# ETHICS REVIEW PROTOCOL SUBMISSION FORM FOR SUPERVISED AND SPONSORED RESEARCHERS

(For use by graduate students, post-docs, CBR researchers and visiting professors/researchers)

**SECTION A – GENERAL INFORMATION** 

1. IIILE OF RESE	ARCH PROJECT
HIV Positive Gay Me	en and the Negotiation of HIV Disclosure within the Canadian Legal Context
2. INVESTIGATOR	NFORMATION
Investigator:	
Title: Mr.	Name: Chris Tatham
Department (or orga	nization if not affiliated with U of T): Department of Sociology, University of Toronto
	5 Spadina Avenue. Toronto, ON.
Phone: 519 835 486	4 Email: chris.tatham@utoronto.ca
Level of Project	
Faculty Research	CBR/CBPR Research
Post-Doctoral Resea	<u>—</u>
Student Research: [	Poctoral Masters Student Number: 996379459
Faculty Supervisor	r/Sponsor:
	<u></u>
0 - 1 1 1	
Co-Investigators:	Secretary 10 Very D. Ne M.
Are co-investigators	
Title:	Name:
	nization if not affiliated with U of T):
Mailing address:	Tenna Tennan
Phone:	Fax: Email:

Email:

Please append additional pages with co-investigators' names if necessary.

# 3. UNIVERSITY OF TORONTO RESEARCH ETHICS BOARD:

Fax:

Name: Department (or organization if not affiliated with U of T):

Title:

Phone:

Mailing address:

UT Office of Research Ethics – Protocol Submission Form for Supervised and Sponsored Researchers 12 Queen's Park Crescent West – McMurrich Building, 2<sup>nd</sup> floor, M5S 1S8, Toronto

1 of 14

Version Date: July/09

Health Sciences Social Science, Humanities and Education HIV REB Please consult <a href="http://www.research.utoronto.ca/ethics/eh rebs.html">http://www.research.utoronto.ca/ethics/eh rebs.html</a> to determine which Research Ethics Board (REB) your proposal should be submitted.				
4. LOCATION(S) WHERE THE RESEARCH WILL BE CONDUCTED:				
If the research is to be conducted at a site requiring administrative approval/consent (e.g. in a school), please include all draft administrative consent letters. It is the responsibility of the researcher to determine what other means of approval are required, and to obtain approval prior to starting the project.				
University of Toronto   Hospital  specify site(s) School board or community agency  specify site(s) Community within the GTA  Toronto International  specify site(s) Other  Guelph, Kitchener, Cambridge, Hamilton.				
The University of Toronto has an agreement with the Toronto Acad (TAHSN) hospitals regarding ethics review of hospital-based researcheral role. Based on this agreement, certain hospital-based review at the University of Toronto. If your research is based at a following document to determine whether or not your research reconto. http://www.research.utoronto.ca/ethics/eh_where_tahsn.html.	arch where the University plays a esearch may not require ethics FAHSN hospital please consult the			
5. OTHER RESEARCH ETHICS BOARD APPROVAL(S)				
(a) Does the research involve another institution or site? Yes ☐ No ☒ (b) Has any other REB approved this project? Yes ☐ No ☒ If <b>Yes</b> , please provide a copy of the approval letter upon submission of this application. If <b>No</b> , will any other REB be asked for approval?  Yes ☐ (please specify which REB) No ☒ Please note that REB approvals from other sites must be submitted to the ORE at U of T				
6. FUNDING OF THE PROJECT				
(a) Please check one:	Fund #: 4 (6 digits)			
Funded Agency: Agency:	Fund #: 4 (6 digits) Fund #:4 (6 digits)			
Applied for funding Agency:	Submission date:			
Agency:	Submission date:			
Unfunded  My research is a small scale, qualitative study of gay men and HIV disclosure negotiation which I am undertaking as a component of class work of the Department of Sociology's Practicum.				
If one protocol is to cover more than one grant, please include all	fund numbers:			
(b) If waiting for funding, do you wish to postdate ethics approval to the Yes ☐ No ☒	e release of funds?			
(c) For funded research, will more than one protocol be submitted to corespective grant? Yes $\hfill \square$ No $\hfill \square$	ver all research funded by the			

