

RESEARCH FOR HEALTH JUSTICE -

Ethical guidance for linking grants programs and research projects to health equity and social justice

Guidance for *researchers* when designing global health research* projects

* Global health research is defined as research focused on health problems typically (but not exclusively) experienced in low and middle-income countries. It encompasses research with groups considered marginalised or vulnerable in high-income countries as well as research in low and middle-income countries.

As a matter of health and social justice, global health research should generate new knowledge to improve the health and well-being of those considered disadvantaged or marginalised, foster their participation in decision-making about its conduct, and build research capacity in low and middle-income countries (LMICs). It should contribute to reducing health disparities between and within countries.

Yet simply undertaking global health research will not necessarily generate the knowledge needed to help improve health care and systems for those considered disadvantaged or marginalised. Global health research grants programs and projects must be structured in a particular way to generate that type of information. But how exactly should they be designed to do that?

The aim of this ethical framework is to guide researchers in their design of global health research projects so that their projects are better structured to promote global health equity. The **Research for Health Justice framework** provides researchers with guidance on the following domains:

- **Selecting research populations**
- **Selecting research topics and questions**
- **Research capacity development**
- **Providing ancillary care**
- **Promoting knowledge translation**

It provides a structure for individual reflection, collaborative research team discussions, and decision-making by those responsible for designing global health research projects. The central questions to ask when reading through the framework's guidance individually or collectively are: how well does the global health research project we're developing align with the framework's guidance and, if there are areas of weakness, is it possible to strengthen their alignment?

Research for Health Justice Guidance for Designing Global Health Research Projects

Framework Domain	Guidance	How to Uphold the Guidance in Research Practice
<p>Research population</p>	<p>External researchers from high-income countries (HICs): Seek partnerships in a host country(ies) that exhibits a sizeable gap in health or well-being from the optimal level achieved worldwide.</p> <p>All researchers: Where the research findings can be generalised to worst-off populations within the host country, select a research population or host community whose health or well-being is close to the optimal level achieved in the host country.</p> <p>Where the research findings cannot be generalised to worst-off populations within the host country, select a research population or host community that either:</p> <ul style="list-style-type: none"> exhibits a sizeable gap in health or well-being from the optimal level achieved in the host country, or sufficiently includes such communities/populations to be able to produce knowledge of difference or equivalence of health or health system issues across different social or geographical stratifiers, or intersections between several stratifiers. 	<p>To select host countries based on health¹ status, consider:</p> <ol style="list-style-type: none"> The level of health achievement: does the country's population exhibit a large gap in health status from the optimal level² achieved worldwide? The level of health security: does the country have a low prospect of sustaining its achieved level of population health over time? The length of time: how long has the country experienced poor health achievement and/or health insecurity? <p>AND</p> <ol style="list-style-type: none"> The level of health inequality within a country: does the country have high health inequality relative to the optimal level achieved worldwide? <p>The gap from the optimal global level of health achievement (highest achieved worldwide) and health inequality (lowest achieved worldwide) should be substantial: Host countries should fall into the bottom third of performers worldwide.</p> <p>Those countries that exhibit all four characteristics are seen as being of highest priority, ie low health achievement and security over a long period, and high levels of health inequality.</p> <p>To select host countries based on well-being status, consider:</p> <ol style="list-style-type: none"> The level of poverty: does the country exhibit a large gap in the amount of poverty its population experiences relative to the optimal level of poverty achieved worldwide? This identifies countries with the greatest poverty worldwide using multidimensional poverty metrics, e.g. Multidimensional Poverty Index³, rather than unidimensional poverty metrics, e.g. Below the Poverty Line. The length of time: how long has the country experienced high levels of poverty? <p>AND</p> <ol style="list-style-type: none"> The level of within-country inequality: does the country have a sizeable gap in well-being between the poor and the rest of its population? This identifies countries with the largest gaps between the rich and the poor.

¹The framework endorses relying on an indicators related to the central health capability of avoiding premature morbidity and mortality. It does not endorse using one indicator over all others. There is flexibility to rely on different measures. This is because many current measures have shortcomings. For example, there is significant debate as to whether the DALY and the age and disability-weights it uses are appropriate. Depending on the weights used, different priorities may be identified. As such, the DALY is not endorsed as the definitive measure of shortfall inequality, but the framework does not entirely reject the DALY or other disability and morbidity-related measures of disease burden like the QALY. Such measures could be used in combination with mortality and other indicators.

²The optimal level of health in terms of morbidity and mortality indicators like life expectancy, infant mortality, maternal mortality, etc.

