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Best practices guidance in conducting HIV research with gay, bisexual, and other men who have sex with men (MSM) in rights-constrained environments

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SPECIFIC AIMS

This publication has been developed to guide researchers, community-based organizations (CBO), and governmental agencies engaging in research in rights-constrained environments. The guidance is intended to help these stakeholders to:

- Better design and conduct meaningful research on human immunodeficiency virus (HIV) among men who have sex with men (MSM) in challenging social, political, and human rights contexts;
- Identify essential factors for researchers and community organizations to consider in the design, conduct, implementation, validation, and dissemination of research studies to protect the rights and safety of MSM participants and communities involved in research; and
- Offer lessons learned through case studies of research and community partnerships, recent successes, and challenges.

BACKGROUND

Researchers, activists, and donors in the HIV field are increasingly aware of the disproportionate scale, scope, and severity of the global HIV epidemic among MSM in every corner of the globe. Current interventions for HIV prevention, access to care, treatment, and a range of other issues related to HIV and sexually transmitted infections (STIs) are inadequate. And those interventions that are supported by evidence of efficacy have not been taken to scale for MSM in much of the world.

An ambitious research agenda targeting MSM is urgently needed to develop new and combined preventive interventions, markedly improve access to antiretroviral treatment, and evaluate the role of existing and potentially efficacious prevention tools (e.g., treatment as an oral and injectable pre-exposure prophylaxis/post-exposure prophylaxis [PrEP/PEP] and rectal microbicides, among others). While there is promise of unprecedented scientific opportunity, there also are enormous challenges facing all who are engaged in this effort or seeking to become involved. Not least among these challenges is that in much of the world MSM and other sexual and gender minorities still face violence and discrimination, including discrimination while seeking healthcare, denial of their existence by some states, criminal sanctions, lack of mental health and psychosocial support networks, and social exclusion. As a result, it remains challenging to undertake research with MSM populations in many places, and in some settings the safety of participants and research and clinical staff is a very real concern. Nevertheless, this important work must be done and done well, so how are we to proceed?

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This guidance—developed by a collaborative group of investigators, community advocates, and leaders in the field of HIV working with MSM—seeks to address these challenges. It is meant to be a living document that will be useful to anyone working across the spectrum of this research effort.

Terminology and Focus

"Men who have sex with men" (MSM) is a behavioral sciences term that was developed in the 1990s to encompass the full range of male-to-male sexual contact. Its use was a deliberate attempt to move away from sexual orientation or identity categories (homosexual, bisexual, heterosexual, or gay, bi, and straight). We will use this term here, since, from a research perspective, HIV interventions largely focus on reducing risks and improving services for all MSM, regardless of how they self-identify.

However, for community organizations, the term "MSM" can have limited usefulness. The "LGBTI" term covers a broad range of identities that includes lesbian, gay, bisexual, transgender, and intersex individuals. This umbrella term is embraced and used by many of the individuals and organizations working for equality, civil and human rights, and access to quality healthcare for sexual and gender minorities. Few community groups identify as "MSM groups," just as few individuals self-identify as MSM. Thus, LGBTI is used when referring to community-based organizations that embrace the term because they often are leaders in both the rights struggle and the HIV response.

Transgender (trans) persons, and particularly trans women who were assigned a male gender at birth, have often been inappropriately included in the category of MSM. *It should be noted that the authors of this guidance have not addressed the vitally important HIV research agenda for trans persons—and gender identity more broadly—within this publication because it is clear to us that many of the unanswered research questions are different, and because separate and dedicated gender identity research guidance is needed.*

Finally, "rights-constrained environments," in relation to MSM/HIV services and research, are environments where there are major challenges in meeting the needs of MSM due to significant structural inequalities. These structures may be legal, such as where same-sex sexual behavior is criminalized, or they may be societal attitudes that overtly stigmatize such behavior. This document is targeted to low- and middle-income countries, but some of its themes pertain to rights-constrained environments in high-income countries as well.

Additional Terminologies

Antiretroviral therapy (ART): ART generally refers to the regimen of antiretroviral drugs prescribed to patients living with HIV in order to suppress the virus and control progression of the disease within the body. By successfully suppressing the virus, patients can also reduce the likelihood of transmitting HIV to others.

Community-based organization (CBO): A CBO is an organization or group of individuals that are representative of a specific community and conduct operations within that community. CBOs often partner with governments and larger non-governmental organizations (NGOs) to help provide services to individuals within their communities.

Community engagement and ownership (CEO): Meaningful CEO in this context refers to a research practice which ensures that communities are meaningfully engaged throughout every phase of the research process, from defining the research questions to disseminating the results. Meaningful CEO is not a one-off engagement of the community, but rather a sustained effort which ensures that the capacity of communities involved in research is strengthened, that community members and researchers work collaboratively, and that research results benefit the community and support efforts to influence positive change.

Civil society: This refers collectively to the multitude of associations, CBOs, indigenous peoples' organizations, and NGOs around which society voluntarily organizes itself and which represent a wide range of interests.

Dissemination: This refers to the process of sharing research findings with the wider community. It can include engagement of the MSM community, media, government, and other stakeholders in order to share research results with as many people as possible. International dissemination can be achieved through conferences and publications.

Hidden populations: Due to the stigmatization and criminalization of same-sex sexual activities in many communities, MSM often fear disclosing their sexual orientation or practices, and often avoid seeking health services or participating in research due to fear of prosecution or retribution. This can make MSM a "hidden" or "hard-to-reach" population. Hidden populations can also include other stigmatized and criminalized key populations, such as sex workers, people who inject drugs (PWID), and transgender people.

Informed consent: To provide informed consent, participants must be given sufficient information about the study project, including risks and benefits in a language they comprehend, so that they can make an informed decision about their participation.

Institutional review board (IRB): Sometimes known as independent ethics committees (IEC), ethical review boards (ERB), or research ethics boards (REB), IRBs often consist of a group of individuals specifically designated within a hospital, university, or other research setting to review and either approve or disapprove research with human subjects based on the risks and benefits of a given research project. In order to receive IRB approval, researchers should take sufficient steps to minimize and address the risks of those who will be involved. If approved, IRBs are also responsible for monitoring the progress of a given project. In many high-income countries, IRBs are housed within the institutions sponsoring or conducting the research. However, many low- and middle-income countries house their IRBs within government.

Key populations: Once referred to as most-at-risk populations, key populations consist of groups who are at increased risk of HIV regardless of the epidemic type and local context.[1] Key populations often include MSM, transgender people, sex workers, people in prisons, and PWID, though this term can be extended to apply to any disproportionally affected population.

Non-governmental organization (NGO): The term NGO, or civil society organization (CSO), encompasses a broad range of organizations that are not part of government but are also not considered as for-profit businesses. NGOs can exist at the local, national, or international level and thus include CBOs.

Research: Though often interrelated, in the context of this document, research should be differentiated from program evaluation and service provision. The role of research is to use science and methods to provide an evidence-base to inform societal and political change.

Research protocol: A written summary of the goals, objectives, and methods to be used in conducting the research, as well as examples of any research instruments, such as informed consent documents, participant surveys, questionnaires, and/or verbal questions that will be asked during individual interviews and/or focus group discussions.

Situational assessment: For the purposes of this document, situational assessments will refer to either rapid or more detailed evaluations of the environment for MSM within the country and community in which researchers intend to work. Understanding the context for MSM will help determine whether the time is right to conduct research and if so, what infrastructure exists to assist with such research.

Stigma: Stigma involves the act of discrediting an individual or group of individuals based on a perceived attitude, behavior, or reputation.[2] MSM often face high levels of stigma at the individual, societal, and policy levels. Such stigma can impact psychological and physical health, and the ability to access necessary HIV services.

Validation: The role of validation is to ensure quality and determine that research findings reflect the reality of the community in which it was done. Researchers should work in coordination with LGBTI leaders and organizations to validate their findings.

The Current Context

There is growing recognition among national governments, researchers, civil society groups, and donors of the global nature of HIV epidemics among MSM. Advocacy efforts at the local, national, regional, continental, and global levels have produced increased recognition of rising HIV infection rates among MSM and increased investment in HIV/MSM-related research. The iPrEx trial of a daily pill of ART to prevent HIV infection, also known as pre-exposure prophylaxis or PrEP, was a watershed and the first large-scale, multi-country preventive intervention study that demonstrated efficacy (44% reduction in the acquisition of HIV) among MSM. These results have since been confirmed by the PROUD study in the UK, and the Ipergay study in France and Canada. The iPrEx study was particularly novel in terms of biomedical research for MSM since it was conducted not only in the United States, but also in middle-income countries, including Ecuador, Peru, South Africa, and Thailand.

Opportunities to study emerging HIV prevention approaches also create challenges in working with MSM in diverse contexts. Differences in power dynamics often exist between research teams, international NGOs, donors, and the local community groups that often have unique access to otherwise hidden populations. In countries where same-sex sexual practices are criminalized, research can have unintended adverse outcomes when it brings increased attention and government awareness to previously hidden populations. Inadvertent exposure of MSM populations has led to increases in rights abuses in some settings. Even where same-sex sexual practices are not criminalized but are significantly stigmatized, the risks in working with MSM can be just as great.

Finally, during the last five years in HIV research, we have seen increased attention given to implementation science, which is the study of how to optimize the delivery and effectiveness of programs focused on HIV prevention, treatment, and care. There are specific complexities in ensuring the effective provision and uptake of services for MSM populations, and implementation science methods can characterize the best ways to achieve meaningful coverage of these services for stigmatized populations. In addition, undertaking implementation science research requires balanced partnerships between academia and community, representing another example of how these guidelines can be used to ensure equal involvement.

This guidance builds upon existing documents (e.g., *Good Participatory Practice: Guidelines for Biomedical HIV Prevention Trials [UNAIDS/AVAC, 2011]*[3] and *Ethical Considerations in Biomedical HIV Prevention Trials* [UNAIDS/WHO, 2007]), and aims to better inform:

- Researchers of their roles and responsibilities related to best practices in meaningful CEO and community partnership models in these settings;
- MSM/LGBTI community-based organizations and activists of their rights, roles, and responsibilities as partners in conducting this research; and
- Researchers, MSM/LGBTI communities, and funders of security issues and potential risks that must be considered, especially in contexts where same-sex sexual behavior is criminalized or stigmatized.

The focus of this guidance is practical, expounding on ways in which all concerned partners can increase the benefits of research and minimize the potential risks and harms for all concerned. It seeks to enhance the capacity of scientists to meet their research obligations, while encouraging MSM and LGBTI leaders and organizations to understand and exercise their rights and responsibilities when participating in research. Finally, it provides examples of engagement rules for studies and projects that encounter or engender threatening media, political, or social/religious backlash.

