Canadian Association for HIV/AIDS Research

Ethics Issues for Canadian HIV/AIDS Researchers in International Settings

The Canadian Association
for HIV Research

L'association canadienne
de recherche sur le VIH

We welcome your comments and suggestions
for future editions of this booklet.

Canadian Association for HIV Research
155 College Street, 5th Floor, Suite 526
Health Sciences Building, University of Toronto
Toronto, Ontario M5T 3M7

fax: (416) 971-2704

email: ethics@cahr-acrv.ca

Foreword

The need for this resource emerged over time from discussions between stakeholders representing civil society, government, research, and frontline practitioners working in the field of HIV/AIDS within Canada and internationally. Borne out of conversations held at the International Institute on Gender and HIV/AIDS (IIGHA) in Johannesburg in June 2004, the project evolved out of consultations with a multitude of stakeholders, and included face-to-face meetings in Ottawa and Toronto, Canada, and Cape Town, South Africa, as well as a series of in-depth interviews with Canadian researchers experienced in international HIV/AIDS work. The research scenarios presented in this resource are grounded in the international experiences of some of Canada's leading HIV/AIDS researchers.

This resource is primarily designed to serve as a practical tool for Canadian HIV/AIDS researchers working internationally. It is meant to assist new as well as experienced investigators considering the tensions and dynamics associated with the ethics of international HIV/AIDS research, and may also be of interest to:

- Community representatives, civil society organizations and ethics review committees in Canada and/or other countries who may decide to work with Canadian HIV/AIDS researchers;
- Government decision-makers, funders and donor organizations that fund HIV/AIDS research and programs, policy analysts, and programmers who work with HIV/AIDS researchers and/or community representatives and civil society organizations;
- Potential HIV/AIDS research participants and their representatives, both individuals and organizations in other countries;
- Canadian research ethics boards (REBs) reviewing HIV/AIDS research protocols; and
- Organizations not directly mandated to focus on HIV/AIDS issues that want additional perspectives to inform their understanding of their own research ethics issues.

This resource was prepared in consultation with national and international experts from government, policy, research, and community and civil society organizations in Canada and internationally.

This resource provides background information on Canadian research ethics standards in relation to HIV/AIDS-specific research, as well as practical research scenarios to illustrate the complexities associated with applying research ethics principles and approaches in other countries. It may serve as a refresher for current HIV/AIDS researchers, for those teaching HIV/AIDS-related research courses, and for those who may wish to partner with university-based HIV/AIDS researchers. This first edition of the resource is not meant to present an exhaustive overview of all the ethics issues associated with HIV/AIDS research across a range of disciplines. Rather, it is a starting point intended to expand, illuminate, and advance the discussion on these important research ethics issues by raising questions, rather than providing answers.

How to use this document

This resource highlights important factors to consider at all stages of the research process. In doing so, it seeks to avoid a prescriptive code of ethics for international HIV/AIDS research. As each research project's context is unique, consultations with and review by a researcher's own research ethics board will be a necessary part of planning and implementing ethical international HIV/AIDS research.

The document presents four composite research scenarios informed by in-depth interviews with Canadian researchers experienced in international HIV/AIDS research. These research scenarios illuminate some ethics challenges – often posed by the uniqueness of international HIV/AIDS research – that may be relevant during the research process.

The research scenarios are organized according to the four research tracks represented by the Canadian Association for HIV Research (CAHR): basic science, clinical science, epidemiology and public health, and social science (for definitions of each track, see Appendix III). In addition to track-specific issues, each research scenario also addresses important ethics issues that could arise in any research track and provides useful advice for research across disciplines (for an index of the ethics issues discussed, see Appendix I: Index of Ethics Issues).

Given the multi-disciplinary nature of much HIV/AIDS research, cross-cutting research ethics issues create opportunities for increased dialogue and cross-fertilization of scenarios, best practices, and lessons learned between the four research tracks. Thus, readers are encouraged to read scenarios from multiple tracks – not only the scenarios closest to their own area of research.

These research scenarios are composite cases built from the real experiences of Canadian researchers. In order to demonstrate multiple ethics dilemmas, however, creative liberties have been taken. The research projects, characters and countries are fictional. Perspectives embodied by the characters in the research scenarios do not necessarily reflect the perspectives of the researchers interviewed.

The final part of this resource discusses some of the persistent complexities related to applying Canada's *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS) to international HIV/AIDS research and provides some additional frameworks that may be helpful throughout the research process.

A summary table of issues researchers may want to consider when conducting international HIV/AIDS research is included at the end of the document (see Appendix I).

Canadian researchers conducting HIV/AIDS research in other countries will also encounter foreign country-specific instruments and guidelines: research ethics guidelines specific to the country where the research will be conducted. Canadian researchers working in other countries must comply not only with the TCPS, but also with instruments from other countries. Because they vary from country to country, these instruments are not addressed within this document. Researchers are strongly encouraged to be familiar with local ethics requirements and procedures in the area of study throughout the study design process. Researchers working with Aboriginal communities are advised to refer to the *CIHR Guidelines for Health Research Involving Aboriginal People* (CIHR 2007), prepared collaboratively by the CIHR Ethics Office and an external advisory board, the Aboriginal Ethics Working Group, to address the gap left in section six of the TCPS which addresses research involving Aboriginal peoples. Other resources and documents addressing international research and ethics can be found in Appendix II.

Limitations

This resource does not pretend to be an exhaustive collection of all the ethics issues related to international HIV/AIDS research. Nor does it try to address every situation that researchers could encounter. Rather, scenarios are presented in order to illustrate some of the complexity of ethics in this unique context. Readers are encouraged to use these scenarios as a basis for considering some of the ethics issues that their own research may elicit and to consult with their own research ethics board on issues of specific concern.

This resource provides a sample of Canadian researchers' perspectives on this important topic and can serve as a basis for discussion between investigators and other stakeholders (including international partners) as research is designed and implemented. Hopefully this will help Canadians respond effectively to the HIV/AIDS pandemic in a respectful, mutually beneficial, and ethical way.

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Acknowledgements

This resource came to fruition through a series of consultations with Canadian and international researchers and stakeholders in international HIV/AIDS research. It is with sincere gratitude that we acknowledge the contribution of all those who gave input throughout this document's evolution.

CIHR Institute of Infection and Immunity Comment

"It is important to safeguard human dignity and human rights in any situation, but even more so when research participants are in a vulnerable position such as people living with HIV/AIDS who also face poverty, discrimination and social injustice. This guide will assist Canadian researchers in building awareness of ethical, economic, social and cultural realities when carrying out research in difficult circumstances around the world.

Although this document is aimed at HIV/AIDS researchers, its underlying themes are universal and will likely be useful to a diverse research community in a wide range of situations.

This document would not have been possible without the dedicated effort, professionalism and idealism of the people at the Canadian Association for HIV Research (CAHR). The Canadian Institutes of Health Research (CIHR) are proud of our collaboration with CAHR and our funding for this important guide. On behalf of CIHR, I congratulate all those who gave their time and talent to bring this effort to a successful conclusion. I hope it will guide and inspire all those involved in the extraordinary effort required to respond to the greatest health challenge of our time."

Dr. Bhagirath Singh
Scientific Director, Institute of Infection and Immunity
Canadian Institutes of Health Research

"If you go there naively, thinking that everything is clear in terms of ethics, you can have big problems. You know, you don't arrive and just do your research and go. You really need partnerships with local agencies. It's key."

quote from Canadian researcher

Overview

This resource was created by CAHR to provide Canadian HIV/AIDS researchers working in other countries with a resource to help in dealing with some of the key research ethics issues that they may face, in a way that:

1) Focuses specifically on HIV/AIDS research;
2) Builds on the guiding principles and values of the Canadian Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS);
3) Reflects the spectrum of CAHR disciplines;
4) Draws on lessons learned from Canadian HIV/AIDS researchers with experience working in other countries; and
5) Takes into account important structural, cultural, political, social, and economic determinants that influence research.

No existing instruments or guidelines incorporate all of these features. Canada's main research ethics reference, the TCPS, offers a solid starting point for considering research ethics issues. This resource extends the TCPS by addressing exclusively the uniqueness of international HIV/AIDS research, which is contextualized by:

- Stigma and culturally-embedded conceptualizations of the virus and the pandemic itself;
- Local and global politics;
- Gender inequities, power dynamics, and sexual roles; and
- Economics and the allocation and availability of resources for research and health systems and services.

"Sometimes, the...issues that [the local partners] see from their perspective may not be what you think needs to be done as an outsider with a different view."

quote from Canadian researcher

Part One

Introduction: International HIV/AIDS research and Canadian ethics guidelines

This section outlines the purpose of this resource and highlights the unique dynamics of **HIV/AIDS¹** research in an international setting. The discussions of research ethics issues are grounded in the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* **(TCPS)**, the tenets of which are also outlined in this section.

Purpose of the document

This resource was created by the Canadian Association for HIV Research **(CAHR)**, the primary Canadian organization for HIV/AIDS researchers and those interested in advancing HIV/AIDS research. CAHR membership is composed of Canada's leading HIV/AIDS researchers, and is dedicated to fostering collaboration between HIV/AIDS researchers in various research tracks, including **basic science, clinical science, epidemiology and public health, and social science**. Since its inception in 1990, CAHR has, as part of its mandate, focused on improving the quality of HIV/AIDS research by exchanging information about the prevention and control of HIV infection and the improvement in care and treatment for people living with HIV/AIDS, both in Canada and around the world. CAHR recognizes that Canada holds some of the world's best HIV/AIDS researchers, whose expertise is extremely valuable not only in relation to Canada's HIV/AIDS epidemic, but also in the response to the pandemic on a global scale. It is hoped that this resource will assist Canadian HIV/AIDS researchers working internationally to continue this important work in an ethically sensitive and responsible manner, grounded in the TCPS but recognizing that research ethics standards differ from country to country.

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1 All **bold** terms are defined in Appendix III.

International HIV/AIDS research poses unique ethics challenges. This resource seeks to shed light on some of these issues, and to provide thoughtful guidance to Canadian researchers and other interested stakeholders who aim to make a meaningful contribution to the struggle against HIV/AIDS through high-quality, ethically sound research.

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The uniqueness of HIV/AIDS research in international settings

Ethical tensions in research arise everywhere in the world and are not unique to the international research environment. In international HIV/AIDS research these tensions are exacerbated, however, as the complexities of global health dynamics and multidisciplinary health research are combined with one of the most challenging epidemics of our time. International HIV/AIDS research is an important endeavour that is often accompanied by unique challenges, including those related to:

- *Stigma* and culturally-embedded conceptualizations of the virus and the pandemic itself;
- Local and global politics;
- *Gender inequities*, power dynamics, and sexual roles; and
- Economics and the allocation and availability of resources for research and health systems and services.

Stigma and culturally-embedded conceptualizations of the virus and the pandemic itself. The stigma of HIV/AIDS has a powerful influence on how research can or should be conducted. Stigma affects everything from project design, through recruitment, to dissemination.

The unique challenges, features, and implications of HIV/AIDS should be at the forefront of a researcher's considerations when designing a study to ensure sensitivity to the study's impact on populations and individuals. When recruiting research participants, for instance, large-scale advertisements promoting the participation of HIV-positive people, injection drug users (**IDU**s) or commercial sex workers (**CSW**s) are often inappropriate. In many such instances, regulations for recruitment must be more stringent because of the discrimination that is likely to arise from culturally-embedded conceptualizations of the effects of the virus and, in some instances, its association with illegal behaviour. In the dissemination phase, researchers should be aware of the potential to unintentionally stigmatize particular ethnic or other groups by associating them with high rates of HIV infection. Some researchers new to international research may find it difficult to anticipate and fully grasp the magnitude of the stigma which impacts all aspects of society, often destroying families, jobs, and communities.

Stigma is complex. Stigma is generally regarded as simply the use of negative labels to identify a person. However, stigma may also occur when an individual does not exemplify a certain identity. Stigma comes in many forms – it may relate or reflect upon behaviours, or appearance, or assumed characteristics, associated with, for example, a particular disease. It is often justified and reinforced on the basis of moral arguments.

Stigma is less likely to exist if behaviours or identities are private, have not been noticed or are hidden. Therefore, stigma can result in behaviours and fears that prevent individuals from being motivated to access services or change behaviour. Homosexual behaviour, for example, may be accepted as long as it occurs along with heterosexual activities and identity. An illness may not be stigmatized as long as it remains unidentified.

Stigma is relative. What may be seen as negative, weak or potentially dangerous in one society or group may be accepted or revered in another culture or at another point in time. Much depends on the social, cultural, and even economic context.

Stigma can lead to the creation of barriers, denial of access, rejection, and aggression or violence toward individuals.

Fortunately, stigma can be reduced and even reversed. We have seen recently that as wellness among HIV-infected individuals reappears, stigma towards those individuals may be reduced. Also, as characteristics or diseases become more common, they often become less stigmatized.

Silencing stigma, stigmatizing silence. Because of the stigma surrounding HIV/AIDS, many people are unwilling to openly discuss the illness. According to UNAIDS, "The stigma associated with AIDS has silenced open discussion, both of its causes and of appropriate responses. Concealment encourages denial that there is a problem and delays urgent action. It causes people living with HIV to be seen as a 'problem', rather than as a solution to containing and managing the epidemic. Stigmatization associated with AIDS is underpinned by many factors, including lack of understanding of the illness, misconceptions about how HIV is transmitted, lack of access to treatment, irresponsible media reporting on the epidemic, the incurability of AIDS, and prejudice and fears relating to a number of socially sensitive issues including sexuality, disease and death, and drug use" (UNAIDS, 2005).

Local and global politics

Political conditions make HIV/AIDS a unique area of research. In many countries or states, participation in a particular activity that may be associated with a high risk of HIV transmission – such as commercial sex work, injection drug use, or homosexual activity – is illegal. The political decision to make these activities illegal affects those who perform these activities (for example, by affecting their ability to access services or participate in research). Careful consideration of the illegality and punishable nature of these behaviours often associated with those highly vulnerable to HIV infection is important, because identifying participants engaging in such behaviour may lead to unintended consequences such as arrest, denial of access to healthcare, loss of jobs, disownment by families, and other types of social isolation or humiliation. Respecting the political conditions and regulations that may, at times, conflict with the intended research protocol is also important.