³Multidimensional poverty measurement focuses on a set of ten deprivations across three dimensions—health, education, and standard of living. The ten indicators are: years of schooling, school attendance, child mortality, nutrition, electricity, sanitation, water, housing, cooking fuel, and assets. Each dimension is equally weighted and each indicator within a dimension is also equally weighted. A person is identified as multidimensionally poor if s/he is deprived in at least one third of the ten indicators. If a person is deprived in 20–33.3 % of the ten indicators, s/he is considered 'Vulnerable to Poverty', and if s/he is deprived in 50 % or more s/he is identified as being in 'Severe Poverty'.

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Research population (continued)	<p>Where safety concerns or funding constraints prevent conducting projects in certain regions of the host country, researchers should, nonetheless, work with populations or communities that meet the above criteria in those regions of the country where they are able to perform research.</p>	<p>The gap from the optimal global level of poverty (lowest achieved worldwide) and inequality (lowest achieved worldwide) should be substantial: Host countries should fall considerably above the optimal multidimensional poverty levels achieved worldwide (i.e. 0); they should fall into the bottom third of poorest countries worldwide.</p> <p>Those countries that exhibit all three characteristics are seen as being of highest priority, ie low health achievement and security over a long period, and high levels of health inequality.</p> <p><u>To select research populations or host communities based on health status, consider:</u></p> <ol style="list-style-type: none"> The level of health achievement: does the population exhibit a small or large gap in health status compared to the healthiest populations in the host country? Access to health care and services: does the population have similar or substantially worse access to health care and services compared to the populations in the host country with the best access? <p>AND/OR</p> <ol style="list-style-type: none"> Financial protection against catastrophic health spending: does the population have similar or substantially worse protection against catastrophic health spending compared to the populations in the host country with the best protection? <p>Where research findings can be generalised, the gap from the optimal level of health attainment, access to health care and services, and financial protection (best achieved in the country) should be small: Research populations should fall into the top third of performers in the country.</p> <p>Where research findings cannot be generalised, the gap from the optimal level of health attainment, access to health care and services, and financial protection (best achieved in the country) should be large: Research populations should fall into the bottom third of performers in the country or sufficiently include such populations.</p>

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Research population (continued)		<p>To select research populations or host communities based on well-being status, consider:</p> <ol style="list-style-type: none"> 1. Domination: is the research population a dominated or non-dominated group within the country? A dominated group is a group whose members are not treated as dignified human beings worthy of equal moral concern simply because they are part of the group. They are not given equal respect. They are often stigmatized or discriminated against due to being group members. Dominated groups can be defined by different characteristics such as gender, ethnicity, race, caste, sexual orientation, and/or living with disability. <p>OR</p> <ol style="list-style-type: none"> 2. Poverty: does the population exhibit a small or large gap in the amount of poverty it experiences compared to other populations in the host country? This would identify populations with the least or greatest poverty in the country using multidimensional poverty metrics, e.g. Multidimensional Poverty Index, rather than unidimensional poverty metrics, e.g. Below the Poverty Line. <p>Where research findings can be generalised, the research population should be a non-dominated group, or exhibit a small gap if any from the optimal level of poverty (lowest achieved) in the country. Where the research population exhibits a small gap, it should fall into the top third of performers in the country (in terms of the proportion of its members classified as multidimensionally poor).</p> <p>Where research findings cannot be generalised, the research population should be a dominated (e.g. stigmatized or discriminated) group, exhibit a large gap from the optimal level of poverty (lowest achieved) in the country, or sufficiently include such populations. Where the research population exhibits a large gap, it should fall into the bottom third of performers in the country (in terms of the proportion of its members classified as multidimensionally poor).</p>