UT - Office of Research Ethics – Protocol Submission Form for Supervised, Sponsored and CBR Research 12 Queen's Park Crescent West – McMurrich Building, 2<sup>nd</sup> floor, M5S 1S8, Toronto

Please list these protocols by title and RIS # (if known):
7. CONTRACTS
Is there a University of Toronto funding or non-funded agreement associated with the research?  Yes No S
If <b>Yes</b> , please include 3 copies of the agreement upon submission of this application.
Is there any aspect of the contract that could put any member of the research team in a potential conflict of interest? Yes \( \subseteq  \text{No } \subseteq \)  If yes, please elaborate under #10.
8. PROJECT START AND END DATES
Estimated start date for this project: August 2010 Estimated completion of involvement of human participants for this project: January 2011
<b>9. SCHOLARLY REVIEW</b> (Please note: for submissions to the <b>HIV REB</b> from community investigators, scientific review is a prerequisite for ethics review. If your study is unfunded, please contact the OHTN to arrange a scientific review prior to completing your ethics submission.)
Please check one:
<ul> <li>☐ The research has been approved by a thesis committee or equivalent (required for thesis research)</li> <li>☐ The research has undergone scholarly review prior to this submission for ethics review         <ul> <li>Department of Sociology's Practicum Committee</li> </ul> </li> <li>☐ The research will undergo scholarly review prior to funding         <ul> <li>(Specify review committee – e.g., departmental research committee, CIHR peer-review committee, OHTN scientific review, etc)</li> <li>☐ The research will not undergo scholarly review</li> </ul> </li> </ul>
10. CONFLICTS OF INTEREST
(a) Will the researcher(s), members of the research team, and/or their partners or immediate family members (i) Receive any personal benefits (e.g. financial benefit such as remuneration, intellectual property rights, rights of employment, consultancies, board membership, share ownership, stock options, etc.) as a result of or in connection to this study? Yes \( \subseteq \) No \( \subseteq \) (ii) If <b>Yes</b> , please describe the benefits below. (Do not include conference and travel expense coverage, or other benefits which are standard to the conduct of research.)
Not applicable.
(b) Describe any restrictions regarding access to or disclosure of information (during or at the end of the

Not applicable.

study) that has been placed on the investigator(s). This includes controls placed by sponsor, funding body,

advisory or steering committee.

(c) Where relevant, please explain any pre-existing relationship between the researcher(s) and the researched (e.g. instructor-student; manager-employee; minister-congregant). Please pay special attention to relationships in which there may be a power differential.

Not	apı	olic	abl	le.
	MPI	0110	a	Ο.

(d) Please describe the decision-making processes for collaborative research studies. If Terms of Reference exist, please attach them.

The data will be interpreted and decisions will be made by myself, Chris Tatham, under the guidance of

## SECTION B - SUMMARY OF THE PROPOSED RESEARCH

### 11. RATIONALE

Describe the purpose and scholarly rationale for the proposed project, and, if relevant, the hypotheses/research questions to be examined. The rationale for doing the study must be clear.

As a vaccine for HIV/AIDS lies perpetually beyond the grasp of science, condom use remains one of the most effective safeguards against potential infection. Research reveals, however, that gay men are expressing apathy towards condom use and are partaking in increased sexual risk behaviours. Over the past eight years, gay men have accounted for a growing proportion of Canada's total reported HIV infections, negating the substantial decline of infection rates between 1985 and 1999. Research pertaining to gay men and HIV/AIDS tends to involve the proclivity towards casual sex, drug use and risk behaviours, often ignoring a core element of transmission – HIV disclosure.

The criminalization of non-disclosure within Canada introduced a new element into the convoluted issue of gay men and HIV/AIDS vulnerability. HIV positive individuals are required to disclose their HIV status to sexual partners when engaging in risky sexual activity. Few studies have explored the criminalization of non-disclosure's affect upon sexual risk behaviour. Fewer still studies have examined HIV disclosure within the Canadian context. A dearth of knowledge surrounds gay men's interpretations of these laws, what affect they have upon disclosure practices in the field and the techniques and processes by which gay men navigate, enact or neutralize this newfound responsibility.

I plan to interview 15 HIV positive gay men about their HIV disclosure negotiation processes, condom use patterns and interpretations of their legal responsibilities. For it is only by acknowledging the perspectives of gay men on the frontlines of the epidemic that policy makers and health prevention workers will have any chance at ascertaining whether or not criminalization is having the desired affect upon the decision making processes and choices of individuals at risk, or if they merely serve to further exacerbate the state of the HIV/AIDS epidemic in Canada.