Gender inequities, power dynamics, and sexual roles

Sexual roles and relationships are central to the nature of the HIV/AIDS pandemic throughout the world, power and gender dynamics between men and women often exerting considerable influence on HIV transmission. Women are attributed lower rank in many societies, making them particularly vulnerable to HIV infection as they lack the support and socioeconomic status to fully determine their sexual relations.

These social and sexual conditions greatly affect the transmission of HIV, and sometimes determine who is able to participate in research and how.

Economics and the allocation and availability of resources for research and health systems and services

The availability and allocation of resources in a country influence the level and nature of HIV/AIDS research that can be or is conducted. Health systems and standards of care in developing countries may have limited resources and can thus provide only a basic level of healthcare. Often, the regions that are least equipped to deal with HIV/AIDS effectively are also those hardest hit by the pandemic. The resources available and allocated to addressing HIV/AIDS, as well as the surrounding social conditions or circumstances, vary substantially from one region to another and affect the care and treatment received by those affected. Carrying out HIV/AIDS research in these countries sometimes means the introduction of research funds and resources where there previously weren't any. This distinguishes HIV/AIDS research within the general population of Canada from research carried out internationally, mostly in developing countries.

Prevention prohibition

"Carrying condoms could get women arrested and jailed for up to one year. As a researcher, you really need to have your finger on the pulse; know what the laws are and what is happening on the street. If a woman gets stopped and she has a few condoms, the police assume she is a sex worker. So giving out condoms, as part of a prevention trial, can end up putting women at risk rather than protecting them. International work is a big responsibility. If not careful, researchers can unintentionally cause more harm than good."

Canadian HIV researcher

Research ethics standards internationally and in Canada

The modern era of research ethics has evolved for over 60 years and has been a product of research abuses, reactions, and preventative measures against future occurrences. The fundamental standards of research ethics were created through the judgements at Nuremberg for atrocities conducted by Nazi physicians against individuals under the guise of research during World War II. The resulting *Nuremberg Code* focused on the fundamental principle of ***free and informed consent***, requiring three components:

1) Legal capacity to give consent;
2) Voluntariness of consent, without any form of constraint or coercion; and
3) Sufficient knowledge and comprehension of the subject matter involved to enable the prospective participant to make an understanding and enlightened decision.

It is the duty and responsibility of the researcher to ensure that consent is always obtained in accordance with these three components. Moreover, the research must be scientifically motivated, important to the benefit of society, and the risks of harm to the participants should never outweigh the benefits to the participants or society.

In the 1960s, the World Medical Association drafted the *Declaration of Helsinki,* which further established the parameters for free and informed consent and provided ways in which study populations without legal capacity – e.g. children, mentally handicapped people – could be involved in research that would directly benefit them. This document also specified the need for research ethics review by a committee, and further detailed what components need to be assessed: scientific validity, risks and benefits, and the informed consent process.

In response to several research ethics scandals in the 1960s and 1970s in the United States, the Department of Health, Education, and Welfare – later renamed the Department of Health and Human Services (HHS) – created a report entitled *Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, which became known as the *Belmont Report* (1979). This document emphasized three key principles for research ethics:

1) Respect for persons: protecting the autonomy of all people and treating them with courtesy and respect;
2) Beneficence: maximizing good outcomes for humanity and research participant, while minimizing or avoiding risks or harm; and
3) Justice: ensuring reasonable, non-exploitative, and well-considered procedures are administered fairly.

These principles remain the basis for the HHS federal regulations, known as the Common Rule or 45 CFR 46.

The Canadian research ethics standard: The TCPS

In the mid 1990s, a working group was established to create guidelines for research ethics in Canada. Once written, this document was approved and implemented by the three federal granting agencies – the Medical Research Council *(MRC)* (now called the Canadian Institutes of Health Research *(CIHR))*, the Natural Sciences and Engineering Research Council *(NSERC)*, and the Social Sciences and Humanities Research Council *(SSHRC)*. The document became known as the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS).

"When you work with a developing country where there's a resource disadvantage of some sort, and a power disadvantage, you really have to be careful, because that experience will colour future experiences, who they're willing to work with. You go in there and you're a researcher. And then you're an AIDS researcher. And then you become a diplomat. You become a representative of your country. So it's not just a relationship between some researchers. This is international work. If you can't do it right, then stay home!"

quote from Canadian researcher

The TCPS is the fundamental research ethics guiding document in Canada. While it is not regulatory like the US Common Rule, compliance with it is required for all research involving humans that is conducted at or under the auspices of an institution that receives agency funding. More importantly, however, the TCPS is principle-based and provides guidance to all researchers, institutions and research ethics boards *(REBs)* on the issues and requirements for ethical conduct of research involving humans. It is a "living" document, evolving as research and research ethics practices and issues do. Current areas for additions and revisions include Aboriginal research, research in the social sciences and humanities, proportionate review, and efficiency in review of multi-site research.

What does this document mean by "ethics"?

International HIV/AIDS research is laden with ethical tensions. The TCPS states that an ethic of research involving humans should include two essential components:

1) The selection and achievement or morally acceptable ends, and
2) The morally acceptable means to those ends.

The TCPS is built on the assumption that research involving human participants is premised on a fundamental moral commitment to advancing human welfare, knowledge and understanding, as well as examining cultural dynamics. In addition, the TCPS acknowledges that the norms for ethics of research involving humans are applied and refined within an ever-evolving societal context that includes the need for research and the research community, moral imperatives and ethics principles, and the law. For this reason, ethics review boards exist in order to support researchers and the pursuit of ethical conduct in research. In this resource, we assert that the global HIV/AIDS pandemic presents a unique context in which the moral imperative of ethical research must be not only applied, but also challenged in its application, both by researchers and the ethics review processes that support them.

TCPS requirements

The TCPS is divided into ten sections. The first five sections address general requirements for ethical research from the perspective of ethics review by a research ethics board (REB). The first section details the authority, mandate, responsibilities and composition of the REB and specifies that, in order to comply with the TCPS, a board must have the requisite scientific expertise to competently review research proposals in Canada and must include scientists, a person knowledgeable in ethics, a person knowledgeable in the relevant law, and a member not affiliated with the institution, but coming from the "community" (not defined in the TCPS). For HIV/AIDS research, it is recommended that the community member be a person living with HIV/AIDS *(PLWHA)* or caregiver. This is in accordance with other ethics documents, including the *United Nations General Assembly's Special Session on HIV/AIDS (UNGASS)*. The REB must review the research in accordance with ethics principles and practices outlined in the TCPS (see below). Virtually all Canadian research proposals, if attached to any Canadian university or any of the three research institutions listed above, must be approved by at least one such REB, regardless of the geographical location or jurisdiction in which the research is to be conducted.

The latter sections of the TCPS discuss eight guiding principles of ethical conduct in research. These principles are presented below. Framing these principles in the context of international HIV/AIDS research adds complexity to their meaning and raises important questions about applying them directly in such a context.

Respect for human dignity

The principle of respect for human dignity is the fundamental tenet of Canadian research ethics. This principle is meant to protect the multiple and interdependent interests of research participants, including psychological, bodily, and cultural integrity. It prohibits research that is degrading or dehumanizing, regardless of how well-intentioned or potentially beneficial the research is. Researchers should be aware of cross-cultural variations in the values surrounding human dignity and make efforts to avoid imposing their own values.

Free and informed consent

This principle assumes that all individuals should be free to make autonomous decisions. It requires researchers to be honest with potential research participants about what research is being conducted, why it is being done, and what the possible risks to the research participant are. All relevant information about the research should be provided to participants, and any questions or concerns should be addressed before asking for consent. Participants have the right to withdraw their consent at any time during the research without providing an explanation for their withdrawal, and without experiencing any negative consequences relating to their continued healthcare. The balancing of collective rights and responsibilities versus individual rights and responsibilities varies cross-culturally and may challenge this principle in international HIV/AIDS research.

Respect for vulnerable persons

The TCPS explains that respect for human dignity necessitates high ethical obligations to ***vulnerable persons*** – those who experience diminished competence and/or decision-making capacity. Such persons, including children or those stigmatized by society, are entitled to special protection from abuse, exploitation, or discrimination on the grounds of human dignity, caring, solidarity, and fairness. This ethical obligation will often translate into special procedures to protect their interests. Vulnerable persons may include people living with HIV/AIDS (PLWHAs). Protecting participants living with HIV/AIDS is important throughout the entire HIV research process, particularly in settings where stigma may be severe, less visible or very subtle.

Respect for privacy and confidentiality

In many cultures, privacy and confidentiality are considered essential to human dignity, even though the understanding and practice of these principles or values may vary from culture to culture and from community to community. Every research project must make provisions for protecting the privacy and confidentiality of research participants. This includes regulating the access, control, and dissemination of information. Such standards help to protect mental and psychological integrity. Respect for privacy and confidentiality is particularly critical in HIV/AIDS research given the high stigma often associated with HIV/AIDS. In many societies where the concept of privacy and confidentiality differs, particularly where individual rights may clash with communal rights, respecting privacy and confidentiality may be more difficult.

Respect for justice and inclusiveness

The principle of respect for justice and inclusiveness, according to the TCPS, has two components. First, it states that no segment of the population should be unfairly burdened with the harms of research. Second, it emphasizes that no segment of the population should be denied the benefits of research. This principle imposes particular obligations toward those who are vulnerable and unable to protect their own interests, to ensure that they are not exploited for the advancement of knowledge. People living with HIV/AIDS and those deemed at high risk of infection are sometimes unfairly burdened with research studies and the conditions the studies entail. This is a particularly important consideration for HIV/AIDS research conducted in an international context, notably in developing countries.

Balancing harms and benefits

The TCPS requires a favourable harms-benefits balance: the foreseeable harms should not outweigh the anticipated benefits. The rationale for research is that it is likely to generate a benefit, if not directly for research participants, then for society as a whole. Because research involves gaining new knowledge, it often involves uncertainty about the precise magnitude and kind of benefits and harms that will be experienced. These realities, as well as the principle of respect for human dignity, impose ethical obligations on the prerequisites, scientific validity, design, and conduct of the research. These concerns, according to the TCPS, are particularly evident in biomedical and health research. In international HIV/AIDS research, anticipating what harms may

ensue from participation in a study can be difficult, and measures used to conduct the research can be seen as unnecessarily harmful when the potential benefits of it are not yet apparent.

Minimizing harm

The TCPS accepts the principle of **non-maleficence**, or "do no harm." This implies the duty to avoid, prevent, or minimize harm to others. Research participants must not be subjected to unnecessary risks of harm, and their participation in research must be essential to achieving scientifically and socially important aims that cannot be realized without the participation of human subjects. In the context of international HIV/AIDS research, the concept of harm may become more complex. For example, in HIV/AIDS research, some groups have been studied intensively and extensively – for example, men who have sex with men, commercial sex workers, injection drug users, pregnant women, and heterosexual adults living in areas with particularly high rates of HIV/AIDS. The concern is that such exposure or participation levels in research may in itself represent harm or present risk of harm.

Maximizing benefits

The final principle of the TCPS is that of beneficence, or the positive duty to help and maximize net benefits. Research should strive to maximize the benefits for individuals and society, as well as the advancement of knowledge. In international HIV/AIDS research, the boundaries of what constitutes benefits and a researcher's obligation to maximize them can be challenged. For example, maximizing benefits to individuals and society could include paying attention to:

1) What the outcomes of the research will be for the community;
2) What is left behind; and
3) Ensuring capacity building and academic training for locals.

Each research situation poses unique circumstances that challenge the direct applicability of these principles and often bring them into conflict with one another. In the ethics of international HIV/AIDS research, there are no easy answers. Each situation calls for a specified approach and application of ethics principles. The TCPS presents these principles in order to provide a framework and guidance for thoughtful discussion and ethical conduct in research, fostered and supported by the formal ethics review process. Though the ethical value of these principles is unquestioned, their application becomes more complicated in the context of international HIV/AIDS research, which poses challenges in a new and complex constellation of factors. This resource seeks to address some of the challenges associated with applying the TCPS to HIV/AIDS research in international settings, and some of the ways in which the unique context of international HIV/AIDS research may call for researchers, and the ethics review processes that support them, to think above and beyond the eight TCPS principles.

Part Two

Research scenarios: Highlighting ethical tensions

In this section, four research scenarios are presented. Organized by research track (for definitions of research tracks, see Appendix III: Terms and abbreviations used), these scenarios were compiled to emphasize the

ethical tensions in international HIV/AIDS research that emerged from interviews and consultations with Canadian researchers. Designed to highlight the practical implications of these tensions in applied scenarios, the narratives presented in the following section have been created from an amalgam of experiences and ethics themes. As such, although rooted in actual experiences, the countries and communities in which the scenarios take place are fictional, as are the research projects and associations with funding bodies (specific calls for proposals, ethics requirements or requests, etc.). The scenarios have been designed to highlight persistent ethical tensions; thus, the perspectives demonstrated by the characters in the research scenarios do not necessarily reflect the perspectives held by CAHR, nor the organizations, universities, or researchers who contributed to this document.

Research Scenario One: Basic Science

Summary

This scenario addresses issues that may arise in international research when the host country or community does not have research infrastructure or previous research experience. In this scenario, the absence of a local ethics review process in the host country challenges the Canadian researcher to develop appropriate measures to ensure community involvement and long-term human capacity development in the project. In doing so, however, conflicts of interest arise and an unequal distribution of power between Canadian and local research partners creates tensions. Balancing local researchers' input with Canadian ethical principles and views about research participant recruitment and compensation becomes difficult. Questions about where to conduct data analysis, and considerations of who truly benefits from the research come into play. Alternatives for how best to exit the project are considered. This scenario illustrates the potential payoffs of long-term commitments to international partnerships that can result in local control over research and meaningful development of local capacity.

Background

Since the late 1980s, HIV/AIDS has been a persistent concern in Caribbean countries. Transmitted predominantly through heterosexual contact, HIV/AIDS in the Caribbean is set in the context of harsh gender inequalities and is fuelled by a thriving sex industry in which many young women engage in an effort to ameliorate their economic circumstances. Vulnerability to HIV infection is high among the general population, exacerbated by factors such as early sexual initiation, many sexual partners, and low condom use.

