

# RESPECT PROTECT FULFILL

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 guidance has been developed for both researchers and community-based organizations in rights-constrained environments. The guidance is intended to help both researchers and community organizations to:

- Better design and conduct meaningful research on HIV among MSM in challenging social, political, and human rights contexts;
- Provide a check list of factors for researchers and community organizations to consider in the design, conduct, and implementation of research studies;
- Offer lessons learned through case studies of research and community partnerships, recent successes, and challenges.

## BACKGROUND

The HIV community is increasingly aware of the scale, scope, and severity of the global epidemics of HIV among MSM. Current interventions for HIV prevention, access to treatment, and a range of HIV- and STI-related issues 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 is urgently required to develop new and combined preventive interventions, to markedly improve access to ARV treatment, and to investigate the role of treatment as a prevention tool for MSM. This is a moment of unprecedented scientific opportunity. Yet enormous challenges face all who are engaged in this effort or seeking to become involved. Not least of these is that in much of the world MSM and other sexual and gender minorities still face discrimination, including discrimination in health care, denial of their existence by some states, and criminal sanctions and social exclusion in others. 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 can be a very real concern. Yet this important work must be done, and done well. How are we to proceed?

This guidance, developed by a collaborative group of investigators, community advocates, and leaders in the field of HIV work with MSM, seeks to address these challenges. It is meant to be a living document, hopefully of use to those 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 capture 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 will largely focus on reducing risks and improving services for all MSM, regardless of orientation or identity.

For community groups, the term “MSM” can have limited usefulness. The lesbian, gay, bisexual, and transgender (LGBT) umbrella covers a broadly shared identity that is embraced by many of the groups working for equality, for civil and human rights for sexual and gender minorities, and for health care access and quality. Few community groups identify as “MSM” groups, as few people identify as MSM. In this guidance, we use LGBT when referring to community-based groups that embrace the term and that may be leaders in both the rights struggle and in the HIV response.

Transgender (TG) persons, and particularly TG women who have been assigned the male gender at birth, have often been inappropriately included in the broader category of MSM. We have not addressed the vitally important HIV research agenda for TG persons in this guidance as it is clear to us that many of the unanswered research questions are different, and that a separate TG research guidance is clearly 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 based on structural inequalities. These structures may be legal, such as where same-sex behavior is criminalized, or they may be unofficial societal attitudes where same-sex behavior is overtly stigmatized. This document is written from the perspective of low- and middle-income countries, but some of its themes pertain to rights-constrained environments in high-income countries as well.

## The Current Context

Recognition of the global nature of MSM epidemics is growing. Advocacy efforts at the local, national, regional, and global levels are seeing results, with increasing recognition—by many national governments, researchers, civil society groups, and

donors—of rising HIV infection rates among MSM, and increasing investment in HIV/MSM-related research studies. The recent iPrEx trial of daily oral chemoprophylaxis was a watershed and the first multi-country phase III preventive intervention for MSM that demonstrated preventive efficacy (44% reduction in HIV acquisition) among MSM. The research was conducted in Peru, Ecuador, South Africa, and Thailand. These opportunities also create challenges in working with MSM in diverse contexts. Power asymmetries can and do exist among research teams, international NGOs, donors, and local community groups who may have unique access to otherwise hidden populations. In countries where same-sex sexual practices are criminalized, research can have unintended adverse outcomes when such research brings increased attention and government awareness to previously low-profile populations. Inadvertent exposure of MSM populations has led to increases in rights abuses in some settings. Even where same-sex practices are not criminalized but are significantly stigmatized, the risk in working with MSM can be just as great. Further, these conditions impact the mobility and migration of MSM populations around the world, contributing to additional challenges in accessing and following particular vulnerable populations over time.

This guidance expands upon existing documents (e.g., *Good Participatory Practice: Guidelines for Biomedical HIV Prevention Trials* [UNAIDS/AVAC, 2011]<sup>1</sup> and the guidance document, *Ethical Considerations in Biomedical HIV Prevention Trials* [UNAIDS/WHO, 2007]), and informs:

- Researchers of their roles and responsibilities related to best practices in community participation models in these settings; and
- MSM/LGBT community-based organizations and activists of their rights, roles, and responsibilities as partners in conducting this research.

The focus of this guidance is practical, expounding on ways in which all concerned partners can increase the benefits of such research and minimize the potential risks and harms for all concerned. It seeks to increase the capacity of researchers to meet their research obligations, while encouraging gay, bisexual, and other MSM leaders and LGBT organizations to understand and exercise their rights and responsibilities when participating in research. Finally, it provides sample 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 1.8 million new infections in 2009, compared to 2.2 million in 2001.<sup>2</sup> Even more significant is the decrease in HIV-related mortality globally.<sup>3,4</sup> That said, HIV is still a major health concern (especially in Africa) and while the rate of new infections may have slowed, there are still 34 million people living with HIV worldwide.<sup>2</sup>