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Research topic and question	<p>All researchers: Select an equity-oriented research question through an inclusive process, involving not only the research team but also relevant community members.⁴</p> <p>Involving community members who are considered disadvantaged or marginalised is essential to ensure that their voices are captured and reflected in projects' research topics and questions.</p>	<p>Process of selection</p> <p>Research questions should be selected through processes with the following features:</p> <p>Leadership Where health research projects are a collaboration between external and local senior researchers from the host country, senior local researchers should lead or be amongst those leading the selection of the research topic and questions. Where more junior local researchers partner with senior external researchers, initially, senior external researchers may be more likely to lead priority-setting. Over the course of the partnership, however, local researchers' research capacity should be enhanced so that they can take an increasing role in possibly through learning by doing approaches. For long-term partnerships, local researchers should lead or be amongst those leading the selection of research topics and questions for collaborative projects.</p> <p>It is also important that, where research teams include community partners, they are amongst those leading health research priority-setting. Community partners could be community organisations, disabled persons organisations, NGOs, persons with lived experience, service users, patients, members of the public, service providers, and/or policymakers. Ideally, one or more community partner(s) should represent and be able to access the research population or host community, including those who are considered disadvantaged or marginalised within it. For more guidance on selecting community partners, see the Ethical Toolkit for Sharing Power with Communities in Health Research Priority-setting (Worksheet 1).</p> <p>Who participates All members of the research team, including community partners, should ideally participate. However, where the research team is very large, it may be necessary to rely on representatives. Here, inclusion demands that participants in priority-setting processes not only represent all the different partner institutions/organisations but also reflect the range of positions and demographics within them, for example, men and women, senior and junior faculty members and postdoctoral researchers, etc. It is highly desirable that a greater number of representatives from LMIC institutions/organisations be included relative to HIC institutions/organisations.</p>

⁴Community membership can be based on geography; on shared interests or goals; or on shared characteristics, situations or experiences, including experiences of marginalisation. Communities encompass (amongst others) community leaders and elders, non-aligned community members (the general public), and people who are part of the health system in the given community: namely, patients, health care providers, health care managers, insurers, policymakers, and others. Community members are not part of the research team that initiates the priority-setting process.

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Research topic and question (continued)		<p>Community members from the research population or host community should also participate. They could include: patients, carers, people with lived experience, members of the public, policymakers, community leaders, and/or health care providers. Two reasons for selecting community participants are suggested:</p> <ol style="list-style-type: none"> 1. they have pertinent knowledge of the health needs of those considered disadvantaged or marginalised, and/or 2. they have the power to change policies and practices that affect the health of those considered disadvantaged or marginalised. <p>Here, achieving diversity and a sufficient mass of community members is also important. Achieving diversity means that participants span a wide spectrum of relevant roles in the two above categories of participants (e.g. patients, policymakers) and include those considered disadvantaged or marginalised within the host community or research population. Sufficient mass means the number of community partner staff and community members is greater, equal or, at a minimum, not too different from the number of academic researchers during priority-setting.</p> <p>Scope of priority-setting Ideally, health research priority-setting processes have an open scope to set health research topics (no or very few topics related to health are off the table), articulate research questions, and design interventions. But funding and other constraints often make this impossible. In such cases, it is essential to be transparent with partners and community members about what health problems and interventions can and cannot be the focus of priority-setting and subsequent research projects, and why.</p> <p>How they participate There are four phases of priority-setting in research projects:</p> <ol style="list-style-type: none"> 1. Conceptualising and planning the priority-setting process, 2. Research topic solicitation, 3. Research topic prioritization, 4. Formulating the research question(s) and interventions <p>All research team members/representatives should participate from the start of priority-setting and community members should participate from either the start of priority-setting or, at a minimum, from research topic solicitation.</p>

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Research topic and question (continued)		<p>Power is more evenly shared where community partners and members participate in health research priority-setting as collaborators (decision-makers) rather than consultants. For a given project, the research topic and questions are ideally set through a deliberative process that is structured to pay attention to power disparities between participants. Being deliberative means participants are able to voice their ideas for research topics, how they should be prioritised, and their ideas for research questions and to provide the reasons behind their selections. Once suggestions have been made and justified, the entire group of participants should then have an opportunity to debate the pros and cons of various proposals. Proposals are refined and/or weeded out and participants coalesce around their preferred option(s). The final outputs (research topic and questions) are agreed upon by all participants.</p> <p>In some cases, however, it may be necessary to consult community members or to use a mix of consultative and deliberative methods. For example, consultations may be ethically necessary because community members cannot safely share the same deliberative space. Even so, mixed and pure consultative mechanisms can still share decision-making power with the community where local researchers, community partners, and field investigators from the community participate in: 1) identifying research topics from the data collected at consultations with the wider community, 2) prioritising amongst them, and 3) formulating research questions.</p> <p>The priority-setting process should be structured to ensure that LMIC participants, especially those considered disadvantaged or marginalised, have a greater or equal chance to speak during consultations and deliberations. This might entail setting certain ground rules that give greater time to LMIC participants to speak, privilege ways of speaking like storytelling and rhetoric, and affirm everyone has an equal right to speak. It could also entail facilitation approaches that give an equal or greater chance to LMIC participants to speak and that make them feel comfortable sharing their views and relevant, personal stories about their country or community's health problems.</p> <p>Such measures (ground rules, facilitation) should also be in place to give other participants an opportunity to voice their ideas for priorities and their reasons for favouring/opposing certain priorities.</p>

