Improving the Accessibility of Research Ethics Boards for HIV Community-Based Research in Canada

HIV CBR ETHICS

Informed consent

5

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HIV CBR Ethics Fact Sheet Series:

1. Ethical issues related to compensation
2. Recruiting hard to reach individuals and communities in CBR
3. Managing multiple roles and boundaries
4. Ethical issues in visual image-based research
5. Informed consent
6. Confidentiality in close-knit communities
7. Community consent in Aboriginal communities
8. Supporting Peer Research Assistants (PRAs)
9. Engaging youth in CBR
10. Learning about illegal, sensitive and stigmatized topics

We are a group of Canadian HIV researchers interested in community-based research (CBR) and research ethics. We conducted interviews with over 50 academic researchers and community service providers from across Canada involved in HIV CBR. They told us about the ethical issues they encounter in their daily work with communities affected by HIV. They also described how they work with their research ethics boards (REBs) to ensure participants will be protected from research related harms. In this series of 10 evidence-based fact sheets, we identify key ethical considerations when designing HIV CBR projects and seeking ethics review. We encourage HIV CBR teams to use these fact sheets to assist in project planning. They may also be useful for engaging REBs in a dialogue about the range of strategies employed by Canadian researchers for ensuring the protection of diverse individual and community needs.

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In this fact sheet, we discuss five key issues:

- Grounding informed consent in community norms
- Navigating 'vulnerability' and informed consent
- Making consent materials as accessible as possible
- Finding alternatives to obtaining signatures
- Understanding consent as a process and as a relationship

Background

A central aspect of research ethics is the belief that participation must be based on free and informed consent; that is, participants must be able to make the choice about whether to participate in research. They should not be constrained, coerced, or have limited capacity, and they must have all the information necessary for making decisions (Beauchamp & Childress, 2009). Modern research ethics guidelines were developed, in part, in response to historical examples of individuals who were forcibly experimented on (Annas & Grodin, 1992; Bachrach, 2004), or who were misinformed about the nature of the research (Brandt, 1978; Curran, 1973). Research ethics boards (REBs) are particularly interested in personal autonomy and ensuring that individuals are able to consent, or withdraw their consent, to participate in research and not be penalized for doing so.

In community-based research (CBR), the principles of autonomy and informed consent are complemented with consideration for community norms and values, and relational approaches to negotiating consent (see also *Fact Sheet #7 on community consent in Aboriginal communities*).

When researching with people who are living with and affected by HIV, additional protections may need to be put in place in order to ensure that they are able to provide free and informed consent. This is because personal health status is private information and thus an issue of confidentiality, and also because research dealing with criminalized and stigmatized activities (such as sex and drug use) can put participants at greater risk than other forms of research might. In CBR projects, this may require altering or extending the traditional consent process to meet community members' needs. REBs expect very specific processes for obtaining informed consent that have been developed from the medical model of research. It is crucial to be aware of the standards of informed consent enforced by your institution's REB to ensure that your research can move forward. However, communal informed consent is also important because community-based research is grounded in a desire for research to benefit communities and not harm them. Unfortunately, the standard approach to obtaining informed consent enforced by REBs may conflict with the approaches preferred in community settings. REBs may not understand why CBR teams need to modify established approaches for specific communities. It is up to us as researchers to find ways to resolve these conflicts as best we can.

In this fact sheet, we identify various approaches to obtaining informed consent and describe the strategies employed by Canadian HIV CBR teams to balance these sometimes competing issues.

Research ethics boards (REBs) expect very specific processes for obtaining informed consent that have been developed from the medical model of research.

Issue 1: Grounding informed consent in community norms

"I was required to go through a consent form with them, or the interviewer was, and these are lengthy forms with a lot of detail, and yes, people need to be informed—and fully informed—but what does that really mean? How much information is overwhelming?"

Conceptions of autonomy and informed consent as defined by REBs have been challenged by scholars who argue that they are westernized, make assumptions about the individual providing consent, and ignore the complexity of decision-making processes (Mackenzie & Stoljar, 1999; Maclean, 2009). Approaches to obtaining consent that are promoted by REBs tend to be based on the idea that all participants will understand the research process (i.e., a high level of education is assumed) and that all participants will be comfortable with signing forms. The researchers we heard from told us that many of the communities they research with have historically had negative experiences with researchers and others in positions of authority. The supposed neutrality of the consent process therefore masks complex historical and current power relations that need to be discussed. As well, decision-making about whether to participate in research often goes beyond an individual person providing consent; in reality, research processes may need to account for the consent of families and whole communities (Corrigan, 2003). This can be especially true when research results may perpetuate stereotypes about a community, or when research is critical of community institutions. When individuals understand the impact that research may have on them and others within their networks, they are in a better position to provide informed consent to participate. Thinking about consent as a community-wide process does not displace the concept of individual consent, but may aid researchers attend to cultural differences when deciding on preferred informed consent processes (Manning & Gaul, 1997).