INTRODUCTION

Fortunately, the HIV pandemic is gradually slowing. UNAIDS estimates that there were 2.1 million new infections in 2013, compared to 3.4 million in 2001.[4] Even more significant is the decrease in HIV-related mortality globally.[5, 6] That said, HIV is still a major health concern, especially across sub-Saharan Africa. While the rate of new infections may have slowed, there are still 35 million people living with HIV worldwide.[4] In 2014, to help ensure that those infected with HIV can access lifesaving ART, UNAIDS announced the aggressive 90-90-90 treatment target for 2020.[7] Under this plan, 90% of all PLHIV will know their HIV status, 90% of those who have tested positive will be receiving ART, and 90% of those on ART will achieve viral suppression.

However, while the pandemic appears to be decreasing in magnitude, infections among gay men, other MSM, and other key populations continue to increase. Several studies have documented increasing rates of new infections among MSM in high-income settings.[8] Moreover, there is emerging and consistent prospectively collected HIV data from low- and middle-income settings—including such countries as Nigeria, Senegal, Malawi, Thailand, and Kenya—that show very high incidence among MSM.[9, 10] The relative proportion of an HIV epidemic that is attributable to MSM within concentrated epidemics is relatively uncontroversial. However, there is strong disagreement about the proportion of HIV infections attributable to transmission among MSM within more generalized epidemics. There is consistent, mounting evidence of disproportionate HIV risk and rates of infection among MSM within the generalized epidemics in sub-Saharan Africa, Asia, Latin America, the Caribbean, and Eastern Europe/Central Asia.[11, 12] Therefore, reaching the ambitious 90-90-90 targets will require significant changes in funding, policy, and programming to close the prevention and treatment gap for MSM and others.

The Global HIV Prevention Working Group has estimated that in areas with concentrated epidemics where prevalence is high among MSM, less than 4% of all HIV-related expenditures are allocated to addressing the needs of these populations.

The current global response, however, is not commensurate with these realities.[11] Recent global assessments of existing HIV services suggest that few HIV/AIDS prevention, treatment, and care programs include targeted programming for MSM. The Global HIV Prevention Working Group has estimated that in areas with concentrated epidemics where prevalence is high among MSM, less than 4% of all HIV-related expenditures are allocated to addressing the needs of these populations.[13–15] In generalized epidemics, where there is emerging evidence of disproportionate HIV burden among key populations, less than one-tenth of 1% of such expenditures actually address the needs of MSM/LGBTI populations. There are many factors that contribute to inadequate coverage of HIV services for MSM, including overt and sanctioned homophobia, lack of political will to address MSM issues, limited data that accurately reflect the true burden of HIV risk and disease among MSM, insufficient targeted funding, and little or no commitment or resources to define and implement an optimal package of services for MSM in resource-constrained settings.[16,17] Comprehensive responses are needed. It is necessary to improve epidemiologic surveillance of MSM and define appropriate packages of HIV services—including biomedical, behavioral, and structural approaches—using the highest standard of attainable data. These data can then be used to advocate for targeted and effective HIV interventions for MSM and appropriate scale-up of such programs to address evidence-based needs.

In response to the need for improved epidemiologic data describing patterns of disease burden among MSM, as well as new implementation science data characterizing effective preventive interventions and treatment access programs, there has been growing interest in MSM/HIV research among academic organizations, HIV program implementers, advocacy organizations, CBOs, and funders. From 2005–2010,[17] new studies to characterize HIV prevalence among MSM were implemented for the first time in countries across Africa, Asia, the Caribbean, Latin America, Eastern Europe/Central Asia, and the Middle East/North Africa.[18, 19] In addition, prospective cohorts of MSM—including studies in Bangkok, Thailand, and Mombasa, Kenya—were established and followed across multiple time points to characterize HIV incidence rates or levels of new HIV infections. While the majority of research among MSM in low- and middle-income countries has focused on assessing disease burden and associations of prevalent and incident infections, there has been a move towards evaluating preventive interventions. This has included research on new prevention tools (NPTs), including biomedical strategies such as oral and topical ART, using treatment of people living with HIV as prevention by lowering community viral load, and increasing implementation science studies to evaluate optimal implementation approaches.[20, 21] There is also a need to increase research and understanding on negative social, cultural, and structural elements, such as stigma and discrimination, and their effects on mental health, wellbeing, behavior, and HIV disease burden. Social stigma among MSM has previously been linked with screening positive for depression, testing positive for HIV,[22] reduced rates of HIV testing,[23] engaging in condomless anal sex,[24] and meeting new male sex partners on the internet.[25]

Ethical Principles

Working with MSM presents unique challenges given the stigma, discrimination, and danger that are often rampant in these communities. These challenges are exacerbated by the absence of community structures that offer protection and safe spaces in which to interact and socialize. Engaging MSM in scientific studies must be done in a manner that is safe and beneficial for both individuals and communities across all stages of research, from study design and implementation through dissemination and afterwards.

The *Belmont Report*[26] highlights ethical principles and guidelines for the protection of human research subjects. Ethical research should be consistent with the general principles of autonomy, beneficence, non-malevolence, and justice.[27, 28] These concepts are a component of human research in general, but are particularly important and difficult to achieve within challenging contexts.

Autonomy implies that people have given their free and fully informed consent to participate in a project, that they have been given ready access to all relevant information about risks and benefits, and that they are of “sound body and mind.” **Beneficence** implies that the researcher is aiming to promote the wellbeing of participants, either at an individual level or for overall public health. Epidemiologic and clinical research among MSM generally provides little direct individual benefit to participants, even though individual risks could be great if sexual practices or orientation are disclosed. The concept of **non-malevolence** ensures that the researcher will not intentionally do harm, and in the context of research with stigmatized populations this means taking all possible measures to protect participants, which includes protecting volunteer data, physical safety at study sites, and securing study files during close out of a project. Finally, **justice** implies that decisions are made on the basis of well-recognized principles and rules in an impartial and verifiable manner, with a view to ensuring the fair and equitable treatment of all study participants. It also suggests that communities that are the subject of research will directly benefit from that research, rather than being used for the sole benefit of others.

Engaging MSM in scientific studies must be done in a manner that is safe and beneficial for both individuals and communities across all stages of research.

Additional ethics guidance can be found in the *Declaration of Helsinki*.[29] While researchers working with MSM must abide by these ethical guidelines to protect participants as they would with any human subjects, additional steps may be required for safe and effective engagement of MSM within challenging contexts.

Many MSM are intentionally secretive about their behaviors due to very real fears of facing social exclusion, stigma, discrimination, persecution, and physical violence. Clearly, stigma is pervasive in societies and cultures, and is often reflected in laws that criminalize consensual same-sex sexual practices. Research projects undertaken in such settings are intended to identify and address the needs of MSM populations, but in doing so they can inadvertently increase their public visibility and generate both positive and negative attention and social responses. The unintended consequences of research projects aiming to help MSM can include heightened stigma and increases in human rights violations, including violence and blackmail. These realities can shift the ethical balance of costs and benefits, so careful consideration of the potential negative consequences of "minimal risk" scientific research is of special importance in study conception, design, implementation, and dissemination.

In recent years, researchers have employed advanced technology and estimation methods to better identify hidden populations such as MSM. Researchers conducting size estimations (assessments of the number of MSM present in a given area) are now able to identify and visualize concentrations in HIV prevalence and service coverage through the use of mapping software. While such mapping practices provide invaluable information to decision makers seeking to ensure service coverage for MSM, they may also involve a great deal of risk. *It is crucial to consider the ethical implications of collating and releasing such data*. For example, if a geographical mapping process identifies higher rates of HIV at a specific 'hot spot' for MSM (e.g., bar, club, public park, etc.), this information might result in homophobic attacks on individuals who frequent such places if the research data is made public.

General guidelines on data protection are readily available, yet there is little or no guidance that addresses newer and more advanced research methods, particularly within rights-constrained contexts. This raises key questions for both researchers and communities: What are the ethical considerations of data visualization and programmatic data use, and who should have access to information that clearly identifies locations where MSM can be found? One recent addition to this ongoing discussion comes in the form of a working guidance document produced by MEASURE Evaluation at the University of North Carolina. The Priorities for Local AIDS Control Efforts (PLACE) method is a rapid assessment tool to monitor and improve AIDS prevention program coverage in areas where HIV transmission is most likely to occur (available at: www.cpc.unc.edu/measure/resources/tools/hiv-aids/place/place-files-1). The document offers support to countries in developing proposals and protocols for conducting size estimation and programmatic mapping of key populations by providing a step-by-step guide, including worksheets on designing a stakeholder engagement plan and assessing ethical risks. This document also represents a vital first step towards increased understanding of the need for strategic guidance on the ethical considerations of research that offers information to the public about the locations and practices of MSM that could prove extremely dangerous for such a vulnerable population.

The Human Rights Framework and Research with MSM

The World Health Organization (WHO) states that: "Enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being."

This research guidance is intended to be a framework to *Respect, Protect, and Fulfill* the fundamental human rights of individuals and populations studied.[30, 31] Respecting the rights of people means refraining from interfering with the enjoyment of their human rights. In the context of research with various types of MSM, researchers and communities must not simply limit themselves to the rights to information, non-discrimination, and access to healthcare.

Protecting the rights of vulnerable people also means anticipating and creating mechanisms to prevent violation of their human rights and/or social harm by others. For MSM, this means doing the utmost to ensure that neither state authorities nor non-state parties violate the rights of participants or staff as a result of their participation in research. Researchers and communities working on issues relevant to MSM must not tolerate, nor be complicit in, attempts by others to limit the rights of sexual and gender minorities.

> Protecting the rights of vulnerable people also means anticipating and creating mechanisms to prevent violation of their human rights and/or social harm by others.

Fulfilling human rights means putting in place policies, procedures, and resources to enable people to exercise these rights. This is the most active component of the guiding framework and CEO, meaning that researchers have an implicit responsibility to help ensure the human rights of their study participants. Importantly, the threat of human rights violations extends beyond the life of a research project, and attention must be given to possible violations occurring after—and as a result of—the dissemination of data and findings.

All HIV research should focus on fulfilling the rights of all participants to an adequate standard of healthcare throughout the duration of any study. This includes, at minimum, the rights to privacy, autonomy, confidentiality, informed consent, dignity, and nonjudgmental and *humane treatment in interactions with all staff, from security guards and intake clerks to investigators and physicians*.

THE ROLE OF RESEARCH INSTITUTIONS INVOLVED IN MSM/ HIV RESEARCH

Engagement

Effectively engaging LGBTI communities is crucial for the development and implementation of comprehensive and effective HIV/AIDS responses. Meaningful engagement with those at risk and with their communities can markedly improve the quality of research, as well as its uptake and implementation. The more repressive the environment and the more unwilling governments and service providers are to offer services to MSM and other sexual and gender minority populations, the more critical the role of community engagement becomes. In the most challenging environments, LGBTI community organizations may be best suited to take on research, service provision, and advocacy for MSM at risk, and working without them would simply not be feasible.