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Research topic and question (continued)		<p>Priority-setting should be undertaken in a space that is accessible to all participants and that is not imbued with norms, behaviours, and languages that favour certain participants over others because they are better versed in those behaviours and languages or favoured by those norms.</p> <p>The final outputs of priority-setting (research topic and questions) should reflect the inputs of both the research team and community members, with the inputs of all participants being treated equally or with the inputs of local researchers, community partners, and community members being weighted more heavily and thus more strongly reflected in the research topic and questions.</p> <p>Community partners and members should be compensated for their participation. For community partners, staff members' time should be compensated at their pay rates within their organisation. Individuals unaffiliated with an organisation should be employed by a research partner (in their country), put on a contract, and paid at an appropriate rate. For community members, compensation should fully cover but not exceed their time and transport.</p> <p>For more guidance on sharing power with communities in research priority setting, see the Ethical Toolkit on Sharing Power with Communities in Health Research Priority Setting.</p> <p><u>Outputs of the selection process</u></p> <p>For health systems research: Research questions should fall into one (or more) of the following categories:</p> <ol style="list-style-type: none"> 1. Measure (aspects of) the performance of the host country health system in terms of achieving equal access to health services and/or equitable health system financing 2. Explore causes of poor health system performance in terms of equal access and/or equitable financing in the host country 3. Develop and evaluate an intervention to improve health system performance on equal access and/or equitable financing in the host country 4. Develop and evaluate an implementation strategy for an existing health system intervention or program that has already been proven effective at improving equal access and/or equitable financing 5. Develop a scale-up strategy for the implementation of a health system intervention that has already been proven effective at improving equal access and/or equitable financing <p>(Please note, category 3 can encompass both intervention efficacy research and intervention effectiveness research.)</p>

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Research topic and question (continued)		<p>Research questions should also focus where a need for health systems research exists and interventions-under-study must be appropriate (acceptable and implementable) in the research population.</p> <p>For basic science and clinical research: Research questions should focus on diseases that are a major contributor to shortfalls in the research population or host community's health status from the optimal level achieved worldwide. They are the major causes of the research population or host community's poor health status relative to the optimal level.</p> <p>Research questions should also focus where a need for biomedical and clinical research exists. For example, clinical research-related innovation gaps will likely lie in the following areas:</p> <ol style="list-style-type: none"> 1. Developing diagnostics, prevention interventions, and treatments for diseases where none exist. 2. Developing treatments for diseases where emerging resistance or other factors have significantly reduced the effectiveness of existing treatments in a specific population. 3. Adapting and optimising existing prevention interventions and treatments so that they are accessible and affordable in resource-poor settings (e.g., vaccines that don't require refrigeration). <p>Finally, where such research tests an intervention, the intervention-under-study must be appropriate (acceptable and implementable) for the research population or host community.</p> <p>Long-term collaborations should alter their research agendas to align with changes in the burden of disease experienced by their research populations, i.e. changes in the diseases driving its gap in health status from the optimal level. The transition may be made more gradually in contexts where the disease-specific nature of research expertise and the research funding environment create barriers.</p>

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Research capacity development	<p>Build the independent capacity of LMIC institutions and researchers to perform health research.*</p> <p>*Here, the framework is not suggesting that capacity building cannot or should not be performed for HIC research partners. It recognizes that capacity development is a two-way process than can occur from HIC to LMIC, LMIC to HIC, HIC to HIC, and LMIC to LMIC partners. Instead, the framework is arguing that strengthening the capacity of LMIC partners is a priority as a matter of justice, particularly given that funding for capacity development within individual research projects is usually limited. Those resources should be spent on LMIC partners to help reduce global disparities in research capacity. Nonetheless, it is also important that HIC researchers learn from these partnerships, e.g. build their understanding of diverse types of knowledge and their awareness that different ways of knowing count and are valid.</p>	<p>Research projects should:</p> <ol style="list-style-type: none"> 1. Be conducted through partnerships with local research groups and institutions in the host country. These should generally be of lengthy duration and span more than one project. 2. Utilise strategies that build independent LMIC research capacity at the individual and institutional levels. <ol style="list-style-type: none"> a. Individual level strategies for junior researchers could include: <ol style="list-style-type: none"> i. Completion of post-graduate degrees or post-doctoral positions ii. Learning by doing: Places for junior researchers on grants b. Individual level strategies for senior researchers could include: <ol style="list-style-type: none"> i. Learning by doing: Have principal investigators from LMIC partners ii. Devolving responsibility⁵ c. Institutional level strategies could include: <ol style="list-style-type: none"> i. Building financial management and technical capacity ii. Building post-graduate education programs for health research iii. Building research teams iv. Linking institutions with weak research capacity to institutions with strong capacity 3. Be tailored to address the particular needs of LMIC research institutions and their investigators. 4. Build research-to-policy or research uptake and translation capacity. 5. Utilise capacity development strategies that have been proven effective.
Ancillary care	<p>All researchers: Deliver ancillary care to study participants for a limited subset of conditions that meet certain criteria.</p>	<p>During research projects, ancillary care should be provided for health conditions that meet the following five criteria:</p> <ul style="list-style-type: none"> • They are major contributors to the research population or host community’s gap in health status relative to the optimal level of health achieved worldwide. • There is an absence of others able to meet the health needs, including public or private health facilities run by the local government, local NGOs, or international NGOs.