While the pandemic appears to be decreasing in magnitude, infections among MSM continue to increase. Several studies have demonstrated increasing rates of new infections among MSM in high-income settings.<sup>5</sup> And although there is limited prospective data from lower-income settings, HIV incidence reports among MSM from cities such as Bangkok and Mombasa show similar trends.<sup>6,7</sup> The attributable risk of MSM in concentrated epidemics is relatively uncontroversial, but there is growing evidence of disproportionate HIV risk among MSM within varied HIV epidemics, including those in Africa, Asia, Latin America and the Caribbean, and Eastern Europe/Central Asia.<sup>8,9</sup>

The current global response, however, is not commensurate with these realities.<sup>8</sup> Recent assessments of global HIV prevention methods 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 address the needs of these populations.<sup>10-12</sup> In generalized epidemics where there is emerging evidence of disproportionate HIV burden among ‘most at-risk populations,’ less than 0.1% of expenditures address the needs of MSM/LGBT populations. There are many causes of this inconsistent implementation of HIV interventions for MSM, including outright homophobia, lack of political motivation to address MSM issues, lack of data describing burden of HIV or risk status, insufficient targeted funding, and lack of a means to define an optimal package of services in resource-constrained settings.<sup>13,14</sup> 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

specific HIV prevention interventions for MSM and appropriate scale-up of these programs to address evidence-based needs.

In response to the need for improved epidemiologic data describing patterns of disease burden, as well as implementation science data characterizing effective preventive interventions and treatment access programs, there has been a significant new interest in MSM/HIV research among academic organizations, HIV program implementers, advocacy organizations, and funders. From 2005 to 2010, studies were implemented in countries across Africa, Asia, the Caribbean, Latin America, Eastern Europe/Central Asia, and the Middle East/North Africa, characterizing HIV prevalence rates among MSM for the first time.<sup>15, 16</sup> In addition, there have been some prospective cohorts in which participants are followed across multiple time points to characterize HIV incidence rates or levels of new HIV infections, including studies in Bangkok and Mombasa. 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 biomedical strategies such as oral and topical chemoprophylaxis and the use of treatment as prevention by lowering community viral loads.<sup>17,18</sup> There is also a need to increase research on negative social outcomes, such as stigma and

discrimination, and their effects on behavior and HIV disease burden.

### Ethical Principles

Working with MSM presents unique challenges given the stigma, discrimination, and danger that are often experienced, plus the lack of community structures offering protection and safe social space. Engaging MSM in research must be done in a manner that is safe and beneficial for both individuals and communities involved across all stages of research.

The Belmont Report highlights the 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.<sup>19, 20</sup> This is a given for human research subjects in general, but is particularly important and difficult to achieve in challenging contexts.

Autonomy implies that people have given their free and fully informed consent to partake in the project, and that they have had access to all relevant information about risks and benefits, and 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

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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. 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 benefit from that research, rather than taking risks so that another community can benefit.

Additional ethics guidance can be found in the Declaration of Helsinki. While researchers working with MSM must abide by these ethical guidelines to protect their participants as any other human subjects require protection, additional steps may be required for safe and effective engagement of MSM in challenging contexts.

Many MSM remain purposefully secretive about their behaviors due to reasonable fears of social exclusion, stigma, and persecution. Clearly, stigma is pervasive in societies and cultures and is often expressed in laws criminalizing consensual same-sex practices. Research projects in these types of settings are intended to identify and address the needs of the MSM population, but in doing so can highlight their existence and generate both positive and negative attention and social responses. The unintended consequences of research projects intending to help MSM can include heightened stigma and increases in human rights violations, including violence. 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.

### **The Human Rights Framework and Research on 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<sup>21, 22</sup>. 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 health care.

Protecting the rights of people often means creating mechanisms to prevent violation of human rights and social harm by others. For MSM this will most commonly mean doing the utmost to insure that neither state authorities nor non-state actors violate the rights of participants or staff as a result of participation in research. Researchers and communities working on issues relevant to MSM must not tolerate or be complicit in attempts by others to limit rights for sexual and gender minorities.

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, implying that researchers bear a responsibility to work toward fulfillment of the human rights of their study participants as one of the components of meaningful engagement.

All HIV research should focus on fulfilling the rights of all participants to an adequate standard of health care relevant to the research study. This would include, at a minimum, the rights to privacy, autonomy, confidentiality, dignity in health care, and to nonjudgmental and humane treatment in interactions with all staff, from security guards and intake clerks to investigators and physicians. Realizing these rights in the context of research protocols is the minimum standard we propose for MSM research.



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# ROLE OF RESEARCH INSTITUTIONS IN RESPECT, PROTECT, AND FULFILL

## Engagement

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

Adequate input from the MSM/LGBT community legitimizes the research aims and improves measures of appropriateness, transparency, and social equity across the study spectrum. Given that working with MSM/LGBT community organizations is also a primary means of accessing gay, bisexual, and other MSM for research, there is concern that the engagement of communities is limited to the use of these organizations as a means of recruiting potential study participants. To counteract this, it is crucial that the participation of communities not be limited to any one stage of the design, implementation, analysis, or presentation of research studies; rather, this participation should be a consistent component throughout the research process. Long-term, committed engagement of researchers with communities can result in building of capacity within these community organizations to solve their own problems, such as reducing the spread and impact of HIV, with continually decreasing external involvement and support.

