequate language skills.

Informed consent

Although signing an informed consent is a typical requirement for studies conducted in the U.S., the process of signing an informed consent document may not be culturally acceptable in some societies. Researchers, therefore, may think about alternative consent strategies to fulfill these requirements. *Language and literacy capabilities* of the potential participants should be assessed by the local research site personnel. In any case, the language used in the informed consent documents should be simple and the meaning and content of the document should be double checked with the local interpreters and researchers. Providing repeated information using different methods should be considered as an option in some cases. In addition, any informed consent document should explicitly state that participants have the right of refusal with no adverse consequences to their welfare.

Population with increased vulnerabilities

When conducting international research, all researchers need to pay careful attention to populations with increased vulnerabilities. Given that people with mental illness are considered to be one of the vulnerable groups that may be exposed to high risks of unintentional adverse outcomes, additional safeguards have to be put in place to ensure the protection of rights, well-being, and safety of research participants. For example, employment of a legal guardian for participants with limited intellectual capacity, ensuring privacy when collecting information from participants, employing a clinician and/or a therapist who is ready to provide psychological counseling in case of unexpected emotional distress during, or immediately following data

collection, as well as guaranteeing confidentiality of information, are critical aspects that the researcher needs to be aware of and follow.

Incentives and compensation for the study participants

This principle of justice as outlined in the *Belmont Report* demands fairness in the treatment of individuals and communities. As such, there should be an equitable distribution of the burden and benefits of research. While it implies that risks should be allocated equally, it suggests a similar approach to the distribution of the benefits, including compensation to research participants. Although paying study participants is a common practice in the U.S., it can present an ethical challenge when it comes to international research. This is specifically an issue when studies are conducted in developing countries and where the international compensation rates would pose undue influence. To avoid this situation, the researchers should compensate participants in a culturally sensitive manner, taking into consideration the customs and practices of the community as well as local economic conditions and local regulations.

Tips for successful global research

When conducting global research, it is imperative that the researcher plan ahead, anticipate delays, and engage in clear and consistent dialogue with partners on the ground where the research will be conducted.

Build your global research infrastructure with human capital

- Plan ahead (at least 1- 2 years) and identify a local principal investigator/collaborator well-grounded in local norms and who understands the U.S. research process.
- Develop personal awareness and understanding of the culture from engagement with collaborators such as:
    - Common languages and dialects spoken and understood
    - Literacy rate of population
    - Political and economic status including potential volatility
    - Security risks
    - Learn the local and national laws specific to your area of research.
    - Utilize collaborators to identify research assistants and data collectors.
    - Identify from communities and collaborators what is appropriate and culturally respectful as incentives for participants.
    - Schedule a visit to the host country and/or a video conference a year or two before research.
    - Keep lines of communication open and practice in a transparent manner.
- Remain open to feedback from participants and local community members.
- Engage in research practices that value human rights and the protection and empowerment of all participants.
- Build in time for and add budget for local dissemination of findings.

Enhance your international research infrastructure knowledge

- Plan and understand the research and ethical guidelines of the host country. Become familiar with the following international guidelines:

- International Compilation of Human Research Standards (https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html)
- social-behavioral Research Standards (https://www.hhs.gov/ohrp/international/social-behavioral-research-standards/index.html)
- Compilation of European General Data Protection Regulation (https://www.hhs.gov/ohrp/international/gdpr/index.html)
- Spanish Translation: Pre-2018 Common Rule (https://www.hhs.gov/ohrp/international/translations/spanish/index.html)
- Listing of Clinical Trial Registries (https://www.hhs.gov/ohrp/international/clinical-trial-registries/index.html)
- Ethical Codes & Research Standards (https://www.hhs.gov/ohrp/international/ethical-codes-and-research-standards/index.html)
- Equivalent Protections (https://www.hhs.gov/ohrp/international/equivalent-protections/index.html)

Develop a team of experts in the U.S.

- Contact your institution IRB 1-2 years before the projected research start date for guidance and assistance in submitting IRB application for international study.
- Understand realistic timeline necessary for IRB approval, including obtaining essential documents such as letters of support and documentation to conduct research in host country.
- Create an interdisciplinary team with experts that understand the culture and your research.
- Know who to contact at your home institution while abroad if you encounter any problems or need to change your IRB-approved protocol.

Evaluate the process

- Develop and strengthen partnership synergy through trust.
- Evaluate strengths, weaknesses, and opportunities during and after the research project to identify areas of improvement.
- Include feedback from all consenting entities such as community partners, academic partners, participants, minister of health and research team.
- Ask about experience with power-sharing, co-governance, equitable partnerships, and co-constructed research or lack of within the current research project.
- Make revisions to the research process based on feedback when needed.
- Prepare documents, papers, and presentations to disseminate the study findings within host country/community.