Adequate input from the MSM/LGBTI community legitimizes the research aims and improves measures of appropriateness, transparency, and social equity across the study spectrum. Because MSM/LGBTI community organizations are often a primary means of enlisting gay, bisexual, and other MSM for research, there is concern among some community organizations that they are engaged by researchers only for enrolling potential study participants and not as full partners in the work. To counteract this, it is crucial that the participation of communities should not be limited to any one stage of the research; rather, *their inclusion should be a consistent component throughout the research process*. Moreover, committed and long-term engagement with communities by researchers can, and often does, result in building the capacity of community organizations to solve problems and to be more effective agents in reducing the spread and impact of HIV.

Working with MSM/LGBTI Communities

The conventional role of community advisory boards (CABs) has been to provide cultural competence, represent the community in research efforts, "bring back" research issues to constituents, and facilitate access to potential study participants. The vital role played by CABs is absolutely necessary, but they may not be equipped to address the range of issues involved in MSM research within rights-constrained contexts.

Finding LGBTI leaders: Though laws criminalizing same-sex sexual behavior pose a challenge to the rise of LGBTI leadership, increasingly LGBTI activists in low- and middle-income countries are gaining the strength to organize and demand their rights. In these countries, health issues, including increased vulnerability to HIV, are allowing LGBTI leaders to engage with key healthcare stakeholders. At the regional and sub-regional levels, LGBTI rights and MSM health networks have formed, such as the African Men for Sexual Health and Rights Network (AMSHeR), the Asia-Pacific Coalition on Male Sexual Health (APCOM), the Association for Integral Health and Citizenship in Latin America (ASICAL), the Caribbean Vulnerable Communities Coalition (CVC), the Eurasian Coalition on Male Health (ECOM), and the M-Coalition (Middle East and North Africa).

> Meaningful engagement with those at risk and with their communities can markedly improve the quality of research, as well as its uptake and implementation.

In many countries, national MSM networks have also been set up to champion MSM/LGBTI research and programming. For example, the Gay and Lesbian Coalition of Kenya (GALCK) has incorporated a National LGBT Research Advisory Committee (the G10) as an active agency within its structure. The G10 is a core group of nationally diverse and representative MSM/LGBTI organizations that convenes regularly to define the community's research agenda. The group also coordinates, facilitates, and archives MSM/LGBTI-specific research issues on behalf of the broader community. These networks link national, regional, and local MSM/LGBTI community organizations, encourage the sharing of intervention and advocacy strategies, and can confer a sense of legitimacy on research teams interested in engaging with LGBTI community groups. Thus, investigators interested in engaging LGBTI leaders in order to collaborate on research projects are strongly encouraged to work through these regional, sub-regional, and national networks (see Acknowledgments, p. 34, for the names of additional networks).

Study design: Study design includes the development of research instruments, such as surveys and questionnaires, as well as determining the characteristics of participants and methods of engagement. In the case of biomedical research, it also usually involves the development of protocols for the collection, storage, and testing of biological samples such as blood and urine. It is vital that MSM/LGBTI community leaders be fully engaged in the planning stages of each of these components, given their knowledge of the communities they serve. Their involvement will broaden the reach of the research and also build research literacy, help protect the rights of participants, and potentially build the capacity of community leaders to be engaged in all stages of the research. For example, community leaders should be involved in the development of research instruments (question by question) and, where possible, should also be invited to give feedback on a protocol synopsis before it is submitted to an IRB. This will help to ensure that study tools and methods are culturally and linguistically appropriate, and informed by the lived realities of individuals on the ground.

It should be noted that some community leaders will not be familiar with research design and thus will require training on research principles. However, in some settings, MSM/LGBTI leaders have educated themselves and become savvy with research concepts, and some have even begun developing research priorities for their communities. Such community-driven processes reflect the fact that too often, researchers' priorities do not match the needs of MSM/LGBTI communities. Thus, both researchers and MSM/LGBTI community leaders should collaborate and communicate closely in order to develop a unified research agenda that will have maximum value for everyone involved. The use of written agreements, such as memorandums of understanding (MOUs), can also assist in making roles and responsibilities clear between the players involved (see Appendix IV for a sample MOU).

Implementation: Members of the community should be engaged in the implementation of the research, as this can strengthen the capacity of the community itself. Investing in strengthening the capacity of community groups will also facilitate the implementation of future research studies and ensure that community members will present results with their peers.

Validation: Community members should also play a key role in the validation of results. Before results are finalized and disseminated, it is good practice to convene MSM who participated in the study to share and validate the final results. This step not only helps to confirm the findings, but also builds community ownership of the data, helping to ensure that the research findings are used to improve HIV programs and policies targeting MSM.

Dissemination: Community members are often interested in being included as co-authors on study publications; this also ensures that they are a meaningful part of the dissemination process. This does not mean token inclusion, but actually being involved in writing such papers. While noting that community members may have limitations in this regard, researchers nevertheless should use such opportunities to train and involve them in writing scientific papers. They should also be considered as potential co-authors, depending on their respective role(s) and level(s) of input.

MSM/LGBTI community leaders also should be encouraged to present research findings at local, national, and international forums. This likely would involve providing technical support in the development of presentations and reports, and ensuring that community presenters are prepared to address both scientific and policy-related questions about the research, and to defend research results. Because increased visibility can bring increased risks, MSM/LGBTI communities also should be poised to respond to any homophobic backlash from the media, government, or the wider society in general.

Community members should also be engaged to determine the best channels for dissemination, as adverse effects of publication or media attention may not be fully understood or anticipated by researchers. It should be noted that in addition to engaging the MSM community in the dissemination phase, researchers must also consider strategies for engaging and communicating with the media. Media plays a critical role in framing the MSM discourse. Since journalists must report in a way that is easily understood by a wide variety of audiences, they can simplify or modify the scientific language used by researchers. In the process, important messages may be lost or even misrepresented. In contexts where MSM are stigmatized and even criminalized, the media may frame research outcomes in a way that further enhances stigma and discrimination.

Developing a plan for media engagement, especially during critical junctures such as study inception and dissemination, should be undertaken in collaboration with MSM community leaders. Researchers and community members will want to find ways to clearly describe what the study findings suggest—and also what they do not suggest. Media briefs and/or press statements should be written in simple, unambiguous language and should also clearly spell out the risks of negative reporting for the MSM community and the country at large.

Funding/Engagement Rules

Research with MSM has been identified as a priority by multilateral funding agencies, such as the President's Emergency Plan for AIDS Relief (PEPFAR) and the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), as well as international organizations such as the World Health Organization, the World Bank, and the United Nations Development Programme. As previously described, this has produced a significant increase in the level of interest in working with these populations among domestic and international entities alike. Thus, this guidance proposes a set of basic engagement rules that should be followed before research plans are finalized and funding is sought.

Engagement rules include conducting a situational assessment of the environment affecting MSM within a particular location, including discussions with local MSM/LGBTI community groups and other stakeholders to assess whether the timing is right for a study targeting MSM given existing sociopolitical dynamics. In some cases, this may mean delaying a research project until conditions have stabilized. It is also vital to determine the level of organization of the MSM/LGBTI community within the planned research setting. If there is a lack of established infrastructure, then the study sponsors and implementers should commit to strengthening local capacity as a component of the research program. Engagement rules also include assessing the level of interest of the MSM/LGBTI community regarding research programs that specifically target MSM. As described above, this process should capitalize on existing networks of organizations that serve MSM with evidence-based and rights-affirming advocacy or health services. History suggests that most community organizations will likely be motivated to take part in research projects based on the importance of gathering data to support their advocacy strategies. Finally, engagement should be preceded by an assessment of the research organization's willingness to *respect, protect, and fulfill* the rights of MSM participants according to the guidance presented in this document.

One additional note of caution that researchers should heed when engaging MSM/LGBTI community leaders in HIV-related research studies is the fact that, depending on the setting, HIV may not always be a major concern for the community. In many contexts, the effects of stigma and discrimination associated with MSM/LGBTI identities is a much larger issue than HIV, often resulting in a lack of access to education, employment, familial support, legal protection, and psychosocial support. In some settings, this discrimination is severe, with outright hostility and violence occurring and with little support or protection provided by police or legal professionals. While not necessarily directly linked to HIV acquisition, stigma and discrimination do have an impact on MSM/LGBTI individuals accessing health services. Hence, these structural issues are usually much higher on the list of major concerns among MSM/LGBTI leaders and may factor into a stated desire to see research address these issues. Consequently, it is important to consider how collaborative research teams can work to integrate these issues into broader HIV-related studies.

Working with Governments and National Institutional Review Boards (IRBs)

Global guidance documents on research involving human participants require that researchers obtain ethical approval at institutions sponsoring and conducting the research and in any locations where a study protocol will be implemented. In many low- and middle-income countries, these ethical review boards are either housed within government bodies or include government representation.[32] Thus, engagement with government agencies may be necessary when conducting research with MSM. Given that interaction with such government bodies may be mandatory before research can begin (which may not be the case for service provision), it may be advantageous for research organizations to be proactive in engaging government entities. Moreover, researchers will likely benefit from "partnering" with community-based MSM/LGBTI organizations at an early stage of planning in order to get assistance in interacting with local government entities. It is the responsibility of researchers at this stage to build coalitions with relevant local organizations and partner with them to maximize the protection of the rights of the MSM/LGBTI community members through thoughtful interactions with government entities.

> **If unanticipated resistance or opposition from government or society occurs before, during, or after the study, it will fall to the research team to effectively engage the MSM/LGBTI community to seek guidance on how to respond.**

Successful coalitions often begin with a context analysis that characterizes key thought leaders, research teams, and service providers. In nearly all settings, communities of MSM have organized to some degree, although this can vary greatly. In many countries, there may be only one organized community group that represents MSM. In others, there may be hundreds. The goal should always be to achieve meaningful local community representation. In cases where there are numerous organizations, the focus would be to seek guidance from the one that is most appropriate in the location in which the research is being planned. For multi-site studies, a more thorough assessment of representation is recommended. Using a strategy that is adapted to the country in which the work is to take place, these broad coalitions can generally succeed in achieving approval from in-country ethical review boards. When not successful, the coalition should carefully consult with key community members to assess the range of appropriate next steps.

When viable review boards do not exist within a country, or when government review boards fail to review a protocol, other actions may be taken. For example, in one MSM study, "…the head of the only university-based [research ethics committee] REC informed the research team that, since homosexuality was criminalized in the country, no research protocols related to MSM would be accepted for review." Researchers then turned to the community and "engaged community-based organizations serving MSM within the country to gauge the level of support for the study, and trained community leaders on research ethics. The study was then reviewed by community leaders, who suggested protocol changes based on further community consultation."[33]

If unanticipated resistance or opposition from government or society occurs before, during, or after the study, it will fall to the research team to effectively engage the MSM/LGBTI community to seek guidance on how to respond.