## Finding and Working with the MSM/LGBT Community

The conventional model of community advisory boards (CABs) has been for them to provide cultural competence, represent the community in research efforts, “bring back” research issues to constituents, and to facilitate access to potential research

participants. This vital work is necessary but may not be enough to address the many issues involved in MSM research in rights-challenged contexts.

*Finding LGBT Leaders:* Increasingly, LGBT activists in low- and middle-income countries are gaining the strength to organize and demand their rights. In these countries, health issues (often in the name of increased HIV vulnerabilities) are allowing LGBT leaders to engage with key healthcare stakeholders. At the regional and sub-regional levels, LGBT rights and MSM health networks have formed, such as *the Asia-Pacific Coalition on Male Sexual Health (APCOM)*, *the African Men for Sexual Health and Rights Network (AMShEr)*, *Asociación para la Salud Integral y la Ciudadanía de América Latina y el Caribe (ASICAL)*, *the Purple Sky Network (Greater Mekong Region/SE Asia)*, and most recently *the Eurasian Coalition on Male Health (ECOM)*. These networks link national, regional, and local MSM/LGBT community organizations, encourage the sharing of intervention and advocacy strategies, and offer legitimacy for research groups interested in engaging with LGBT community groups. Thus researchers interested in finding legitimate LGBT leaders to be collaborators should enquire through these and similar regional, sub-regional, and national networks (see appendix for listing of networks).

*Study Design:* Study design includes development of instruments, consideration of participant characteristics and accrual, and in many cases biological testing protocols. It is vital that MSM/LGBT community leaders **be fully engaged** in the planning stages of each of these components, given their knowledge about 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) to ensure that each is culturally and linguistically appropriate, while addressing the needs of the community group’s own strategic plans. Most of these community leaders will not be familiar with research design and may require training on research principles. Also, memorandums of understanding may assist in making roles and responsibilities clear between researchers and community organizations and leaders.

*Implementation:* Members of the community should be engaged in the implementation of the research, as this can build capacity in the community group itself. For example, if the community group would like to develop programs or a strategic plan, researchers could identify resources to help the organization accomplish these goals. Investing in building the capacity of the community group will also facilitate the implementation of future research studies and ensure

the strength of programming that might be developed as a consequence of research efforts.

*Validation/Dissemination:* Validation of research findings with MSM/LGBT community leadership is an important component of qualitative, quantitative, and intervention studies. The validation process is made much simpler if MSM/LGBT community voices have been heard at all stages of the research, including

## Questions for Researchers to Ask for MSM/HIV Research (see Appendix I)

RESPECT	Status	Notes
Have you included the MSM/LGBT community in:		
Engagement rules		
Situational assessment		
Have you assessed the relevance of the research and potential reactions from greater community structures?		
Have you assessed the interest amongst the MSM/LGBT 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 health care 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/LGBT		
Healthcare service providers		
Media		
Government		
Influential community leaders		



members of the community presenting results to their peers. MSM/LGBT community leaders should be encouraged to present research findings in domestic and international forums. This implies providing technical support in the development of presentations and reports, and ensuring that MSM/LGBT community leaders are ready to address both scientific and policy-related questions about the research. These representatives should also be prepared to respond to

and defend research results and, because increased visibility can bring increased risks, potentially organize MSM/LGBT communities to respond to any homophobic backlash from the media, government, or communities in general.

Finally, community members should be involved in the written dissemination of findings, including participation in writing teams for both peer-reviewed

<b>PROTECT</b>	<i>Status</i>	<i>Notes</i>
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?		
<b>FULFILL</b>		
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/LGBT community capacity-building and informed participation?		
Secure funding to build capacity of MSM/LGBT community members		
Allow local groups to use resources such as meeting spaces		
Ensure representation of MSM/LGBT on staff		
Train MSM/LGBT 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/LGBT 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?		

and non-peer-reviewed publications describing these data sets. In turn, they should be included for consideration as authors pending appropriate input for these reports.

## 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, and international organizations such as the World Health Organization, World Bank, and United Nations Development Programme. As previously described, this has driven 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 a situational assessment of the environment affecting MSM in a particular location, including discussions with local MSM/LGBT community groups and other stakeholders to assess whether the timing is right for a study targeting MSM given ongoing and expected sociopolitical dynamics. It is also vital to determine the level of organization of the MSM/LGBT community in the planned location. If there is a lack of established infrastructure, then the research study implementers should commit to building local capacity as a component of the research program. Engagement rules also include assessing the level of interest of the MSM/LGBT community in research programs that specifically target MSM. As described above, this process capitalizes on existing networks of organizations serving MSM with evidence-based and rights-affirming advocacy or health services. History suggests that most community groups will likely be motivated to take part in research projects by 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.

## Working with Governments and National Institutional Review Boards (IRBs)

Global guidance documents on research involving human participants require that research protocols



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obtain ethical approval at institutions sponsoring and conducting the research, and in locations where a 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.<sup>23</sup> Thus, engagement with government may be necessary when conducting research with MSM. Given that interaction with such government bodies may need to happen for research (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/LGBT organizations at this early stage of planning to get assistance in interacting with government entities. It is the responsibility of researchers at this stage to build coalitions or partner with them to maximize the protection of the rights of the MSM/LGBT community members through thoughtful interactions with government entities.

