



Contents lists available at ScienceDirect

Research in Social and Administrative Pharmacy

journal homepage: www.elsevier.com/locate/rsap

An Ethics-based Approach to Global Health Research Part 2: Strategies for Overcoming Logistic and Implementation Challenges

Stephanie Lukas^{a,*}, Susie J. Crowe^{b,1}, Miranda Law^{c,1}, Abby Kahaleh^{d,1}, Joyce Addo-Atuah^e, Nkem P. Nonyel^f, David Ombengi^g, Mudit Singhal^h, Dawood Sultanⁱ, Robert Tamukong^j^a St. Louis College of Pharmacy, 4588 Parkview Place, St. Louis, MO, 63110, USA^b Bill Gatton College of Pharmacy, Maple Avenue, Bldg. 7. Mountain Home, TN, USA^c Howard University College of Pharmacy, 2300 4th St NW, Washington, DC, 20059, USA^d Roosevelt University College of Pharmacy, 1400 N Roosevelt Blvd Schaumburg, IL, 60173, USA^e Touro College of Pharmacy, 230 W 125th Street, Room 429, New York, NY, 10027, USA^f University of Maryland Eastern Shore, School of Pharmacy and Health Professions, 1 College Backbone Road, Princess Anne, MD, 21853, USA^g Medical College of Wisconsin School of Pharmacy and Department of Family Medicine, 8701 Watertown Plank Road, Milwaukee, WI, 53226, USA^h D'Youville School of Pharmacy, 320 Porter Avenue, Buffalo, NY, 14201, USAⁱ Mercer University College of Health Professions, 3001 Mercer University Drive, Atlanta, GA, 30341-4155, USA^j Mbarara University of Science & Technology, P.O.Box 1410, Mbarara, Uganda

A B S T R A C T

With the growth of global pharmacy partnerships and collaborative research, particularly between high-income countries and low- or middle-income countries, it is necessary to establish best practices for fair and ethical collaboration and research. There is a gap in the pharmacy literature in this regard. Through this commentary, authors will present a pathway for future global health researchers including generating ideas based on mutual needs of the partnership and the community; exploring the importance of regulations including the need to conduct research and partnership projects within the confines of each participant's professional scope of practice, expertise, and licensure; describing the need to develop agreements and the components that should be included in such an agreement; discussing ethical guidelines for research planning, obtaining ethical approval, and planning for adverse events; and illustrating ethical considerations for research implementation with considerations around consent, data collection, linking patients to care after the completion of the study, and dissemination. Global examples, with a pharmacy-specific approach where applicable, within each section highlight the importance of discussion and action around ethics and equity when pursuing collaborative research, recognizing that many of these situations involve difficult decisions.

Introduction

Health inequities exist within and between countries. These disparities are perpetuated by social determinants of health rooted in socioeconomic, political, ethnic, and cultural stratifications.¹ Inequities extend into global health research as is evidenced by high-income countries (HICs) having a force of health researchers that is 73 times that of low-income countries (LICs); disparities in research funding – both in terms of who receives the funding and the mismatch between disease burden and available funding; as well as access to published results.^{2–5} When global health research is done ethically – and as part of a mutually beneficial, collaborative, trusting relationship – it can begin to bridge these divides if partners are mindful of the historical context

and the continuing power imbalances.

Pharmacists are poised to positively impact global health inequities as illustrated by the International Pharmaceutical Federation (FIP)'s oath of the pharmacist; pharmacists apply their knowledge and abilities to support the health and well-being of all served and are duty bound to address disparities.⁶ However, limited literature exists to guide collaborative global health research in the context of pharmacy partnerships. This paper provides a pathway for researchers to follow – from idea generation to implementation – as they undertake equitable, collaborative research; authors will provide recommendations and real-world examples. (see Fig. 1). This paper builds on the premise that the researcher is working as part of a mutually beneficial, mutually respectful partnership that allows each member to bring something to

* Corresponding author.

E-mail addresses: stephanie.lukas@stlcp.edu (S. Lukas), crowesj@etsu.edu (S.J. Crowe), miranda.law@howard.edu (M. Law), akahaleh@roosevelt.edu (A. Kahaleh), joyce.addo-atuah@touro.edu (J. Addo-Atuah), nnonnyel@umes.edu (N.P. Nonyel), dombengi@mcw.edu (D. Ombengi), muditm@dyc.edu (M. Singhal), sultan_dh@mercer.edu (D. Sultan), rtamukong@must.ac.ug (R. Tamukong).¹ Lead Authors.<https://doi.org/10.1016/j.sapharm.2020.07.010>

Received 17 February 2020; Received in revised form 29 June 2020; Accepted 6 July 2020

Available online 24 July 2020

1551-7411/© 2020 Elsevier Inc. All rights reserved.

the table (e.g., technical knowledge, cultural context, facilities). This relationship serves as the foundation for building ethical research agendas and implementation plans. If that partnership is still in development, refer to the principles outlined in *An Ethics-based Approach to Global Health Research Part 1: Building Partnerships in Global Health*.

Idea generation

Collaborative research aims to explore potential solutions to problems that a single institution may not be able to solve alone. Research priorities have the ability to impact future public health interventions and promote effective delivery of affordable health care.⁷ Historically, research agendas have been driven by researchers and funding agencies from HICs with little input from low- and middle-income countries (LMICs), and while there have been concerted efforts to turn this tide, the movement appears to be slow.⁸ However, decisions on global health research priorities should include considering research results' impact on improving population health, with priority given to the most disadvantaged.⁷ Considering that only 5% of resources dedicated to health research are applied to LMICs,⁹ it is imperative that collaborative research focuses on topics that may positively impact underserved populations in LMICs.

When selecting a topic for collaborative research, it is important to consider two key factors: first, the expertise available among the partnering institutions and second, the combined human and financial resources that the partnering institutions are willing to put forth for the project. Research topics should incorporate the expertise of faculty and other stakeholders from all participating institutions and should be an area that is of mutual interest, meeting the needs of all partners. In setting research priorities and agendas in a given location, consideration should be given to the funding source as well as the local and national needs and concerns. In many cases, the determination of the collaborative research project may require multiple discussions and a few months to make a final joint decision. Once mutual research interests are identified, a decision on the contribution of resources and other potential funding sources needs to be made so that planning can begin. Consider reading more on funding in *A Ethics-based approach to Global Health Research Part 3: Emphasis on Partnership Funding*.