#### Research Questions

- Are HIV positive gay men aware of the legal responsibilities and ramifications surrounding HIV infection and disclosure? What are their perceptions of these responsibilities?
- How do HIV positive gay men conceive of, contend with and respond to these laws?
- If they do disregard these legal responsibilities, what are their rationalizations and motivations?
- How do gay men negotiate HIV disclosure within their sexual and romantic relationships?

• How could HIV prevention messages be adapted to contend with these issues?

## 12. METHODS

Please describe all formal and informal procedures to be used. Describe the data to be gathered, where and how they will be obtained and analyzed. If research includes intentions to publish in other than standard academic venues, please indicate.

# Attach a copy of all questionnaires, interview guides or other non-standard test instruments.

I, the student investigator, shall communicate with potential respondents either over my prepaid cell phone, or, if necessary, with my utoronto.ca email. Upon response, all emails will be deleted.

Upon agreeing to participate in the research, I will ask the respondent to call my prepaid cell phone and we will set up an interview time. I will ask if I may digitally record the conversation, and then read the consent form and ask if the respondent wishes to participate. Upon agreement, the phone interview is designed to last an hour. All participants will be asked to choose a pseudonym for the duration of the study. The interviews will broach topics of identity, sexuality, condom use patterns, HIV negotiation, HIV disclosure and interpretation of the Canadian legal system's approach to HIV/AIDS, and demographical information such as ethnicity and age. The interview guide will consist of questions phrased in general grade 8 level English. Please see attached interview guide for more information (Appendix A).

This research will not involve any physical assessments, psychological tests, questionnaires or surveys.

Attach a copy of all questionnaires, interview guides or other non-standard test instruments. Please include a **list of appendices** here for all additional materials submitted (e.g., Appendix A – Informed Consent; Appendix B – Recruitment script, etc.):

Appendix A – Interview Guide

Appendix B – Research Poster

Appendix C - Consent Form/FAQ

# 13. PARTICIPANTS OR DATA SUBJECTS

(a) Describe the participants to be recruited, or the subjects about whom personally identifiable information will be collected. Where recruitment is required, please describe inclusion and exclusion criteria. Where the research involves extraction or collection of personally identifiable information, please describe from whom the information will be obtained and what it will include. Strategies for recruitment are to be described in section #15.

I intend on interviewing 15 respondents. Participants will be English speaking, self-identified HIV positive gay males, over the age of 19, living in Southern Ontario.

(b) Is there any group or individual-level vulnerability related to the research that needs to be mitigated (for example, difficulties understanding informed consent, history of exploitation by researchers, power differential between the researcher and the potential participant)?

Not applicable.

#### 14. EXPERIENCE

(a) Please provide a brief description of (i) the principal investigator's, (ii) the research team's and (iii) the people who will have contact with the participants' experience with this type of research. If there has not been previous experience, please describe how the individual/team will be prepared.

I have undertaken Masters level research at the University of Guelph in 2008-2009. I interviewed 11 gay men pertaining to their negotiation of sexual boundaries, condom use patterns and HIV/AIDS navigation within their romantic relationships. This research received approval from the University of Guelph's Research Ethics Board (REB) and was conducted under the guidance of the gui

(b) For projects that will involve community members (for example, Peer Researchers) in the collection and/or analysis of data, please describe their status within the research team (e.g. are they considered employees, volunteers or participants?) and what kind of training they will receive.

Not		

### **15. RECRUITMENT**

Where there is recruitment, please describe how, by whom, and from where the participants will be recruited. Where participant observation is to be used, please explain the form of insertion of the researcher into the research setting (e.g. living in a community, visiting on a bi-weekly basis, attending organized functions). Please make it explicit where it is reasonable to anticipate that all or some of the participants who will be recruited will not speak English or will speak English as a second language. Describe any translation of recruitment materials, how this will occur and whether or not those people responsible for recruitment will speak the language of the participants.

Attach a copy of all posters, advertisements, flyers, letters, e-mail text, or telephone scripts to be used for recruitment. This copy should be exactly as it will appear for recruitment.