Successful coalitions often begin with a stakeholder analysis characterizing key thought leaders, research teams, and service providers. In nearly all contexts, communities of MSM have organized at some level, though this can vary greatly. In many countries, there may be only one organized community group that serves to represent MSM. In others there may be hundreds. The ideal is to achieve local representation, suggesting that if 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 multisite studies, more thorough assessment of representation is a vital component. 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 members of the community to assess the broad range of appropriate next steps.

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/LGBT community to seek guidance on how to respond.

### **Preparing and Responding to Hostile Reactions**

Emergency plans may be appropriate in settings where governments or other stakeholders (religious leaders, media, opposition political partners, community leaders, etc.) are known to be hostile to LGBT communities. Such plans are best developed in advance of engagement with stakeholders. Researchers and community organizations should look to human rights organizations to develop such plans. However, should social harms emerge, it is vital that decisions on appropriate next steps be made with guidance from MSM/LGBT community leadership. Researchers should never forget that the local LGBT community will likely remain and will have to address any lasting consequences long after studies are shut down or stalled before implementation.

While some researchers doubtless prefer to take apolitical stances, the engagement of stigmatized populations does imply the need to engage in advocacy on behalf of that community. These may be quiet “under the radar” efforts with key allies and opponents, but addressing potential social harms generated 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 interest, and developing strong partnerships with MSM/LGBT individuals and community organizations may reduce the likelihood of researchers “getting out in front” of the community on rights issues. Researchers who are not willing to engage with community groups should think hard before attempting to conduct research with populations that are criminalized or marginalized.

## **ROLE OF COMMUNITY ORGANIZATIONS IN RESPECT, PROTECT, AND FULFILL**

### **Partnerships with Researchers**

For MSM/LGBT 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 sexually transmitted infections (STIs) including HIV, as well as to develop appropriate evidence-based prevention programs. Research can clarify the demographics and behaviors of MSM that impact on 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 behavior, working to alleviate poverty among MSM/LGBT individuals, and making health services more MSM/LGBT-friendly.

Unfortunately, in the past there have been multiple reports of MSM/LGBT 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/LGBT 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/LGBT communities. In the absence of effective guidance from an MSM/LGBT community team, the research teams will have limited access to the MSM/LGBT communities. Even if they do gain access, it will be difficult for them to undertake a research project that harnesses actionable data without MSM/LGBT community input.

Deciding 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/LGBT community leaders and organizations. If after reviewing the checklist on page 11, MSM/LGBT

community leaders do not think their rights will be promoted, protected, and secured, they do not need to participate in the study.

MSM/LGBT leadership need to recognize the role they play in the success of such research studies and should actively inform all MSM/LGBT community members of their rights not to participate in a study. Clearly, challenges may arise. Some research projects offer incentives, for example. MSM/LGBT leaders should understand they have recourse to address problems and ensure their needs are being 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 studies.

### Meaningful Participation

*Design:* Before research studies are conducted, an ample amount of time is given to the design. This includes gaining permission from various stakeholders, including an IRB, which exists to ensure that individuals being studied are not going to be harmed by the conduct of such research. It also includes developing a study protocol (or a list of the goals, objectives, and methods used in conducting the research) and research instruments such as a questionnaire for participants to fill out or for in-depth interviews and/or focus groups discussions.

LGBT 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 and other study instruments and plans, including how the researchers expect to access and engage the MSM/LGBT 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. LGBT leaders need to help researchers understand the context where the research will take place and develop strategies to deal with any structural barriers. Researchers and LGBT community leaders need to be creative, finding the appropriate balance between promoting, protecting, and fulfilling rights.

*Implementation:* Depending on the type of research being conducted, community leaders can play various roles in the implementation phase. LGBT community leaders can help recruit staff from the local LGBT community to assist in formative research, 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 LGBT organization and enhance its credibility among key stakeholders.

*Validation/Dissemination:* Once the research is completed and results are analyzed, it is important for researchers and MSM/LGBT community groups to share findings with the greater LGBT community. An effective strategy is to initially hold “dissemination meetings” to ensure that the results obtained are understood by the community and that the messages in the conclusions are appropriate.

Once the findings are validated, LGBT community groups should work with researchers to implement an effective dissemination strategy to reach 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 actively reaching out to stakeholders. Examples include hosting consultations in which the data are presented, engaging media to inform editors and journalists about the implications of the data, and presentations using different media. Planning for dissemination, including ensuring that there is an appropriate budget, should be considered at the beginning of the study.

Finally, MSM/LGBT community leaders should be given the opportunity to play a significant role in the dissemination of these data, including presentations at local, national, and international conferences and participation in writing manuscripts.

Before research begins, communities need to be engaged to gain legitimacy. There should be meetings to hear input from the greater MSM/LGBT community about participating in research. In addition there should be meetings with the NGO community and media to inform them of the research and potential results.