Research design

In 1988, Canadian researcher Nadia Allam, a recent doctoral graduate of microbiology, applied for funding from the Medical Research Council (MRC) of Canada[1] for a research project looking at immunological resistance to HIV among female sex workers and their clients. The research was set in Urban Centre, the capital city of Imagination, a country in the Caribbean region with an adult **HIV prevalence** rate of approximately five percent. Through a connection she had made at a conference during her graduate training, Allam identified and requested the involvement of two Caribbean researchers, Pietro Rodriguez and Juan Maricano, with whom she hoped to collaborate on the project.

Unknown territory

What, if any, are the problems with a novice Canadian researcher identifying and applying for funding for a research project before developing relationships with prospective local partners?

Ethics approval

Prior to Allam's departure to Urban Centre, her research proposal was scrutinized rigorously by her home institution, as required by the project's funding agency. The research ethics board required Allam to reconsider some of the proposed methods of data collection. Eventually, Allam was granted ethics approval on the condition that the host country, Imagination, give its approval as well.

During her first visit to Urban Centre, Allam found herself within a world completely different from that to which she was accustomed. The culture of research that Allam had come to know so well in Canada was non-existent in this host country. To her amazement, given the urgency with which she felt the AIDS epidemic in the Caribbean needed to be addressed, Allam knew of no others carrying out research of this kind in Urban Centre. There didn't seem to be any formal ethics review process, and hence no infrastructure for study approval. Where would she find the expertise needed to effectively review the proposal?

Breaking new ground

Conducting HIV/AIDS research internationally may involve working in areas that lack adequately developed research infrastructure.

She questioned the ethics of pursuing the research at all, given that without local review, she could not ensure that the project would abide by local ethics principles. At the same time, however, Allam anticipated that the proposed research would help

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1 This research scenario has been placed in the past in order to focus on some of the ethical issues associated with long-term projects. In 2000, the Government of Canada created the Canadian Institutes of Health Research (CIHR) and dissolved the Medical Research Council of Canada.

the local population and felt that by cancelling it to conduct the study elsewhere in a country with a formal ethics review process, Allam would be contributing – through non-action – to the unjust conditions within which the subject population lived.

Would it be sufficient for Allam to become familiar with the ethics guidelines of a neighbouring Caribbean country, and apply those to the host country in order to protect the interests of the local communities and research participants?

Ethics review

Canadian REBs usually request ethics approval from a researchers' host country before providing their own ethics approval. In instances where the host country lacks a formal ethics review process, what should a researcher do? Will a surrogate process by a committee or individual community representative suffice? What information are REBs seeking through the local ethics review process, and how does this help in determining who should be involved in the local ethics review process?

In the end, she reported this lack of ethics review process back to her own REB in Canada, who cautiously granted approval for her research but again highlighted the importance of local input and approval. Given the rising HIV prevalence, Allam anticipated that there would be an increasing demand for research in this region in the future. Knowing her own project was likely to evolve into an ongoing research program, Allam felt that helping to create a local ethics review committee was both practical and part of her duty to build local research capacity. Although an important component of the research preparation process, consultation with local communities about advice and wishes for how the research should be conducted would not be sufficient.

The first few years of Allam's work in the Caribbean were fraught with challenges. To formulate an ethics review committee, she brought together representatives of various community and academic groups, hoping eventually to set up a body that would satisfy international standards. While this would evolve over the years as the ethics culture was simultaneously growing and developing internationally, Allam's efforts began slowly, with a spattering of ad hoc ethics review committees that moved around from one project to another, on an as-needed basis. These committees experienced growing pains for many years and were largely dysfunctional, as regular meetings or standardized forms or policies to which research proposals could be applied had not yet been established. Through this process, Allam began to recognize that the concept of research ethics boards was constructed in the developed world, which has the resources and expertise to create and sustain them. In the context of a developing country, however, this was a somewhat foreign concept that did not naturally coincide with how research ethics were viewed there. Today, the culture of research ethics in the Caribbean has undergone many changes, yet the ethics review system remains under-staffed and under-resourced, often relying on a single individual for access to files and information, effectively shutting down the entire review process temporarily if that individual is absent at any given time.

Conflict of interest?

What are the ethical implications of Allam having her research reviewed by an ethics review committee that she essentially put together? How can any apparent, actual, or potential conflicts of interest be avoided?

One of the greatest challenges in developing an ethics review system lay in convincing Rodriguez and Maricano of the importance of community representation. Allam knew well the value of involving those in a position of power and influence in the country where she carried out the research, so she obtained clearance and approval on all aspects of the project from higher levels of government, hospitals, and academic institutions before proceeding with the research. This process was well-received by Rodriguez and Maricano, who were accustomed to Imagination's more autocratic form of governance, in which deference to authority was critical in ensuring projects were properly carried out. Allam's idea of involving locals at the community level, however, was not well understood. The few non-governmental organizations *(NGOs)* that were identified as potentially helpful in gaining access to the subject populations consisted primarily of professionals or retired government officials who had limited knowledge of the true inner workings of the subject community. Not being true insiders of the female sex worker population they claimed to represent, these NGOs did not provide the in that was needed to access these women. To Allam's dismay, the only local involvement in the project at this early stage remained high-level individuals in government, healthcare, and academia, many of whom had been trained in their professions in Europe or America, further diminishing the extent to which they were truly involved in the community of study.

Participant recruitment

Rodriguez and Maricano assured Allam that, if NGOs could not provide assistance in participant recruitment, other professionals with whom they had contact could easily recruit enough female sex workers to satisfy the study protocol. Police and physicians, both of whom were regularly in contact with the subject population, could identify as many individuals as needed. In this process, participants were asked to come to a clinic set up specifically for the project, where data collection could occur.

Data collection

Before being asked to provide blood samples for immunological analysis, recruited participants were asked to participate in an in-depth interview with a social worker. Through this qualitative component of the study, the researchers intended to gain an understanding of the social and behavioural contexts that influence the women's decision-making and sexual behaviour. Both components of the study were considered important, but they were intended as distinct mechanisms of participation in the study. A woman's participation in one capacity was not to be an implicit agreement to participate in the other. Local clinic staff, however, were accustomed to a culture in which those in a position of authority, particularly physicians, are not questioned. The staff recognized the value in obtaining more rather than fewer blood samples for the study. As such, they often strongly encouraged interview participants to provide a blood sample in addition to participating in the interview. They did this by explaining to the participants that the blood sampling was simply the second

Negotiating within conflicting ethical norms

What a Canadian researcher may view as coercion may, to locals, be seen as a routine way of working within the healthcare system. If this is what works well within the local context, should the researcher use it?

Conflicting priorities

How should a conflict in priorities around data collection be handled?

Ethical space

In some cases, disparate world-views may lead to differing approaches when choosing an appropriate research method. Researchers may struggle to reconcile their own approach with that undertaken or expected by local partners.

Movement and use of biological samples

What are the ethical issues with transporting identifiable biological samples across borders? Should researchers be allowed to use data, including biological samples, for analyses not consented to? What are the researcher's responsibilities to report back findings of the analysis to individuals and/or the research community?

Fair compensation

Is it ethically acceptable to provide participants with more financial compensation than recommended by the local research partners? What issues should be considered?

component of a study they had already agreed to participate in, and assuring them that they had nothing to lose in providing their blood. Although this was done in a kind manner, it seemed – according to Canadian ethics principles – to be coercive and an abuse of the power differential that existed between those involved. This desire to provide the Canadian researchers with "perfect" data, although appreciated by Allam, demonstrated that the different partners involved had inherently different approaches to research. In order to negotiate and come to an agreement about following high ethical standards, Allam tried to appeal to what she believed her local partners felt was important.

Regardless of the means by which the blood was collected, Allam now found herself with a large collection of blood samples from a population that, under most circumstances, would be difficult to access. Allam received a request from a colleague to use these blood samples to investigate an unrelated, but very scientifically valuable, research question related to HIV. Allam knew that using the blood samples for this purpose wasn't included in the informed consent process, but she also recognized how potentially valuable the new research could be for furthering the knowledge about HIV, especially for such a hard-to-reach population.

After careful thought, Allam decided to allow her colleague access to the blood samples.

Participant compensation

Rodriguez and Maricano strongly advocated that the money initially allocated for participant compensation in the research budget be used solely to pay the costs associated with running the clinic and to reimburse participants for the costs they incurred in travelling to their appointments. For Allam, this seemed grossly inadequate, as she measured the poverty of the participants against the research budget, which could provide much more compensation for them.

After much discussion, however, Rodriguez and Maricano convinced Allam that access to high-quality free healthcare, treatment of and preventive measures for other sexually transmitted infections *(STIs)*, and counselling about how best to remain HIV-negative – or reduce the risk of transmitting to others for those who were HIV-positive – were benefits far beyond what the average citizen could obtain. Access to these health services, they assured Allam, was compensation enough for the participants.

Capacity building

The relationship between Allam and Rodriguez and Maricano at times lay in a precarious balance, each recognizing the importance of the other's cooperation and commitment to the project, yet wanting more authority and control over the project than they felt they had. Allam recognized that capacity building, in the form of strengthening and broadening Rodriguez and Maricano's, as well as the local staff's, capacities to design, implement, and analyse research studies, was an important component of the project. At the same time, she felt pressure to get things done in a timely manner in order to be able to report to the funding agency and her own academic institution at the required regular intervals.

Allam's reputation as a researcher was also at stake, given that this was the first time she led a project of this magnitude in international HIV research. She also felt strongly about following stringent ethical guidelines – both those outlined in the TCPS as well as her own personal sense of what was ethically right or wrong. Feeling very strongly about the importance of conducting research in an ethical manner, Allam undertook to create a culture change in research being carried out for the project, particularly with regards to the issue of confidentiality. She wanted to ensure that she could eventually leave the project, confident that the local partners understood the basic principles of research and the rigour required in order to carry it out well, the importance of adhering to ethical guidelines, and particularly the need to maintain and ensure the confidentiality of research participants throughout the entire process.

Rodriguez and Maricano were delighted to have international collaboration and funding for a project they had long envisioned undertaking, yet for which they could not access the political and financial support within their country. While appreciating Allam's commitment to the project, however, they were well aware of the power imbalance between themselves and their Canadian partner. During the first few years of the project, Allam, through support from the MRC and her home institution, provided all of the funding for the project. In doing so, she also took on a strong leadership role, deciding how the study should be designed, how money should be spent, and other logistics such as selecting who should go on treatment and how follow up with participants would occur.

Allam took responsibility for ensuring rigour in the research and systematic tabulation of data. She did this because she saw that – even though she was a novice by Canadian standards – her skills and experiences in conducting research were more developed than those of Rodriguez and Maricano, who had not yet had the opportunity to develop their skills to her level. This created an awkward tension for Rodriguez and Maricano, who felt limitations to what they should contribute to the project. Providing too much input

Cultural differences

The ethical guidelines outlined by the TCPS were created in a society that values the rights and freedoms of the individual. Many countries in which HIV/AIDS research is conducted more strongly emphasize the well-being of communities. In this context, is it ethical for a Canadian researcher to impart her ethical values to the society in which she is working, even if the locals do not see these ethical standards as important or appropriate?

Sustainability

Is it ethical to carry out research projects on a scale far beyond what could reasonably be sustained locally? Conversely, is it unethical not to carry out such research that could benefit communities?

Power structures

Particularly in the early years of research projects, Canadian researchers may take on a strong leadership role and make important decisions about the study from design through dissemination. How does this conflict with efforts to build local capacity? Are such power imbalances between the Canadian and local researchers ever justified?

Data ownership

Can we justify taking data out of the country for Canadians to analyze when it is the local population that provided all the data and is most affected by the results?

Local input

Given Allam's objectives for capacity building, how ethical is it to exclude the local partners from data analysis and presentations, even early on in the partnership?

or challenging Allam's ideas could result in termination of their partnership or the project. Allam was somewhat aware of this tension and made an effort to solicit her local partners' input, yet they often hesitated to insist on conducting the research in ways they felt most appropriate, knowing they could only back up their views with personal experience and cultural knowledge, not methodological or theoretical evidence published in peer-reviewed journals. Although Allam wanted to treat her partners as equals and felt she made efforts to do so, this power imbalance in their relationship lingered on for many years.

Data analysis

In the early stages of the project, all the collected data were sent to Canada for storage and analysis. Allam had initially intended to help develop local capacity for this component of the research, yet she knew that, given her partners' current levels of experience and education, local data analysis would not be possible at the level required, at an adequate speed, and with the same rigour as could be achieved in Canada. Allam felt pressured to do it properly and in a timely fashion in order to meet the reporting periods required by the MRC and to complete the study within the budget's timeframe. Being a new researcher, she also pressured herself to succeed and complete the project in the time designated for it. These expectations, she felt, could not be met if these tasks were assigned to Rodriguez and Maricano. From what Allam observed, she anticipated that the data would simply be eyeballed and subsequent recommendations would be made based on a rough analysis of the results. The thought that policy recommendations might be made and implemented based on this type of data assessment frightened her. Allam was convinced that, for the time being, she had to take the collected data home and carry out the analysis herself in order to ensure that it was done accurately. Given her deep involvement in the project, particularly in the data analysis component which she did without any local input, Allam felt the most familiar with the study findings and was also the first to author journal articles and presentations that resulted from it. Many times in the first six years of the project, Allam presented at one conference after another, rapidly building her career and establishing a reputation as a solid international researcher.

Exiting

During the first four years of the project, Allam was deeply concerned about the initial four-year time limit imposed on the project. She recognized that, unless more funding was acquired, there would probably be no local handover and the project would simply halt at the end of the four years. Even three years into the project, Allam was still apprehensive about the capacity of Rodriguez and Maricano to sustain the project. At that point, the prospect of a handover to the local partners was not feasible.

Allam considered two options. One option was to avoid imposing a timeframe on the project, but rather to build a permanent partnership with the locals, eventually relying more on local resources, expertise, and leadership. This would mean continuously working towards developing infrastructure for eventual transfer of leadership to the locals, who she hoped would, over time, internalize her values of rigour and confidentiality in order to continue to follow them without Canadian involvement. Allam's role would evolve into one of consultation rather than leadership. Evidence of success with this approach would be seen when locals analyzed and presented all data arising from the project. One obvious challenge with such an approach, Allam realized, would be to secure funding for an unlimited timeframe.

The second option was to impose a strict time limit for Canadian involvement in the project (for example, six years), after which the locals would be expected to be self-sufficient and capable of continuing the project in every respect. If, by that time, this was not the case, the project would be terminated nevertheless.