In the spirit of doing research in ways that are in line with community norms, CBR teams often host community consultations in order to develop research questions and choose appropriate methods. These consultations are an excellent opportunity for researchers and community members to anticipate ethical issues that might come up in a project and to establish who should be involved in the informed consent process (e.g., a trusted community-based organization) (Woodman, Tully, & Barranti, 1995). Another strategy is to develop an advisory board of community members that is made up of people who are representative of both participants and service providers, and informed about the issue at hand. This process can help to shape the informed consent process (Fisher et al., 2008). Woodsong and Karim (2005) suggest also using this pre-enrollment phase to decide how to explain research concepts, identify concerns the community may have, and learn about the context of individual vs. group consent.

"If I am marginalized, if I am poor, if I have been screwed over by the system, if I signed something and gave away all my peoples' land, you're going to have to treat me a little different, than you know the whole thing about informed consent, and going over the informed consent, and then getting somebody to sign, and then interviewing them..."

Issue 2: Navigating 'vulnerability' and informed consent

"With the kids, there were all these things that they had to learn how to get consent, how to recognize when consent can't be given, all of that kind of stuff, but telling people right out...when they sign things like for the honoraria or whatever I say, 'Make up a name. Don't tell me your name, just make one up.'"

Current approaches to informed consent frame some people as able to provide consent and others as unable to provide consent. Minors, prisoners and those with cognitive impairments are among those who are usually deemed unable to provide free and informed consent for themselves. In theory, these rules are in place to protect participants from abuses of power. It is also important to understand that 'vulnerability' as a social category has been socially constructed, and has changed over time; historically, many marginalized groups of people (including women, Aboriginal people, etc.) have been thought of as incapable of moral reasoning for various social, political, and cultural reasons. Therefore, it is important to think critically when making decisions about who is able to properly consent to research, and why. Furthermore, a participant's capacity to consent may change over time (Manning & Gaul, 1997). For example, people who use drugs are often considered unable to provide consent while they are "high" because of the effects of substances on their decision-making processes. Some definitions of consent have been expanded to include the concept of "economically and socially disadvantaged persons" being less able to consent freely (Fisher et al., 2008, p. 2). These distinctions flag important considerations, but should not necessarily exclude whole groups from participating in research; after all, some of the most important research in the field of HIV is and must be conducted with people who are characterized as vulnerable.

Similarly, the researchers we heard from in this study understood the importance of assessing capacity and informed consent, but challenged assumptions about who is able to consent. For example, a number of researchers we heard from who had experience researching with people who use drugs stressed the importance of working with participants in the moment to assess if they could give informed consent. For example, while conventional approaches make assumptions about lack of capacity when under the influence, someone who is under the influence may actually be in a better position to provide consent than someone who is experiencing withdrawal symptoms. Thus, when researching with drug users, a consent process should consider the effects of intoxication and withdrawal (Bell & Salmon, 2012). The researchers we heard from emphasized the importance of thinking critically about 'vulnerability' and not turning participants away simply because of assumptions about who has the capacity to consent freely. Rather, the onus was on the research team to develop ways of working with community members to effectively explain the research, assess capacity in the moment, and find alternative ways to obtain consent if traditional methods are not working. This could be as simple as rebooking data collection for another time (e.g., when the individual is more sober). For other projects, it required rethinking the research goals and whether it might be possible to reduce the level of risk involved (e.g., if participants with HIV-related cognitive issues are having difficulties repeating back what they will be asked to do, then perhaps another approach needs to be considered). Researchers should develop easy-to-understand presentations with accessible language in order to ensure that a diversity of participants are able to participate, and budget accordingly to support this (London, Kagee, Moodley, & Swartz, 2012).

"I mean capacity is sort of an ongoing thing that you evaluate as you're discussing what the purpose of the project is, risks, benefits and things like that, and essentially I think if you're talking to someone and they can sort of engage in some questions or recite back to you what it is they're being asked to do then you know I think that's how we've gone about things in terms of trying to delineate capacity, I think it's very difficult. That's a tough one and a bit of a grey area."

Issue 3: Making consent materials as accessible as possible

"I've worked with groups and tried to see how we can develop plain language consent and it is quite a difficult exercise because a lot of terminology that is very difficult to translate into very plain language or because the university is requiring that you include these paragraphs, from their own that they have, so it presents a lot of challenges or the fact that people may come from war affected countries where signing anything would have put them in trouble and they don't trust that kind of communication."