Regulation

When considering collaborative global health research, global,

national, and local regulations related to conducting the study must be addressed. In 1948, the Constitution of the World Health Organization (WHO) defined health as a basic human right. It gave member states the responsibility to ensure the promotion and the protection of the health of their populations.¹⁰ The Universal Declaration of Human Rights by the United Nations (UN) reiterated health as a human right along with the protection of civil and economic rights for all people irrespective of their socioeconomic status or geographic locations.¹¹ Subsequently, the WHO and the UN worked in tandem to build consensus among its members to secure covenants and enact global health regulatory measures.^{12,13} The World Health Assembly and the Committee on Economic, Social and Cultural Rights created measures that can be translated into national public health policies.¹⁴ National public health regulations are then used to formulate and ideally actively implement public health policies to address current and emerging health issues and promote population health worldwide.^{15–18} Global frameworks, such as the Sustainable Development Goals, and the correlating national frameworks can be used to chart a path for researchers on health priorities and potential areas for further research.¹⁹

Despite concerted efforts by global agencies to promote health as a fundamental human right and to ratify regulations to reduce disparities, the attainment of an adequate level of health still remains challenging. Communities worldwide still struggle with safe and potable water, sanitation, food, housing, health-related information and education, and gender equality. This is partially due to significant inequalities in geopolitical and economic powers, social histories, and technical capacities between HICs and LMICs. Also, despite good intentions to improve global health, universal enforcement of global public health laws faces significant barriers in part because global health regulations are not an organized legal system or a universally sanctioned defined body of law. They are simply legal norms, processes, and institutions that are designed primarily to promote attainment of the highest possible standard of physical and mental health for the world's population.²⁰ While keeping this global perspective in mind, it is important that researchers also consider the national and local laws, regulations, and policies in place in the areas where the research will be conducted. Conducting collaborative research with local partners and regularly communicating with local stakeholders will assist researchers in navigating these frameworks and complying with local laws. Those laws and policies may include licensure or registration, medication procurement laws and regulations if working in government facilities, dispensing and controlled substance laws, and Good Manufacturing Policies, as well as

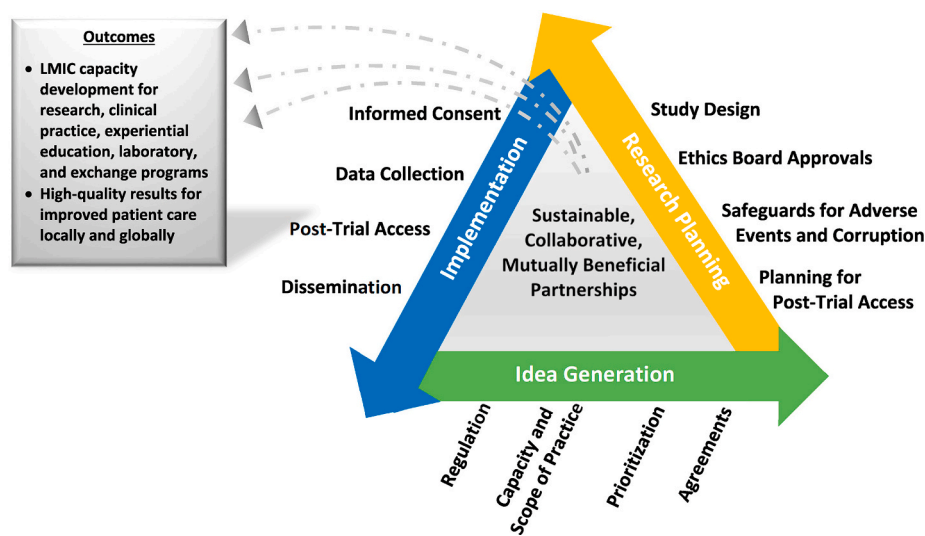


Fig. 1. Pathway for Sustainable, Mutually Beneficial Global Health Research

[Caption: A solid partnership is the core of high-quality global health research. Together, researcher partners move through the process of generating ideas, planning the study and implementing the research. This process is not linear but rather interlinking and ideally continuous.

working within national formularies and treatment guidelines. Although outside the scope of this paper, an additional consideration for researchers is to review visa regulations in all countries where they may travel.

Research capacity and scope of practice

As collaborative research topics are determined, specific attention should be paid to the research skills, capacity, and scope of pharmacy practice of all individuals involved. If there is a clinical component to the research, then individuals from different countries may expect the scope of pharmacy practice to be similar in their partner country, but this is often not the case. Countries in which pharmacists have advanced clinical roles may allow pharmacists to prescribe some medications and provide routine vaccinations without the need for authorization from a licensed physician,^{21,22} while pharmacists in other countries may be more focused on product and supply chain management.²³ Perceptions or misunderstanding of clinical abilities of pharmacists from these backgrounds, as well as limited human resources in LMICs, may place pharmacists in a position to practice beyond their scope in LMICs when asked or if an emergency need arises.

An understanding of the scope of pharmacists' practice at each partner institution can avoid the development of collaborative research that extends beyond the scope of practice of those involved. In a clinical setting, practicing outside of one's scope can have negative consequences for patients, providers, and the health system overall. As Hunt et al. describes, this is especially challenging at the boundaries of one's scope where limits in resources and options may force practitioners to make life or death moral decisions in high-stakes cases. In lower-stakes cases, practitioners may find that activities on the fringe of their scope become integrated into their work without discussion.²⁴ Without being familiar with the context in which they are practicing, practitioners may misdiagnose or inappropriately treat patients²⁵ or expose them to products that can be harmful if not used properly.²⁶ If medications or devices not available in the LMIC are introduced, it may make followup difficult or even potentially unmanageable.²⁵ This implication puts pressure on the LMIC healthcare system, which may also be eroded if patients feel the HIC providers are more competent, leading to distrust or non-reliance on the local health systems.²⁵ The pressure to practice outside of one's scope can also lead to emotional and moral distress for practitioners, making it important to both prepare and debrief providers. Partnerships can help to navigate these challenges.²³ Additionally, regardless of the type of research, safeguards must be put in place to ensure appropriate supervision so that when researchers are requested to practice outside their scope,²⁷ they know how to triage questions or requests to more appropriate personnel. Supervision and guidance from health care researchers local to the research institution can often be helpful and prevent foreign researchers from feeling like they must extend beyond their scope of practice in emergency or limited-resource situations.