Allam preferred the first option, and she spent considerable time and energy to try to build a permanent partnership that would eventually evolve into a locally-led project.

Epilogue

Now, many years later, Allam often reflects on the many challenges and doubts she overcame throughout the decades of intense collaboration with Rodriguez and Maricano and the many local staff, volunteers, and participants who became involved in the project over the years. The change in the nature of the project has been phenomenal. Although still not ideal, the culture of ethics and the infrastructure to host research projects of this scale in Imagination have developed dramatically. Proposed projects are now reviewed thoroughly by a national research ethics board that, most of the time, includes representation from all the required community groups. A number of local staff, graduate students, researchers, and volunteers now feel comfortable with all stages of the research process. Capacity building has thus benefited not only the local co-investigators, Rodriguez and Maricano, but also local technicians and junior scientists by enhancing their skills.

Research into immunological resistance to HIV continues in Imagination, jointly funded by the local government and Canadian research bodies. Data are stored within the country and only a duplicate is taken back to Canada, so analysis can be carried out in either place. Since the late 1990s, dissemination of the research findings has been done primarily by Rodriguez and Maricano and their colleagues, who senior author most peer-reviewed publications that result from the study and present the findings at international conferences. They continue to work toward using the research results from their ongoing studies to implement effective HIV/AIDS-related programs and create positive change in their communities. Allam's commitment to using the project's findings to implement positive change in the communities where the research took place has been gratefully accepted by the locals, who see that their participation in research has led to positive changes.

Research Scenario Two: Clinical Science

Summary

In response to a Canadian call for proposals, an experienced clinical researcher begins a clinical trial for a new antiretroviral agent in HIV-positive pregnant women in Southeast Asia. Challenges associated with conflicts of interest in local politics, cultural understanding of clinical interventions, and the ethics of continuing antiretroviral treatment beyond the life of a research study arise. Bureaucratic regulations and the effects of previous researchers' attitudes and behaviour affect the research. Issues around undue inducement, the effect of religious beliefs on data collection, and the transferability of cultural experiences come to light. Ethical considerations around the choice of participant population are considered, as are the sustainability of the project and the challenges in balancing rigourous data collection with cultural sensitivity.

Background

Identified as important components of the United Nations' **Millennium Development Goals**, maternal and child health have been given high priority at the Canadian International Development Agency (**CIDA**) and other organizations addressing issues of poverty, inequality, health, and development issues throughout the world. Given the situation of women in many societies, particularly in the developing world where they often suffer disproportionate conditions of ill health, and considering their central role in ensuring the health of children as their primary caretakers, this priority is hardly surprising. Canadian HIV/AIDS researchers also consider maternal and child health a priority and make tremendous efforts to be leaders in this demanding and important field.

Research design

When CIDA issued a call for proposals for a clinical study addressing the transmission of HIV from mother to child in Southeast Asia, Canadian researcher Alain LeBlanc was excited by the prospect of working in such an important and challenging field.

He submitted a proposal to examine the effectiveness of antiretroviral *(ARV)* drugs on *vertical HIV transmission* (mother-to-child) in pregnant mothers in the capital city of a newly industrialized country in the region. Funding would last for four years with the possibility of additional phases in four-year increments thereafter. The HIV prevalence in the country was relatively low but growing, with significant risk associated with a thriving sex industry. The epidemic was concentrated in already marginalized risk groups such as commercial sex workers and injection drug users. The stigma and discrimination associated with HIV/AIDS were also extremely high in the country. LeBlanc suspected that this concentrated and sharpened stigma contributed to low testing rates and likely underestimations of the true prevalence rate within the country. Based on the apparent low prevalence, local health authorities focused resources on what were considered higher priority problems and paid little attention to the provision of HIV-specific services. LeBlanc hoped his work would illuminate the real situation of HIV infection in the country, and lead to the ultimate development of a prevention of mother-to-child transmission *(PMTCT)* programme that could be implemented on a national scale.

LeBlanc had spent much of his career in sub-Saharan Africa and had no experience working or travelling in Southeast Asia, yet he felt confident in his inter-cultural communication skills and knew he could adapt well to new cultures. His proposal was successful and his project began.

At the time of the project's inception, no antiretroviral (ARV) drugs were available in the country, not even ARVs administered as a short course to prevent vertical transmission during pregnancy. LeBlanc proposed to conduct a clinical trial of a new *triple combination therapy* to be administered to HIV-infected pregnant women. Pregnant

Setting priorities

What is unique about a project developed around a call for proposals, rather than based on the need for a project expressed by locals?

Transference

Researchers may have extensive experience working in a particular region, yet be relative newcomers to another area in which they are conducting research. What might be dangerous about making assumptions about one culture's HIV/AIDS context based on experience with another?

women would be recruited from five local health clinics that had been identified with the help of LeBlanc's primary local collaborator, Dr. Prajit Chandar, a researcher at the local university. Recognizing that this trial would likely be these women's only opportunity to receive treatment, LeBlanc felt it was ethical to offer ongoing treatment and care to the research participants and their babies. Thus, continuing antiretroviral treatment was built into the funding proposal and approved by the funders for the four-year funding period. Monitoring clinical outcomes including HIV plasma *viral load* and *CD4 cell* counts was included in the research protocol. LeBlanc also hoped that success in this project would demonstrate the feasibility and benefit of a national HIV treatment program, in addition to the PMTCT initiative.

Ethics approval process

Upon request by his Canadian research ethics board and CIDA, before leaving Canada LeBlanc sought ethics approval from the University of Capital City, where his local co-investigator, Chandar, was a professor. To his surprise, the ethics approval from the local university came promptly and no changes to his study design were requested. Only after arriving in the country some months later did LeBlanc discover that one of the members of the local research team he had recruited based on Chandar's recommendations was also on the REB that reviewed his study.

An additional *conflict of interest* became glaringly apparent shortly after LeBlanc arrived in the country. The drug to be tested on the subject population was produced by a local company owned by a member of the Health Minister's family. The drug company was the only one approved to provide ARV drugs through the government (and the new drug being tested would be included in this sole source arrangement), so all medications had to be procured from this company. The company produced only one variation of triple combination therapy. This caused a number of concerns for LeBlanc, who understood well the risks and ramifications of *ARV resistance*. He felt strongly that, should a participant show resistance to the first-line regimen, provisions should be made to follow the World Health Organization *(WHO)* recommendations and move to second-line regimens. This suggestion, however, was quickly hushed by local authorities, who threatened to terminate the entire project should LeBlanc raise the idea again. LeBlanc discovered that if resistance to this drug did indeed develop, local physicians would attribute this to improper adherence to the drug and advocate for its continued use without mentioning the possibility of alternative regimens. LeBlanc knew he would be expected to do the same if he were to continue his work and maintain cooperative relationships with government officials who were responsible for any type of access to medications. Although this pushed LeBlanc to his ethical

Conflict of Interest

In Canada, REB members that are intimately involved with a researcher or research project must remove themselves from deliberations and decisions on that ethics protocol. What responsibility does the researcher have to ensure fair, unbiased local review processes?

Human dignity

Rules and regulations may prohibit the promotion or use of particular drugs. When a country doesn't allow testing or production of drugs that would ensure the best fit for a given population, how can a researcher deal with the impact of this on the fundamental TCPS principle of respect for human dignity?

Continuing care

In Canada, HIV drugs that are shown to be effective in a clinical trial must be available to research participants until they are covered by provincial formularies. Should this principle apply in any or all international research?

Local influence

How much local influence are you willing to accept when it involves deception (by either omission or commission)?

Community involvement

What are the benefits and risks of involving the local community in the design, development and execution of the research? Do the benefits of community involvement outweigh the risks?

Paving the way

Researchers' attitudes and conduct in a particular community can affect future research with a given population. What is our responsibility as researchers to ensure the community accepts future research in the area?

Undue inducement

If no other drug for prevention of HIV transmission from a mother to her child is available, does this study constitute **undue inducement**?

limits, he felt the study was of sufficient importance and urgency to abide by the local authorities' absolute requirements and continue endorsing the one drug regimen made available for use in the country.

Confident in his skills and experience as a clinical researcher, LeBlanc had few concerns about building a strong partnership with his local counterparts. Involving a select group of researchers and physicians in the study would be sufficient to meet CIDA's criteria for local involvement and would surely provide enough local contacts to carry out the study successfully. His research proposal had been approved by two respectable ethics review processes which, from LeBlanc's perspective, indicated that he did not need to involve community members in the project design.

Recruitment and sampling

When it came to participant recruitment, LeBlanc was surprised by the reluctance he sensed among local healthcare providers to participate in the study. It was only through Chandar that LeBlanc learned of previous clinical studies that had been carried out recently in Capital City by international researchers who gathered the information in a way that showed insensitivity to the local customs and beliefs. Furthermore, the researchers had returned to their home country without ever sharing any of the research results or benefits. LeBlanc was thus faced with the challenge of convincing Chandar, his local team, and the community that the study would be carried out with cultural sensitivity, and that the results and benefits of the research would be shared with the community. Advantageous for gaining support for the project, however, was that no other drug was currently available or acceptable for HIV-positive pregnant mothers in the region. From the women's perspective, there was little choice but to participate in the study in order to prevent transmitting HIV to their babies, as well as securing life-prolonging treatment for themselves. This incentive was virtually impossible for these women to pass up. LeBlanc and Chandar soon found that they had more women wanting to participate than they could enrol. This level of interest left the research team with the task of choosing who would be eligible for participation and who would not. Given his lack of connection with the community, LeBlanc decided to leave the screening of participants in the hands of the local health professionals, under the supervision of Chandar.

Data collection

Carrying out the project design as initially intended also proved to be a challenge. Although reviewed by two ethics review processes, one in Canada and one in the host country, neither group of reviewers had considered the culturally-embedded beliefs around drawing blood. According to local religious beliefs, taking blood was considered extremely intrusive and used only as a last resort when no other measures could be applied. When potential study participants were informed that blood would have to be taken frequently and on a relatively large scale to monitor clinical outcomes, a considerable cohort of pregnant women declined to participate. Such procedures would violate the sanctity of their bodies and be disrespectful to their cultural and religious beliefs. LeBlanc was surprised by these concerns, given the ease with which issues of informed consent had been accepted by the review committees. Realizing he would get little participation if he pursued the study exactly as planned, and wanting to ensure long-term sustainability of the project, LeBlanc negotiated with the local community to reduce the frequency of blood drawing, even though that might reduce the study's ability to demonstrate the treatment's effectiveness. This would be a significant sacrifice for the study, which would likely have to extend beyond the initially anticipated timeframe in order to gather sufficient evidence to ensure clinical validity.

Data analysis and dissemination

Data collected for the study were stored locally. Issues surrounding storage were of little concern to LeBlanc, as the funding from CIDA ensured that the project was well-equipped with proper technology specifically intended to keep the data secure. Once analysed, the data showed suitability of the tested drug for preventing the transmission of HIV from mother to child, although its efficacy was not optimal. LeBlanc felt the women would fare better if given the widely accepted PMTCT regimen of AZT, 3TC, and Nevirapine. He decided to be clear about this limitation of the study and assert the alternative recommendation when disseminating the results through peer-reviewed journals. Upon hearing of his intentions, however, the local authorities – knowing that the only non-nucleoside reverse transcriptase inhibitor *(NNRTI)* produced by the drug company associated with the government was Efavirenz, which, unlike Nevirapine, could be toxic to the foetus – quickly intervened and placed stringent restrictions on what he could publish and how it was to be presented. In order to maintain a civil relationship and not affect future chances of researchers conducting studies in the area, LeBlanc abided by these restrictions.

Inclusion and exclusion

When the need for treatment far exceeds a clinical trial's capacity for enrolment, how can equity be ensured in deciding who can participate and who can't?

Learning from locals

Researchers may encounter numerous religious and cultural beliefs and customs that define how and what research may be conducted. What can researchers do to foresee the impact of such beliefs on their study design? Could the involvement of local informants prior to ethics submission help avoid inappropriate project design?

Sustainability

Research funded through Canadian sources may come with financial and technological resources vastly different from what can be acquired or sustained locally. Is it appropriate to use technologies and processes that are not sustainable beyond the life of the project, even if they ensure the quality of the project at the time?

Censorship

The TCPS requires freedom to publish research results. However, in international contexts, actual freedom may not always be predictable.

Long-term planning

If continued drug provision beyond the life of the project can not be guaranteed by the locals at the outset, do you go ahead with the study regardless?

Exiting the field

Despite sub-optimal results from the drug efficacy trials, LeBlanc made efforts throughout the life of the project to demonstrate to his co-investigators the effectiveness of drug treatment in this setting, especially when measures were instituted to maximize adherence. This, he hoped, would ensure that they would continue to provide treatment to all participants even after CIDA's funding ceased and LeBlanc terminated his partnership with them. To this end, LeBlanc began negotiating with the host country's government, who would need to continue supplying the ARVs. They had reached a verbal agreement, but by the time LeBlanc was ready to exit from the study, he had not been able to secure the agreement in writing. Given his pending responsibilities back home, LeBlanc agreed to transfer to Chandar the responsibility of finalizing the agreement, with whatever support he could provide from Canada. LeBlanc briefly regretted having introduced the drugs in the first place, recognizing now what a challenge it would be to ensure their continued provision. But he had no choice but to trust that his local partners would see the project through. The thought of what would happen to his research participants if they were suddenly denied access to the life-long drug regimen worried him deeply.

Epilogue

One year later, LeBlanc returned to the research site to follow up on the progress that had been made since his departure. To his great relief, the mothers who had participated in the study were still receiving government-funded ARVs. However, the drug company was providing only the first-line regimen of triple combination therapy. The local health professionals informed LeBlanc that this combination therapy had seemed to lose its effectiveness in a small number of women. This change did not seem to be due to a problem with adherence as the local health professionals, under Chandar's supervision, had devised and applied adherence support and monitoring systems which seemed to translate into very high adherence rates. LeBlanc recognized that the loss of efficacy might well be due to the development of resistance, and the women should likely be receiving second-line regimens to restore virologic efficacy of the ARV therapy. LeBlanc began discussions with Chandar on how they might be able to secure these drugs, which were not supplied by the drug company associated with the government. LeBlanc was also distressed by a new facet of the continuing epidemic in the population. After a few consultations with participants, LeBlanc realized that although they had been able to prevent vertical transmission to some babies and successfully enrol mothers on treatment, the current benefits did not extend to the women's husbands and/or families. In many cases, women who had participated in the study continued to engage in the sex trade to fund treatment for their families. At the time, there were no prevention programs in place for sex workers. LeBlanc realized that his work with this population was far from over, and he and Chandar began devising plans for future collaborations.