## Questions for Community Organizations to Ask for MSM/HIV Research (see Appendix II)

<b>RESPECT</b>	<i>Status</i>	<i>Notes</i>
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?		
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?		
<b>PROTECT</b>		
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?		
<b>FULFILL</b>		
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?		

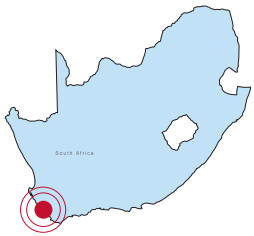


## CASE STUDIES

The following case studies offer practical examples of challenges and lessons learned from engagement between researchers and community members in the operationalization 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 I: 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 US National Institute of Allergy and Infectious Diseases (NIAID)

iPrEX study, a large-scale study of pre-exposure prophylaxis (PrEP) among MSM that produced promising results in December 2010. In fact, DTHF staff recognizes that community engagement was a key factor in the success of their study. Careful planning and budgeting helped make this a reality.

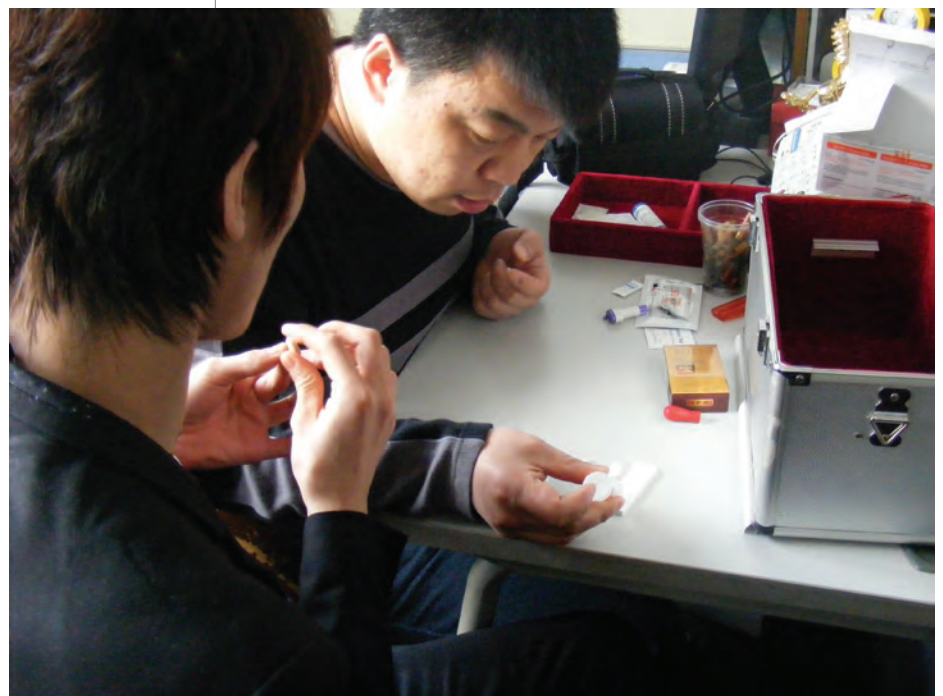
From its inception, DTHF developed a strategy and a supporting budget for "community engagement" activities aimed at promoting, protecting, and fulfilling services for MSM. DTHF engaged and empowered LGBT community members through its community advisory board, and partnered with various community-based LGBT organizations to gain legitimacy and build their capacity

to engage in research. Through these linkages with Gender Dynamics, Anova Health Institute – Men4Health 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 local Ministry of Health and international donors (e.g., PEPFAR, Global Fund), various venues have been 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, as well as other MSM. The outreach officer also helped create social space for these individuals 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

#### *Loving Support Center – Shenyang, China*



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 interview skills), and to hire local MSM for the study. These efforts not only helped provide services, but also helped recruit additional research participants.

From its inception, DTHF also developed specific plans for community challenges to their study, with 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 LGBT community to disseminate results and specifically targeted more challenging stakeholders, such as religious and traditional leaders.

Although LGBT 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 gain confidence of some leaders for protection. 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 to be able to help study participants with their family lives, vocational training, same-sex relationship issues, among other concerns. DTHF ensured counselors were prepared to work with participants beyond their basic HIV needs.

*Key recommendations for greater MSM/LGBT community involvement:*

- Dedicated budget for “community engagement” – Donors should require community engagement plans and provide funding to support them. This should require little justification as it should be viewed as a basic element of community research. For example, linking a “gay sports league” to the project was not initially thought to be an activity that would lower HIV risk-taking behavior, but its presence clearly impacted uptake in the study.
- Take time to do formative research on current community resources. It is important to know who is who in the LGBT community, who is already

working with MSM populations, and what services are already MSM-friendly. It is vital to engage all stakeholders.

- Dedicated budget for incentives. DTHF was quite successful because they had budget for T-shirts and other incentives. Free food was a major motivation for being more involved in the study.
- Focus on services that are important to MSM. Often, direct HIV services such as providing condoms are not as important as other factors such as social support, skills building for healthy romantic relationships, job training, and/or pleasurable anal sex.
- Research groups must challenge themselves to move beyond their research agenda – to institute a “community capacity-building” role as a part of any research.