As a genuinely random sample of a gay population is impossible, I will recruit 15 gay men from the Southern Ontario area through posting an information poster with local HIV/AIDS related groups, such as ACT (AIDS Committee of Toronto) and the Guelph AIDS Council, and on the online gay communities - <a href="www.gay.com">www.gay.com</a> and <a href="www.gay.com">ww

The poster has been altered to suit the aesthetic requirements of the University of Toronto's Visual Identity and has been approved by the Visual ID Helpdesk. For more information on the Research Poster, please see Appendix B.

Additionally, copies of the poster will be posted in community areas where HIV positive gay men are known to frequent, such as community centres, gay bars and bathhouses in the Church and Wellesley area. I will offer a copy of the Consent Form/FAQ to individuals representing each place/organization I approach in order to give them more information about my study. Furthermore, I will approach local HIV clinics and ask if they feel comfortable placing a copy of the poster on their information board. This recruitment approach is consistent with previous research conducted on HIV positive gay men in Toronto.

16. COMPENSATION					
(a) Will participants receive compensation for particip	ation? Financial In-kind Other	Yes  Yes  Yes  Yes	No ⊠ No ⊠ No ⊠		
(b) If <b>Yes</b> , please provide details and justification for t	he amount or th	ne value of	the compens	ation off	fered.
Not applicable.					
(c) If <b>No</b> , please explain why compensation is not pos	sible or approp	riate.			
Compensation is not within my means.					
(d) Where there is a withdrawal clause in the research compensation be affected?	h procedure, if p	oarticipants	s choose to w	ithdraw,	how will
Not applicable.					
SECTION C –DESCRIPTION OF THE RISKS AND E	BENEFITS OF	THE PROF	POSED RESE	EARCH	
17. POSSIBLE RISKS					
Risks to participants as individuals or as members of	a community m	nay include	:		
(a) Physical risks (including any bodily contact or adm	ninistration of a	ny substan	ce) Yes 🗌	No 🏻	$\boxtimes$
(b) Psychological/emotional risks (feeling uncomfortal	ble, embarrass	ed, anxious	s or upset); Y	es 🛚	No 🗌
(c) Social risks (including possible loss of status, priva	acy and/or repu	tation); and	d/or Yes □	No 🏻	$\boxtimes$
(d) Legal risks (potential of apprehension or arrest or group).	being identified	l as a mem	ber of a lega Yes ⊠		romised
Please describe the risks involved in the study, and w managed and/or minimized.	hat steps will b	e taken to	ensure that th	ney will b	ре
All attempts will be made to minimize any possible ris involved no risk of bodily harm or deception, there are					
As detailed in the consent form, the subject matter of HIV/AIDS. The interviews will broach topics of identity					nd

UT - Office of Research Ethics – Protocol Submission Form for Supervised, Sponsored and CBR Research 12 Queen's Park Crescent West – McMurrich Building, 2<sup>nd</sup> floor, M5S 1S8, Toronto

approaches to HIV disclosure, condom use, and the criminalization of non-disclosure under Canadian law, and demographical information such as ethnicity and age. By asking questions about past experiences, I hope to minimize the change in behaviour due to the respondents' explicit participation in the study. (Please see Appendix A – Interview Guide, for more details.)

Although participation in this study could potentially cause mental duress due to, for example, a decision to disregard condom use or to forgo disclosure, it is unlikely that a respondent's participation would be the premier source of such introspection. Any emotional apprehension experienced by participants, due to their condom or disclosure patterns, could very well manifest within their everyday lives, as the Western gay community has a massive cultural emphasis on condom use and HIV/AIDS preventative knowledge.

There is no viable way to discuss a respondent's sexual behaviours and HIV/AIDS without potentially causing discomfort and unease. The very subject matter of HIV/AIDS betokens notions of fear and apprehension. By disclosing the subject matter at the very beginning of communication with potential participants, I hope to minimize any discomfort which may result from their reflecting upon their experiences. I will also remind participants that they can decide to stop any interviews and have their information expunged at any time.

Although HIV exposure has been criminalized within Canada, the few charges which have been successfully laid have been within circumstances of malicious, premeditated exposure after recorded sero-conversion. In the unlikely event that I were confronted by legal or public health officials and asked to disclose information pertaining to a specific respondent within my research, I would, after consulting representation, cooperate as much as legally necessary.