Security and safety should concern everyone within and outside the organization conducting research with MSM/LGBTI communities. It is therefore useful for researchers and community members to collaboratively put in place a security plan that addresses volunteer, data, and staff security. Such a plan can be discussed with other CSOs that are experts in the field to get their input. Some key things to consider when developing such plans would include: who is to be involved in developing the plan, both within and outside the organization; how will potential internal risks be minimized (for example, ensuring individuals' confidentiality during screening of study participants); and how will the location of the research facility, as well as other potential external factors, affect safety and security? Developing a plan that has broad support and includes a training component is essential to ensuring proper implementation. For example, conducting "what if" exercises to test hypothetical situations during implementation can be quite useful in preparing staff for potential threats.

Preparing for and Responding to Hostile Reactions

Emergency plans should be developed, especially in settings where governments or other stakeholders (e.g., religious and community leaders, members of the media, opposition political leaders, etc.) are known to be hostile to LGBTI communities. Even in places that may not seem hostile, the situation could change rapidly. Such plans are best developed in advance of engagement with stakeholders. Researchers and community organizations should develop plans that detail a participant sampling and enrollment strategy,* as well as "what if" scenario planning. In addition, they should consult with human rights organizations to obtain input into such plans. However, should social harms emerge, it is vital that decisions on appropriate next steps be made with guidance from MSM/LGBTI community leadership. Researchers should never forget that the local LGBTI community will have to address any lasting consequences long after studies are shut down or stalled before completion.

While some researchers doubtless prefer to take apolitical stances, working with stigmatized populations usually signals the need to engage in advocacy on behalf of that community. These may be "under-the-radar" efforts done quietly with key allies and opponents, but addressing potential social harms produced by research protocols is an accepted responsibility for investigators in all contexts.

Clearly, there is a delicate balance. The research agenda should not supersede the community's interests, and developing strong partnerships with

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* In clinical research, there are distinct differences between "recruitment" and "enrollment". Recruitment is the period of time preceding the start of a study when an activity such as screening of participants occurs. Once a participant provides informed consent and becomes an active member of a study, he/she is considered enrolled. Community organizations, on the other hand, often avoid the use of the term "recruitment" so as not to be accused of recruiting individuals (including children) into a "LGBTI lifestyle." Hence, researchers should be careful when using this term.

MSM/LGBTI individuals and community organizations may reduce the likelihood of researchers harming a community's efforts to promote their rights. Researchers who are not willing to engage with community groups should deliberate carefully before deciding to conduct research with populations that are criminalized or marginalized.

THE ROLE OF COMMUNITY ORGANIZATIONS INVOLVED IN MSM/HIV RESEARCH

Partnerships with Researchers

For MSM/LGBTI community organizations, research data can be a useful tool for advocating increased availability of effective MSM-specific HIV-related services. The research can be used to learn more about risk factors for STIs, including HIV, as well as to develop appropriate evidence-based prevention programs. Research can clarify the demographics and behaviors of MSM that impact HIV vulnerability, including sex work, drug use, age, migration status, ethnicity, and race. Research can also help to advocate increased prevention, treatment, and care programs. Finally, research can assist in focusing on more structural interventions, such as decriminalizing same-sex sexual behavior, working to alleviate poverty among MSM/LGBTI individuals, informing policies and practice, and making health services more MSM/LGBTI-friendly.

> Unfortunately, in the past there have been multiple reports of MSM/LGBTI communities experiencing stigma and discrimination as a result of research studies being conducted and research data being presented.

Unfortunately, in the past there have been multiple reports of MSM/LGBTI communities experiencing stigma and discrimination as a result of research studies being conducted and research data being presented. Thus, there is a need for MSM/LGBTI community leaders to work closely with research teams in all phases of a study in order to minimize the potential for stigma and discrimination, and to mitigate their impact.

Research teams can provide technical support to implement these research programs, but they are often not experts on addressing the needs of MSM/LGBTI communities. In the absence of effective guidance from within the MSM/LGBTI community, the research teams likely will have limited access to the very population(s) they wish to study. Even if they do gain access, it will be difficult for them to undertake research that produces actionable data without MSM/LGBTI community input.

The decision about whether or not to support a research project is a complex one and includes considering the needs of community members, current and future programming and advocacy priorities, and the strategic objectives of the local MSM/LGBTI community leaders and organizations. If after reviewing the checklist in Appendix II (Questions for Community Organizations to Ask Regarding MSM/HIV Research), MSM/LGBTI community leaders do not think their rights will be promoted and protected, they can elect not to participate in the study.

MSM/LGBTI leadership need to recognize the vital role they play in the success of such research studies and should educate all MSM/LGBTI community members about their right to refuse participation in any study. Clearly, challenges may arise. Some research projects offer incentives, for example by providing salaries, office space, equipment, and stipends for their members. While such resources are vitally needed, they are often not sustained after a study ends, and they can cause jealousy or resentment among other MSM/LGBTI community members who are not involved and thus derive no benefit from the project. MSM/LGBTI leaders should understand they have recourse to address problems and ensure that their needs are met, including reaching out to entities that have power over researchers, such as IRBs and other ethical bodies, as well as donors who are funding such studies.

Meaningful Community Engagement and Ownership (CEO)

Conceptualization and design: Before research studies are conducted, a significant amount of time is devoted to conceptualization. One key to meaningful participation is ensuring that the priorities of researchers and MSM/LGBTI community leaders are aligned. Hence, brainstorming meetings need to happen to ensure both groups' priorities are met. Brainstorming meetings will also identify if the intended research has already been done in the area, and if so, if there were any gaps that need to be addressed to avoid repeating the past research.

Moving forward together in design also includes gaining permission from various stakeholders, including an IRB, to ensure that individuals being studied are not going to be harmed by the conduct of such research. It also includes working together to develop a study protocol and research instruments, such as questionnaires for participants to fill out and/or a written list of questions that will be asked verbally during in-depth interviews and/or focus group discussions.

MSM/LGBTI community members should insist on being involved in the study design to ensure that the research will actually work to their benefit. If the community is not informed about research study design, they should ask to be instructed on the topic. Research results may enhance existing advocacy efforts. Involvement may mean attending meetings with community advisors, IRB members, or government entities. It may also mean providing input on the questionnaires—ensuring relevant community research questions are included (where possible) as part of the study—and on other study instruments and plans, including how the researchers expect to access and engage the MSM/LGBTI community.

It is also important to avoid potentially negative reactions from the broader community, such as hostility from healthcare workers, government officials, religious leaders, police, or the media. LGBTI leaders need to help researchers understand the context where the research will take place and develop strategies to deal with any structural barriers. As mentioned previously, researchers and LGBTI community leaders need to be collaborative and creative, finding the appropriate balance between promoting, protecting, and fulfilling the rights of participants and the broader community.

MSM/LGBTI community members should insist on being involved in the study design to ensure that the research will actually work to their benefit.

Implementation: Depending on the type of research being conducted, MSM/LGBTI community leaders can play various roles during the implementation phase; they can help recruit staff from the local LGBTI community to assist in formative research. They can also reach out to key stakeholders, recruit participants, conduct interviews, enter data into electronic databases, and analyze findings. This kind of engagement can bring legitimacy to the research team, helping build trust between researchers and study participants. Similarly, it can raise the profile of an LGBTI organization and enhance its credibility among key stakeholders.

Validation/dissemination: After the research is completed and results have been analyzed, it is important for researchers and MSM/LGBTI community groups to share findings with the greater LGBTI community. An effective strategy is to initially hold "pre-dissemination meetings" to ensure that the results obtained are understood by the community and that the messages in the conclusions are appropriate. MSM/LGBTI organizations can then use study findings to influence national policies, identify service gaps, and advocate increased funding for needed programs.

Once the findings are validated, LGBTI community groups should work with researchers to implement an effective dissemination strategy to share results with other key stakeholders. In general, there are passive and active dissemination strategies. A passive dissemination strategy might be to simply present a report on a website, whereas active strategies involve reaching out to and engaging relevant stakeholders. Examples include hosting public consultations to present the data, and engaging media practitioners to inform editors and journalists about the implications of the study findings. A useful means of establishing a clear, inclusive dissemination strategy is through the development of a memorandum of understanding (MOU) or data use agreement (see Appendix IV). Documents such as these outline clear procedures, protocols, and roles in the dissemination of sensitive data, including mandating the need for community engagement and ownership in the dissemination process. Planning for dissemination, including ensuring that there are appropriate financial resources for it, should be considered at the beginning of the study.

Community organizations should be encouraged to establish and maintain a repository of past and current research; this can be managed by a MSM/LGBTI research advisory committee or any other entity identified by the community for such purposes.

Finally, MSM/LGBTI community leaders should be given the opportunity to play a significant role in the dissemination of these data, including by making presentations at local, national, and international conferences and participating in writing manuscripts as co-authors. These roles can and should be clearly defined before the research project begins in MOUs and data use agreements.

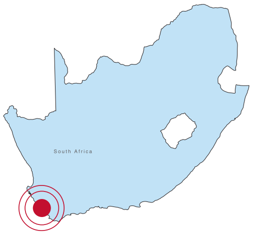
Before research begins, communities need to be engaged to give the project legitimacy. There should be meetings to hear input from the greater MSM/LGBTI community about participating in research, as well as opportunities to explore potential research questions the community may have that could fit into the proposed study as part of the overall effort. In addition, there should be meetings with the NGO community and media to inform them of the research and potential results.

CASE STUDIES

The following case studies offer practical examples of challenges and lessons learned from engagement between researchers and community members in the conduct of research projects involving MSM in difficult contexts. We have focused on three main categories:

- Conducting HIV research with MSM in contexts where homosexuality is criminalized and stigmatized;
- Conducting HIV research with MSM in contexts where homosexuality is legal but stigmatized; and
- Conducting HIV research with MSM in contexts where homosexuality is legal and broad protections are in place and enforced.

Case Study 1: Conducting HIV research with MSM in contexts where homosexuality is legal but stigmatized



Desmond Tutu HIV Foundation (Cape Town, South Africa)

Community leadership was a central element of the Desmond Tutu HIV Foundation's (DTHF) participation in the U.S. National Institute of Allergy and Infectious Diseases (NIAID) iPrEx study, a large-scale investigation of the use of PrEP to prevent HIV acquisition among MSM that produced promising results in December 2010. In fact, DTHF staff recognized that community engagement was a key factor in the success of their study and that careful planning and budgeting helped make this a reality.

From its inception, DTHF developed a strategy and a supporting budget for "community engagement" activities aimed at promoting, protecting, and fulfilling services for MSM. DTHF engaged and empowered LGBTI community members through its community advisory board and partnered with various community-based LGBTI organizations to gain legitimacy and build their capacity to engage in research. Through these linkages with Gender Dynamics, Anova Health Institute – Men4Health

Desmond Tutu HIV Foundation staff and community outreach staff share materials during Cape Town Pride.

Project, and the Triangle Project, among others, DTHF was able to refer research participants to an array of services offered throughout Cape Town. With support from both the local Ministry of Health and international donors (e.g., PEPFAR and the Global Fund), various venues were set up in Cape Town to provide MSM-specific health services.

DTHF also utilized social networks within low-income communities to inform and recruit participants. Staff spent sufficient time informing local health service personnel of their study and setting up referral points for specific services needed by study participants. They also hired a "community outreach officer" who was responsible for facilitating weekly skills-building and discussion sessions with study participants and other MSM. The outreach officer also helped create social spaces for these individuals to gather and disseminated general health information along with updates about the study. One unanticipated benefit of the study was that participants formed themselves into community-based organizations, and DTHF has been assisting them with formal registration processes and fundraising with local government entities.

DTHF also recognized the need to provide services for MSM. Beyond referrals for physical and mental health issues, the study team also developed a manual for healthcare workers on MSM-friendly HIV services, which has been turned into a training module with support from the International AIDS Vaccine Initiative (IAVI), the U.S. CDC, and PEPFAR. In addition, staff was able to refer some research participants to job training programs (e.g., on resume writing and job interview skills), and to hire local MSM to help with the study. These efforts not only helped provide services, but also helped recruit additional research participants.

From its inception, DTHF developed specific plans for community challenges involved with their study, including clear protocols to deal with community leaders, as well as a plan to work with media practitioners on study development, implementation, and dissemination. DTHF also worked with local government and the LGBTI community to disseminate results, specifically targeting more challenging stakeholders, such as religious and traditional leaders.

Although LGBTI rights are protected by the South African Constitution, those rights do not necessarily translate into social acceptance. Thus, confidentiality of research participants was essential. DTHF worked with various community activists to meet in secure locations, as well as to gain the confidence of some leaders who could help offer protection for participants. For example, in one site, research meetings were consistently conducted in the home of a lesbian activist who had taken specific measures to ensure the security of the premises. In terms of services, DTHF worked with clinic-based counselors in order to help study participants with their family lives, vocational training, and same-sex relationship issues, among other concerns. DTHF ensured that counselors were prepared to work with participants beyond their basic HIV needs.

Case Study 2: Conducting HIV research with MSM in contexts where homosexuality is legal and broad protections are in place and enforced

Projeto Praça Onze (Rio de Janeiro, Brazil)

One of the greatest challenges researchers face in undertaking MSM-related research is effectively managing the long-term expectations of the community. Various changes can occur that will affect this relationship: Science and research priorities evolve, protocols start and end, recruitment criteria need to be adapted, and research results transform the way the community perceives research and the prevention options available to them.

Projeto Praça Onze, an HIV research center linked to the Federal University of Rio de Janeiro, began working with the MSM/LGBTI community in 1995 on projects that included multiple prevention research approaches (i.e., vaccines, PEP, and PrEP), as well as treatment for those living with HIV. Through the years, contextual issues have changed, most notably the membership of the MSM/LGBTI community itself. The history of Projeto Praça Onze is one of constant adaptation and an evolving relationship with the community.

A Projeto Praça Onze campaign poster

Getting to Know the MSM/LGBTI Community

Rio de Janeiro is a large city with a cosmopolitan attitude and a reasonable level of acceptance of MSM, especially in the middle- and upper-class areas. But this is not necessarily true for all MSM in Rio. Many men face daily discrimination, and direct violence against MSM is not uncommon, leading some MSM to remain in the closet or avoid sharing information about their sexual behavior beyond a certain circle. Given this contradiction, initially Praça Onze directed outreach to the general population, seeking to attract a diverse set of MSM who may or may not identify as gay. However, it soon became apparent that this was not an effective recruitment strategy, and specific efforts targeting gay meeting places led to a much better response. Even men who did not identify as gay would eventually go to gay bars or cruising areas.

As a first project, the research center recruited for a large seroincidence study involving 1,000 MSM. This gave the team a very rich understanding of the needs, motivations, and diversity within the Rio de Janeiro MSM community. The project included not only regular visits for testing, medical appointments, and counseling, but also provided educational workshops that regularly attracted volunteers to the research center. These workshops and the MSM-friendly health services provided at the research center led to strong bonds among volunteers, who would meet regularly in the clinic, and between the volunteers and the research team. During the course of the study, the research center became a safe haven for men to interact socially, discuss their experiences, and receive adequate care.

The Research Center as a Reference for Volunteers

Many of the initial volunteers remained linked to the research center in one way or another, either because they joined a different protocol or because they chose to visit the staff or seek referrals. The MSM-friendly care provided, especially counseling and treatment of STIs, has proved to be an important added value for the volunteers, as it ensured access to care they might not have sought otherwise. For a number of years the center maintained a walk-in clinic that was open to former volunteers, but this led to continued demand that was overburdening the staff, which had to deal primarily with current studies. Today the center remains open to former volunteers and, whenever possible, provides basic care and counseling on the spot. It has also developed a strong referral network for former volunteers. At the end of a study, volunteers are encouraged to seek care within this network of services linked to the public health system, and there is a transition period that allows for volunteers to be followed by both the research physician and the public health system doctor.

Over the years, the research center has developed partnerships with other health units that have a track record of serving the MSM community. Given this focus, physicians, counselors, and other health professionals who are part of this community—or that have significant experience with it—often present themselves as natural partners for the research center, spontaneously helping to build up a network of MSM-friendly services to which volunteers and former volunteers can be referred.

Projeto Praça Onze learned early on that it was important not only to have a strong team of MSM and MSM-friendly staff to guide their daily work, but to also ensure that volunteers had strong connections to the staff members with whom they interacted more frequently. A well-trained, culturally-sensitive, and consistent team helped to ensure a productive relationship with volunteers and other members of the MSM community.

In the early days of Praça Onze, its research activities offered an opportunity for some volunteers to end their isolation and develop social ties. Their main reasons for volunteering were altruistic and connected to their own personal experiences with HIV/AIDS and their commitment to overcoming the epidemic.

This contrasts with the way new volunteers approach the research center today. Since 2006, as the Internet has become a central feature of gay social life, younger MSM have been coming to the research center because of their existing social networks, and through referrals from friends and online social networking services. Potential volunteers approach the center to strengthen their sense of belonging in the community. Rather than creating a new social circle, today the center provides continuity to the volunteers' existing social network.

Involvement of Local Civil Society

In order to ensure adequate support from the broader MSM and HIV/AIDS communities, the research center started its work by briefing local gay and AIDS organizations in detail about the project. Visits to community groups started years before a protocol was under way, and they evolved into trusted relationships. After initial briefings targeting the most relevant NGOs, the center started the first community advisory board (CAB) in Brazil. The CAB was responsible for developing a framework for its work that was adequate for the Brazilian context, with a mix of representatives from multiple communities—especially MSM—and prominent NGOs.

Today, members of the local CAB play a role in the global advisory bodies linked to the research networks that support studies at the center. In that capacity they can influence the international research agenda and impact the timelines and priorities for research locally, though admittedly this impact is limited. Most of the projects in which Praça Onze participates involve research centers in many countries, and in this complex international environment there normally isn't extensive opportunity for consultation with local communities in advance of new protocols. However, Praça Onze's ongoing relationship with the local NGO and MSM communities—through the CAB and otherwise—informs their perspective on what is feasible and acceptable for the populations with whom they work, and decisions about upcoming protocols take that perspective into account.

The local NGOs are trusted partners that provide advice and often invite research staff to brief community members on the science of HIV prevention. Although this is a mutually beneficial relationship, its impact is not one that can be felt in recruitment numbers, as this daily interaction has proven to not have a direct relationship with the number of potential volunteers coming to the research center. The impact of NGO engagement is mostly felt in two ways: through the sharing of knowledge and information about the community being recruited for a given project (for example, when sex workers were being targeted for a Praça Onze study); and in the overall credibility of, and support for, the research activities themselves.

Developing relationships with NGOs with established credibility among MSM was essential as the research center was being established in the mid-90s. It continues to prove extremely valuable at the start of each new study, as the researchers are able to provide in-depth briefings to NGOs, who can then share accurate information with their networks. This procedure helps ensure there is transparency around new research projects and allows for multiple trusted sources of accurate information for the community. It has also been an important component in communicating results from prevention trials, both negative and positive.

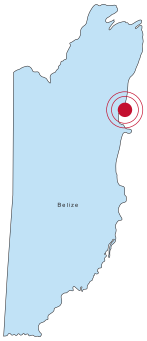
Communicating Research Results

Praça Onze has been engaged in some groundbreaking research projects and has provided important input to help guide the debates around HIV prevention in Brazil and worldwide. Early on, they were responsible for a unique safety trial on PEP's impact on sexual transmission among MSM, which provided preliminary evidence that PEP could be a valuable prevention tool beyond occupational exposure to HIV. They were also engaged in two important efficacy trials: the STEP vaccine trial, which demonstrated that the vaccine was not effective against HIV infection; and the iPrEx trial, which demonstrated the efficacy of PrEP among MSM. These experiences were important tests for the team and opportunities to reinforce their ties with the MSM community.

The STEP trial was interrupted ahead of schedule due to overwhelming evidence that the vaccine was not effective. Over the course of a couple of days, the research center had to pull off an emergency operation to reach out to all volunteers and provide them with information on the results immediately before, or at the same time as, the news was hitting the media. Over several months of follow-up visits and counseling sessions, volunteers were provided with extensive details on the implications of the results. The same was true for the local NGOs that approached the center with many requests for information and opportunities to discuss the implications of the results for their communities and the trial participants.

With iPrEx, the situation was quite different. The trial ended on schedule and there was extensive time to plan for sharing results. Policy makers, media representatives, and trusted NGO partners were briefed in advance and had a chance to digest the results before they became a media sensation. The research team had the satisfaction of being able to communicate broadly about results that had immediate relevance for the community engaged in the project. As the results make their way into policy debates about whether or not to incorporate PrEP into prevention toolboxes in Brazil, the research team continues to play a role in sharing information and informing the public debate among civil society and policy makers.

Case Study 3: Conducting HIV research with MSM in contexts where homosexuality is criminalized and stigmatized



Collaborative Network of Persons Living with HIV (C-NET+) (Belize City, Belize)

The Collaborative Network of Persons Living with HIV (C-NET+) is a community-based organization in Belize City working with gay men, other MSM, and transgender individuals (collectively, GMT) living with HIV. For many years, C-NET+ has worked with researchers on specific studies, with mixed results. In 2012, the U.S. CDC supported a bio-behavioral HIV/STI study among MSM and trans individuals, sex workers, and people living with HIV, comparing HIV/STI prevalence and risk behaviors across several Central American countries. The study was conducted by the Universidad de Valle de Guatemala (UVG), in close collaboration with Ministries of Health (MOH) in each country. UVG developed the study protocols and processes based on past research they had conducted with marginalized communities in the region. Once approved by the CDC and ethics review, UVG researchers sought assistance from the MOH in Belize to recruit participants for the study in Belize. However, due to laws criminalizing same-sex sexual behavior, this arrangement proved problematic.

EriKa Castellanos, executive director of C-NET+, presents at amfAR's New York office on research that she and her team are doing in Belize.

Initially, a meeting of leaders from all four sub-populations was held by UVG and the MOH to explain the objectives of the study and gain community support and cooperation. However, the meeting raised several challenges with regards to MSM and trans individuals. First, the MOH instructed UVG not to invite the United Advocacy Movement in Belize (UNIBAM), a LGBTI rights organization that had formally challenged the Belizean penal code. The MOH decided that since this civil society organization was challenging the government, they should not be a part of the study. Second, other leaders representing GMT individuals felt they were only being used to recruit participants and validate findings, that various issues of concern to MSM and trans individuals were not being studied, and that they had no involvement in the design, development, and implementation of the study. Hence, the leaders did not endorse it, which proved problematic.

Because both UNIBAM and C-NET+ did not endorse the study, enrolling participants was very slow. Because the researchers were not able to reach enough people, the size estimate component of the study was not possible. A few MSM were hired to assist in enrollment and administering the study; however, they were treated poorly and resigned before the study began. Hence, UVG was forced to use interviewers who were not GMT. There also were language barriers, in that the investigators from the university all spoke English, yet the protocols and intake forms were in Spanish. In Belize, Spanish and English are spoken in different regions of the country, and not everyone is bilingual.

Many GMT individuals were afraid to participate in the study. The enrollment protocol called for respondent-driven sampling (RDS), whereby five initial contacts would each give five referrals to other participants and so on. However, due to fear of the potential stigma of being involved in such a major study among GMT, many participants did not feel comfortable referring five additional participants. In turn, the study organizers began giving the initial participants 15–20 referral cards to recruit others, instead of five, thereby biasing the enrollment sample. The researchers then recruited individuals they thought were leaders in the community, effectively ignoring the rest of the GMT population. In addition, those individuals who eventually did participate in the study seemed more driven by financial compensation than actual sharing of information. In the end, after over a yearlong delay, only 136 MSM participated in the study.

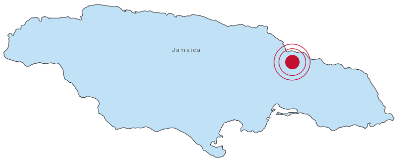
Following the study, community involvement was also limited. There was little to no community consultation when the results were shared by CDC, MOH, and UVG, and to date, only preliminary findings have been shared with them, not the final results.

Most alarmingly, the preliminary results were used to further propagate and justify the anti-sodomy law and discredit the constitutional challenge against it. The media embellished results, creating more stigma and discrimination for GMT individuals, especially GMT living with HIV, by further fueling stereotypes that GMT individuals are dangerous, promiscuous alcoholics, and/or 'disease vectors.' In addition to being used as further evidence for upholding the sodomy law, the publicity also drove more GMT individuals into hiding. While the constitutional challenge is still pending, the fierce rhetoric against GMT individuals continues to rage. As a result of these challenges, many GMT leaders in Belize question the validity and reliability of the study results. However, because there is no further data available, they are forced to use the 13.85% HIV prevalence found in the study in their work and materials.

Staff from CVC and Jamaica AIDS Support for Life (JASL) perform outreach and peer education.

Researchers conducting subsequent studies among GMT individuals in Belize have learned from these difficult and costly experiences. The GMT leaders are now much more astute about their role in defining and implementing research. Today, if any research is being conducted, the MOH and CBOs work together to design, implement, analyze, validate, and disseminate findings. More and more, civil society organizations like C-NET+ are the ones calling for such research and spearheading the efforts by securing funding and researchers to collaborate with them.

Case Study 4: Conducting HIV research with MSM in contexts where homosexuality is criminalized and stigmatized



Caribbean Vulnerable Communities (CVC) (Kingston, Jamaica)

Caribbean Vulnerable Communities (CVC) is an association of community leaders and NGOs committed to serving key populations in the context of the HIV epidemic. Headquartered in Kingston, Jamaica, but serving the entire Caribbean region, CVC supports member organizations in advocacy efforts, HIV treatment and prevention, and monitoring and evaluation of programs serving key populations, including MSM.

Central to this mission is the need for sound research on HIV prevalence and service provision for these populations. In countries such as Jamaica, where homosexuality is not only stigmatized but also punishable by law, accurate information on HIV prevalence and treatment coverage is critical to best serve this hidden population. Over the years, CVC has engaged in research both autonomously and as a partner to member organizations and the MOH.

In 2011, CVC collaborated with the MOH to undertake the Men's Health Survey, an island-wide study of 449 MSM in Jamaica. The bio-behavioral survey, initiated by the MOH and approved by the Ministry of Health Ethics and Medico-Legal Advisory Panel, aimed to estimate HIV prevalence and incidence among MSM, while also exploring underlying determinants of HIV infection that could inform prevention efforts.

From the survey's inception, researchers were committed to sustained, long-term engagement of the MSM community. Before constructing and finalizing a protocol, CVC and the MOH reached out to the Jamaica Forum for Lesbians, All-Sexuals and Gays (J-FLAG), a prominent LGBTI rights organization in Jamaica with a longstanding relationship with CVC. J-FLAG worked with researchers to identify and connect with MSM community groups. One by one, researchers met with groups to describe study aims, gain input into the design, and discuss possible ethical or legal implications of the research.

After these initial discussions and the subsequent design of the study, the research team established a steering committee to coordinate implementation. The committee was made up of both researchers and MSM leaders from the groups identified by J-FLAG. The committee met regularly to ensure that all ethical safeguards remained in place.

As data were analyzed, researchers also identified the need for a strategic approach to dissemination. For example, the survey estimated an HIV prevalence of 31.4% among all MSM and an even higher prevalence among MSM sex workers (41.1%). Both researchers and MSM leaders involved in the study had to carefully consider what these elevated estimates could mean for the MSM community, and how this information would be interpreted by both the community and media.

It was clear that a dissemination strategy must simultaneously consider both the messenger (the media) and those possibly affected by the message (the MSM population). Before results were formally released, researchers held a series of pre-meetings with the MSM community to present and discuss emerging findings. These pre-meetings served two purposes: 1) to gain feedback and input on the validity and implications of the results, and 2) to ensure that MSM/LGBTI community leaders were able and willing to speak to science- and policy-related questions about the research.

To manage information flow, CVC called upon relationships with media practitioners that the coalition has taken care to foster. CVC had supported a number of media trainings with journalists over the past few years, allowing them to develop a trusted cadre of journalists to manage the initial release and messaging of sensitive information. Importantly, this strategic information flow represents only a first step in dissemination; once trusted media sources report information, other outlets may misread and misreport such results. It is for this reason that community leaders should be adequately engaged in both the study and dissemination strategy, so that they can respond to any issues resulting from the reporting of results.

Case Study 5: Conducting HIV research with MSM in contexts where homosexuality is criminalized and stigmatized

Stop AIDS in Liberia (SAIL) (Monrovia, Liberia)

Stop AIDS in Liberia (SAIL) was founded in September 1998 to reduce the spread and impact of HIV/AIDS among MSM/LGBTI youth and sex workers. SAIL initially raised awareness about HIV/AIDS among each sub-population and provided peer counseling and home-based HIV palliative care for community members. Currently, SAIL implements HIV prevention, testing, and care services and promotes human rights, including LGBTI rights, as core strategies to reduce the HIV burden in Liberia. In addition, most of

SAIL's leadership and members are from the LGBTI community. SAIL envisions a Liberian society free of HIV/AIDS and discrimination, with all Liberians living healthy and happy lives.

With financial support from amfAR, in 2009, the University of Liberia School of Social Science and the Pacific Institute for Research and Evaluation (UL-PIRE) initiated a qualitative study to assess the HIV risk knowledge, attitudes, and behaviors of MSM in the capital city of Monrovia. The study aimed to conduct in-depth interviews with 25 MSM. After nine months of implementation, only three individuals had been interviewed. The UL-PIRE researchers claimed that it was very difficult to find MSM who were willing to discuss their sexual behavior due to fears regarding confidentially. amfAR staff then encouraged the researchers to engage SAIL as a partner in the study. Within a month of beginning the collaboration with SAIL, all 25 MSM participants had been enrolled and interviewed. This clearly demonstrated that working through a LGBTI-led organization helped establish trust among MSM within the community and increased their willingness to take part in the interviews. Results indicated that stigma and discrimination regarding both sexual orientation and gender identity (SOGI) and HIV status were the key factors hindering access to HIV services.

Following this success, in 2010 SAIL was brought on as a full partner with UL-PIRE and the Liberian National AIDS Commission in the conceptualization, design, implementation, analysis, and dissemination of a study to estimate the population size of three key affected populations—female sex workers, MSM, and PWID. In addition, SAIL was a full partner in an Integrated Bio-Behavioral Survey (IBBS) of key populations that included MSM, female sex workers, miners, uniformed services personnel, long-distance transport workers, PWID, in- and out-of-school youth, and mobile traders. Working in collaboration from the start of the IBBS, UL-PIRE and SAIL were able to enroll 343 MSM in the study. Results indicated that MSM had the highest HIV prevalence among all sub-populations (19.8%), more than twice that of female sex workers. The survey also showed that MSM had the lowest level of knowledge about effective HIV prevention, with 76.7% reporting being unaware of at least two methods to prevent HIV transmission.

SAIL staff perform outreach during the launch of Liberia's National Condom Promotion Campaign.

Results from the study informed a new national strategic framework, which for the first time recommended strategies to address the HIV burden among MSM. In time, SAIL was able to secure financial support from UNAIDS, through the Liberian National AIDS Commission, to implement prevention and care services for MSM, including MSM living with HIV and male sex workers. Based on the success of this survey, SAIL is now recognized as a key partner for any research conducted in Liberia that relates to MSM. Since 2010, SAIL has been an active partner in a number of studies, including an HIV stigma index study in 2012, a National AIDS Spending Assessment study in 2013, the UNICEF-supported most-at-risk adolescents survey in 2013, and a Human Rights Watch report documenting the lived realities of LGBTI individuals, among others.

Case Study 6: Conducting HIV research with MSM in contexts where homosexuality is criminalized and stigmatized

The Gay and Lesbian Coalition of Kenya (GALCK) and the National AIDS and STI Control Program (NASCOP)
(Nairobi, Kenya)

The increased focus on HIV research involving MSM and lesbian, gay, bisexual, and queer (LGBQ) communities in Kenya highlighted a fundamental need to ensure their meaningful

Community leaders, researchers, and funders during a consultative forum in Nairobi

engagement in and ownership of research. To address this need, a coalition of organizations—including the Gay and Lesbian Coalition of Kenya (GALCK), which is the national LGBQ umbrella organization, the National AIDS and STI Control Programme (NASCOP), and supporting partners the East African Sexual Health and Rights Initiative (UHAI), amfAR, and IAVI—developed and implemented a research preparedness plan that has changed the landscape of MSM/LGBQ engagement in HIV research in Kenya.

Initially, a two-day training workshop on research was conducted that brought together key MSM/LGBQ advocates and leaders and program staff from various community groups in Kenya. During the workshop, participants learned about research concepts and processes, shared positive and negative experiences working with researchers, developed a community-unified research agenda, and formed a National LGBQ Research Advisory Committee (G10) led by two co-chairs.

NASCOP and the G10 then worked with GALCK to co-convene the first-ever consultative forum on strengthening research partnerships with the MSM/LGBQ community in Kenya. The forum—which brought together the G10, key social and biomedical researchers, government officials, and funders—focused on the need to include the MSM/LGBQ community in all research processes from conceptualization through dissemination of study findings, including co-authorship of research papers. Forum participants worked collaboratively to revise the community-unified research agenda, and approved it as a national research plan that included two priority questions and three reserve questions each under the biomedical, structural, and behavioral study components. A mechanism to monitor the implementation of this national research plan was also identified. Working as an agency within GALCK, the G10 now coordinates all MSM/LGBQ research in Kenya on behalf of the community.

In the wake of the forum, many research groups in Kenya have reached out to the G10 to ensure alignment with the nationally-endorsed research agenda. For instance, the Kenya AIDS Vaccine Initiative – Institute of Clinical Research (KAVI-ICR) subsequently convened a one-day consultation with the G10 and existing MSM and sex worker CABs to provide input on an HIV Simulated Vaccine Efficacy Trial (SiVET) protocol—a double-blind, randomized, placebo-controlled trial using a licensed hepatitis B vaccine—prior to its submission to the ethical review committee. In addition, the Kenya Medical Research Institute – Center for Geographic Medicine Research (KEMRI-CGMRC) partnered with selected members of the G10 whose work is specific to coastal Kenya, called Utafiti Pwani, and co-authored a paper that was published in the *KEMRI Bioethics Review*, Volume IV, Issue 3, 2014, titled “Collaborating with GMT Organizations on HIV Prevention and Care Research in Coastal Kenya” (page 10). Researchers also partnered with members of the G10 as co-investigators when they submitted three implementation science grant proposals to amfAR in the same year.

The sustained implementation and strengthening of this community engagement model has ensured meaningful CEO and strong buy-in and commitment at the grassroots level. This in turn has continued to inform changes in research-related policy and practice at the county and national levels in Kenya.

Case Study 7: Conducting HIV research with MSM and sex workers in contexts where homosexuality is legal but stigmatized

Service Workers in Group (SWING)
(Bangkok, Thailand)

Service Workers in Group (SWING) is a community organization that works with sex workers of all genders in Thailand’s tourist “hot-spots.” It was formed when

Members of Service Workers in Group (SWING) bring HIV prevention education to Thai sex workers.

Surang Janyam, an employee at an organization serving female sex workers called EMPOWER, uncovered a lack of healthcare and advocacy services for male and transgender sex workers, including those who self-identify as either gay or MSM. Surang joined forces with a group of male sex workers in the community to develop a bottom-up strategy for reaching hidden populations. Today, 80% of SWING's staff self-identify as current or former sex workers, which is a strong testament to the organization's community-based approach to advocacy and research.

In 2010, SWING conducted a survey on violence against male, transgender, and female sex workers in the city of Pattaya. The survey was meant to inform SWING programming in this urban "hotspot," as well as add to the general understanding of issues facing sex workers in such settings. The survey was based on an earlier study—conducted by SWING in 2007 in partnership with the Institute for Population and Social Research (IPSR) at Mahidol University—that engaged community leaders to serve on the research team. In preparation for the 2010 survey, SWING held a workshop with community leaders to train sex workers on methods used in conducting social research. The workshop covered various topics, including research methodology, questionnaire design, and data collection, analysis, and use. After the workshop, community leaders conducted the survey with support and mentoring from IPSR staff.

The survey found that many sex workers did not know their legal rights when faced with violence from clients, peers, or police. In an effort to ensure that the survey resulted in meaningful outcomes, SWING modified their services in Pattaya to include basic education in human rights. In addition, SWING has worked to assist research participants by developing a network of human rights defenders in the Pattaya area.

The participatory and results-oriented approach to conducting the survey was well received by the sex worker community. Key personnel who participated in the project reported feeling as though they were part of a meaningful solution to fighting violence against sex workers. This approach also allowed the community to understand and claim ownership of both the findings and implications of the research, which in turn better equipped them to effectively advocate for change.

SWING also undertook an initiative to engage and educate the police force in Bangkok. (While not a research effort, the approach that SWING used provides a useful model for other organizations conducting research in rights-constrained environments.) Due to a history of police brutality and corruption when dealing with sex workers, SWING began facilitating sensitivity trainings with police in "hotspot" areas in 2004. In 2005, this grew into a full-fledged Police Cadet Training

Program, in which third-year cadets fulfilled a mandatory community service requirement through an internship with SWING. During these three-week internships, the police cadets served as SWING staff, and were responsible for doing everything from cleaning floors to conducting community outreach. In effect, the cadets became part of the SWING team, which gave them a better understanding of the hardships faced by sex workers. The program not only allowed police to forge lasting relationships with the sex worker community, it also provided SWING with strong links to a trusted law enforcement network that they could call upon when the organization or its members were in need of advice or assistance.

KEY RECOMMENDATIONS FOR RESEARCH WITH KEY POPULATIONS

- Formative research on current community resources is vital for conducting studies of any kind. It is important to know who's who within the LGBTI community, who is, or has already been, working with MSM populations, and what types of MSM-friendly services are already in place. MSM/LGBTI community members should be engaged in setting the research agenda. Dialogue with civil society is key for establishing the credibility and good intentions of the research team; it can also help with study recruitment. It is also important that the research benefit the community, not simply the researcher's interests. The best way to ensure that research activities are respectful and relevant is to include members of the population being studied within the research team. A steering committee should be established that includes both researchers and MSM/LGBTI community members to coordinate study implementation. The group should reflect the diversity of the study context, with community members from various groups and regions represented.
- Research budgets should include funds dedicated for "community engagement." Many donors are now requiring community engagement plans and will provide funding to support such activities. This engagement should be viewed as a basic and necessary element of community research. Researchers may also want to allocate a portion of the study budget to supporting community/volunteer welfare, such as reimbursements for transportation and providing meals/snacks during day-long meetings. Some groups found that including incentives such as t-shirts strengthened community engagement. However, participation must not be coercive, and items or funds given should be based on reasonable costs of participation in the study.
- In cases where MSM face social or institutionalized discrimination, researchers may need to do more than simply reach out to law enforcement or the general public. Bridging this gap often requires a significant investment on the part of researchers and their partners. Activities such as recurring sensitivity and experiential trainings and internship programs can help to build long-term relationships with important legal and political allies.
- A multidisciplinary team that is sensitive to the issues faced by the community is an essential component of study success. Different skill sets and profiles allow research centers to be responsive to the diverse needs of volunteers, and having a strong team of sensitized physicians, nurses, counselors, and community educators closely identified with the MSM community is also critical.
- MSM/LGBTI community members need to be engaged to identify which services are most important to them, and study teams should be willing to explore how these priorities can be integrated into research plans and protocols. In many cases, direct HIV services, such as providing condoms, are not as important as other factors, such as job training, social support, and enhancing interpersonal skills for healthy romantic relationships and/or pleasurable sex.
- Researchers and MSM/LGBTI community leaders should think beyond implementation of the research to how the eventual findings may have a meaningful effect on programming. Research teams must also challenge themselves to include a "community capacity-building" role as part of any study, and should understand that engagement is not a one-off activity.
- Both researchers and MSM/LGBTI community leaders should be involved in dissemination, especially with the media. It is vital to ensure that the community is well informed about study results and that leaders are prepared to respond to questions from the media or the public. Developing relationships with a trusted corps of journalists who can handle the initial release of results helps in making dissemination smoother.

APPENDIX I

Questions for Researchers to Ask Regarding MSM/HIV Research

RESPECT	*Status*	*Notes*
Have you included the MSM/LGBTI community in:		
Engagement rules		
Situational assessment		
Have you assessed the relevance of the research and potential reactions from the community at large?		
Have you assessed the interest amongst the MSM/LGBTI community, as well as current infrastructure (or lack thereof)?		
Have you assessed the willingness of your research institution to Respect, Protect, and Fulfill rights of participants?		
Have you developed an MOU with community-based organizations—clearly involving them in all aspects of the research?		
Have you clearly defined roles and responsibilities of all stakeholders?		
Have you conducted a comprehensive identification process with stakeholders including:		
Community stakeholders, NGOs, CBOs, community groups, informal networks, etc.		
Government ministries, leaders, etc.		
Local healthcare facilities and services		
Local religious leaders		
Media		
Have you engaged government, while first discussing effective models of engagement with community representatives?		
Have you secured funds for community involvement (e.g., providing financial Incentives, etc.)?		
Will you start by conducting formative research activities to learn more about the target populations and their priorities? (This would also include learning about what prior research has been conducted in this population and what are the local perceptions of this research [both from MSM and from non-MSM].)		
Have you included research on human rights protections/violations within the research context?		
Will you provide research literacy training to key stakeholders?		
Local NGOs, CBOs, informal networks of MSM/LGBTI		
Healthcare service providers		
Media		
Government		
Influential community leaders		

PROTECT	*Status*	*Notes*
Have you developed policies for dealing with hostile/intrusive media, media that may blame MSM for ‘spreading HIV’ in a country?		
Have you developed certificates of confidentiality to help participants feel safe, knowing that their information will not be shared with others?		
Have you developed personal identifiers that protect people’s identities, or considered conducting research anonymously?		
Have you ensured safe storage of any data that would link participants’ sexual orientation information or behavioral practices?		
FULFILL		
Have you (or others) conducted formative research activities to learn about:		
MSM needs and specific priorities		
Prior research in this community		
Local perceptions of past research (both from MSM and from non-MSM)		
Have you (or others) conducted formative research to learn more about and address structural drivers of HIV and STI risk when researching MSM in low- and middle-income countries?		
Criminalization		
Stigma and discrimination		
Violence/sexual violence		
Poverty		
Have you planned for MSM/LGBTI community capacity-building and informed participation?		
Secure funding to build capacity of MSM/LGBTI community members		
Allow local groups to use resources such as meeting spaces		
Ensure representation of MSM/LGBTI on staff		
Train MSM/LGBTI community members to be involved as study staff to build capacity for the future		
In disseminating results, do you have plans to work with MSM/LGBTI community leaders on data dissemination and a utilization plan, including media advocacy?		
Do you plan to build the skills of activists to disseminate/use data locally for advocacy?		

APPENDIX II

Questions for Communtiy Organizations to Ask Regarding MSM/HIV Research

RESPECT	*Status*	*Notes*
What is motivating the research team to conduct this research in your community?		
Who is funding the research?		
On what level and how will community stakeholders be involved in the research process?		
Has a community advisory board (CAB) that is representative of the population(s) being studied been established, and was the community consulted in its formation?		
How can we be sure that the research will respect our priorities and needs and include our input?		
What role can we have in designing, conducting, analyzing, and reporting results of the research?		
Who will “own” the data?		
How can we be sure that once the data are collected, the researchers won’t just go away and publish our data in another country?		
Who will be involved in decisions on how data and results are disseminated?		
Will we have authorship on publications derived from the research?		
How will the data be used to improve the situation for the target population?		
How will we be compensated for our involvement (financially or in-kind) in the research?		

PROTECT		
How will the research team protect our confidentiality and safety before, during, and after the research?		
What is the timeline for the research and what are the stages?		
What sort of support will the research team provide us so we can better understand the research and participate in a more equitable way?		
What plans are there to guarantee protection of personal data from police, media, and the community?		
Is there budget to assist in emergency situations? For example, if a study participant is arrested based on sexual orientation and needs to be bailed out of jail, or if participants’ lives are being threatened and they need to find safe housing.		
After data are analyzed, how will results be shared with the broader community without jeopardizing the safety of the target population, or further stigmatizing us?		

FULFILL		
What sort of services will be provided to research participants?		
In what concrete ways will this research benefit the population?		
Once the study is completed, what assurances can you offer that prevention, treatment, and care services will continue?		

APPENDIX III

Checklist for Data, Volunteer, and Staff Security

Security in research settings refers to a state in which research data, volunteers, and staff are protected from any threat and/or danger that may come as a result of working with MSM/LGBTI communities. Though this may seem difficult to guarantee, measures can be put in place to progressively ensure security is maintained.

Factors to be considered by researchers and community organizations to protect data, volunteers, and staff:

Data can be physical (print) or electronic and will be classified under:

- **Ultra-Risk Data –** Patient's name or national ID number, biometrics with information pertaining to a study
- **High-Risk –** Volunteer ID and/or date of birth with lab data
- **Low-Risk –** Volunteer ID without sensitive data
- **Electronic data –** Data stored in any electronic data processing system or device, such as computers, disks, etc., that contain trial data. Good clinical practice (GCP) provides guidelines under section 5.5.3 on how this can be secured (Barnett Educational Services, 2014).
- **Closed System –** Refers to a system in which access is controlled by a person(s) who is/are responsible for the content and security of electronic records.
- **Open System –** Refers to a system in which access is not controlled by a person(s) who is/are designated responsible for the content of electronic records.[34]

Data

Topic	Questions	Current Status	Notes
Planning/Setup	Are stored print data in a lockable cabinet securely locked all the time?		
	Have the databases been validated and confirmed as working properly?		
	Are there processes to uniquely identify volunteers?		
	Have the various enrollment strategies (e.g., snowball, online) been assessed for possible security risks to volunteers?		
Operations	Is there any unauthorized access to data?		
	Is the list of authorized users up-to-date?		
	Are **tabletop exercises*** scheduled to test a hypothetical situation, e.g., a raid?		
	Are reputable/secure courier services used to transfer sensitive hard copy documents?		

Topic	Questions	Current Status	Notes
Implementation phase	Is there adequate data backup?		
	Are changes to Case Report Forms (CRFs) documented?		
	Are there audit trails showing how data is moved?		
	What continuous monitoring and evaluation is being done to ensure confidentiality, integrity, authentication, and non-repudiation?		
Close out and archiving	Have access privileges been revoked from users who have left the organization?		
	Is there a policy on record retention/archiving?		

Volunteer

Topic	Questions	Current Status	Notes
Planning/setup	Is there an emergency response and crisis management plan in place (if yes, was it developed with input from the community)?		
	Is there a contingency budget to assist in emergency situations?		
	Who has access to detailed volunteer-identifying information? What levels of controls are in place to ensure confidentiality?		
	Which documents contain volunteer-identifying information?		
	Is patient-identifying information/ data shared on email?		
	What plans are to be undertaken to empower and strengthen civil society organizations (CSOs) working with key populations (KPs) to provide legal and security support?		
	Are there linkages with paralegals, partners, and other NGOs who support the work of KPs?		

Topic	Questions	Current Status	Notes
Operations	Does the research institution engage with communities or institutions with the power to inflict harm on, disrupt, or support research activities (e.g., law enforcement, the Ministry of Health, religious groups, CSOs)?		
	Are there any best practice guidelines in use to protect volunteer security? List them.		
Implementation phase	Are photographs and/or biometrics of volunteers taken at enrollment and volunteer visits?		
	What measures are in place to protect volunteers against police entrapment based on existing laws?		
	Are volunteers discouraged from sharing their full names with other volunteers?		
	How is sensitive print data destroyed/filed/audited/stored?		
Close out and archiving	What plans are in place to share data with the community and society at large when the research is complete? Are there plans to manage any negative responses from the public?		

Staff

Topic	Questions	Current Status	Notes
Planning/Setup	What communication plans for the community advisory board (CAB) are in place to ensure regular updates and feedback are provided to the community?		
	Are there referral mechanisms with legal aid entities and CSOs that support staff?		
Operations	Is staff adequately trained on working with KPs?		
	Is there sufficient security to protect against a mob raid/attack?		
	Are there security escalation and response mechanisms in place?		
	Are standard operating procedures discussed at meetings and what mechanisms exist to ensure implementation?		

Topic	Questions	Current Status	Notes
	What security drills are conducted at the facility? How often?		
Implementation phase	What mechanisms exist to ensure that the right staff is hired?		
	Are staff aware of any available support in case of a breach of security?		
	What security mechanism exists to ensure access to the facility is controlled?		
Close out and archiving	What mechanism exists to ensure that all data is returned to the facility when a staff member leaves?		
	What mechanisms are there to ensure all study documents are archived or destroyed appropriately?		

**Tabletop exercises* are activities designed to test the theoretical ability of a group (e.g., a researcher/community collaborative research project team) to respond to a situation. These exercises allow staff to test a hypothetical case without causing disruption to the research site and community. They also help test cooperation and readiness to respond to such situations. In these exercises, a facilitator lays out a scenario to which the study team responds. The scenario shifts and continually evolves depending on how the staff responds and other external factors.

Recommendations for securing data

Electronic and non-electronic data

It is important to ensure confidentiality, integrity, authenticity, and where possible, non-repudiation of electronic and non-electronic data for both open and closed systems. The following suggestions may be useful to accomplish this:

a) Protect data/records from unauthorized access, e.g., by securing electronic data in databases with passwords and limiting access to data considered ultra-risk.
b) Non-electronic, ultra-risk data that could link a participant unique identifier and his/her actual name or ID should be kept separately and under lock and key.
c) Assign a person(s) who will maintain electronic data storage and manage the database containing sensitive data—this includes regular backups, time-stamps, etc.
d) Restrict access to data rooms/filing centers to authorized personnel.
e) Ensure that data are stored accurately and can be easily retrieved when needed for the entire retention period.
f) Establish data management and storage policies and protocols that will be enforced.
g) Ensure regular updates and upgrades of passwords and access codes, and perform tests to check the robustness of the security system.
h) Conduct regular tabletop exercises to help test readiness to respond to hypothetical situations that may threaten data security.

APPENDIX IV

Sample Memorandum of Understanding

MEMORANDUM OF UNDERSTANDING
Between [Research Partner] and [Community-Based Organization] and [All other partners]

I. **Purpose**

The [Research Partner] (hereinafter referred to as "[x]", [Community-Based Organization] (hereinafter referred to as "[y]") and [All other partners] (hereinafter referred to as "[z]") (each a "Partner" and collectively the "Partners") seek to share their respective strengths in order to complete [specific research project].

The purpose of this Memorandum of Understanding ("MOU") is to set forth the understandings and intentions of the Partners to further the goals and objectives set forth below (the "Goals"). The Partners seek to share their respective strengths, experiences, technologies, methodologies, and resources (including human, in-kind, and financial) in order to achieve these Goals. The Partners are entering into this MOU while maintaining their own separate and unique missions and mandates and their own responsibilities and funding framework. Nothing in this MOU shall be construed as superseding or interfering in any way with other agreements or contracts entered into between two or more of the Partners, either prior to or subsequent to the signing of the MOU. The Partners further specifically acknowledge that this MOU is not an obligation of funds, nor does it constitute a legally binding commitment by any Partner.

II. **Background**

[Include several paragraphs on the background and purpose of the partnership. This can also include mission statements or descriptions of each individual partner. It should also describe the common challenge(s) that the partners intend to address through research.]

III. **Goals and Objectives**

The Partners agree to share in the following goals:
[Goals can be high level and consist of 2–3 sentences. The objectives for each goal should be more measureable and specific.]

- Goal #1:
    - Key Objectives:
- Goal #2
    - Key Objectives:
- Goal #3
    - Key Objectives:

II. **Partner Roles, Responsibilities, Funding, and Support**

1. [Research Partner]

Role of Partner: [NOTE: The role should summarize each partner's contribution to the program and management/implementation role in the project.]
Under the Partnership, it is expected that the Partner's role will be to

- [ex., include monetary and actionable contributions]

Point of Contact:

2. [Community-Based Organization]

Role of Partner: [NOTE: The role should summarize each partner's contribution to the program and management implementation role in the project.]
Under the Partnership, it is expected that the Partner's role will be to

- [ex., include monetary and actionable contributions]

Point of Contact:

3. [Include other Partners using the same format]

III. Implementation

1. Governance Structure

[This section should outline how decisions will be made, frequency of partner meetings, and mechanics of how meetings may be called and run.]

[This section can also include more detailed descriptions on funding and communication, validation, and dissemination plans.]

IV. Effective Date, Duration, Amendments, and Termination

This MOU becomes effective on the date of the last signature of all the Partners and is expected to continue for [X] years from such date. However, the Partners may decide in writing to extend this agreement. In addition, this MOU may be modified or amended if agreed upon by all Partners in writing. Any Partner may terminate this MOU at any time but should provide at least [X] days written notice to the other Partners.

IN WITNESS WHEREOF, the Partners, each acting through their duly authorized representatives, have caused this MOU to be signed in their names and delivered as of this [X] day of [Month, Year].

[Research Partner]

____
Name *(Specify Authorized Representative)*

____
Title *(Specify)*

____
By *(Signature)*

____
Date

[Other Partner]

____
Name *(Specify Authorized Representative)*

____
Title *(Specify)*

____
By *(Signature)*

____
Date

[Community-Based Organization]

____
Name *(Specify Authorized Representative)*

____
Title *(Specify)*

____
By *(Signature)*

____
Date

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