Researchers and any trainees should ensure they operate within the parameters of their education and training because operating outside their scope can lead to suboptimal care of patients or even negative clinical outcomes.²⁸ A survey assessing health professionals and trainees from HICs who worked or volunteered in LMICs showed that 49% of respondents were asked to perform outside their scope of practice while overseas, and of those, the majority agreed to do so.²⁷ Common reasons reported for practicing outside the individuals' scope of practice included a mismatch of expectations, suboptimal supervision, inadequate preparation to decline the request, and a perceived absence of alternative options.²⁷ Approaching research from an interprofessional standpoint may also be helpful in alleviating discrepancies in the scope of practice. Incorporating other health care professions such as physicians, nurses, social workers, and community health workers into the research team will bring additional expertise to the project and allow pharmacists to focus on their research roles within the interprofessional

team. Additionally, health care professionals practicing and conducting research in a foreign country should consider obtaining overseas liability insurance or working with the local partner institution to determine if their liability insurance can cover foreign partners. If it can, it is important that a partnership agreement includes a clause extending the liability insurance.²⁹

Efforts have been made over the past two decades to strengthen the research capacity of LMICs through a variety of modalities, recognizing the value and impact this strengthening can have on advancing health and development of health care.³⁰ It could be argued that collaborations or partnerships between HICs and LMICs are inherently unequal. To reduce this possibility, every effort should be made to reach an equal sharing of the benefits of research.³¹ Partnerships between HICs and LMICs should consider the impact of the partnership on capacity development and how research activities can not only include the expertise of those involved but also build upon already existent skills. Thought should be given to any needs in providing and using laboratory or technical equipment and the ability for researchers in LMICs to both accommodate such equipment and have the skills to utilize it.³²

Quality improvement versus research

Decisions on what projects to pursue should ensure each partner understands the differences between pursuing quality improvement (QI) initiatives and research initiatives, and how each impacts outcomes. QI often focuses on pre-established programs and makes an effort to monitor and evaluate a process that could be advanced or improved. These projects may undergo cycles of testing to make incremental changes to develop a sound, sustainable program. Additionally, although QI projects may not always benefit the end users, they are more often than not of very low-risk potential. Ultimately, the goal of a QI project is to benefit or improve a process, program, or system, and not necessarily to generate new knowledge. Research is distinct from QI as it aims to test a hypothesis, answer a question, or establish a new clinical practice standard. Research is designed to contribute to generalizable knowledge and may place research participants at risk. Research often follows a systematic data collection that undergoes statistical analysis to provide new answers and knowledge.³³ Understanding the difference between QI and research will aid in the planning and execution of the interventions. However, regardless of which is pursued, it is important to ensure that the host community benefits from the outcomes.

Irrespective of whether a project is a QI initiative or a research study, all collaborators should consider institutional review board (IRB)/ethics board approval to protect human subjects prior to starting the project (and should undertake this process in each country, as described later). Research generally requires pre-approval of the project before commencing. Within QI projects, it may be determined that pre-approval is not necessary to begin the project and would only be pursued if there is interest in publishing the project findings. Pharmacists are well-positioned in many health systems to become involved in QI projects that could lead to published results. If a team is starting a new QI project and is considering publication, it should reach out to the ethics board prior to starting to determine if ethics approval is needed; if a review is not needed, the ethics boards will often provide a letter of exemption that can be submitted to journals. HIC and LMIC partnerships seeking to advance pharmacy practice could focus on QI projects in health information technology (i.e., establishing electronic health records, advancing medication administration techniques, etc.) or improved processes to prevent medication errors.³⁴ These projects would include pharmacists from all partnering institutions to provide both the technical expertise as well as knowledge of the local health care system.

Agreements

Execution of a Memorandum of Understanding (MOU) or a

Memorandum of Agreement (MOA) is an important step to complete before embarking on a collaborative project. We define an MOU/MOA as an agreement between the two parties. In some instances, an MOU or MOA is insufficient and would require additional contracts/documents³⁵; however, this can be variable depending on each institution's requirements. MOUs/MOAs establish working guidelines that all partners agree to abide by and often aid in ensuring that all partners understand the goals and aims of the partnership. MOUs/MOAs often delineate, but are not limited to, the scope of the cooperation, general areas of cooperation, intellectual/technical property rights including data ownership, renewal/termination/amendments, and signatories. Additional sections or even addendum documents can be added depending on what each partnering institution desires and may include agreements on the division of costs and benefits.

In some cases, institutions may already have draft templates of MOUs/MOAs developed that can be utilized to expedite the drafting process. In general, one of the partners will offer to develop or provide a draft MOU/MOA for the other party or parties to review. If edits are desired by the reviewing party, they are made and sent back for the initiating party to accept or continue editing. The time it takes to complete the review and editing process can be variable depending on how many iterations of editing the document are required and can vary from a few weeks to a few months. In addition, it is recommended that each institution's legal department be involved in reviewing the MOU/MOA to ensure that the terms delineated are in the institution's best interests.³⁶ In doing so, collaborators should be aware of each partner's legal contract capacity and understand that not all institutions have formal processes or personnel in place to evaluate legal contracts. Special consideration should be made to ensure the agreement is fair for all parties and that any lack of legal capacity does not adversely impact the LMIC partner. TRUST and the Council on Health Research for Development offer resources and a toolkit through Fair Research Contracting, which could be a starting point.³⁷ Once both parties are comfortable with the content of the MOU/MOA, each party's signatory signs and the MOU or MOA is executed.

If not done as part of the MOU/MOA, the next steps is to set expectations for contribution to the project prior to and during the research and authorship for any resulting publications. This is an opportunity for each collaborator to indicate their interest in the project and what roles they would like to contribute to. This step is vital to ensure that all involved in the partnership understand their roles to avoid any confusion that could result in a future conflict. The identified project lead(s) should ensure that each collaborator's role(s) are clear and understood and indicate where their name would likely be placed in authorship order when/if publications are created and submitted. Discussions should include clear expectations on what authorship entails to eliminate confusion around the expected contribution of each person involved. At the same time, leads should also discuss the process(es) and implications on authorship for researchers who do not contribute as expected and the process for dissolution of the project or partnership. Ensuring open communication early and throughout this process helps to avoid conflict within the partnership after the project is implemented, protecting the established relationship.