Despite my cooperation, it is unlikely that any respondent accounts would be traced back to any specific participant. To protect respondent's privacy, I will, as part of my research design, not collect any easily identifiable personal information (such as name, date of birth, address, phone number), immediately delete digital recordings upon transcription (approximately two days after the interview) and delete and purge all record of emails after they are responded to and sent. Furthermore, since the interviews will take place over a prepaid cell phone, call records will be difficult to procure. Also, since I will not have seen the participant, I will likely not be able to identify a specific respondent, as I feel it would be difficult to match a random voice with a specific transcription.

Furthermore, in my interviews, I will explicitly indicate that respondents should not discuss specifics of any events of non-disclosure (persons, places, dates, etc), for their own legal protection, thereby severely limiting the evidentiary worth and validity of any of my interviews.

### 18. POSSIBLE BENEFITS

Discuss any potential direct benefits to the participants from their involvement in the project. Discuss any potential direct benefits to the community, including any capacity building which is integrated into the study design. Comment on the potential benefits to the scientific/scholarly community or society that would justify involvement of participants in this study.

There is a value inherent with one knowing one's self. Participation in my study may result with participants enjoying a deeper awareness of their own motivations and justification processes, provoked by their reflection upon their past experiences. Also, they may feel a sense of pride for assisting in the fight against HIV/AIDS and contributing to the broader understanding of the human condition.

My research will contribute to the development of scholarly knowledge by filling the void within Canadian research surrounding the pertinent issue of how HIV positive gay men negotiate, or disregard, HIV disclosure within their relationships. Research findings will be of practical use for social policy and health education as they will aide with the creation of innovative and efficacious HIV/AIDS prevention strategies.

#### SECTION D – THE INFORMED CONSENT PROCESS

### 19. THE CONSENT PROCESS

Describe the process that will be used to obtain informed consent. Please note that it is the quality of the consent, not the format that is important. If the research involves extraction or collection of personally identifiable information from a research participant, please describe how consent from the individuals or authorization from the data custodian will be obtained. If there will be no written consent, please provide a rationale for oral or implied consent (e.g., discipline, cultural appropriateness, etc.) and explain how consent will be recorded.

For information about the required elements in the information letter and consent form, please refer to <a href="http://www.research.utoronto.ca/ethics/eh">http://www.research.utoronto.ca/ethics/eh</a> best.html.

Where applicable, please attach a copy of the Information Letter/Consent Form, the content of any telephone script, screening materials, introductory letters, letters of administrative consent or authorization and/or any other material which will be used in the informed consent process. If any of the information collected in the screening process - prior to full informed consent to participate in the study - is to be retained from those who are excluded or refuse to participate in the study, please describe how those individuals will be informed of this.

The project's consent form has been written in accessible, grade 8 level language and contains no deception tactics. This form contains a list of subject areas in which the interviews will touch upon and the motivations for my research. Please see attached consent form (Appendix C).

## 20. COMMUNITY AND/OR ORGANIZATIONAL CONSENT, OR CONSENT BY AN AUTHORIZED PARTY

(a) If the research is taking place within a recognized community or an organization which requires that formal consent be sought prior to the involvement of individual participants, explain whether consent from that community/organization will be sought. Describe how this consent process and attach any relevant documentation. If consent will not be sought, please provide a justification and describe any alternative forms of consultation that may take place.

# Not applicable.

(a) If any or all of the participants are children and/or are not competent to consent, describe the process by which capacity/competency will be assessed, the proposed alternate source of consent - including any permission/information letter to be provided to the person(s) providing the alternate consent – as well as the assent process for participants.

My research will not involve the participation of minors.

### 21. DEBRIEFING and DISSEMINATION

(a) If deception or intentional non-disclosure will be used in the research study, please justify.

This research study will not use any deception or non-disclosure tactics.

Please provide a copy of the written debriefing form, if applicable.

Not applicable.

(b) Will participants and/or communities be given the option of withdrawing their data following the debriefing? Please explain.

At the beginning of the interview, all participants will be informed that they can halt their participation and decide to have any of their information expunged at any time. This information is also clearly stated on the consent form, which will be read to them at the beginning of the interview.

(c) Please explain what information/feedback will be provided to participants and/or communities after their participation in the project is complete. (e.g., report, poster presentation, pamphlet, etc.)

As I will not be asking for any contact information, findings cannot be offered to respondents.