The consent process involves written materials that are presented for participants to review. This usually includes project goals, a description of procedures and what will be expected of participants, who is involved (e.g., researchers, organizations, and funders), a discussion of risks and benefits, how the data will be managed, assurances of confidentiality, and any compensation that will be provided. CBR projects may include other materials or processes when obtaining consent. Researchers need to balance giving comprehensive information (i.e., where all of the relevant information is presented) with comprehensible information (i.e., usually at a grade 8 reading level) (London et al., 2012; Manning & Gaul, 1997; May, Craig, & Spellecy, 2007; Penn & Evans, 2010; Woodsong & Karim, 2005). Long consent forms that are based on assumptions of education, literacy, and communication style might be hard for some participants to understand, which can impede their ability to give informed consent (May et al., 2007). The ways in which forms and consent processes are orally explained are also important; those tasked with obtaining consent should be trained and taught communication skills, and given a checklist to ensure that the consent process is comprehensive (Penn & Evans, 2010). Consent materials do not have to be limited to written documents. The researchers we heard from described creative ways for engaging participants in the informed consent process, and reaching those for whom legalistic, academic forms might not work well (e.g., turning the informed consent process into an interactive workshop). To reach participants who are typically alienated from research processes, it can be helpful to use a variety of informed consent strategies (drama, fact sheets, etc.) based on adult learning principles, community norms, and individual needs (Woodsong & Karim, 2005).

"I did a project and we actually did a whole thing on informed consent with groups and then sort of had a game afterwards, like, you know who, who can name, two rights that you have as people participating in this workshop...to emphasize that this is quite an important part of the process. That's [not] just going to be running through a form and telling people, you know, these are your rights and you don't have to agree, and its confidential or whatever, but there's actually a teaching piece about this."

Issue 4: Finding alternatives to obtaining signatures

"They're based on an oral tradition, so this whole process of reading informed consents is not part of who they are and what they represent...one of the ways was to get the consent done orally, in terms of get it on tape recorder. And in some cases, we just get people to do an X."

The most common approach to obtaining informed consent is through signed consent forms that are kept on file by the researcher. The researchers we heard from explained that for many of the communities they research with, obtaining a signature is seen as inappropriate for a range of cultural and practical reasons. For example, many Aboriginal cultures are based on an oral tradition and signatures have a negative connotation because of the ongoing use of contracts to limit and restrict Aboriginal peoples' rights and land claims. As well, for some groups who engage in criminalized, illegal, and/or socially unsanctioned activities (e.g., sex work) or who have had negative experiences with authority figures (e.g., political refugees who have experienced torture) providing one's signature could involve a greater risk than the experience of participating in the study. Signatures on forms in relation to a study on criminalized activities could be subpoenaed (see also: Fact Sheet # 10 on Learning about illegal and sensitive topics). Many of the researchers we heard from were successful when they asked their REBs to allow them to use verbal consent (possibly included in the recording if it is an interview or focus group), if they explained why the accommodation was necessary. In order for this REB approval to be acquired, researchers must explain why it would be inappropriate to obtain signatures in this particular circumstance, and what alternative precautions will be put in place in order to demonstrate that consent was obtained.

Issue 5: Understanding consent as a process and a relationship

"It was a group who pointed out to me 'why are you asking me to consent to you using this before I know what I've said.' So now I do it one of two ways: either there's a consent just to participate, and then there's a second consent, where you say, okay I'm happy with what I used, or, you look at the informed consent [but] don't sign it until at the end."

The consent process is often understood by researchers as a contract that is ratified before the research starts. In this process, a participant agrees to take part in the research, they sign the form, and then the research is conducted. However, consent is, in fact, a process (rather than an event) that should extend throughout the entire research encounter, and sometimes beyond. Woodsong and Karim (2005) differentiate between the enrollment and post-enrollment phase. The enrollment phase involves giving individual participants time to discuss the research and consult with others in their groups and communities as appropriate. This approach encourages discussing consent at multiple points in the process rather than at just one time. Post-enrollment involves ongoing discussion with participants and community representatives. Some of the researchers we heard from asked participants to sign consent forms at the end of the procedures (e.g., after the interview) and gave them additional opportunities to re-consent or withdraw their consent if they were unhappy with how the experience unfolded. This does take additional time, but it appeared to improve relations between researchers and communities by showing an ongoing commitment to ensuring participants would not feel exploited. In some circumstances it may be more appropriate to receive information at a different time or multiple times (London et al., 2012). Ongoing consent procedures are also particularly important when engaging in knowledge mobilization and advocacy efforts; giving participants control over how their words are represented in the public sphere can go a long way in terms of ensuring that the community is engaged and in control of the research process throughout. These kinds of extended consent procedures will not always be needed or useful, but researchers should consider them when developing their projects.