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



### Kenya Medical Research Institute (KEMRI) (Kilifi, Kenya)

The research team at the Kenya Medical Research Institute (KEMRI) realized in the early 2000s that coastal Kenya had a complicated HIV epidemic significantly impacting MSM and female sex workers (FSW). In response, the research team felt that the development of prospective cohorts of MSM and FSW would facilitate increased understanding of risk factors for sexually transmitted infections including HIV. The researchers had focused mostly on individual risk factors for this group, though now they are paying increased attention to structural level HIV risk drivers, including stigma and discrimination. Outside of South Africa, this team was the only one in Africa to develop a cohort made up mainly of MSM in addition to some female sex workers. To maintain this cohort and provide services, the team established a research clinic in Mtwapa. This clinic serves as a fully functional research site that also provides clinical services such as voluntary counseling and testing and reproductive health services.

Appreciating the risks of this work, the KEMRI research team developed a community advisory board for the

MSM study that provided support in the development of protocols, including survey instruments and accrual methodology. The community advisory board has 13 permanent members, approximately half from Kenyan MSM-led community organizations, along with representatives of human rights groups and other key stakeholders. Study staff in the early stages included local MSM. In addition to the planned research, services such as peer-education programs and voluntary counseling and testing services were also provided in the early stages. Limited resources and staff turnover were impediments to sustainable training programs for the community in the delivery of high-quality and confidential peer education as well as anonymous prevention services.

To support operationalization of the research in the early stages, the KEMRI research group helped establish an advocacy organization called the Mombasa Movement for Men. This was part of a strategy involving the Coastal Sexual Health Workers, who were functioning as highly sensitized peer educators for MSM sex workers as well as female sex workers. KEMRI also provided training for journalists and police on the public health issues surrounding their work. As a result, press coverage of these issues was increasingly grounded in evidence. Members of the MSM-led community organizations took part in meetings with the media, but were less receptive early on to meeting with the police.

Comprehensive dissemination plans for the research included both domestic and international forums. Kenyan MSM-led community organization members have been involved with the presentation of data in a variety of settings, which helped build capacity within the community.

From the outset, there was a clear appreciation of the risks associated with these projects. In 2009, the clinic was attacked by homophobic mobs. The attack was unexpected and likely reflected the belief held by many in the surrounding community that most-at-risk populations had access to special services not otherwise available to the general population and that external forces were encouraging the disclosure of same-sex practices. Study staff and participants were taken into police custody and the principal investigator of the project went to the police station to advocate the safe release of staff and participants. The initial response focused on the medical and emotional needs related to the attacks, such as paying for people to seek care in Nairobi. The research site was closed

for a week, and a crisis committee team was formed with members of the community advisory board and high level management at KEMRI. The Committee decided to form a Study Advisory Group that included increased representation from the community at large to provide a forum for bilateral communication and education.

IAVI has funded several KEMRI research projects, including the development and creation of the cohort, and studies involving the cohort. Recent studies include a pilot assessment of intermittent oral chemoprophylaxis, evaluation of the role of MSM networks in HIV infection, and a study of the effectiveness of community health worker training. IAVI has also supported community development, including capacity building and some community healthcare services.

KEMRI has formed a strong and committed partnership with local MSM as a research partner, service provider, and advocate of appropriately scaled responses to HIV among the MSM community. However, the KEMRI team realizes that structural barriers such as stigma, discrimination, and criminalization can force MSM to remain hidden, adversely affecting the ability to do research. The key challenges include building trust and a collaborative partnership, as well as a disproportionate level of poverty among these men due to workplace discrimination. While the immediate goal is to strengthen service provision, long-term aspirational goals include garnering political support by demonstrating that, in order to enact comprehensive responses, all at-risk MSM need services and support. To effectively scale up research and service provision, government entities need to address the enforcement of laws that criminalize high-risk populations.

*Key recommendations for greater MSM/LGBT community involvement:*

- MSM should be engaged in all aspects of studies, from advisory committees to research staff to service delivery staff. When appropriate, researchers should assist in developing the capacity of MSM-led organizations to build leadership skills for future programming.
- Various advocacy activities are necessary before a study is begun, especially informing and gaining support from local leadership and society in general.





Rainbow Sky Association – Bangkok, Thailand

- Contingency plans should be drawn up to prepare for any homophobic response that could derail research or service delivery. Budgets should be set aside to address such a scenario, covering items such as security for project staff and participants, bail monies for staff or participants who may face legal challenges from local authorities, and related costs.

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

### Getting to know the MSM/LGBT 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

### Case Study III: 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 engaging in MSM-related research is long-term community expectations. 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.

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 these initial volunteers have remained linked to the research center in one way or another, either because they have 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 sexually transmitted infections, has proven to be an important added value for the volunteers, as it ensures access to care they might not have sought otherwise. For a number of years the

#### *Eesti HIV-positiivsete vorgustik (EHPV) – Tallinn, Estonia*



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 *Praça Onze's* focus on MSM, physicians, counselors, and other health professionals that are part of this community, or that have significant experience with it, will 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 not only important to have a strong team of MSM and MSM-friendly staff to guide their daily work, but that it was also important to ensure 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. The main reasons for volunteering were altruistic and connected to their own personal experiences of HIV/ AIDS and their commitment to overcoming the epidemic. This contrasts with the way new volunteers approach the research center today. Since 2006, younger MSM have been coming to the research center and they are often doing so because of their existing social networks, through referrals from friends and online social networking services, as the Internet has become a central feature of gay social life. 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 the 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 *Praça Onze* was targeting sex workers for a study); and in the overall credibility of, and support for, the research activities.

Developing relationships with NGOs with established credibility among MSM was essential as the research center was being established in the mid-90s. It also

proves to be extremely valuable now at the start of each new study, as the researchers are able to provide in-depth briefings to NGOs, who then can share accurate information among their networks. This procedure helps ensure there is transparency around new research projects, and allows for multiple and 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 Post-Exposure Prophylaxis (PEP) for 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 impact of the results for their communities and for 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 and may or may not be incorporated in the prevention toolbox, the research team continues to play a role in sharing information and informing the public debate among civil society and policy makers.

*Key recommendations for greater MSM/LGBT community involvement:*

Monica Barbosa, a site coordinator for *Projeto Praça Onze* who started out as a counselor, shared some of the key lessons learned in her more than 15 years working on research projects with the MSM community:

- A multidisciplinary team that is sensitive to the issues faced by the community is an essential component of their success. Different skill sets and profiles allow the research center to be responsive to the diverse needs of volunteers. The center has a strong team of sensitized physicians, nurses, counselors, and community educators closely identified with the MSM community.
- Instead of using a recruitment team and then relying on a different group to ensure volunteer adherence to research studies, Praça Onze maintains a single team of recruiters who play an ongoing role at the research center and become an important reference point for volunteers over the course of a given study.
- Dialogue with civil society may not be essential for recruitment, but it is key for establishing the credibility and good intentions of the research team. Publicizing a research project or its results needs to go beyond soundbites and must happen through establishing trust with organizations respected by the affected community.

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



**Centre for the Development of People (Blantyre, Malawi)**

The Centre for the Development of People (CEDEP) was established in 2005 to address the human rights and health needs of minority groups in Malawi. Presently the organization focuses on minority groups such as prisoners,

commercial sex workers, and people involved in same sex relationships. CEDEP completed the first knowledge, attitude, and perceptions study of HIV among 100 MSM in Malawi, and secured an operating grant from HIVOS to continue this work. While the results of this project were useful, CEDEP realized that data characterizing HIV prevalence and associated behaviors were vital to advocate for dedicated HIV prevention expenditures for MSM in Malawi.

CEDEP was therefore motivated to assess potential funding mechanisms to complete such a study among MSM in Malawi and was able to get funding from the Open Society Initiative for Southern Africa (OSISA). The CEDEP team consulted with the community and there was significant support for an HIV prevalence study among MSM, so the team moved forward. OSISA mediated introductions with a team from the Center for Public Health and Human Rights at the Johns Hopkins School of Public Health (JHSPH), which shared an interest in characterizing the level of risk among MSM in Malawi. The group worked together to develop a functional protocol in Malawi that focused on human subjects protections while ensuring a methodologically sound study.

The subsequent study, completed in 2008, revealed that MSM in Malawi had an HIV prevalence of 21.4%, representing a rate that was double the national rate among men of reproductive age. At that time, MSM were not included as a risk population in the National AIDS Strategy of Malawi. The study also revealed that blackmail was significantly associated with disclosing same sex behavior to a healthcare worker. Nearly 18% of study respondents reported that they were afraid to seek health services, and among MSM who were HIV positive, over 95% were unaware of their HIV status. CEDEP partnered with investigators from JHSPH to improve their skills in presenting data and answering questions related to the methodologies used. Subsequently, CEDEP staff presented these results at the International AIDS Conference and the Global Forum on MSM and HIV Pre-Conference in August 2008 in Mexico. The research results were also disseminated at the International Conference on AIDS and STIs in Africa (ICASA) in December 2008 in Dakar, Senegal. In addition, the National AIDS Council invited CEDEP to present the results at the Malawi National AIDS conference in June 2008.

Since this project ended, CEDEP has been granted additional research funding, including as a partner organization to a UNFPA- and UNDP-funded study

evaluating the prevalence of HIV among MSM using respondent-driven sampling and a USAID-funded study evaluating the outcome of basic service provision for MSM in Malawi along with prospective follow-up of these men.

The key achievements of the organization have been threefold. First, the organization has been successful in advocating for the recognition and inclusion of sexual minorities in HIV prevention programs. Good examples are: the inclusion of MSM in the National HIV Prevention Strategy and Action Plan; inclusion of MSM as a key target group in the country proposal to the Global Fund to Fight Tuberculosis, AIDS and Malaria for the Round 10 application, plus the involvement of CEDEP in the development of the proposal; the formation of the Civil Society Technical Working Group on Most At-Risk Populations (MARPs) that would take the government to task on human rights of MARPs; and the eventual release from police custody of a Malawian man and his transgender partner.