## 22. PARTICIPANT WITHDRAWAL

(a) Where applicable, please describe how the participants will be informed of their right to withdraw from the project. Outline the procedures which will be followed to allow them to exercise this right.

At the beginning of the interview, all participants will be informed that they can halt their participation and decide to have any of their information expunged at any time. This information is also clearly stated on the consent form, which will be read to participants at the beginning of the interview.

(b) Indicate what will be done with the participant's data and any consequences which withdrawal may have on the participant.

If the participant decides to withdraw from the study, they will be asked if they would also like their information to be used or destroyed. If they decide upon the later, all references to their specific case will be expunged.

(c) If participants will not have the right to withdraw from the project at all, or beyond a certain point, please explain. Ensure this information is included in the consent process.

UT - Office of Research Ethics – Protocol Submission Form for Supervised, Sponsored and CBR Research 12 Queen's Park Crescent West – McMurrich Building, 2<sup>nd</sup> floor, M5S 1S8, Toronto

Not applicable.  SECTION E –CONFIDENTIALITY AND PRIVACY  23. CONFIDENTIALITY				
23 CONFIDENTIALITY				
20. COM IDENTIALITY				
(a) Will the data be treated as confidential? Yes $\boxtimes$ No $\square$				
(b) Describe the procedures to be used to protect anonymity of participants or informants, where applicable, or the confidentiality of data during the conduct of research and dissemination of results.				
As aforementioned, in order to protect the privacy of my participants, all interviews will be conducted over the telephone. Respondents will be asked to call a prepaid cell phone at an arranged time in order to conduct the interview.				
During the interviews, I will inform the participants that they can choose a pseudonym. If not, I will choose one for them. Also, I may alter their selected pseudonym if it coincides with that of another respondent. All digital recordings and text transcripts will be augmented to remove any inadvertently disclosed identifying information. After transcription, the digital recordings will be deleted.				
As detailed in Section 17, to increase the anonymity of my respondents, I will not take personal information (name, date of birth, address, contact information), delete digital recordings after transcription and delete all emails after responding and conduct interviews over a prepaid cell phone.				

(c) Describe any limitations to protecting the confidentiality of participants whether due to the law, the methods used or other reasons (e.g., duty to report)

As detailed in my interview guide, my questions are phrased to include the respondent and his peer group. By doing so, I allow the respondent to be able to discuss potential illegal occurrences of non-disclosure while not indicating that the actor was indeed himself. It is my hope that this will facilitate their not censuring themselves.

As indicated in Section 17, at the beginning of the interview, I will instruct respondents to not discuss specifics within their responses (where, when or with whom). By asking general questions as to disclosure/non-disclosure without specifics, I am severely limiting the evidentiary worth of my data.

(d) Explain how written records, video/audio recordings, artifacts and questionnaires will be secured, how long they will be retained, and provide details of their final disposal or storage. Describe the standard data security procedures for your discipline and provide a justification if you intend to store your data for an indefinite length of time. If the data may have archival value, discuss this and whether participants will be informed of this possibility during the consent process.

In order to increase the security of the respondents' personal data, all transcripts pertaining to this study will be kept on a computer without an active internet connection at my home. All transcripts, digital audio files, emails and field notes will be encrypted with 256 bit AES (Advanced Encryption Standard) software. This

encrypted data will be further encrypted with 1024 bit RSA encryption software. All digital recordings will be deleted upon transcription (approximately two days after the interview).
(d) If participant anonymity or confidentiality is not appropriate to this research project, please explain.
Not applicable.
24. PRIVACY REGULATIONS

For research involving extraction or collection of personally identifiable information, provincial, national and/or international laws may apply. I will report any apparent mishandling of personally identifiable information to the Office of Research Ethics. My signature as Principal Investigator, in Section G of this protocol form, confirms that I am aware of, understand and will comply with all relevant laws governing the collection and use of personally identifiable information in research.

# SECTION F – CONTINUING REVIEW OF ONGOING RESEARCH

## RISK MATRIX: REVIEW TYPE BY GROUP VULNERABILITY AND RESEARCH RISK - check one:

Group Vulnerability	Low	Research Risk Medium	High
Low Medium High	1	1	2

See the <u>Instructions for Ethics Review Protocol Submission Form</u> for detailed information about the Risk Matrix.