Research planning

Once a clear research idea has been generated, the team should begin designing the research study in a way that ensures the development is collaborative and all voices are heard. This step may overlap with the crafting of the agreements outlined above, especially in relation to roles and expectations. Similar to collaboration in idea generation, when undertaking research in global settings, there is a tendency for HIC partners and funders to dictate the research agenda to local researchers and practitioners.³⁸ These actions may lead to LMIC researchers acting in a supportive role rather than an integral part of the research design team. For example, Bishoff found the majority of research papers

produced in Central Africa were produced with a foreign partner and with inequities. While the HIC partner designed the studies, the African partners were often left to provide samples and conduct fieldwork.³⁹ This imbalance of power may adversely affect the local research partners' development, the research participants and the results, especially if local and cultural contexts are not taken into consideration. Researchers should also consider working with an advisory committee of stakeholders. Adding a member of the local community to the team during the early stages of research design is seldom done in global health but may prove beneficial for the health and wellbeing of participants and their local community especially when working with vulnerable populations who often receive little direct benefit from the research in which they participate.⁴⁰

Ethics board approval

Global health researchers must be cognizant while designing their study to ensure that research participants will be protected during all phases of the study and through the dissemination of results. The global requirement for ethical approval of research studies – no matter where they are conducted – is to ensure that research subjects have privacy and decision-making autonomy while being protected from the following three cases: (1) unnecessary exposure to harmful procedures and/or health technologies including pharmaceuticals for which there might not be any immediate local need, (2) undue coercion with excessive incentives taking advantage of participants' low socioeconomic status and inequities in access to care outside of a research setting, and (3) threats of withholding treatment or care because of participant refusal.⁴¹

In taking steps to ensure that human research subjects are protected from unintended harm, ethics board approval must be obtained not only through the HIC but also in the LMIC. Each researcher should identify the most appropriate ethics review board for their institution, whether an academic, hospital, or private institution committee or one at a regional or national level.^{42,43} Researchers must follow the rules and regulations set out by the ethics boards to ensure they are addressing both international and local ethical standards.

Ethics boards are faced with various challenges for both the HIC and the LMIC. HIC IRBs often struggle with the context in the international location, difficulty understanding the local health systems and the risks and benefits from the local perspective, as well as the long-standing corruption present in some settings.⁴⁴ For example, HIC IRBs may not fully understand the impact of inequities in access to healthcare and how that impacts the vulnerability of research participants who may join a study simply because they have few other options to access care.⁴⁵ Some LMIC institutions do not have an ethics review board, and those that do may be slow to progress due to infrequent meetings, workload, training, and/or technology. Unfortunately, those who do not have an ethics board available may not be a candidate for collaborative research unless one can be established. However, research that is conducted as part of mutually beneficial partnerships may provide an opportunity for the support, training, and development of a local IRB as part of the partnership. Ultimately, the ethics board in the implementation country should serve as the lead; however, if the research collaborators are able to connect their ethics boards, the committees may also benefit from collaboration potentially leading to a streamlined process and capacity building on the part of both boards.⁴⁶

Planning for adverse events

With pharmacy-related research, occasionally, patients may experience adverse events or other negative consequences as a result of the study intervention. Some events may be serious and require chronic management extending beyond the end of the study. The identification of such events may also extend beyond the study. Regardless of when identified, researchers are ethically responsible for assuring that the participant receives the necessary medical treatment to manage these

types of events.^{47,48}

Researchers should plan for potential adverse events and should carefully consider the financial implications and responsible parties.⁴⁷ Ambiguity may arise and may be impacted by power dynamics, especially if researchers from HICs fail to question their own authority. Therefore, it is important that discussions occur and plans are in place prior to implementing the research study.⁴⁹ The plan for adverse events, including deaths, should also include reporting in a timely manner to all study investigators, the institution where the study is conducted, and the relevant ethics boards.^{50,51}

Planning for post-trial access

The ultimate goal of research in any setting should be to benefit the population being studied; however, this is not always the case in LMICs.^{47,52,53} For example, several studies conducted in Vietnam, Thailand, and South Africa have evaluated the use of flucytosine in combination with amphotericin B for cryptococcal meningitis.⁵⁴ However, apart from the study, flucytosine has limited to no availability in many parts of Asia or Africa.⁵⁵ Working to increase the availability of the drug so that the general population benefits from the results of these studies is an important, ethical step in the research process.

It is vital that researchers plan for post-trial access and benefits for participants of studies where patient care or medications have been provided. Moreover, it is critical for researchers to consider the availability of sustainable and affordable long-term treatment options for the study participants.⁴⁷ A controversial addition to the 2004 revision of the Declaration of Helsinki included the responsibility of sponsors, researchers, and host country governments to plan for “post-trial access by study participants to prophylactic, diagnostic and therapeutic procedures identified as beneficial in the study or access to other appropriate care.”^{45,56,57}

However, this issue becomes more complex as researchers consider studies that involve phase I or phase II trials that may not lead to the development of a viable medication.⁴⁵ It is vital that these participants and their communities still benefit from the research. Some of the benefits may be product-based, such as the provision of vaccinations or diagnostic tests, while other potential benefits might be collateral, including employment, training of healthcare or research personnel, and public health or clinical services.⁵⁸ The WHO also provides some guidance on these ethical issues and includes presenting research findings to local health officials and advocating for improvements.⁴⁷

Implementation

Once researchers have received ethics approval, the implementation phase begins. There is a critical need for sound ethics during the implementation of global health research as studies often include vulnerable populations, and participants may have language barriers, cultural differences, and low health literacy. While conducting research, using appropriate study design and data collection methodologies is vital for obtaining quality data, and data analysis must be done appropriately prior to dissemination; however, specific principles of research design and analysis are outside of the scope of this paper. There are numerous resources available on these topics. The World Health Organization, for example, provides data collection tools as well as tools for data analysis.⁵⁹ As the study is carried out, it is important that researchers refer back to and implement their plans for addressing adverse events and post-trial access.

The impact of corruption

Corruption is endemic in many LMICs and can be a barrier to research approval and implementation.^{44,60} Corruption can take many forms, including fraud, theft, bribery, and improper use of funds.⁶⁰ From a workload perspective, absenteeism is a common form of corruption. In

settings where incomes are low, it is common for employees – including healthcare professionals – to hold multiple positions with overlapping hours, missing work by splitting their time, while collecting full compensation at all positions.⁶⁰ This can lead to tension if researchers employ a worker who is used to this system but is expected to function otherwise. Corruption also occurs when study participants have been asked to pay unauthorized fees to be enrolled in the study or receive treatment.^{60,61}

From a researcher’s perspective, teams may face the theft of study materials, such as drugs or laboratory supplies, as well as embezzlement of study funding.⁶⁰ Pharmacists or those who order medications on behalf of the study may be influenced by kickbacks from manufacturers, which could lead to purchasing medications of lower quality or inflated prices.⁴⁴ Careful accounting and regular auditing is necessary to reduce corruption from occurring and impacting research. Finally, counterfeit and substandard medications flood the markets in many LMICs, which may lead to unexpected research outcomes if researchers distribute these medications.⁶² While research teams may be vigilant in procurement of quality study medications, if patients use other medications outside of the study protocol itself, counterfeit and substandard medications may ultimately have an impact on research results depending on the nature of the research study.