⁵Devolving responsibility means a visible change in the balance of responsibilities is achieved over the course of joint projects. For example, where LMIC partners have very little capacity at the start of a collaboration, they might eventually take over the day-to-day implementation of the research project in their country from HIC partners.

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Ancillary care (continued)		<ul style="list-style-type: none"> • Researchers, or study staff, possess the expertise and technical capacity to meet the health needs safely. • Available interventions for the health conditions are cost-effective and appropriate for use in the host community (e.g. don't violate any cultural or religious norms). • Expenditure of funds, time, and expertise on the provision of ancillary care is not so great as to unduly burden the conduct of the study. <p>Where health conditions do not meet all the criteria, researchers should, at a minimum, refer patients to other health care providers and arrange for their transport.</p> <p>Where rare diseases with severe health implications occur, if resources permit and the diseases meet the other selection criteria for ancillary care, researchers should address them as well. However, treating diseases that are not driving the research population or host community's health shortfall is of secondary concern from the standpoint of justice. Ancillary care is not a replacement for comprehensive health systems.</p>
Knowledge translation	<p>All researchers: Create lasting change to reduce health disparities.</p>	<p>Creating lasting change means purposefully promoting the use of research results in policy and practice in ways that benefit those considered disadvantaged or marginalised. It also means conducting follow-up studies.</p> <p>Research uptake and translation</p> <p>Research projects should have a set of research uptake and translation objectives, identify strategies for achieving the objectives, and execute those strategies during research projects. Where projects test intervention efficacy and/or effectiveness, they should have research uptake and translation objectives and strategies for promoting sustainable intervention implementation post-study in the host community and more broadly if possible. The objectives and strategies would:</p> <ol style="list-style-type: none"> 1. support delivery and/or policy components of successful interventions remaining adopted by participating health facilities and/or governments post-study and 2. promote their implementation being smoothly handed over to local and/or external actors involved in health care delivery, health policymaking, product manufacturing, product distribution, health programming, and/or health systems strengthening.

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Knowledge Translation (continued)		<p>For example, product development partnerships have adopted the following objectives for promoting post-study access to the new medical products they develop: achieving product registration, manufacturing, and distribution to disease endemic countries; assuring a low-cost product; and achieving product adoption in national treatment guidelines and by health care providers⁶.</p> <p>Research uptake and translation responsibilities during projects are jointly shared by academic researchers, research uptake and translation managers and staff, and community partners. These parties' roles should be explicitly defined at the start of research projects, though they can be refined or redefined during studies as well.</p> <p><u>Follow-up studies</u></p> <p>New research projects should follow from the current project and be conducted after it ends. There is a responsibility to conduct follow-up research.</p> <p>For example, where health systems research evaluates health system performance and identifies inequities in access and/or financing, external and local researchers should design follow-up studies to investigate their causes. Where health systems research explores why particular health system weaknesses occur, external and local researchers should design follow-up studies to design and evaluate interventions that address identified barriers to equal access and equitable financing. Sustainable implementation of efficacious interventions often requires the subsequent conduct of effectiveness research or implementation feasibility studies, particularly where policymakers demand evidence of feasibility before committing to adopt or implement an intervention. It is necessary that pilot studies demonstrating intervention efficacy be followed up by implementation research in instances where intervention sustainability is questionable.</p>

⁶Pratt, B. & Loff, B. (2013). Linking research to global health equity: The contribution of product development partnerships to access to medicines and research capacity-building. *American Journal of Public Health* 103(11): 1968-1978.

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