Questions for consideration:

The following questions may be useful for HIV CBR teams to reflect on when establishing processes for obtaining informed consent. Thinking about these issues in advance may help facilitate the research process and maintain positive relations with individual participants and the community.

1. What information is needed for your participants to be fully informed and provide consent?
2. How will you determine if a person is able to give informed consent? What factors will you need to take into consideration in your specific research (e.g., age, parental consent, institutional permission, community acceptability, mental health, substance use, etc.)?
3. What are the standards for obtaining informed consent with youth and children in your legal jurisdiction? Could obtaining parental consent potentially be harmful to youth participants (e.g., in the case of talking with youth about sexual orientation or sexual activity)?
4. Have you considered alternative approaches or strategies for obtaining informed consent that would help reconcile REB and community needs?
5. Have you considered requesting an in-person meeting with your REB to discuss your proposed consent procedures?
6. What would an ongoing process for informed consent look like in the community you are working with? For example, could you be implementing strategies such as community check-in meetings?
7. Is it important to get community consent in the particular community with which you are working? If so, what is the appropriate strategy for obtaining this consent? Is there a community board or group of representatives who has been entrusted to consent to research on behalf of a community? If so, who are they?

Works cited:

Annas, E.R., & Grodin, M.A. (1992). 1: Introduction In G.J. Utley, & A. E.R. (Eds.), *The Nazi Doctors and the Nuremberg Code: Human Rights in Human Experimentation* pp. 3-12: Oxford University Press.

Bachrach, S. (2004). In the name of public health: Nazi racial hygiene. *The New England Journal of Medicine,* 351, 417-420.

Beauchamp, T.L., & Childress, J.F. (2009). *Principles of Biomedical Ethics (6th ed.).* New York: Oxford University Press.

Bell, K., & Salmon, A. (2012). Good intentions and dangerous assumptions: Research ethics committees and illicit drug use research. *Research Ethics,* 8, 191-199.

Brand, A.M. (1978). Racism and research: The case of the Tuskegee Syphilis Study. *The Hastings Center Report,* 8, 21-29.

Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada. (2010). *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans.*

Corrigan, O. (2003). Empty ethics: The problem with informed consent. *Sociology of Health and Illness,* 25, 768-792.

Curran, W.J. (1973). The Tuskegee Syphilis Study. *New England Journal of Medicine,* 289, 730-731.

First Nations Centre. (2007). OCAP: *Ownership, Control, Access and Possession.* Sanctioned by the First Nations Information Governance Committee, Assembly of First Nations. Ottawa: National Aboriginal Health Organization.

Fisher, C.B., Oransky, M., Mahadevan, M., Singer, M., Mirhej, G., & Hodge, D. (2008). Marginalized populations and drug addiction research: Realism, mistrust, and misconception. *IRB: Ethics and Human Research,* 30, 1.

London, L., Kagee, A., Moodley, K., & Swartz, L. (2012). Ethics, human rights and HIV vaccine trials in low-income settings. *Journal of Medical Ethics,* 38, 286-293.

Mackenzie, C., & Stoljar, N. (2000). *Relational autonomy: Feminist Perspectives on Autonomy, Agency, and the Social Self.* New York: Oxford University Press.

Maclean, A. (2009). *Autonomy, Informed Consent and Medical Law: A Relational Challenge (Cambridge Law, Medicine, and Ethics Series). Cambridge, UK: Cambridge University Press.*

Manning, S.S., & Gaul, C.E. (1997). The ethics of informed consent: A critical variable in the self-determination of health and mental health clients. *Social Work in Health Care,* 25, 103-117.

May, T., Craig, J.M., & Spellecy, R. (2007). Viewpoint: IRBs, hospital ethics committees, and the need for "translational informed consent". *Academic Medicine,* 82, 670-674.

OCAP: Ownership, Control, Access, and Possession (FNC, 2007): http://cahr.uvic.ca/nearbc/documents/2009/FNC-OCAP.pdf

Penn, C., & Evans, M. (2010). Assessing the impact of a modified informed consent process in a South African HIV/AIDS research trial. *Patient Education and Counseling,* 80, 191-199.

The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (CIHR et al., 2010): http://www.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf

Woodman, N.J., Tully, C.T., & Barranti, C.C. (1995). Research in lesbian communities: Ethical dilemmas. *Journal of Gay & Lesbian Social Services,* 3, 57-66.

Woodsong, C., & Karim, Q.A. (2005). A model designed to enhance informed consent: Experiences from the HIV Prevention Trials Network. *American Journal of Public Health,* 95, 412-419.

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