Autonomy, enrollment, and informed consent

After receiving ethics approval from all necessary review boards, enrollment of study participants and data collection can begin. There are a number of ethical principles to consider during the enrollment phase of a study. One major ethical principle mentioned in the Belmont Report is the principle of autonomy, which requires both the protection of the rights and privacy of study participants through the informed consent process and the need to educate participants on their right to withdraw consent at any time.⁴¹ Autonomy involves study participants receiving information and then making decisions based on the participant’s understanding of the information given. One way this autonomy can be violated is in the instance where researchers may not appropriately disclose themselves as researchers. There are numerous examples where this has occurred. In 1974, a famous study was published by Laud Humphreys where Humphreys did not disclose himself as a researcher while observing homosexual encounters in public bathrooms.⁶³ Another violation of participant autonomy is a therapeutic misconception, or the instance where researchers have not appropriately disclosed their work as research. This may lead participants to believe they are receiving standard medical care.⁶⁴ While the goal for standard medical care involves the provision of the best possible care for a specific patient, the goal of research is to gain new information that may inform future disease management for similar patients. Individuals holding therapeutic misconception beliefs about the study may consent to participate without having a true understanding. Various studies have shown that more than half of study participants held misconceptions about study randomization, thinking they are being treated based on their medical needs and not realizing that some study participants may receive a placebo.⁶⁵ Although there is a limited representation of LMIC settings in literature, it is reasonable to expect the same or greater risk for therapeutic misconception in LMIC study participants.⁶⁶ Therefore, being clear about the design and goals of the study as well as assessing participant understanding can help combat this issue.⁶⁴

Researchers must also be aware that study participant autonomy can be affected by cultural differences between researchers and study subjects. Important cultural differences may include beliefs about health care and illness in general, beliefs about gender, and the role of the community in health care. In some cases, local community leaders may give consent for research participation for the entire community, or females in certain cultures may also require a male authority figure’s consent prior to participating in research and may need to be interviewed, examined, or evaluated by female researchers and vice versa for

male research subjects.⁶⁷ Researchers should, therefore, take careful steps to ensure that the correct ethical procedures are always adhered to, including voluntary informed consent of research subjects, before study participation.⁶⁸ This demonstrates the need for local partners to be part of the research as they are the experts of their culture.

The stigma within some cultures surrounding various diseases, such as HIV, can also greatly increase the need for patient privacy. One way to address stigma is by working closely with local health care providers that have pre-established relationships with patients. For example, researchers in one study in Ghana utilized HIV adherence counselors, pharmacists, nurses, doctors, and HIV peer counselors to serve as facilitators during research implementation.⁶⁹ This study highlighted the importance of listening to the advice and local wisdom of these trusted healthcare professionals concerning how to deal with potential study participants and not to jeopardize their hard-earned trust by ignoring their insights.⁶⁹

Low health literacy or language barriers can also affect participant autonomy.^{32,70} One small study examined research participant understanding of informed consent in a LMIC setting and found that only 20% of participants understood the consent form after the standard consent process. However, when given more time to understand through informational meetings utilizing visual aids, meeting with a counselor, and then meeting with the study investigator, the understanding of informed consent increased to 80%.⁷¹ Similar to low health literacy, language barriers may also significantly impact the efficiency of interactions with study participants, resulting in increased time needed for individual interactions and translators.

One method of combating many of these challenges is using the teach-back method during the consenting process. This involves discussing important study information with the potential participant during the consenting process and then assessing understanding by asking them to describe the information back to the researcher using their own words.^{70,72} Another method that may be useful is the teach-to-goal method, where potential study participants are given important information about the study and then asked a series of questions to assess understanding of study details. Any deficiencies in understanding are followed up with the requisite study related information until the appropriate level of understanding is reached.^{70,73} Translating informed consent forms into the local language is an ethically appropriate practice. That said, even translated forms may pose some challenges for research participants if unfamiliar terminology is used or if the participants with low health literacy have a limited understanding of the health concepts involved. For example, one study conducted in northern Ethiopia discovered that many details of a Human Papilloma Virus study protocol were poorly understood, such as obtaining vaginal specimens, blood samples, as well as the concept of the term cancer.⁷⁴ In addition, participants in this study population preferred verbal over written consent; one reason was that study participants associated signing a consent form with other binding legal agreements in the local culture. This study concluded that, because of this association, having a consent form that requires a signature may prevent people from openly sharing needed information in the study.⁷⁴

Data collection

Prior to coming into contact with study participants or collecting data, it is important, and often required by ethics boards, for all researchers from both LMIC and HIC settings as well as any student researchers to undergo human subjects training, which typically includes historical perspectives, ethical principles, and regulatory and guidance information.⁷⁵ Ethics review boards or academic institutions may have specific approval processes for involving students in researchers as either participants or research assistants. Once trained from an ethics perspective, all researchers and data collectors should be trained on the tool or technique they will be using. A challenge in LMICs is healthcare providers are not often trained in data science.⁷⁶ Often research studies

in LMIC settings utilize local study sponsors to manage and collect data. Therefore, it is important for these individuals to be fully aware of the study protocol and when to communicate information, such as adverse effects, with the study's primary investigators or their designee. All members of the research team, as well as the IRB, should be made immediately aware of any deviations from the study protocol that occurred as a result of the potential hazard to participants.⁵¹

Translators are often an integral part of global health research, be it translating tools or interacting directly with participants. They must be well-trained in translating complex research and medical terms. For example, in one participant-researcher adverse drug reaction counseling session, researchers identified that participants did not clearly understand the translated version of the information. The reason for the misunderstanding may have been due to the information being lost during translation or due to the participant's lack of knowledge in basic human physiology.⁶⁵

Maintaining trial documentation and confidentiality of data can be especially challenging in a global health setting. According to the Good Clinical Practice Guidelines, proper expertise is required of any individual that manages and/or authenticates data.⁵⁰ Any confidential materials or data in paper form should be in a safe, lockbox, cabinet, drawer or the like. This may mean providing locks or locksmith services to the clinic or other research settings. All electronic data should be stored in an encrypted, password-protected file or database. Researchers should consider working with their IT departments to ensure secure transmission of data among researchers in different settings. Challenges with electronic systems in LMICs include power surges, power outages, and computer viruses, so laptops, tablets, and external harddrives should regularly be backed up and stored in a secure, locked location.

Dissemination

While there are risks for study participants and their communities when participating in research, dissemination of results is an opportunity for communities to benefit from the findings. Dissemination is an important component of continued relationship building with research participants, local communities, and collaborators.⁷⁷ Sharing research findings prior to publication may also serve as a checkpoint to confirm the validity of findings.⁷⁸ Often the LMIC partner is able to identify the most effective and accepted way to distribute findings. Researchers could consider presenting at study sites such as at hospital staff meetings or conferences, distributing research summaries translated into the local language, or holding open community meetings that could include research participants and their support systems.^{77,78}

When preparing to publish the results of a study, assigning authorship holds importance for all because of the potential impact on finances and career advancement for individual authors. There are a number of ethical considerations when assigning authorship, which may be influenced by power differences between the HIC and LMIC partner. One author describes this through a case study where researchers conducting a study in a foreign area assigned the primary investigator role to a qualified in-country researcher who carried out all of the operational tasks of the study from IRB approval through collecting study data. However, this primary investigator was not included in writing the study manuscript, and, although included as an author, was overlooked when assigning the order of authorship on the publication.⁷⁹ Language barriers may also prevent LMIC partners from contributing to the written manuscript, which may lead to lack of recognition of his or her contributions to the research through authorship.⁸⁰ Partners should refer back to the agreements put in place prior to implementing the study to ensure authorship conforms to the guidelines. Unfortunately, editor biases about authors and publications originating from LMICs may lead to LMIC partners deferring more prestigious authorship rankings to the HIC partner.⁸⁰ As a result of these challenges, heightened awareness is needed surrounding the issue of authorship in global health settings, as is more research on assigning authorship.⁸⁰ More can be found on this

topic in *An Ethics-based Approach to Global Health Research Part 4: Scholarship and Publications*.

Conclusion

It is imperative that global health researchers are led by ethical principles and regulations that govern and prioritize the protection of human subjects in research. Researchers should be knowledgeable of the socioeconomic, political, ethnic, and cultural inequalities between HICs and LMICs. When researchers follow the roadmap outlined in this article, stronger bidirectional global health partnerships can be built. This levels the playing field, generating higher quality research results and ultimately will advancing patient care locally and public health globally.

References

- Marmot M. Achieving health equity: from root causes to fair outcomes. *Lancet*. 2007; 370(9593):1153–1163.
- World Health Organization, Global Observatory on Health R&D. Health researchers (in full-time equivalent) per million inhabitants, by income group (second set of charts). Published January https://www.who.int/research-observatory/benchmarking/researchers_income/en; 2020. Accessed February 10, 2020.
- World Health Organization, Global Observatory on Health R&D. About the global observatory on health R&D. https://www.who.int/research-observatory/why_what_how/en/. Accessed February 10, 2020.
- Cash-Gibson L, Rojas-Gualdrón D, Pericás JM, Benach J. Inequalities in global health inequalities research: a 50-year bibliometric analysis (1966–2015). *PloS One*. 13(1): e0191901. <https://doi.org/10.1371/journal.pone.0191901>.
- Vidyasagar D. Global notes: the 10/90 gap disparities in global health research. *J Parinatal*. 2005;55–56, 2006.
- The Pharmaceutical Journal. FIP adopts model oath for pharmacists. Published <https://www.pharmaceutical-journal.com/news-and-analysis/news-in-brief/fip-adopts-model-oath-for-pharmacists/20066399.fullarticle?firstPass=false>; 2014. Accessed February 13, 2020.
- Pratt B, Sheehan M, Barsdorf N, Hyder AA. Exploring the ethics of global health research priority-setting. *BMC Med Ethics*. 2018;19(1):94.
- Franzen SR, Chandler C, Lang T. Health research capacity development in low and middle income countries: reality or rhetoric? A systematic meta-narrative review of the qualitative literature. *BMJ Open*. 2017;7(1), e012332. <https://doi.org/10.1136/bmjopen-2016-012332>. Published 2017 Jan 27.
- Commission on Health Research for Development. *Health Research: Essential Link to Equity in Development*. Oxford: Commission on Health Research for Development; 1990. http://www.cohred.org/downloads/open_archive/ComReports_0.pdf. Accessed January 29, 2020.
- World Health Organization. WHO Constitution (1946): human rights and health. <http://www.who.int/news-room/fact-sheets/detail/human-rights-and-health>. Accessed August 27, 2019.
- Lahti R, Eide A. *Article 11: The Universal Declaration of Human Rights. Commentary*. Oxford: Scandinavian University Press; 1992. Available at: <https://researchportal.helsinki.fi/en/publications/article-11-the-universal-declaration-of-human-rights-a-commentary>.
- World Health Organization. Commission on Social Determinants of Health. Closing the gap in a generation: health equity through action on the social determinants of health. Accessed https://www.who.int/social_determinants/final_report/csdh_finalreport_2008.pdf; 2008. Accessed February 17, 2020.
- World Health Organization. *International Health Regulations*. third ed. Geneva, Switzerland: WHO Press; 2005. <https://www.who.int/ihr/publications/9789241596664/en/>. Accessed February 17, 2020.
- United Nations, Office of the High Commissioner for Human Rights. International covenant on economic, social and cultural rights. Available at: <https://www.ohchr.org/Documents/ProfessionalInterest/cescr.pdf>; 1966.
- United Nations, Office of the High Commissioner for Human Rights. International convention on the elimination of all forms of racial discrimination. Available at: <http://www.ohchr.org/Documents/ProfessionalInterest/cerd.pdf>; 1965.
- United Nations, Office of the High Commissioner for Human Rights. International covenant on economic, social and cultural rights. Available at: <https://www.ohchr.org/Documents/ProfessionalInterest/cescr.pdf>; 1966.
- United Nations, Office of the High Commissioner for Human Rights. Convention on the rights of the child. Available at: <https://www.ohchr.org/Documents/ProfessionalInterest/crc.pdf>; 1989.
- United Nations, Office of the High Commissioner for Human Rights. Vienna declaration and programme of action. Available at: <https://www.ohchr.org/Documents/ProfessionalInterest/vienna.pdf>; 1993.
- United Nations. The sustainable development goals report. Published 2019 <https://unstats.un.org/sdgs/report/2019/The-Sustainable-Development-Goals-Report-2019.pdf>; 2019.
- Gostin LO. *Global Health Law*. Cambridge, MA: Harvard University Press; 2014.
- Faruquee CF, Guirguis LM. A scoping review of research on the prescribing practice of Canadian pharmacists. *Can Pharm J*. 2015;148(6):325–348.
- American Society of Health-System Pharmacists. ASHP guidelines on the pharmacist's role in immunization. *Am J Health Syst Pharm*. 2003;60:1371–1377.
- Crowe SJ, Karwa R, Schellhase EM, et al. American College of Clinical Pharmacy Global Health Practice and Research Networks opinion paper: pillars for global health engagement and key engagement strategies for pharmacists. *Journal of the American College of Clinical Pharmacy*. 2020. <https://doi.org/10.1002/jac5.1232>.
- Hunt MR, Schwartz L, Fraser V. "How far do you go and where are the issues surrounding that?" Dilemmas at the boundaries of clinical competency in humanitarian health work. *Prehospital Disaster Med*. 2013;28(5):502. <http://search.ebscohost.com/login.aspx?direct=true&db=edo&AN=ejs13205203&site=eds-live&scope=site>. Accessed June 6, 2020.
- Asgary R, Junck E. New trends of short-term humanitarian medical volunteerism: professional and ethical considerations. *J Med Ethics*. 2013;39(10):625–631.
- Berry NS. Did we do good? NGOs, conflicts of interest and the evaluation of short-term medical missions in Sololá, Guatemala. *Soc Sci Med*. 2014;120:344–351. <https://doi.org/10.1016/j.socscimed.2014.05.006>.
- Doobay-Persaud A, Evert J, DeCamp M, et al. Practising beyond one's scope while working abroad. *Lancet Global Health*. 2019;7(8):e1009–e1010.
- Jacobs J, Naro G. Who is served best by health professions service learning trips? *AMA J Ethics*. 2019;21(9):E715–E721.
- Hudspeth JC, Rabin TL, Dreiffuss BA, et al. Reconfiguring a one-way street: a position paper on why and how to improve equity in global physician training. *Acad Med*. 2019;94(4):482–489.
- Franzen SRP, Chandler C, Lang T. Health research capacity development in low and middle income countries: reality or rhetoric? A systematic meta-narrative review of the qualitative literature. *BMJ Open*. 2017;7(1), e012332.
- Aellah G, Chantler T, Geissler PW. Whose capacity? Collaboration through capacity building. In: *Global Health Research in an Unequal World*. Oxfordshire, UK: CAB International; 2016.
- Ravinetto R, Tinto H, Diro E, et al. It is time to revise the international Good Clinical Practices guidelines: recommendations from non-commercial North-South collaborative trials. *BMJ Glob Health*. 2016;1(3), e000122.
- Government of Western Australia Department of Health. Quality improvement activities. Published https://ww2.health.wa.gov.au/-/media/Files/Corporate/general_documents/SMHS/PDF/Research/Quality-Improvement-vs-Research.pdf; 2017. Accessed November 8, 2019.
- American Society of Health System Pharmacists. The pharmacist's role in quality improvement. <https://www.ashp.org/-/media/assets/pharmacy-practice/resource-centers/leadership/leadership-of-profession-pharmacists-role-quality-improvement-guide>. Accessed February 5, 2020.
- US Department of Veterans Affairs. Partnerships and memoranda of agreement/understanding. https://www.benefits.va.gov/WARMS/docs/admin28/M28R/Part1/SectionA_Chapter3.pdf; 2012. Accessed February 17, 2020.
- Marais D, Toohey J, Edwards D, Ijsselmuiden C. Where there is no lawyer: guidance for fairer contract negotiation in collaborative research. <https://www.cohred.org/wp-content/uploads/2012/04/Fair-Research-Contracting-Guidance-Booklet-e-version.pdf>; 2013. Accessed February 5, 2020.
- Fair Research Contracting. FRC toolkit. Available at: <https://frcweb.cohred.org/abouut/>. June 12 2020.
- Parker M, Kingori P. Good and bad research collaborations: researchers' views on science and ethics in global health research. *PloS One*. 2016;11(10), e0163579. <https://doi.org/10.1371/journal.pone.0163579>.
- Boshoff N. Neo-colonialism and research collaboration in central Africa. *Scientometrics*. 2009;81(413). <https://doi.org/10.1007/s11192-008-2211-8>.
- B Benatar SR, Singer PA. Responsibilities in international research: a new look revisited. *J Med Ethics*. 2010;36(4):194–197.
- National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont report: ethical principles and guidelines for the protection of human subjects of research. <https://www.hhs.gov/ohrp/sites/default/files/the-belmont-report-508c-FINAL.pdf>. Accessed October 15, 2019.
- World Health Organization. Global health ethics key issues: global network of WHO collaborating centres for bioethics. Published May 2015 <https://apps.who.int/iris/handle/10665/16457>. Accessed February 14, 2020.
- Loewen P. Ethical issues in pharmacy practice research: an introductory guide. *Can J Hosp Pharm*. 2014;67(2):133–137. <https://doi.org/10.4212/cjhp.v67i2.1341>.
- Klitzman RL. US IRBs confronting research in the developing world. *Develop World Bioeth*. 2012;12(2):63–73. <https://doi.org/10.1111/j.1471-8847.2012.00324.x>.
- Andanda P, Wathuta J. Human dignity as a basis for providing post-trial access to healthcare for research participants: a South African perspective. *Med Healthc Philos*. 2018;21(1):139–155. <https://doi.org/10.1007/s11019-017-9782-1>.
- Ng LC, Hanlon C, Yimer G, Henderson DC, Fekadu A. Ethics in global health research: the need for balance. *Lancet Glob Health*. 2015;3(9). [https://doi.org/10.1016/S2214-109X\(15\)00095-9](https://doi.org/10.1016/S2214-109X(15)00095-9). e516–e517.
- Willis L. Nuffield Council on bioethics. The ethics of research related to healthcare in developing countries. *Med Conflict Surviv*. 2003;19(1):74.
- Council for International Organizations of Medical Sciences. International ethical guidelines for epidemiological studies. https://cioms.ch/wp-content/uploads/2017/01/International_Ethical_Guidelines_LR.pdf; 2009. Accessed February 17, 2020.
- Addiss DG, Amon JJ. Apology and unintended harm in global health. *Health Hum Rights*. 2019;21(1):19–32.
- Center for Drug Evaluation and Research. E6(R2) good clinical practice: integrated addendum to ICH E6 U.S. Food and drug administration. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/e6r2-good-clinical-practice-integrated-addendum-ich-e6r1>. Accessed February 17, 2020.

51. *Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants*. World Health Organization; 2012. Published <https://www.who.int/ethics/publications/9789241502948/en/>. February 17, 2020.
52. Guidelines for good clinical practice (GCP) for trials on pharmaceutical products. Accessed <http://apps.who.int/medicinedocs/pdf/whozip13e/whozip13e.pdf>. Accessed February 16, 2020.
53. World Medical Association. Declaration of Helsinki, 2000 <https://www.wma.net/what-we-do/medical-ethics/declaration-of-helsinki/doh-oct2000/>; 2000. Accessed February 17, 2020.
54. Yao ZW, Lu X, Shen C, Lin DF. Comparison of flucytosine and fluconazole combined with amphotericin B for the treatment of HIV-associated cryptococcal meningitis: a systematic review and meta-analysis. *Eur J Clin Microbiol Infect Dis*. 2014;33(8):1339–1344. <https://doi.org/10.1007/s10096-014-2074-2>.
55. Loyse A, Dromer F, Day J, Lortholary O, Harrison TS. Flucytosine and cryptococcosis: time to urgently address the worldwide accessibility of a 50-year-old antifungal. *J Antimicrob Chemother*. 2013;68(11):2435–2444. <https://doi.org/10.1093/jac/dkt221>.
56. World Medical Association. Declaration of Helsinki. Available at: <https://www.wma.net/what-we-do/medical-ethics/declaration-of-helsinki/doh-oct2004/>. Accessed June 12, 2020. June 1964.
57. Carlson RV, Boyd KM, Webb DJ. The revision of the Declaration of Helsinki: past, present and future. *Br J Clin Pharmacol*. 2004;57(6):695–713. <https://doi.org/10.1111/j.1365-2125.2004.02103.x>.
58. Nwabueze RN. *Legal and ethical regulation of biomedical research in developing countries*. 2016. <https://doi.org/10.4324/9781315591971>.
59. World Health Organization. Health statistics and information systems. https://www.who.int/healthinfo/tools_data_collection/en/. Accessed February 17, 2020.
60. García PJ. Corruption in global health: the open secret. *Lancet*. 2019;394(10214):2119–2124. [https://doi.org/10.1016/S0140-6736\(19\)32527-9](https://doi.org/10.1016/S0140-6736(19)32527-9).
61. Cherecheș RM, Ungureanu MI, Sandu P, Rus IA. Defining informal payments in healthcare: a systematic review. *Health Pol*. 2013;110(2-3):105–114. <https://doi.org/10.1016/j.healthpol.2013.01.010>.
62. Nayyar GML, Attaran A, Clark JP, et al. Responding to the pandemic of falsified medicines. *Am J Trop Med Hyg*. 2015;92(6 Suppl):113–118. <https://doi.org/10.4269/ajtmh.14-0393>.
63. Lenza M. Controversies surrounding Laud Humphreys' tearoom trade: an unsettling example of politics and power in methodological critiques. *Int J Sociol Soc Pol*. 2004;24(3/4/5):20–31. <https://doi.org/10.1108/01443330410790858>.
64. Appelbaum PS, Roth LH, Lidz CW. The therapeutic misconception: informed consent in psychiatric research. *Int J Law Psychiatr*. 1982;5:319–329.
65. Lidz CW, Appelbaum PS. The therapeutic misconception: problems and solutions. *Med Care*. 2002;40(9 Suppl):V55–V63. <https://doi.org/10.1097/01.MLR.0000023956.25813.18>.
66. Lema VM. Therapeutic misconception and clinical trials in sub-saharan Africa: a review. *East Afr Med J*. 2009;86:291–299, 6, (Web).
67. Al Balushi AA. Female patients and informed consent: Oman's cultural background. *Sultan Qaboos Univ Med J*. 2019;19(1):e11–e14. <https://doi.org/10.18295/squmj.2019.19.01.003>.
68. World Health Organization. *Global Health Ethics: Key Issues*. World Health Organization; 2015. https://apps.who.int/iris/bitstream/handle/10665/164576/9789240694033_eng.pdf?jsessionid=0CD725B0A073061F97DA3DB24211F968?sequence=1. Accessed January 31, 2020.
69. Addo-Atuah J, Gourley D, Gourley G, et al. Accessibility of antiretroviral therapy in Ghana: convenience of access. *SAHARA-J (J Soc Aspects HIV/AIDS Res Alliance): Journal of Social Aspects of HIV/AIDS*. 2012;9(2):74–87. <https://doi.org/10.1080/17290376.2012.683581>.
70. Tamariz L, Palacio A, Robert M, Marcus EN. Improving the informed consent process for research subjects with low literacy: a systematic review. *J Gen Intern Med*. 2012;28(1):121–126. <https://doi.org/10.1007/s11606-012-2133-2>.
71. Fitzgerald DW, Marotte C, Verdier RI, Johnson WD, Pape JW. Comprehension during informed consent in a less-developed country. *Lancet*. 2002;360(9342):1301–1302. [https://doi.org/10.1016/S0140-6736\(02\)11338-9](https://doi.org/10.1016/S0140-6736(02)11338-9).
72. Kripalani S, Bengtzen R, Henderson LE, Jacobson TA. Clinical research in low-literacy populations: using teach-back to assess comprehension of informed consent and privacy information. *IRB*. 2008;30(2):13–19.
73. Sudore RL, Landefeld CS, Williams BA, Barnes DE, Lindquist K, Schillinger D. Use of a modified informed consent process among vulnerable patients: a descriptive study. *J Gen Intern Med*. 2006;21(8):867–873.
74. Abay S, Addissie A, Davey G, Farsides B, Addissie T. Rapid ethical assessment on informed consent content and procedure in hintalo-wajirat, northern Ethiopia: a qualitative study. *PloS One*. 2016;11(6), e0157056. <https://doi.org/10.1371/journal.pone.0157056>. Published 2016 Jun 3.
75. CITI Program. Human subjects research (HSR). CITI program: research ethics and compliance training. <https://about.citiprogram.org/en/series/human-subjects-research-hsr/>. Accessed February 14, 2020.
76. *Big Data in Global Health: Improving Health in Low- and Middle-Income Countries*. World Health Organization; 2015. <https://www.who.int/bulletin/volumes/93/3/14-139022/en/>.
77. Aallah G, Chantler T, Wenzel Geissler P. *Global Health Research in an Unequal World: Case Studies from Africa*. Oxfordshire, UK: CAB International; 2016.
78. LeBaron V, Iribarren S, Perri S, Beck SL. A practical fieldguide to conducting nursing research in low and middle-income countries. *Nurs Outlook*. 2015;63(4):462–473.
79. Bukusi EA, Manabe YC, Zunt JR. Mentorship and ethics in global health: fostering scientific integrity and responsible conduct of research. *Am J Trop Med Hyg*. 2019;100(1 Suppl):42–47. <https://doi.org/10.4269/ajtmh.18-0562>.
80. Smith E, Hunt M, Master Z. Authorship ethics in global health research partnerships between researchers from low or middle income countries and high income countries. *BMC Med Ethics*. 2014;15:42. <https://doi.org/10.1186/1472-6939-15-42>.