*amfAR peer review meeting – Johannesburg, South Africa*

While CEDEP was not developed as an emergency response organization, the increased capacity of the organization has allowed it to mobilize international partnerships and to coordinate the response that resulted in the eventual release of men detained in Malawi. However, the increased international recognition of CEDEP and the publicity surrounding issues related to sexual minorities in Malawi have caused a backlash in terms of statements by high-ranking politicians in Malawi demonstrating the tensions associated with “success” in accessing and serving MSM in a setting where same-sex practices are criminalized.

*Key recommendations for greater MSM/LGBT community involvement:*

- Focusing on MSM/HIV issues is an excellent strategy to infuse human rights (including LGBT rights) into a national dialogue.
- Community-based organizations can be equipped to carry out formal research on MSM/LGBT communities, often offering instant access to MSM populations. These CBOs are often much better suited to serve as advocates at the local and national levels, working in partnership with research institutions.
- Community-based organizations need to be fully supported in the event of local or national backlash that may arise from engaging in such research.

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



**United Nations Development Program (Kiev, Ukraine)**

Ukraine features one of the fastest HIV growth rates in Europe. At the end of 2007, an estimated 350,000 people were living with HIV, equating to a 1.3% adult prevalence rate. The epidemic has a disproportionate concentration in most-at-risk populations, including MSM and injection drug users (IDUs).

In 2009, in light of the unfolding situation, the UNDP/ Ukraine received funds from the global UN Thematic Trust Fund (TTR) to implement a multi-component program for MSM in Ukraine. The overall objective of the project was to promote the human rights of MSM, decrease stigmatization, and ensure equal access to HIV/AIDS services.

One of the key activities of the project was to conduct operations research to highlight the prevention, treatment, care and support service needs of MSM. The research was further intended to identify and assess the quality of available services, highlighting existing gaps and providing concrete recommendations on how such health services could be transformed to better serve the MSM community.



*SEROvie – Port-au-Prince, Haiti*

To better understand the needs of the MSM/LGBT community, UNDP hired Zoryan Kis, a representative of the community. Zoryan developed a data collection approach to the research involving two key components. First, the UNDP Governance in HIV/AIDS project team organized meetings with the Standing Reference Group on LGBT and MSM service projects (a group of 10 Ukrainian experts representing various LGBT communities) to introduce the research, gain input on survey instruments, and verify and authenticate subsequent research findings. Second, a survey in four regional (*oblast*) Ukrainian government-run AIDS centers was conducted, utilizing a “mystery client” methodology. Researchers, posing as ordinary MSM, sought HIV testing and counseling services at the AIDS centers, and then filled out a special questionnaire. The objective was to see if the MSM researchers received MSM-specific counseling as envisaged by the national protocol, and to study accessibility of testing for MSM.

The findings of the surveys were presented to both stakeholders and the media. GfK Ukraine, contracted to do the research, subsequently sent press releases and presentations to all media partners. The results were presented in an open manner, regardless of potential social or political pushback. Unfortunately, due to the formal and complicated nature of the UNDP press releases, the results were only popularized amongst HIV/AIDS-combating stakeholders and the MSM/LGBT community. A less formal press release would have been more appropriate for the general public.

Overall reaction to the findings was positive, although negative responses were received from the Ministry of Internal Affairs, due to the research highlighting the police’s policies towards arresting MSM, and the Ministry of Health, due to the research highlighting unsatisfactory examples of services provided to MSM.

*Key recommendations for greater MSM/LGBT community involvement:*

- Researchers should engage MSM/LGBT community representatives as information gatherers to help receive credible responses and community perspectives. “Mystery client” methodologies are recommended to gain further insight.
- Research budgets should provide a sufficient amount for respondent remuneration—this will help reach out to most vulnerable MSM (youth, unemployed, sex workers, etc.).
- Where there are MSM/LGBT organizations, they must be involved in research planning, field work, and discussion and dissemination of results.
- Where there are MSM/LGBT coordination and/or expert groups, they must be involved as experts and advisors during the planning and piloting stages, and in the development of recommendations.





# APPENDIX I

## Questions for Researchers to Ask for MSM/HIV Research

RESPECT	Status	Notes
Have you included the MSM/LGBT community in:		
Engagement rules		
Situational assessment		
Have you assessed the relevance of the research and potential reactions from greater community structures?		
Have you assessed the interest amongst the MSM/LGBT 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 health care 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/LGBT		
Healthcare service providers		
Media		
Government		
Influential community leaders		





## APPENDIX I - Continued

<b>PROTECT</b>	<i>Status</i>	<i>Notes</i>
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?		
<b>FULFILL</b>		
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/LGBT community capacity-building and informed participation?		
Secure funding to build capacity of MSM/LGBT community members		
Allow local groups to use resources such as meeting spaces		
Ensure representation of MSM/LGBT on staff		
Train MSM/LGBT 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/LGBT 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 Community Organizations to Ask for MSM/HIV Research

<b>RESPECT</b>	<i>Status</i>	<i>Notes</i>
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?		
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?		
<b>PROTECT</b>		
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?		
<b>FULFILL</b>		
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?		



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