Research Scenario Three: Epidemiology and Public Health

Summary

The research described in this scenario is locally initiated. Nevertheless, concerns arise about who defines the research questions and the population to be studied. Locals' feeling of ownership of the research is addressed, as are the inherent power imbalances in partnerships involving international players. The Canadian researchers in this scenario worry about rubber-stamping of their proposal and find it challenging to separate the research study from their personal feelings about the bureaucratic context within which they are working. The highly illegal nature of the subject populations' activities calls into question methods of accessing research participants and obtaining informed consent according to TCPS guidelines. Trust between research partners becomes a sensitive issue with concerns about adhering to research protocol, particularly with regards to obtaining informed consent and maintaining confidentiality. Differing approaches to data collection and conflicts in priorities about how this is best done also come to the fore. Cultural biases in data analysis are addressed. Caution in dissemination that aims to reduce rather than exacerbate further stigmatization of already highly-stigmatized populations becomes an issue.

Background

Although AIDS is known to be affecting more people in sub-Saharan Africa than any other region of the world, the former Soviet republics have been experiencing a phenomenal upsurge in HIV prevalence. This region is a critical area for research in HIV transmission, particularly among intravenous drug users (IDUs) who represent a large portion of those infected in the area.

Whose idea was it?

Local ownership of research begins with local definitions of the problem. What might be different about a study that is initiated by locals rather than external researchers? How might this affect the nature of the research study?

Initiation

Alarmed by the rising HIV prevalence in their country, Aleksi Klim and Michail Tobolowsky, health officials from Examplestan, a former Soviet republic particularly hard hit with a rising HIV prevalence, requested the assistance of Canadian epidemiologists Rajindar Singh and Morgan Jones to help fight the high rates of HIV infection among the population. Klim and Tobolowsky wanted assistance identifying the reason for this upsurge in HIV prevalence and ideas for programs that could be implemented to help stem it. They were aware of the good reputation held by both Singh and Jones, and confident in their abilities to provide assistance. Singh and Jones had experience working in similar regions and were continuously looking for new projects to pursue. Their partnership commenced.

Research design

During an exploratory trip to Examplestan, Singh and Jones met with the local health officials to discuss the project idea. Klim and Tobolowsky hoped to conduct a study on youth and HIV, focusing on issues such as sexual debut, number of partners, and use of condoms. In reviewing the information provided to them, however, Singh and Jones discovered that two particular subsets of the population, namely men who have sex with men *(MSM)* and injection drug users, showed particularly high rates of HIV. Singh and Jones suggested that the project should focus instead on these subset populations, who also suffer from additional stigmatization because their behaviour is socially unacceptable and illegal in Examplestan. Klim and Tobolowsky had not considered involving participants from such ostracized groups and did not share the Canadians' interest.

Who owns it?

Ownership of research is a hotly debated topic that gets to the core of the fundamental purposes of research: the advancement of knowledge and the benefit of society. What are the benefits of having local communities or partners feel ownership of the research?

Singh and Jones, however, felt strongly about focusing on MSM and IDU populations in Examplestan in order to acquire valuable information about the nature of the HIV epidemic there. This conviction developed from many years of experience working internationally with issues surrounding rising HIV prevalence and was based on evidence and experience from many other studies carried out throughout the world. Their task now lay in convincing their co-investigators that the research study the Canadians proposed would yield valuable results that could help stem the increasing prevalence of HIV among the Examplestani population.

The proposed research initiative, although markedly different from that which the Examplestani officials had originally intended, was enthusiastically encouraged by Singh and Jones. Eventually, the local partners were convinced and complied with the Canadians' suggestions.

Funded by the Canadian Institutes of Health Research (CIHR), the design of this four-year project eventually focused on interventions to reduce transmission of HIV among MSM and IDUs. Seeking to understand the social conditions that perpetuate or inhibit transmission of HIV among these subject populations, behavioural research would be matched with longitudinal HIV sero-conversion and prevalence data in MSM and IDUs, predominantly in urban centres of Examplestan.

Ethics approval

Early in the project design stage, Singh and Jones observed that the research ethics principles in Examplestan differed from and appeared much less rigourous than those to which they were accustomed at Canadian institutions. Some ad hoc research ethics boards existed in Examplestan, but it quickly became apparent through discussions with local health officials and others conducting research in the same region that these ethics boards were keen to support international researchers and would readily give their approval, regardless of how ethically sound the proposal was. These relaxed ethics review procedures, however, were countered by, from Singh and Jones' perspective, frustrating bureaucratic limitations on research design. Singh and Jones found that they were restricted in the type of projects they could implement. Conducting studies to evaluate which HIV testing tool was most appropriate for the subject populations being studied, for instance, was illegal in Examplestan. In Singh and Jones' view, the law limited researchers' ability to carry out quality research. Changing the law would take many years to take effect, and Singh and Jones decided this was beyond their capacity to initiate. Nevertheless, they knew they needed to be particularly cognizant of these regulations to ensure they were respected throughout the research.

Participant compensation

Singh and Jones recognized the community's vital role in being involved with research implementation. To demonstrate this, they discussed with local representatives of a wide range of socio-economic statuses the level and nature of compensation that should be provided to participants for involvement in the study. Before implementing the study, Singh and Jones met with several local representatives in order to determine what effects their research methods might have on the local population. They discussed areas of concern where the research study might be harmful to participants or the broader community, and talked about how to recruit participants

Power imbalance

What power imbalances might exist in international partnerships? How can they be avoided or diminished?

Ethical bypass

In some countries, it may be possible or even expected to conduct research without obtaining in-country ethics approval. How might this affect the quality of the research protocol? What are the implications of not obtaining local ethics review, even if there is a process for it?

Bureaucratic business

A host country's rules and regulations may, to a Canadian researcher, seem discriminatory or inconsistent with ethics standards. How can personal feelings towards the research context be separated from the research itself?

without putting them at risk. The inaccessibility of the MSM and IDU communities with whom they intended to work made it important to involve peer leaders in recruiting participants for the study to ensure that the inclusion and exclusion criteria for participation in the study were adhered to. The exclusion criteria, in fact, became somewhat of a contentious issue, as Singh and Jones were concerned about characteristics that might define a potential participant as too vulnerable to participate in the study. Klim and Tobolowsky felt this was an unnecessary assumption and ultimately discriminatory against potential participants who might benefit from the research.

Conflict of ethics

Research ethics standards as stipulated in the TCPS may confront challenges in international settings, where local norms and customs may not allow for procedures to be carried out according to such stipulations. How does a researcher negotiate conflicting demands between local and Canadian research ethics boards?

Data collection

Male-to-male sex and intravenous drug use are illegal in Examplestan. Therefore, adherence to strict research ethics codes around informed consent – as dictated by Singh and Jones' Canadian institutions and stipulated in the TCPS – needed to be adapted to local circumstances while still maintaining strict research ethics standards. To protect the participants' rights to privacy and confidentiality, an "X" was used in lieu of a signature to record each participant's consent. However, because of the longitudinal nature of the study, a master list linking participants' names to their HIV status had to be kept in order to track participants' sero-conversion.

Given the illegality associated with the participant groups, the existence of this list posed significant risk for the safety of the participants. This risk was heightened by the international aspect of the research, as crossing borders with such information could increase the chances of the implicating information falling into the hands of Examplestani law enforcement. Singh and Jones never felt comfortable taking this risk, but were unable to find a solution to the problem without completely withdrawing from their duties surrounding data analysis.

Data security issues

Researchers may have concerns about leaving identifiable data in the hands of their local partners when they return to Canada. In some circumstances, researchers may be reasonably afraid that such data could place their partners at risk of search or seizure, in turn placing the research participants at risk. What are the risks inherent in transporting research data outside of the country? What concerns might local partners have if the research data are not at their disposal? At what point in the research process should the plan for data retention, transportation, and destruction be laid out?

The project involved concerted efforts to maintain strong communication between the Canadian and Examplestani research partners. Issues of trust and power within the partners' working relationship were a point of tension, however. Singh and Jones recognized that each research partner brought to the project different strengths, skills, and resources, and knew it was important that they not dictate to their local partners what to do. Instead, the Canadians explained how similar situations were addressed in Canada and tried to help the Examplestanis find innovative ways of addressing the situation in their own circumstances.

Singh and Jones were determined to play a consultative role, leaving the final decisions ultimately in the hands of the local partners. Despite this, the inherent power imbalance of the partnership made the trust between the partners precarious. This was due in large part to

beliefs about the tradeoffs between solid research data and sensitivity to potential ethical concerns deeply rooted in the cultural contexts of both sets of research partners. The Canadian researchers were particularly sensitive to protection of individual rights and freedoms in research activities that involved participants without their full and informed consent. The Examplestani partners, conversely, had little experience with non-clinical studies of this nature and perceived that, if participants are responding to their questions, they are, in doing so, implicitly giving their consent. Others responsible for conducting interviews, not accustomed to the stringent research protocols designed in part for ethical sensitivity, simply did not obtain informed consent. Ensuring the proper execution of the informed consent process and guaranteeing confidentiality were high priorities for Singh and Jones, who were deeply concerned about potential repercussions for the participants because of the high stigma associated with their behaviours in a country where such behaviours are illegal. However, the research protocol was so stringent that many participants found amusing such rigour about ethics issues which, in their view, did not exist.

Data analysis
Data analysis for the project was carried out locally and then verified for accuracy by Singh and Jones before any findings were disseminated.

Dissemination
Local community involvement was particularly important in the dissemination of research findings. Klim and Tobolowsky cautioned against widespread dissemination of the research findings to the general public. They noted the intense stigma attached to HIV/AIDS in Examplestan and warned about the potential to stigmatize an entire community by representing them in a particular light. Stigma was further exacerbated by the research participants' involvement in illegal behaviour that was, in itself, highly stigmatized. Extreme sensitivity in how findings were disseminated and to whom the dissemination was targeted was imperative, they explained. The researchers agreed to follow three principles. First, the findings needed to reach the populations with whom the study was conducted. This important feedback mechanism to the research participants required the involvement of community members to ensure it was done appropriately. Second, those in a position to implement programs to effect change and help ameliorate their condition also needed to receive the information arising from the study. In this aspect of the research, strong participation of local partners was essential to ensure that the findings were shared in a manner that led to less rather than more stigmatization. Third, as part of capacity building, local colleagues were promised senior authorship of any peer-reviewed papers or presentations that resulted from the study, and local scientific representation was ensured. These important considerations were built into the research design from

Trusting relationships
Research ethics standards vary cross-culturally and between nations. Canadian researchers may need to trust their local partners to adhere to a prescribed research or ethics protocol despite the locals' view of such a protocol as unnecessary. What can be done to build trust between the partners? What happens if adherence to the research or ethics protocol is not being maintained?

Who interprets the data?
Even the most well-intentioned projects that incorporate local input into research design and implementation often end this involvement when it comes to the analysis stage. How might this alter the findings that result? What kind of cultural biases might Canadian researchers bring into their analyses of research conducted elsewhere?

Spreading the word

Disseminating research findings can lead to unintended consequences for subject populations, who may be further stigmatized or discriminated against because of what the research reveals about them. In light of this, it can be most effective to disseminate research findings only to those directly affected by it or in a position to implement programmes for these groups. At the same time, however, it is important to consider the limiting nature of directed dissemination to select groups. Does this contradict the principles of respect for human dignity, respect for justice and inclusiveness, maximizing benefit, and distributive justice if others who may benefit from the research findings are not made aware of them?

the beginning, to ensure that those influencing decision-making at the local level had the information required to make changes related to the social conditions of MSM and IDUs.

Dissemination was done locally as well as internationally, through community meetings, peer-reviewed journal articles, and select press releases. Singh and Jones were very cautious about how information was presented to the media, however. Colleagues of theirs had experienced a significant blow to their project in Examplestan when the media criticized the methodology used for the study, claiming it was unethically reaping benefits from the local population without giving back to the community, causing an uproar throughout Examplestan and internationally. The use of ethics as a tool for political gain was thus an ever-present concern for Singh and Jones. They felt that this was actually a good thing, though, as it forced them to stay keenly aware of the ethics of their actions throughout the research.

Research Scenario Four: Social Science

Summary

This scenario presents the experience of conducting international HIV/AIDS research from the perspective of a graduate student. The ethical challenges described revolve around a novice researcher who goes to southern Africa to conduct research for her graduate thesis in medical anthropology. Concerns about raising local expectations by discussing the use of microbicides with local women arise. The researcher has difficulty obtaining local ethics review for her project and worries that the approval she did obtain was simply rubber-stamped. Low literacy rates among the subject population challenge her research ethics protocol, and adjustments must be made. With limited resources and space, safe data storage becomes problematic. Power imbalances between the researcher and the participants become evident during data collection, and issues around compensation arise. Local gender and power dynamics between husbands, wives, and village leaders, as well as the researcher's personal biases, affect how and under what conditions data can be collected. The researcher's awareness about and sensitivity to cultural norms and values are important in maintaining good dynamics between herself and her local colleagues. How to most effectively disseminate the research findings becomes a challenge at the end of the researcher's stay in southern Africa.

Raising expectations

What concerns might a researcher have about raising expectations of local communities? How can these concerns be balanced with the need to get local acceptance of the study?

New researcher

What are the potential implications of sending a new researcher into the field?

True review?

What can a researcher do if she feels the research proposal has not been adequately reviewed for approval and is simply being rubber-stamped? In this case, would it be appropriate to approach the host organization to ask for a more detailed review?

Research design

When Jolene Buchanan started her graduate degree in medical anthropology, she knew she wanted to conduct her research on HIV/AIDS in southern Africa. Before starting her degree, she had spent a year on a CIDA-funded internship working with a rural support group for HIV-positive women in Justsuppozia, a southern African country. She had been deeply moved by the experience, and felt strongly committed to the fight against HIV/AIDS in the country. When she finished her internship, she made a promise to the people at the organization with which she was working that she would return soon. She maintained a close relationship with the organization, which expressed support for her imminent return.

Given her past experience working in the country, Buchanan felt that undertaking international HIV/AIDS research would be challenging and that she would need to approach her work with utmost sensitivity. She was very careful to keep the organization in Justsuppozia informed and involved in the design of her research project from the beginning. Although she received very little feedback in her research plans, the organization remained supportive of her return. In consultation with her supervisor, she decided to investigate HIV-positive Justsuppozi women's perception of microbicides by conducting in-depth qualitative interviews. She would work closely with the organization, relying on their assistance to recruit participants. Buchanan put together a very detailed research proposal that was approved by her committee and received a Canada Master's Scholarship from the Social Science and Humanities Research Council.

Ethics review process

Buchanan's research required ethics approval by her university, yet given the research ethics board's limited understanding of local norms in Justsuppozia, Buchanan was asked to also have her research approved by an ethics board in the host country. Having virtually no experience in research, Buchanan's contacts at the organization suggested that she contact the only institute of higher education in the country, the University of Justsuppozia. Following delays in communication and other difficulties associated with the ethics review, Buchanan was finally informed that the University of Justsuppozia's ethics board was only able to review research that was directly linked to the university itself. Buchanan wondered if she might find an ethics board associated with a hospital somewhere in the country, but given her time constraints and the likelihood of encountering the same problem with a hospital ethics board, if she was able to find one, she decided to return to the research ethics board at her university and tell them that she was unable to find a suitable ethics review process in the host country. As a substitute for such approval, Buchanan was then asked to provide proof of support from the host organization with which she was conducting the research. She returned to the host organization, which

provided a letter of support without any questions. Buchanan was relieved to have satisfied the review board's requirements, but wondered whether the organization had even read her research proposal.

Once the research ethics board at Buchanan's university was satisfied on the issue of local review, Buchanan needed to convince them that her approaches to informed consent and reimbursement were ***culturally appropriate***. Throughout her research design, both of these issues had been a concern, and she had carefully chosen methods that she believed were the most ethical. From her previous work with this population, she was aware that literacy rates were relatively low and that English was a second language at best. Given this situation, and her desire to minimize the perception of power imbalances, she felt that insisting on written consent would be inappropriate and that obtaining verbal consent from the women was best. The review board agreed to this on the condition that she read a detailed information sheet to each participant before continuing with the interview. Buchanan also struggled with the issue of reimbursement and how to adequately give back to her participants in a culturally appropriate manner. The research ethics board felt that Buchanan should refrain from compensation altogether. In the end, it was agreed that Buchanan would reimburse any travel costs incurred by the participants, but would provide no compensation in order to avoid undue inducement. With these adjustments, Buchanan's study was approved.

Recruitment

Two months behind schedule, Buchanan boarded her flight to Justsuppozia. She felt prepared. Anticipating very limited resources in the field, she had carefully prepared all her research materials and was armed with a heavy bag of all the academic resources she thought might be essential during her data collection.

Upon her return to the organization, Buchanan was quickly reminded of the resource constraints she would face throughout the data collection. The organization's offices were tiny, crowded, and bustling with activity. This meant she would have to do much of her work in her small room at her homestay, and would have to store her data there as well. Nevertheless, she set about recruiting women to be interviewed. She was surprised at how easy it was to find women willing to be interviewed. She simply asked the assistance of a few of her colleagues at the support group, and soon they had lined up a participant or two nearly every day.

Literacy levels

What other implications might a low literacy rate among the subject population have on the design of the study? How, for instance, might this affect dissemination strategies?

Knowledge production

External researchers may rely on academic information to guide them through their research in the field. What does this tell us about how and by whom knowledge about a particular community is produced? How might the local community react to the researcher's assumption that all this outside "expert" information is required when they feel in a much better position to provide knowledge about their own community?

Data storage

Is it ethical to store data in an easily accessible location when the participants have been promised confidentiality? What other options might Buchanan consider in this situation?

Unintended power imbalance

Research protocols that are designed to protect participants may, unintentionally, exacerbate existing power differentials that exist between a researcher and the participants. How can this be minimized?

Compensation conundrums

Poverty and pronounced inequality can deeply affect researchers at a personal level. In this case, is it ethical for a researcher to provide compensation from her own pocket?

Gender dynamic

How can sensitivity to gender dynamics, which the researcher may find unjust, be incorporated into the research design?

Power structures

Local power structures may exert considerable influence on the dynamics within a community in a way that is foreign to a new researcher from Canada. How can these structures be respected while maintaining rigour in ethics and research?

Informed consent and data collection

Though recruitment seemed to be easy, Buchanan was surprised by how challenging the interviews were. Language, unexpectedly, was not as much of a problem as she had anticipated. However, despite the participants' ability to understand her words, Buchanan wasn't entirely sure that they really understood why they were being interviewed. Buchanan felt that the interviews were made more awkward by her reading the detailed information letter before obtaining verbal consent. This seemed to introduce an unnecessary separation between her and the women, and Buchanan felt that it invited a sense of precisely the kind of power imbalance she wanted to avoid. It seemed obvious to Buchanan that the people she was working with, both the participants and her colleagues, did not share her concepts about the world of research. She wished she could spend the time to sensitize the community to the principles and procedures of research, but she didn't feel that she had the time or capacity to do so. She was also sometimes faced with the uncomfortable situation of being asked for money by her participants after completing an interview. Though compensation was not part of her research protocol, she sometimes gave out of her own pocket, not knowing quite how to respond to what seemed like such an unfair disparity between her life and theirs.

Halfway through the interviewing process, Buchanan suddenly found herself without any participants. The constant stream of interviewees came to a complete halt. After a few days, Buchanan asked some of her colleagues what might have caused this change. With some prodding, Buchanan learned that the husband of one of the women she had interviewed had gotten angry when he learned of his wife's participation in her study. The husband had gone to the village chief and informed him of the *mzungu* (outsider) asking questions in the village without his permission. Word had spread quickly throughout the village that the people were to have nothing to do with Buchanan.

Buchanan made desperate attempts to get advice from her colleagues, who were not nearly as forthcoming as she would have liked. After giving it some thought, she was embarrassed by her oversight. She was annoyed with the husband for getting involved, but realized that she had most likely disrespected the local power structures by failing to inform the chief of her work. Armed with as much information and advice as she could gather, Buchanan decided to visit the chief. She set out to climb the hill that led to his collection of huts overlooking the village, reminding herself to be as humble as she could manage and keep her personal judgements about the chief's reaction to the AIDS crisis in his community to herself.

Buchanan found the largest of the huts at the top of the hill and knocked on the door. A young woman answered, looked at her, and without a word left the room. A few minutes later, a large man appeared. Buchanan looked him in the eye, smiled, and extended her hand. She introduced herself and very politely described her project and what she intended to accomplish through her research, and apologized for not having come to see him sooner. The chief listened to her explanation. When she was finished, he told her that he appreciated her coming, but he could not allow her to continue her project. He promptly left the room and she was left alone.

Once again, Buchanan was baffled. She returned to the organization in hopes that her colleagues would help her make sense of the situation. Seeing that she was obviously distraught, Buchanan's colleagues started asking her questions. "Did you kneel down? Did you give your family history when you introduced yourself? Did you touch your elbow when you shook his hand?" Buchanan was even more distraught. How could she have been so bold? How was she supposed to know she was being bold? How could she fix this? Eventually her colleagues suggested that one of the men from the organization accompany her back up the hill. Although she was irritated by this gender imbalance, she knew it was her best chance of being able to continue. She promised her colleague that she would let him do all the talking.

Together, Buchanan and Maliti Tsonga, her new-found spokesperson, climbed back up the hill. This time the interaction was completely different. Tsonga informed the lady at the house that they were there, and then they waited outside until the chief came to join them. To her surprise, the men left Buchanan behind while they moved into an enclosed area in the yard. Insulted but hopeful, Buchanan waited until the pair emerged again. The men shook hands and the chief returned to his home. Tsonga explained that Buchanan would be allowed to continue her research, on two conditions: she must ensure that every woman she wants to interview receives permission from her husband, and she must report to the chief before each remaining interview.

Data analysis

Abiding by these new conditions, Buchanan carried on with her interviews. Her colleagues admitted to her later that they were glad she was now getting permission from the husbands. They had felt uncomfortable about this before, but hadn't wanted to question her. She also found a way to cover the information about the study less formally in the beginning of her interviews, which seemed to help them go more smoothly. In the end, Buchanan felt that she had collected rich data, and was eager to enter into the analysis phase.

In her proposal, Buchanan had planned to conduct analysis with frequent input from her colleagues to help ensure accurate cultural inter-

Cultural awareness

Social norms and behaviours may vary considerably from one country to the next. By approaching the chief in an assertive manner, Buchanan embarrassed herself and offended the chief. What could she have done to be better prepared for this interaction?

Making sacrifices

Working outside of one's context can sometimes necessitate conceding to requirements or requests that compromise a researcher's personal principles.

Partnership dynamics

Why might Buchanan's colleagues have been hesitant about giving her advice? What does this tell us about the dynamics between them?

pretation. When it came time for analysis, however, Buchanan realized that people's busy schedules left them without much spare time to help with analysis. She was also four months behind her original schedule. Although it was a difficult decision, Buchanan decided to transport her data and continue her analysis from home in Canada.

Dissemination and exiting the field

As she prepared to return home, Buchanan felt she hadn't made any tangible contributions to the fight against HIV/AIDS in Justsuppozia since leaving home, and was beginning to doubt that she ever would. She had been asked several times when the microbicides she was asking her participants about would be available for the women to start using to protect themselves. Buchanan did not know how to answer this, and became very concerned about developing an effective dissemination plan that would bring the information back to the community. She had a meeting with some of her colleagues before she left to get their ideas about how the information would be most useful to them. Though she was still unsure how she would be able to get the information back to the community, Buchanan made yet another promise to ensure that it did. Before returning home, she made a trip to the University of Justsuppozia in hopes of making connections there that might be interested in her work and helping her disseminate it.

Promising results

Considering this will likely raise the locals' expectations, is it ethical for Buchanan to promise to bring back information to the community after her return to Canada when she has no assurance she will be able to do this?

Part Three

Addressing the tensions: Concluding thoughts and considerations

In Part One of this resource, the eight guiding research ethics principles of the TCPS were introduced. Part Two presented research scenarios to illustrate the types of tensions that can arise when applying these eight principles in the context of international HIV/AIDS research. These scenarios have drawn attention to the complex nature of international HIV/AIDS research and the ethical tensions that can be associated with it. Many ethics concerns highlighted in the TCPS have come to bear on the research discussed – including, for example, conflicts of interest, coercion in recruitment, informed consent protocol, undue inducement, dissemination procedures, and respect for human dignity. This document has tried to demonstrate that securing ethics approval, while an important and necessary safeguard to conducting ethically sound research, is not necessarily sufficient to uphold the basic ethical tenet of human dignity. Additional issues of trust, variations in research ethics infrastructures, community involvement, capacity development, equality within partnerships, power and gender dynamics, sacrifices for cultural appropriateness, and ethics issues not directly related to but strongly influencing research have also come to the fore.

The scenarios in Part Two have brought to light several persistent tensions and challenges that permeate international HIV/AIDS research, transcending all research tracks. Part Three will now conclude this document by first discussing a selection of these overarching persistent tensions, and then presenting additional frameworks that may be useful to help international HIV/AIDS researchers predict and address these tensions. The goal is to shed light on some of the many challenges faced by international HIV/AIDS researchers, and to better prepare them for and support them in the field.

Overarching persistent tensions

Effects of researcher attitudes, beliefs, and behaviours in the field

International HIV/AIDS research takes place in human contexts and is affected by researchers' attitudes, beliefs, and behaviours both in the official research realm as well as in informal communications with partners and communities in the host country.

> "It's very difficult as an outsider not to be ethnocentric about these things. It's a dangerous thing to go into a country and say, 'You need to do this my way because it's right.'...I think the most that you can do in a lot of those situations is establish some good communication with at least a few people from the country who have a broader perspective on it, on themselves, and on their society and on their ethno-cultural approach to things...because they have to be the ones to take it forward."

Canadian HIV/AIDS researcher

Researchers working internationally can strengthen their toolkits for navigating through the research ethics landscape by building on personal skills and attributes such as flexibility, humility, and openness to recognizing their own biases, privileges, and perspectives. Maintaining humility throughout the research process and recognizing that sometimes goals are not completely within one's control can lessen the often inherent power differentials between "us" and "them" and help researchers recognize, respect, and value the expertise brought by all members of the research project. A researcher's conduct in the field and interactions with communities can have implications for the feasibility of future research. Productive relationships between researchers and communities can be facilitated through openness, critical reflection, and respect.

Researchers should be careful to avoid unthinkingly imposing their standards of ethics on cultures where things may be seen quite differently. A tension encountered by many Canadian researchers working internationally in the field of HIV/AIDS lies in balancing research ethics standards shaped by Canadian scientific and cultural values and approaches with cultural sensitivity and adaptation to local circumstances. Researchers often find it difficult to be flexible and humble in their approach to international settings when they perceive unfairness, injustice, and the denial of basic human rights.

Motivations for international research

Critical questioning and evaluation of one's motivations for research in a particular setting or with a particular community can be valuable in clarifying biases and assumptions underlying the research. Reflecting on what makes one choose where to conduct research and where it will have the most benefit can be important. Motivations may be driven by a number of forces, such as the researcher's curiosity, sources of funding, local requests for assistance, or a mentor's suggestion. Understanding the roles of various stakeholders, especially project funders, can help clarify these motivations.

Meeting the needs of the subject population is not necessarily synonymous with meeting the needs identified by the researcher. This suggests the wisdom of community involvement in research design. One particularly troublesome dilemma arises when members of the subject population express the "need" to be left alone: in some instances, research can only be carried out in particular contexts, subjecting particular populations to high research demands, and producing a sense of being over-studied and the desire to be left alone.

Seeking a balance between capacity building for Canadian researchers and true quality contributions to research and knowledge is difficult but essential. Many researchers experience tensions around involving a student or novice researcher in international HIV/AIDS research, given their potentially limited contributions to the communities.

Building local capacity

Building local capacity for research and project development has emerged as a central component of international HIV/AIDS work. Building on the TCPS principles of beneficence and maximizing benefits, the centrality of local capacity development in international research suggests that those involved in and contributing to the research process through academic, technical, logistical, and infrastructural support, are also expected to benefit from it. The researchers consulted for this document reported that developing the knowledge, skills, and experience of their local partners, staff, and communities was often central to their research projects. Capacity building may take the form of developing research literacy, providing equipment, or offering training on 1) collaborative teamwork with international partners and 2) how to move research results into action. Respecting the diversity of skills and perspectives available locally while recognizing opportunities to teach can contribute to this development. Although this can contribute to project sustainability and the ease of future collaborations with the community, it is not always valued by academic institutions that prioritize academic interests such as publications, funding opportunities, and promotion or tenure.

Raising expectations around training can be contentious, as trainees may have no practical opportunities to use their skills locally, and may be attracted to apply their skills and knowledge elsewhere. Yet without local capacity development, relationships of dependency and inequity are maintained, and the challenges faced by local researchers to address the needs in their own communities can be exacerbated.

Often a key challenge to effectively developing local capacity is the required time commitment to international partnerships. The benefits of such commitment in the long term demonstrate that this is worthwhile and worth striving for.

"My advice would be for people considering studies to make sure that there's a way for capacity building to occur, even if you're doing basic research and capacity isn't your primary goal. It's an important consideration and is going to make everything a lot easier if you're doing capacity development, if you're doing technology transfer, and if you can do some physical infrastructure development, all of those things. There must be some benefit not just to the study participants, but to the community in that area."

Canadian HIV/AIDS researcher

"Cementing a long-term, open-ended partnership that would eventually devolve to local leadership, without putting a time frame on it, is important. It's unrealistic to me to expect local people who have no experience in research and who have no established experience in even providing the type of care that you're implementing to take something over in three to five years."

Canadian HIV/AIDS researcher

"One thing that's difficult is that you say, as a Canadian researcher, that there's an equal relationship. But one side provides all the resources and the other side provides the environment and all the opportunity. One side has highly trained PhD researchers, and the other one has a lot of people who don't have that same skill set or are early on in their careers, developing that skill set. So, being able to maintain an equal relationship, and equal partnership, although the contributions are very different... It takes ongoing effort to make sure that there's a balance that isn't tipped one way or another."

Canadian HIV/AIDS researcher

Forming local partnerships and establishing trust

Involvement of local researchers, staff, and community or political representatives in research is only the beginning of the formation of true collaborations between partners. Forming local partnerships means developing relationships of trust and respect where everyone's contributions are equally valued. In international projects, this is particularly important in order to ensure local specificity, to open channels for human capacity development, and to help facilitate the research process through collaboratively addressing agreed-upon challenges. In this context, forming local partnerships involves being open-minded and aware of local customs, recognizing that this is the context within which local partners live and that there are limits to how one's standards of ethics can be accommodated without placing international partners in difficult positions. Strong partnerships can facilitate the research process and make for better research, although unequal access to resources and skills can complicate partnerships.

In order to work towards sustainability and the eventual transition of the project to local partners, trust is paramount. Building trust and forming strong local partnerships can be challenging as Canadian researchers find cultural divides and differences in values and perspectives that affect how the project is carried out. The choices preferred by the Canadian researchers at times will not match, and may even contradict, what the local partners see as the best way to conduct the research. This illustrates the dynamic nature of true partnerships, which are in a constant push-pull tension. Compromises for the best interest of the project must be accepted, while each partner's limits on the extent to which they are willing to compromise are respected. Researchers may, for example, question the motives but nevertheless need to accept the decision of their partners to include particular individuals on the research team. Canadian researchers might also insist on obtaining truly informed consent from each participant prior to involvement in the study, a process that the local research partners may see as unnecessary in their context where a village leader's consent is sufficient. Trusting local partners to adhere to a protocol that is not seen as important or valuable thus becomes challenging. Appropriate dissemination and sharing of research findings is also important to maintaining relationships.

Involvement of study populations from local communities

In the cross-cultural nature of international HIV/AIDS research, involving representatives of participant communities is critical to ensuring the relevance and appropriateness of all stages of the research design. It can help predict and mitigate challenges and greatly facilitate negotiating human interactions in a foreign context. This involvement can take numerous forms, ranging from consultation about appropri-

ate levels of participant compensation, to mobilizing locals to become involved in particular initiatives, to disseminating research findings. Community involvement is not always seen as valuable, however, and introducing the value of involving the common person can be challenging and sometimes requires invention. Community involvement holds out the promise of creative solutions that follow Canadian research standards and methods in a culturally appropriate way. In order to ensure true relevance to the communities involved in a study, it is valuable to seek adequate representation from various community groups. Relying on those in a position of power or authority to ensure local relevance may be insufficient as they may be quite far removed from the reality of a community's situation. In addition to consulting with the authorities, consulting with individuals who truly represent the communities from which they come can further facilitate the research process and ameliorate its impact on communities.

"We never tell them what to do. We do tell them how we do things, but we never tell them they have to do it the way we do it. Always trying to help them find innovative ways to do it their way, but improve it. And it's always up to them. You know, what parts of what we share with them that they adopt, and what parts they don't."

Canadian HIV/AIDS researcher

Sharing the benefits among all researchers

The TCPS employs a participant-centred perspective that emphasizes the centrality of research participants in research design and implementation. This is instrumental in ensuring research participants are involved collaboratively and not treated simply as objects in research.

However, the rights and roles of the partners, researchers, staff, volunteers, and communities involved in research also deserve consideration. The principles of respect for human dignity, justice and inclusiveness, and balancing harms and benefits, in particular, can be applied not only to research participants but to all those involved in the research, be they individuals, groups, or communities, in order to ensure equitable benefits among all players. This affects all stages of the research process, from design through implementation and dissemination.

Harms or benefits can result not only for research participants but also for entire communities as well as all those involved in implementing the project. Reconciling different expectations and being open about these up front (such as how and to whom dissemination will occur) is important.

"... for every project I've had to insist that, before we get too far, they allowed me to meet with someone who's HIV-positive, someone who's an injection drug user, to try to walk in their shoes. This was something that's kind of unusual for them, but I think community involvement is imperative in terms of their contribution, and for our understanding."

Canadian HIV/AIDS researcher

Trusting and open relationships between partners and participants can help accurately assess what are considered benefits by each group. Canadian researchers may benefit from the study by advancing their careers. Local researchers may gain important skills and knowledge to advance their careers and build local capacity to conduct such research projects without external involvement. Research participants may benefit from their involvement in the study through access to (better) healthcare, treatment, or benefits to their community that will accrue over time.

"So, if the capacity building isn't built into it, you still have a responsibility to do that capacity building. I know when you think of ethics you always think of the rights of individuals that are being studied, but in this case you also have to think about the rights of researchers and quality of research. I think that's something that people forget. The focus is always on the study participants, but you have to think about the potential harms you're doing to the research community and the research world by not assisting the people that you're working with to do it the best they can."

Canadian HIV/AIDS researcher

"Anything that was framed in terms of charity or philanthropy was a non-starter. That was just completely offensive. And why was it completely offensive to them? Well, because the decades of exploitation that created the mess in the country was created by people in the North in the first place. So we can't take this out of context. It's just got to be connected to history... What there was interest in was an approach of, 'You've got skills and we've got skills, let's find a way to use them in a way that's good for both of us.'"

Canadian HIV/AIDS researcher

Distribution of power, control, and ownership

The unequal distribution of power, control, and ownership is almost everywhere in international HIV/AIDS research. Canadian researchers may feel uncomfortable negotiating this balance and may consider fostering open discussions with partners up front.

Part of the tension around ownership lies in the difficulty of adequately defining it. Definitions include – but are not limited to – local buy-in, access to data, and decision-making power in the research project. Whatever the definition, when the local partners and community feel ownership of a project, the project usually becomes more sustainable and has greater local benefits.

Power can be perceived in more than monetary terms. The value inherent in cultural knowledge and experience also requires recognition.

Finding a balance between imparting ethical values and respecting cultural differences

Research involving human participants and funded by any of the three institutions constituting the TCPS, namely SSHRC, CIHR, and NSERC, is mandated to adhere to the high research ethics standards outlined in that guideline. Furthermore, many researchers hold their own views and beliefs about what constitutes ethical research. In international settings, however, researchers may encounter values that conflict with both the TCPS values and their own – for example, values about the individual versus the collective, the interpretation of human dignity, or the definition of justice. Thus, researchers are sometimes faced with the challenge of conveying the importance of what they – or the TCPS – consider to be universal ethics standards, while respecting the cultural perspectives of their research partners and participants.

The effect of religion on ethics is a telling example. Deeply embedded values enshrined in religious beliefs can be fundamental tenets on which a society is built. These may define the ways in which a society approaches sexual orientation, gender roles, and equity.

Working outside familiar cultural frameworks may sincerely challenge the boundaries of what Canadian researchers consider ethical. Researchers' awareness of and respect for these fundamental differences are important while working toward acceptable compromises. A balance may be sought between maintaining satisfactory levels of ethical conduct as prescribed by the Canadian context and respecting cultural differences that may compromise these standards. The challenge lies in respecting Canadian research ethics guidelines while not blindly imposing Canadian values on others. Recognizing that Canadian ethics

standards are an outcome of contextual factors that differ across societies is a first step in respecting other stances on research ethics issues and not presuming one stance is superior to the other.

Overview of other frameworks

The variety of research ethics dilemmas presented in this document and the different ways in which they were addressed show that, in the ethics of international HIV/AIDS research, there are few clear answers. Research ethics dilemmas for HIV/AIDS researchers in international settings involve matters of social context, individual and community circumstance, societal and individual values, cultural norms, cross-cultural divides and communication, health and medical needs, economics, and the law. These are but a few of the many factors that shape a particular ethics problem and influence decisions and courses of action.

Throughout this document, it has become apparent that no single method of ethical analysis can or should be employed for the broad spectrum of international research in HIV/AIDS. In developing proposals, researchers may find it useful to explore and draw from any of a number of research perspectives and ethics frameworks that can help shed light on the many social, political, and environmental contexts that influence HIV/AIDS and the way it is addressed through research. The perspectives and frameworks reviewed here may be useful in guiding us to consider some of these aspects that influence the ethics of international HIV/AIDS research.

Social determinants of health

The social determinants of health framework addresses social, political, environmental, and economic conditions that influence individual and population health (Marmot 2005). This framework offers an integrated and holistic means of understanding the interplay between a variety of social, biological, economic, and cultural factors that are reflected in health outcomes.

Many social determinants of health have been identified, including but not limited to: safe and secure housing; access to health; social and addictions services; poverty; education; income, income support, and job security; early childhood experiences; abuse; alcohol or substance misuse; discrimination; lack of caring and supportive family and friends; and respect for social and cultural diversity and equality (Ministry of Health British Columbia, Canada, 2007). According to the World Health Organization, the determinants that contribute to ill health include "unemployment, unsafe workplaces, urban slums, globalization and lack of access to health systems" (WHO 2007).

> "Some countries have different values with respect to human dignity, to things that we would think would be a breach of ethics. The thing is, it's part of their lifestyle, their way of dealing with things. Although you say, 'Ugh, how could they do that? We certainly wouldn't allow that to happen,' you have to take into consideration the context of their background and how it evolved over time. On the other hand, you want to be able to sleep at night."
>
> Canadian HIV/AIDS researcher

In the case of HIV/AIDS research in other countries, the determinants of health framework is particularly useful because almost all the economic, social and cultural determinants of health are strongly correlated with HIV status. As a level or type of analysis, it is particularly useful for understanding populations' different vulnerabilities to HIV infection, as well as the impacts of the virus on the individual, family, community, and society at large. If properly informed through solid research using a social determinants of health framework, government policies can positively effect health outcomes by recognizing their impact on all of society (Marmot 2000). In the context of HIV/AIDS research, consideration of the social determinants of health is crucial to determining and ultimately changing those determinants that contribute to susceptibility to HIV infection.

Community-based research

Fundamentally distinguishable from conventional research methodologies in its emphasis on equality, shared control, and true local participation, community-based research rejects the external researcher's traditional monopoly on power. Instead, all those involved share control of all aspects of the research process (Cornwall and Jewkes 1995). Community-based research begins with communities, which have been defined as any "units of identity, for example, membership in a family, friendship network, or geographic neighbourhood" (Israel et al 1998, p. 178). Community-based research values each contributor's expertise equally, and considers each contributor's input as integral to producing research that truly benefits the community. In community-based research, community members are intimately involved in all aspects of the research process, from design through implementation, analysis, and dissemination.

Nine ideal principles, the integration of which characterizes the practice of community-based research, are outlined by Israel and her colleagues (in Minkler and Wallerstein 2002). Community-based research:

1) Recognizes community as a unit of identity;
2) Builds on strengths and resources within the community;
3) Facilitates collaborative, equitable partnership in all phases of the research;
4) Promotes co-learning and capacity building among all partners;
5) Integrates and achieves a balance between research and action for the mutual benefit of all partners;
6) Emphasizes local relevance of public health problems and ecological perspectives that recognize and attend to the multiple determinants of health and disease;
7) Involves systems development through a cyclical and iterative process;
8) Disseminates findings and knowledge gained to all partners and involves all partners in the dissemination process; and
9) Involves a long-term process and commitment.

Community-based research is an iterative and cyclical process that tries to effect social change and improve community health through a combination of knowledge and action (OHTN 2007). As such, it holds enormous potential to enable communities to mobilize for improved health through social change. In the case of international HIV/AIDS research, community-based research has the potential to significantly

contribute to addressing the HIV/AIDS pandemic if undertaken conscientiously and reflectively. No one particular method of community-based research is applicable to all HIV/AIDS research, however, as each community presents unique needs for HIV/AIDS research (Allman et al 1998). Flexibility in using this approach is therefore critical.

Public health ethics

Emerging as a response to the difficulties inherent in applying the individualistic bioethics model that arose in the 1960s and 1970s to society-focused public health research, public health ethics offers an alternative framework for researchers exploring health issues at a community level. While not disputing the value of ethical frameworks that focus on the rights of individuals to exercise autonomy, public health ethics asserts that the health of populations has less to do with biomedical advances than measures to improve the public's health (Callahan and Jennings 2002). Public health ethics focuses on values that in many ways differ from the morals commonly asserted in strictly clinical research (Kass 2001). Ethics concentrating on the good of the community are often seen as paternalistic or antagonistic to individual rights and liberties. In order to further social justice while respecting individual liberties, public health measures should aim to reduce morbidity or mortality, identify and minimize potential burdens of the intervention, and be fairly implemented (Kass 2001).

At the core of public health ethics is a fundamental challenge.

> The conflict, long endemic in our society, between the right of individuals to be left alone and the needs of the larger public does not make it easy to develop population-based health strategies that must, on occasion, ignore the special needs of individuals (Callahan and Jennings 2002, p. 172).

Public health ethics faces many challenges because of its almost inherent infringement on individual autonomy, a value crucially important in most developed or individualistic societies (Roberts and Reich 2002). Many such values do not ring true in more communal societies, however. Applying a biomedical, individually-based model of ethics to many social science or epidemiological research studies in such settings thus ignores the communities' concern about their collective, rather than individual, welfare. In such settings, a public health ethics framework can effectively respect these societies' emphasis on shared knowledge and community.

OCAP

The principles of ownership, control, access, and possession (OCAP) are central to the self-determination in research sought by First Nations Peoples in Canada and apply to all initiatives involving data, research, or information with First Nations (First Nations Centre 2007). OCAP challenges researchers and communities to approach research in a manner that honours these self-determining principles while maintaining methodological research rigour in terms of specificity, reliability, and validity. Emphasizing community control and ownership of data, information, and research, these principles embody "a political response to tenacious colonial approaches to research and information management" (Schnarch 2004, p. 80), enabling First Nations to meaningfully engage in research within their communities, thus building trust, developing capacity, and improving the quality and relevance of the research. OCAP, rather than being a prescriptive framework, provides a set of unifying principles that can guide all aspects of research or information gathering with communities. OCAP considers how, by whom, and for whom knowledge is produced and how this contributes to the perpetuation of colonial relations (Espey 2002). When OCAP is in an outsiders' hands, the knowledge produced reflects only a particular social perspective and experience and leads to the reproduction of that experience through the policies it promotes.

The principle of ownership refers to the collective ownership of cultural knowledge by a group or community. Control implies the right to have power over all research aspects that have an impact on the communities. Access is the right of First Nations Peoples to access information about their communities, and to have a say in how their collective information can be accessed. Possession is a literal implementation of the right to access information, protecting and asserting ownership of data.

Insistence on the application of OCAP principles is an assertion of a community's authority over knowledge production (First Nations Centre 2007). This is applicable not only to First Nations Peoples in Canada. In former colonies where externally-led research often results in a reproduction of colonial relations because of how knowledge is produced and controlled, OCAP can be applied if adjustments to take into consideration local histories and circumstances are applied. This includes international HIV/AIDS research. By focusing on concepts such as participatory and community-based research, cultural sensitivity, and inclusion of traditional knowledge, the OCAP principles can "lessen the power differential between researchers and subjects" (Schnarch 2004, p. 11), a laudable goal that should be integral to any research involving humans.

Concluding remarks

The purpose of this resource has been to highlight key research ethics issues for Canadian HIV/AIDS researchers in international settings. This resource has underscored the importance of cultural sensitivity toward and understanding of differing ethical norms and standards in international HIV/AIDS research. Engagement of local communities in all phases of the research, from hypothesis generation, through development of research methodology, implementation, data analysis, dissemination, and evaluation were highlighted as critical to ensuring cultural sensitivity and research relevance. Consultation with local representatives of communities, civil society organizations, and potential subject populations in order to maximize benefits to the local community while avoiding unintentional physical, social, or psychological harm or offense due to cultural differences or misunderstandings was also identified as integral to the research process. Such consultations can also maximize scientific validity, minimize harm, and set an appropriate standard of care for the research participants.

This document has aimed to illustrate the complexity of conducting ethically sound HIV/AIDS research in international contexts. Though there are rarely easy answers to some of the ethical tensions presented in this document, it is hoped that sensitizing Canadian researchers to some of these debates will allow Canadians to continue to make important contributions to the global HIV/AIDS emergency in a sensitive, humane, and ethical way.

Appendix I:
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Appendix II: Other instruments and guidelines

For Canadian researchers conducting HIV/AIDS research in other countries, there are many relevant **international** instruments and guidelines, including:

- The Abuja Declaration and Framework on HIV/AIDS, Tuberculosis and other Related Infectious Diseases (2001)
- GIPA Greater Involvement of People Living with HIV/AIDS (1999)
- International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use – Guidelines for Good Clinical Practice (1996) (note that this international document has been brought into Canadian law through the Clinical Trials Regulations under the Food and Drugs Act (2005))
- International Covenant on Economic, Social and Cultural Rights (1976) (particularly article 12, on the right to the highest attainable standard of physical and mental health)
- United Nations General Assembly Special Session on HIV/AIDS (2001)
- United Nations Millennium Declaration (2000)
- World Medical Association Declaration of Helsinki, Ethical Principles for Medical Research Involving Human Subjects (2002)
- World Summit for Social Development (2000)

For information on the alternative approach of grounding HIV/AIDS research guidelines and obligations in international law, see the Canadian HIV/AIDS Legal Network, **www.aidslaw.ca**.

Besides the TCPS, Canada also has other relevant **domestic** instruments and guidelines, including:

- Clinical Trials Regulations Under the Food and Drugs Act (1985)
- Good Clinical Practice: Consolidated Guideline (1997)
- Tri-Council Policy Statement: Integrity in Research and Scholarship (2006)

Appendix III: Terms and abbreviations used

AIDS:

Acquired Immune Deficiency Syndrome: The collection of symptoms and infections associated with acquired deficiency of the immune system. Infection with HIV has been established as the underlying cause of AIDS. The level of HIV in the body and the appearance of certain infections are used as indicators that HIV infection has progressed to AIDS.

ART:

Antiretroviral Therapy: Treatment with drugs that inhibit the ability of retroviruses (such as HIV) to multiply in the body. The antiretroviral therapy recommended for HIV infection is referred to as highly active antiretroviral therapy (HAART), which uses a combination of medications to attack HIV at different points in its life cycle.

ARV:

Antiretroviral: A medication that interferes with the ability of a retrovirus (such as HIV) to make more copies of itself.

ARV Resistance:

Resistance is the ability of some micro-organisms, such as bacteria, viruses, and parasites, to adapt so that they can multiply even in the presence of drugs that would normally kill them. Over a period of time, changes in the virus enable it to build up resistance to the drug. The drug is then no longer effective and the virus starts to reproduce to the same extent as before.

Basic Science:

The Basic Science Track of CAHR includes researchers involved in trying to understand the HIV virus, co-infections, the human host, and the interaction between the three at the most fundamental level. Some of the types of research in this track include assessing the cause and effect of viral mutations (drug resistance), understanding viral and host protein and genetic interactions (pathogenesis and drug development), and determining how the immune system fights HIV and how the virus changes to avoid detection (preventative and therapeutic vaccine development). With a better understanding of the complexity of the virus/host relationship, better or novel prevention or therapeutic strategies can be developed.

CAHR:

Canadian Association for HIV Research

CD4 cell:

Also known as helper T cell or CD4 lymphocyte, a type of infection-fighting white blood cell that carries the CD4 receptor on its surface. CD4 cells coordinate the immune response, signalling other cells in the immune system to perform their special functions. The number of CD4 cells in a sample of blood is an indicator of the health of the immune system. HIV infects and kills CD4 cells, leading to a weakened immune system.

CIDA:

Canadian International Development Agency

CIHR:

Canadian Institutes for Health Research, created in 2000 upon the dissolution of the MRC

Civil Society:

In this context, civil society refers to people living with and affected by HIV/AIDS, and the organizations of these people; NGOs currently or potentially working on HIV/AIDS issues; religious organizations; and international NGOs in fields such as development, human rights, education, and health, that are contributing – or could contribute – to preventing HIV infection and reducing the impact of the epidemic on individuals, families, and communities.

Clinical Science:

The Clinical Science Track of CAHR comprises researchers involved in conducting research in HIV-infected persons with the aim of improving the health of persons living with HIV. Clinical research is concerned with studying the etiology, pathogenesis, natural history and diagnosis of HIV, its complications and co-morbidities (including co-infections); evaluating therapeutic interventions including drugs, vaccines and immune-based therapies; performing clinical trials, clinical epidemiologic and pharmacologic studies; and even studying health services and health promotion.

Conflict of Interest:

A situation in which someone in a position of trust has competing professional or personal interests. Such competing interests can make it difficult to fulfil his or her duties impartially. A conflict of interest exists even if no unethical or improper act results from it. A conflict of interest can create an appearance of impropriety that can undermine confidence in the person, profession, or court system.

CSW:

Commercial Sex Worker

Culturally Appropriate:

A culturally appropriate response to HIV/AIDS must include consideration of culturally informed ways of life, traditions and beliefs, perception of life and death, sexual norms and practices, power and gender relations, family structures, languages, and means of communication.

Ethical space:

The place of convergence for two societies with two different worldviews. An ethical space may form when there is an intermediate area of experience that is outside both worldviews. An ethical space can be a fruitful place to devise appropriate research solutions in international settings.

Free and Informed Consent:

Resulting from the *Nuremberg Code*, free and informed consent requires three components: 1) legal capacity to give consent; 2) voluntariness to give this consent without any form of constraint or coercion; and 3) sufficient knowledge and comprehension of the subject matter involved to enable the prospective participant to make an understanding and enlightened decision. It is the duty and responsibility of the researcher to ensure that consent is always obtained in accordance with these three components.

Gender:

The socially defined and learned male and female behaviours that shape the opportunities that one is offered in life, the roles one may play, and the kinds of relationships that one has. It is distinct from sex, which is a biologically determined and fixed set of characteristics for men and women.

Gender Inequity:

On the basis of gender, any inequality which is unnecessary, avoidable, and unjust. While equality is an empirical concept, in which two things are quantifiably equal, equity represents an ethical imperative which is associated with the principles of social justice and human rights.

HIV:

Human Immunodeficiency Virus. HIV is a retrovirus that infects cells of the human immune system (mainly CD4 positive T cells and macrophages – key components of the cellular immune system), and destroys or impairs their function. Infection with this virus results in the progressive depletion of the immune system, leading to "immune deficiency."

HIV prevalence:

The percentage of people in a population affected with HIV at a given time. Prevalence can be thought of as a snapshot of all existing cases of a disease or condition at a specified time.

IDU:
Injection Drug User

Millennium Development Goals:
Adopted in 2000, the Millennium Development Goals are eight goals that 192 United Nations member states have agreed to try to achieve by the year 2015.

MRC:
Medical Research Council of Canada, dissolved in 2000 to create CIHR

MSM:
Men who have Sex with Men

NGO:
Non-Governmental Organization

Non-maleficence:
The duty to avoid, prevent or minimize harms to others

NNRTI:
Non-Nucleoside Reverse Transcriptase Inhibitors: A class of anti-HIV drugs that bind to and disable HIV's reverse transcriptase enzyme, a protein that HIV needs to make more copies of itself. Without functional reverse transcriptase, HIV replication is halted.

NSERC:
Natural Sciences and Engineering Research Council of Canada

PLWHA:
Person Living With HIV/AIDS

PMTCT:
Prevention of Mother-To-Child Transmission

Epidemiology and Public Health:
Epidemiology in the context of HIV research involves the study of the distribution and determinants of HIV infection in a population. Thus, it involves the descriptive examination of HIV incidence and prevalence in the general population and in populations at high risk for HIV infection, including such characteristics as age, sex, race/ethnicity, geography, and trends over time. To identify determinants, we quantify the risk factors for acquiring HIV infection related mostly but not exclusively to risky behaviours. Public health examines various levels of the public health system's response to the HIV epidemic, including issues of legal framework, policy, primary and secondary prevention programs and specific public health interventions such as partner notification.

REB:
Research Ethics Board

Social Science:
The Social Science track of CAHR includes researchers from a wide range of disciplines, professions and service provider groups who study issues including: 1) behavioural, psychological, experiential, cultural, social, economic and political aspects of HIV risk, and life with HIV; 2) the design of, access to, outcomes and effectiveness of HIV prevention, treatment and care services; and 3) the policy, ethical, social and legal contexts of HIV. These researchers typically engage with key populations affected by HIV, and use and develop a variety of quantitative, qualitative and participatory (community-based research) approaches.

SSHRC:
Social Sciences and Humanities Research Council of Canada

STI:
Sexually Transmitted Infection

Stigma:
Stigma is literally a "mark" or "blemish" upon someone or something. HIV is often negatively viewed, and social attitudes may be damaging to those infected or suspected of being infected. HIV is heavily stigmatised in most societies. People who are infected are rejected and scorned because social prejudice against the disease runs so deep. In some cases, people are stigmatised simply because of a suspected association with HIV.

TCPS:
Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans

Triple combination therapy:
Also known as HAART, or Highly Active AntiRetroviral Therapy, treatment regimens that aggressively suppress HIV replication and progression of HIV disease. The usual HAART regimen combines three or more anti-HIV drugs.

UN:
United Nations

UNAIDS:
Joint United Nations Programme on HIV/AIDS

Undue Inducement:
The manner in which a research study proposes to compensate study participants can sometimes constitute undue inducement: rewards, compensations, or payments that would lead participants to undertake actions that they would not ordinarily accept.

UNGASS:

United Nations General Assembly's Special Session on HIV/AIDS, held in 2001, which led to the adoption of the Declaration of Commitment on HIV/AIDS

Vertical HIV Transmission:

The transmission of HIV to an infant from a mother during pregnancy, labour, delivery, and breastfeeding.

Viral load:

The amount of HIV RNA in a blood sample, reported as number of HIV RNA copies per mL of blood plasma. The viral load provides information about the number of cells infected with HIV and is an important indicator of HIV progression and how well treatment is working. Viral load tests are usually done when an individual is diagnosed with HIV infection and at regular intervals after diagnosis.

Vulnerable Persons:

Those who experience diminished competence and/or decision-making capacity. A broad category of persons, including all persons who, due to social or economic exclusion, have reduced power to ensure that they are healthy and their rights are not violated. In the context of HIV/AIDS research in other countries, this category includes at least women, children, the elderly, and the poor, people with mental or behavioural disorders, people in detention, injection drug users, sex workers, people with diminished literacy, and people with access to limited healthcare resources.

WHO:

World Health Organization

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Canadian Association for HIV Research
155 College Street, 5th Floor, Suite 526
Health Sciences Building, University of Toronto
Toronto, Ontario M5T 3M7

fax: (416) 971-2704

email: ethics@cahr-acrv.ca