Briefly explain/justify the level of risk and group vulnerability reported above:

HIV positive gay men are, by definition, afflicted with a long term and debilitating illness. HIV/AIDS is, however, manageable when treated effectively. Moreover, an individual can have HIV in their system for ten years before requiring medication. As such, I consider HIV positive gay men to have 'Medium' group vulnerability.

Although participation in this research may cause respondents some mental unease and anxiety due to the focus on the topics of HIV/AIDS and disclosure patterns, these stressors will not be new to the respondents, as they have likely have had experience contending with such mentally and emotionally within their own experiences. Moreover, those HIV positive gay men who are uncomfortable pondering said issues would be unlikely to offer to participate in my study. I expect it to be extremely unlikely that participation in my study will worsen respondent's medical condition. As such, I consider the research risk to be 'Medium' for participants.

## **Review Type**

Based on the level of risk, please submit the appropriate number of copies of the Protocol Submission Form for Review Type:

Risk level = 1: Delegated Review (formerly expedited) Risk level = 2 or 3: Full Board Review

For delegated review, please submit 2 (double-sided) copies with signatures in place.

For HS full board review, please submit 17 (double-sided) copies of your ethics protocol and study-related documents.

For SSH&E full board review, please submit 15 (double sided) copies of your ethics protocol and study-related documents.

For the HIV REB only (delegated or full board), please submit 2 copies for all research proposals. Electronic submissions are accepted for HIV REB submissions, as long as there are electronic signatures in place. Please submit to <a href="mailto:ethics.review@utoronto.ca">ethics.review@utoronto.ca</a>

Please note that the final determination of Review Type and level of monitoring will be made by the University of Toronto REB and the Office of Research Ethics.

# **SECTION G – SIGNATURES**

The faculty supervisor/sponsor and his/her respective Departmental Chair/Dean or designate must sign below:

As the **Investigator** on this project, my signature confirms that I will ensure that all procedures performed under the project will be conducted in accordance with all relevant University, provincial, national and international policies and regulations that govern research involving human participants. I understand that if there is any significant deviation from the project as originally approved I must submit an amendment to the Research Ethics Board for approval prior to its implementation.

For U of T **student researchers**, my signature confirms that I am a registered student in good standing with the University of Toronto. My project has been reviewed and approved by my advisory committee (where applicable). If my status as a student changes, I will inform the Office of Research Ethics.

Signature of Investigator:	Date:	
----------------------------	-------	--

\*\*\*For **Graduate Students**, the signature of the Faculty Supervisor is required. For **Post-Doctoral Fellows** and **Visiting Professors or Researchers**, the signature of the Faculty Sponsor is required. For **CBR/CBPR**, the signature of Executive Director/Chair of Board of Directors is required. \*\*\*

As the **Faculty Supervisor** of this project, my signature confirms that I have reviewed and approve the scientific merit of the research project and this ethics protocol submission. I will provide the necessary supervision to the student researcher throughout the project, to ensure that all procedures performed under the research project will be conducted in accordance with relevant University, provincial, national or international policies and regulations that govern research involving human subjects. This includes ensuring that the level of risk inherent to the project is managed by the level of research experience that the student has, combined with the extent of oversight that will be provided by the Faculty Supervisor and/or On-site Supervisor.

UT - Office of Research Ethics – Protocol Submission Form for Supervised, Sponsored and CBR Research 12 Queen's Park Crescent West – McMurrich Building, 2<sup>nd</sup> floor, M5S 1S8, Toronto

As the <b>Faculty Sponsor</b> for this project, my signature confirms that I have reviewed and approve of the
research project and will assume responsibility, as the University representative, for this research project. I
will ensure that all procedures performed under the project will be conducted in accordance with all relevant
University, provincial, national or international policies and regulations that govern research involving human participants.

Signature of Faculty Supervisor/Sponsor:	Date:
As the <b>Departmental Chair/Dean</b> , my signature confirms that I am aware of has received appropriate review prior to submission. My administrative unit we procedures which ensure compliance with all relevant University, provincial, and regulations that govern research involving human subjects. My signature the department, faculty or division to administer the research funds, if there a University, regulatory agency and sponsor agency policies.	will follow guidelines and national or international policies also reflects the willingness of
Print Name of Departmental Chair/Dean (or designate:	
Signature of Departmental Chair/Dean:(or designate)	Date: