

THOMPSON RIVERS UNIVERSITY



ETHICAL REVIEW OF ACTIVITIES INVOLVING HUMAN SUBJECTS IN QUESTIONNAIRES, INTERVIEWS, OBSERVATIONS, TESTING, VIDEO & AUDIO TAPES, ETC.

HELP

If you would like assistance with any aspect of the submission, please contact the Chair, Michael Woloszyn (mwoloszyn@tru.ca) or any of the committee members below: (Info accurate as of June 2009)

Michael Woloszyn	Faculty - Social Sciences
Jeff McLaughlin	Ethicist - PHP
Evelyn Penny	Faculty - Student Development
Christine Petersen	Faculty - Faculty of Science
TBA	Faculty – School of Trades
Marion Healey-Ogden	Faculty - School of Nursing
Ehsan Latif	Faculty - School of Business
Robert Hood	Faculty - School of Tourism
Joi Freed-Garrod	Faculty – School of Education
Michael Crawford	Faculty - School of Social Work
Giselle Kolaric	Faculty - Psychology
TBA	Faculty – Faculty of Arts
Mary Anne Mochizuki	Counsellor
Michelle Stanford	Lawyer (volunteer)
Nicole Befurt	Community Representative

Forms are revised periodically. Please be sure that you have an updated copy. Please detach and retain these instructions.

ALL REVIEWS ARE GOVERNED BY THE PRINCIPLES OF ETHICAL RESEARCH SET OUT IN THE TRI-COUNCIL POLICY STATEMENT (2ND DRAFT). YOU MAY FIND A COPY OF THIS DOCUMENT AT: <http://www.pre.ethics.gc.ca>

Please minimize the use of technical language, so that it is clear to the Committee what you are doing.

HUMAN SUBJECT INVOLVEMENT & SCOPE OF RESEARCH

“Research” involves the systematic investigation to establish facts, principles or generalizable knowledge.

Any research project carried out by a person connected with the University which involves human subjects requires review and approval by the Research Ethics Committee before work is started, except as stipulated below by Article 2.2; 2.3; 2.4; 2.5; and 2.6 of the Tri-Council Policy Statement, 2008:

2.2: Research that relies exclusively on publicly available information does not require research ethics board review. This includes research on living individuals and research on organizations such as governments or corporations, so long as the research is based entirely on material to which the public has access.

2.3: Research ethics board review is usually not required for research involving public policy issues, the writing of modern history, or literary or artistic criticism.

2.4: Quality assurance and quality improvement studies, program evaluation, and performance reviews or testing within normal educational requirements are not subject to research ethics board review.

2.5: Research involving observation of people in public places that does not allow for the identification of the individuals in research material and that is not staged by the researchers does not require research ethics board review.

2.6: Creative practice activities in and of themselves do not require research ethics board review.

For more information about how to apply these policies please contact the Committee, or see the TCPS 2nd draft, at www.pre.ethics.gc.ca The general rule is that if a person is a research subject, that is, if you are gathering data directly from a person, (for your own research) who knows you are gathering data, you need to get that person’s consent, and your project needs to be vetted by the Research Ethics Committee.

SUBMISSIONS TO THE COMMITTEE

Submissions must be made on the attached MAIN FORM - Request for Ethical Review form. Because this form is designed to deal with a range of possible projects, not every question is applicable to every project. Applicants should simply enter 'n/a' when this situation occurs. Researchers must use the TRU Informed Consent form, as well as the TRU Human Subject Feedback Form. There are other forms available should you require them.

You should submit the completed Word forms as attachments to an email sent directly to the Committee Chair Michael Woloszyn (mwoloszyn@tru.ca). Your submission will be distributed to Tribunal of REC committee members who will review your proposal.

TURN-AROUND TIME

Submissions may be made at any time. The Committee chair will assign your research proposal to a Tribunal consisting of 3 Committee members and the Committee Chair. Members of the Tribunal will review your proposal and may contact you for clarification. They will then either issue a letter listing revisions that need to be made, or they will issue a Certificate of Approval. If revisions asked for, these will need to be completed before a Certificate of Approval can be issued.

Please note that the Committee makes every effort to process your application in the shortest possible time but you should allow **at least 4 weeks** turn-around time. You must plan ahead.

To help you make sure that every needed item is included, two pages of checklists are included at the end of the form. Please take care that every item in every applicable checklist is dealt with.

CLASS PROJECTS & STUDENT RESEARCH

Student class projects which involve human subjects are to be reviewed by Divisional or School Ethics Committees (SREC). Please see the appropriate forms and guidelines.

THIRD PARTY RECRUITMENT

When subjects' names must be obtained from a third party who is obligated to maintain the confidentiality of their relationship (i.e. the physician/patient relationship), the third party must ask the subjects for permission to release their names to the researcher. This may also be done by asking the third party to distribute an introductory letter describing the study, with details on how to contact the researcher if they are interested in participating. Details of how third party recruitment will be accomplished and copies of any letters sent to either the third party or to the subject via the third party must be provided. If the researcher already has some form of contact with the subject (i.e. a nurse's contact

with a patient) the circumstances of that contact must be fully described.

INTERIM APPROVALS

1. Written proof of agency consent is required for projects carried out at other institutions. When agency approval cannot be obtained without prior approval by the TRU Committee, a letter of conditional approval will be issued for submission to the agency if all other aspects of the protocol are satisfactory. Applications should be submitted concurrently to the TRU Committee and the agency.
2. Projects which require ethical review in order to obtain research grant funds with which to develop a questionnaire, survey or interview may receive conditional approval with the understanding that any part of the project dealing with human subjects cannot commence until the committee has formally approved a final protocol. Provide as much detail as possible on the preliminary Request for Ethical Review making it clear that conditional approval is being sought.

APPROVAL PERIOD

Under Tri-Council policy, Ethics approval can only be given for one year at a time. After one year, you will be sent an Annual Research Status Report for completion and, upon receipt and satisfactory review of this report; an Approval Certificate will be issued for a further one-year period.

Instructions and Information on how to complete the Request for Ethical Review Form

(Numbers listed below correspond to those on the application form.)

Box 1. Principal Investigator (or faculty advisor)

The name of the researcher or, if you are conducting research as part of your Graduate studies, the name of your supervisor.

2. TRU Department

The name of the department that the researcher is in.

3. Phone Number

This is your work number.

5. Student or Co-Investigator(s)

If the research is conducted by a student for a course-based project; please complete a Student Ethics Application Form. If there is more than one investigator or if there is a student involved in the investigation, then their name(s) should appear here.

7. Granting Agency

If you are receiving funding (e.g., SSHRC or SAC) please put the appropriate name here.

8. Title of Project

The title of the project should be as brief as possible to describe the area/focus of the project for which ethical clearance is sought.

Identify Institution, agency, or community group involved in your research. Provide the name of the institution if other than TRU along with a contact name and telephone number if applicable.

If the research does not involve any interaction or intervention with the participants, only this first page needs to be completed.

If the research is a modification of an already approved proposal, you need only cite the protocol number and identify and submit any changes and revised attachment. Minor modifications may not need review (e.g., re-ordering of survey questions). Contact the chair of the Ethics committee for further information.

9. Project Period

Put the start date and end dates for the collection of all data. Researchers should be aware that the committee meets once a month and so the proposal should be submitted well in advance of any proposed start date (e.g., 2 months) in case of a need for extensive revision and/or re-application. **No research may be started** prior to receiving formal ethical approval. Retroactive approval is never permissible. The end date is understood to be approximate. Undergraduate course-based project approval may be expedited.

10. Title/Position of investigator

Please select the box that best represents your position as it relates to this particular project.

11. Describe the project

All studies must have benefit in order to justify being conducted. You must provide a description of known or potential benefits to participants and/or society.

Briefly and in non-technical language describe the nature and purpose of the project including why you wish to conduct it. This is perhaps the most important box – we want to know what the study is about, why you think

your research question is interesting, why the work is important, why you need human subjects, and so on. How does this work contribute to knowledge? What is the question you are trying to answer? What is the impetus of this work? You do not have to answer all of these questions – this is merely a list to give you an idea as to what we are looking for.

12. Signatures: All signatures must be obtained before submission of the proposal. Any missing signatures will result in the proposal being sent back.
The principal investigator or the faculty advisor (if it is a graduate/undergraduate project) signature must be supplied.
13. Student or co-investigator signatures must be supplied when appropriate. If the proposal requires significant modification, new signatures are required for re-submission since it is in the interest of the principal investigator to ensure that all parties are made aware of any changes that may affect their decision to give their signatures. If signatures are not obtainable (e.g., the co-investigator is not available for signing), then all attempts should be made to contact the individuals and review the changes made. Faxes or email signatures are permitted.
14. TRU Chair or Dean Signature entails that this individual has reviewed all aspects of this proposal and, to the best of his/her ability, is satisfied that it meets the appropriate professional ethical standards and guidelines.
15. Provide a summary of the methodology and procedures involved in this research
Method is often intertwined with ethical considerations and thus a non-technical description of the procedures used (along with any citations) is requested. Procedures must be detailed sequentially. For studies involving qualitative techniques (e.g., interviews, questionnaires) a copy of all materials must be included with this proposal. In the case of a standardized scale, a description of its purpose as well as an explanation for why this particular scale was selected must be provided. The committee will be assessing methodology and may bring in an expert to assist. The researcher may be contacted to recommend such a person.

If research is conducted by telephone, the researcher must complete Form 4.
16. How many participants will be used?
When considering the number of individuals you wish to include, be sure that you recognize that while you may approach X number of people, the number who actually consent to participate may vary considerably. If there is a control group, you should determine what number/ratio would be methodologically sound.
17. Who is being recruited (that is, who qualifies as a subject for your study)?
Researchers must describe the criteria used to select the prospective participants. Researchers are reminded that vulnerable groups may be more difficult to include but ought not to be rejected solely for this reason. (E.g. aboriginal groups, minors, persons with disabilities, etc.)
18. Exclusion of participants
Researchers should consider the various factors that may make it more difficult for the participant to be representative of the target population and/or able to offer informed consent. Most importantly, who will you be leaving out of your subject pool, and why?
19. Recruitment process
The source of the participants and the manner in which they will be recruited must be described in detail.
(1) Researchers should be aware of the potential perception of conflict of interest and concerns over confidentiality and risk especially if he or she is requesting his or her own students to participate. (2) Surveys conducted by mail must contain a cover letter to the questionnaire and this should be attached to the application. The covering letter should be typed and on the letterhead of the researcher's department. (3) In case of telephone or door to door surveys, the researcher should ensure that prospective participants receive advance notification about the study enabling them to verify the study's authenticity if they so choose. (4) For studies involving the

recruitment of students and/or teachers from local school systems (i.e., elementary and/or secondary schools), researchers must receive consent from the school board and the principal prior to any request for student or teacher participation. (5) Researchers are reminded that certain groups may experience undue pressure to volunteer as research participants (e.g., University students, developmentally challenged, incarcerated individuals etc.) thus care must be taken to ensure that the research is methodologically and ethically sound.

20. Controls

If control groups are being used and if their selection and/or recruitment differs from #17-19, provide details.

21. Where will the project be conducted?

Describe the location(s) of where the project will take place (e.g., community hall, school, home, university).

22. Who will conduct the study?

The principal investigator may not be responsible for carrying out the various components of the survey. Describe who will be actually fulfilling this role. Researchers are reminded that these individuals must also adhere to all the policies, procedures and ethical standards and guidelines that apply to the project.

23. Problems giving consent

Researchers must consider whether the prospective participants will have difficulties giving consent, either because of a lack of understanding (e.g., a young child) or because of other factors (short time allotted). If language is a concern, the researcher may wish to consider having the project translated if appropriate.

24. Unable to give full consent

While children cannot give fully informed consent, they should be informed as much as possible and allowed to express consent prior to the commencement of any study. Special care should be taken to ensure that the child is excused from the study if he or she shows any signs of distress or boredom. Parental or guardian consent must normally be given in writing and the researcher and parent should both retain copies of this letter. Information in the consent letter must contain all the features described in the consent form and should include any pertinent details to assure the safety and security of the child within the study (i.e., protecting anonymity and confidentiality).

Teenage children present a special case. Depending on the design and objective of the study special provisions may be needed to allow for these subjects to their own consent (without attending parental consent).

25. Vulnerable populations

If the participants in the study are considered members of a (potentially) vulnerable group, this must be identified. Children, institutionalized persons or others who are vulnerable are entitled, on grounds of human dignity, caring, solidarity and fairness, to special protection against abuse, exploitation or discrimination. Ethical obligations to vulnerable individuals in the research enterprise will often translate into special procedures to protect their interests.

26. Benefits and risks

All studies must have benefit in order to justify being conducted. Known and anticipated risks must be identified. Risks may be physiological, psychological, emotional, economic or social in nature. Researchers are required to identify risks as either minimal or greater than minimal risk.

“For the purpose of this Policy, a “minimal risk” situation is defined as one in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by the participant in those aspects of his or her everyday life that relate to the research.” TCPS Article 2.7 (lines 448-452)

27. Discomfort or incapacity

If there are any physical or psychological discomforts or a perceived power imbalance between the researcher

and the subjects (or instructor/students), the researcher should express what these are and how they will be dealt with (e.g., offering the services of TRU's counselling department). Another example would be if the research was about something distressing such as drug addiction or sexual abuse. In those cases you may well want to have a plan to deal with the potential emotional fall out.

The other issue to address in this box is if there may be any perceived coercion, that is, if there are any circumstances under which the subject may feel uncomfortable withdrawing from the study or may feel as though s/he must answer the questions or otherwise participate. For example a student may feel as though she really should help out the professor researcher or she might not do as well in the class, or she may simply feel an obligation to her professor. These things are not barriers to research, but they must be dealt with in the research design.

28. Monetary or other compensation

Researchers may wish to compensate persons for taking the time to participate in their research. Thus, one might offer coffee or refund bus fare if presented with a receipt. One must be careful not to make this compensation a reward for participation.

29. Time required of participant

Researchers must provide the approximate amount of time required for participant's participation. If there is more than one session involved, the individual should be made aware of both the total amount of time involved as well as the amount of time involved in each session (e.g., 2 – 20 minute sessions over a 2 week period, for a total of 40 minutes). Please make sure that the time requirement is the same here as on the Consent Form.

30. Time for control group

See note 29 above.

31. Who has access to data

Researchers should make clear who will have access to raw data and aggregate data.

32. Maintaining confidentiality

Researchers must provide details on how confidentiality and anonymity will be maintained, for example, by using code names or anonymous submissions. Ideally, all identifiers should be removed. If there is the possibility of some information becoming public that could lead to the identification of the participants, reasons must be provided and weighed against any other alternative method of collecting data that would protect identities.

33. Storage and disposal

Researchers must ensure that the data collected is properly handled and protected that the data is appropriately disposed of in a timely fashion. For example, keeping the data in a locked file office cabinet for a maximum of 3 years is permissible. Researchers should be sensitive to the limitations of electronic storage and disposal (passwords, encryption, over-writing vs. deletion, disc shredding etc.)

34. Identifying individuals to persons outside the Research group

Researchers must comply with the Tri-Council guidelines (TCPS 2nd ed, Article 5.3). See also note 32 above. What this section refers to is keeping private information private. If for example, you are going to quote someone, you have to have permission. If you are using audio tape and a person could be identified by his or her voice, you have to have permission to use that audio tape. Maintaining privacy is like confidentiality, but there is a difference. Confidentiality is about how you collect and code your raw data. Privacy is about how you present your data after you've done the analysis and are ready to present the results. It's a little more complicated than this, but in a nutshell, this will do. What the Committee is concerned with here is that identifying information is not leaked when you present your finished study. So depending on how you collect your data, this may not be an issue, but if it might be an issue you need to make sure that you either have permission of the individual, or

that no one can identify any individual from your study in your work.

35. – 38.

Check off ALL appropriate boxes. Incomplete forms will be returned.

39. Additional Information

Provide any additional information that may assist the ethics committee or use this space to continue any box item where there was insufficient space.

Forms

Researchers must complete all forms as required and ensure that all details and information have been provided.

Deviations from the forms are not permitted except in extra-ordinary cases.



RESEARCH INVOLVING HUMAN SUBJECTS
Request for Ethics Review

Protocol Number: _____
(office use only)

1 Principal Investigator (or faculty advisor) Barbara L. Paterson	2 TRU Department School of Nursing	3 Phone Number 250-852-7288	4 Email address bapaterson@tru.ca
5 Student or Co-Investigator(s) Co-PIs: Dr. Lois Jackson, School of Health & Human Performance, Dalhousie University, lois.jackson@dal.ca; (902) 494-1341 (w) Monique Fong, Executive Director of Healing Our Nations: Atlantic First Nations AIDS Network, director@accesswave.ca; (902) 492-4255 #224 (w) Julie Dingwell, Executive Director, AIDS Saint John, aidssj@nb.aibn.com; (506) 652-1582 (w) Co-investigators: Dr. Donna Bulman, UNB Fredericton, Faculty of Nursing, (506) 458-7636, dbulman@unb.ca Dr. Lynne Duffy, UNB Moncton, Faculty of Nursing, (506) 856-2682, lduffy@unb.ca Richard Elliott, Canadian HIV/AIDS Legal Network, (416) 595-1666 #229, relliott@aidslaw.ca Dr. Leslie Jeffrey, UNB Saint John, (506) 648-5609, ljeffrey@unbsj.ca Ralf Jurgens, Private consultant, (450) 438-9292, rjurgens@sympatico.ca Dr. Gayle Macdonald, Saint Thomas University, (506) 452-0460, macdonald@stu.ca	6 Mailing address (complete only if different from Department/Faculty)	7 Granting Agency CIHR	
8 Title of Project PROMISING PRACTICES IN THE ENGAGEMENT OF PEOPLE LIVING WITH OR AT-RISK FOR HIV/AIDS IN RURAL CANADA		9 Project Period (mm/yy – mm/yy) Research: March 2010-March 2013 This submission is for Phase 2: Sept 2011-May 2012	
10 Title/Position (check all that are relevant to THIS project) <input checked="" type="checkbox"/> Faculty Member <input type="checkbox"/> Graduate student Master's <input type="checkbox"/> Ph.D <input type="checkbox"/> (See 10.a. below) <input type="checkbox"/> Other (See 10.b. below)			

ALL INFORMATION REQUESTED IN THIS FORM MUST BE TYPEWRITTEN IN THE SPACE PROVIDED.

IF ADDITIONAL SPACE IS REQUIRED, PLEASE USE BOX 40.

NOTE: ALL GRADUATE PROJECTS MUST RECEIVE APPROVAL FROM THE DEGREE GRANTING INSTITUTION ETHICS BOARD.

UNDERGRADUATE STUDENTS INVOLVED IN COURSE-BASED RESEARCH SHOULD COMPLETE A STUDENT REQUEST FOR ETHICAL REVIEW FORM.

10.a. If this research is for graduate studies, please provide the following information:

- Degree sought
- Area/Department
- University
- Supervisor contact information

N/A

10.b. If you are not a member of Thompson Rivers University (student or faculty), please provide the name of your organization/employer, your affiliation and other details as may be necessary to identify you.

N/A

☐

Identify institution and agency, or community group involved in your research

type here

Contact Person: *type here*

Note: IF THE PROJECT IS LIMITED TO ONE OF THE FOLLOWING, PLEASE CHECK THE APPROPRIATE BOX AND COMPLETE AND SUBMIT ONLY PAGE 1 AND 2 OF THIS FORM:

☐

observation without intervention. (i.e. no tests, interviews or questionnaires)

☐

modification of existing approved protocol # *type here*: indicate **changes** only and submit copies of any revised attachments.

11 Describe the project, including purpose and potential benefits. It is essential to use the minimum of technical language.

The research is a community-based research (CBR) study intended to (1) contribute to the understanding of how the “Greater Involvement of Persons Living with HIV/AIDS” (GIPA) principle is operationalized in rural regions, and (2) to provide direction to AIDS Service Organizations (ASOs), policy makers and people living with HIV/AIDS (PHAs) or at-risk for HIV about how the ideals of GIPA could be fully realized within ASOs in rural regions of Canada, specifically in the rural regions of the Maritime provinces (Nova Scotia [NS], New Brunswick [NB], and Prince Edward Island [PEI]). In future research, the applicants intend to test the framework that arises from the research by assessing its ‘transferability’ to other rural regions and to affected people.

The majority of research to date about GIPA has been conducted in large urban centres. Constraints to GIPA are magnified in rural regions where there is no critical mass of service users and where stigmatization is a significant factor hampering GIPA in rural regions. The operationalization of GIPA is additionally challenged in rural regions by difficulties in accessing and engaging further marginalized sub-groups, such as Aboriginal people and users of drugs.

The research design entails a staged and mixed qualitative approach to effectively address the complex and multidimensional issue of meaningful involvement, including: (1) Stage 1: individual interviews of stakeholders; (2) Stage 2: the use of photovoice to capture the experience of the population of interest and the formulation of a discussion paper and the development of posters from the photovoice component; and (3) Stage 3: a Strategy Workshop. We previously received ethical approval for the first phase of the research study. This submission for ethical approval targets the second phase, photovoice.

The research will potentially heighten national and international awareness of the distinct facilitators and challenges to GIPA that are experienced in rural regions. It will also provide direction to policy makers, ASOs, and ASO client populations as to how these facilitators and challenges could be effectively addressed to mediate the ambiguities and gaps that currently exist in GIPA policy documents and the expectations of funders regarding the enactment of GIPA in rural regions.

SIGNATURES

12 Principal Investigator (or faculty advisor if graduate student project)	13 Student or Co-Investigator(s) (if applicable; give title)	14 TRU Department Chair or Dean
<hr/>	<hr/>	<hr/>
<hr/>	<hr/>	<hr/>
Date	Date	Date

Note: Signatures verify that this project has been thoroughly reviewed by the parties, has been deemed to be methodologically sound and complies with the professional ethical standards and guidelines of the area of research. Signatures of the applicants, Principal investigator, co-investigator, student investigator and supervisors certifies that (a) the information contained in this application is accurate; (b) that the conduct of the proposed research will not commence until ethical approval/ clearance has been granted. Conduct of research using human subjects that has not received ethics approval/clearance is a breach of TRU’s policy in integrity in scholarly activity (policy ED 15-2).

15 Summary of Methodology and procedures. If research is conducted by telephone, complete the *Telephone Contact Form* (Form #4). If your study involves deception, you must also complete the *Deception Form* (Form #5).

Photovoice is a qualitative research strategy in which participants take photographs of the phenomenon under study. We have selected this strategy because (1) marginalized populations that are traditionally difficult to recruit for interviews (e.g., users of drugs, Aboriginal people) have embraced this method worldwide because of its oral-based and interactive design (thus we will provide opportunities for those who may be reluctant to be interviewed to participate in the research), and (2) we intend for the resulting photographs to provide a visual and powerful supplement to the discussion paper generated from the interview data that can be used in the later Strategy Workshop to stimulate discussion among stakeholders.

Photovoice participants will attend an initial day-long workshop to discuss cameras, photographic techniques, ethics and power (with an emphasis on prevention of intrusion, personal safety and permission to take photographs of other people), the photovoice method, and the overall project goals. A written copy of the safety guidelines for the project will be provided to each participant. (see Appendix A: Project Safety Guidelines). The researchers will facilitate a discussion to explore what participants might photograph to achieve the research goals (e.g., “How does living in a rural region affect your meaningful involvement in an ASO?”). Examples from other photovoice projects will be provided by Duffy (co-investigator) to illustrate how to use analogies to photograph sensitive and difficult concepts. Participants will engage in a brainstorming exercise to develop a list of photograph (photo) assignments for future sessions that relate to the research objectives. At the conclusion of the workshop, each participant will be given a 27-exposure digital camera. Participants will also be given an overview of the study and purposes, Project Safety Guidelines (Appendix A), release forms, contact information of the investigators, and basic guides for taking pictures.

After completing the first photo assignment, participants will return their cameras to the project coordinator who will have the photos printed at no cost to the participants. A photo discussion will be held 2-3 weeks following the developing of the photos during which participants will select the photos they want to share with the group and provide an explanation regarding how selected photos relate to the photo assignment (i.e., their interpretation of the meaning of each photo). The group will then choose the photos to serve as the focus for the discussion and analysis. Captions and storylines will be provided by the participants to explain the meaning of each photo. The discussion will be facilitated by the investigators, using a Freirean-based critical dialogue technique (SHOWED) to help participants identify, reflect, and act on issues in regard to meaningful involvement. The questions include (a) What do you See in this photograph? (b) What is Happening in this photograph? (c) How does this relate to Our lives? (d) Why do these issues exist? (e) How can we become Empowered by our new social understanding? and (f) What can we Do to address these issues? The facilitators will also ask, “Were there things that you thought you might photograph but didn’t? If so, tell us why you did not photograph these things.” “What pictures are missing that you would like to include?”

Discussions will be audio taped to document the issues, themes, and stories emerging from the individual analysis and group dialogue for transcription. The group members will decide if they would agree to video recording of their meetings. The decision must be unanimous unless those who decline can be excluded or cannot be recognized.

At the conclusion of the first photo discussion, participants will agree on the focus of the next photo assignment. Each photo discussion is estimated to take approximately 3 hours. The discussion will be audiotaped and later transcribed. The second photo discussion will have a similar format to the first, involving the review and analysis of photos taken in the photo assignment. In addition, the facilitators will ask, “Now that you’ve seen the photos that everyone has taken, what’s missing? What else would you like people to know about meaningful involvement that is not in these photos?” As well, the participants will decide which photographs should be made into poster-sized representations to form an exhibit to be used in the Strategy Workshop. Participants will receive a copy of their photos for their records.

DESCRIPTION OF POPULATION

16 How many subjects will be used in total? Of these, how many in the control group(s)?

7-10

<p>17 Who is being recruited and what are the criteria for their selection?</p> <p>The participants will be purposively recruited from members of the population of interest (i.e., people who are infected with or at risk for HIV/AIDS) who live in Cape Breton, NS. We will specifically target Aboriginal people, immigrants to Canada, women, and people using drugs because these are populations identified as experiencing particular challenges in engaging in ASOs. We selected Cape Breton as the setting for photovoice because there is a significant number of Aboriginal people, a high incidence of poverty and illiteracy, and more known users of drugs than in other rural regions of the Maritimes. All participants will be at least 18 years old, speak and write English and be able and willing to participate in taking photographs and in group discussions, and live in the Maritimes.</p>
<p>18 What subjects will be excluded from participation?</p> <p>Those who do meet the inclusion criteria</p>
<p>19 How are the subjects being recruited? (If initial contact is by letter or if a recruitment notice is to be posted, attach a copy.)</p> <p>TRU Ethics Committee - Human Subjects discourages initial contact by telephone. However, researchers who use telephone contact need to complete the <i>Telephone Contact Form</i> (Form #4).</p> <p>We will recruit participants by requesting permission to recruit in letters to the ASOs in the Cape Breton region of Nova Scotia, as well as other relevant community organizations (e.g., Native Friendship Centres). We will request permission to make a presentation about the study to these groups. If granted permission, we will outline how we wish them to assist in the recruitment process (e.g., by posting posters advertising the research - see Appendix B) and provide a package of information that details the recruitment process and how to address inquiries from organizational members. Those who volunteer for the study will be given pocket-sized laminated recruitment cards advertising the study to provide to those whom they believe meet the criteria for the study. Similar recruitment strategies have been used successfully by the applicants in research in the Maritimes with Aboriginal people, users of drugs, sex workers, and PHAs.</p>
<p>20 If controls are involved, and if their selection and/or recruitment differs from #17 - 19, provide details.</p> <p>N/A</p>

PROJECT DETAILS

<p>21 Where will the project be conducted?</p> <p>Cape Breton, Nova Scotia</p>
<p>22 Who will actually conduct the study?</p> <p>Dr. Lynne Duffy, an expert in photovoice, and a research assistant</p>
<p>23 Will the group of subjects have any problems giving informed consent on their own behalf? Consider physical or mental condition, age, language, or other barriers.</p> <p>At times, it is possible that some members of the population of interest who agree to participate may be unable to give informed consent because they are 'high' on drugs. If a participant is not able to focus on the consent form/process, the researcher will stop the audiotape, state, "It seems like you are having trouble concentrating today. Let's make another appointment and you can come back to complete the consent form" and then reschedule the consent meeting.</p>

24 If the subjects are not competent to give fully informed consent, who will consent on their behalf? What measures will be taken to inform and obtain the consent of the subject inasmuch as that is possible? **(See also Form #2)**

N/A

25 Are the subjects considered members of a (potentially) vulnerable group? ☒ Yes ☐ No

If yes, please describe.

Does your study have the potential for identifying distressed or disturbed individuals? ☒ Yes ☐ No

If your study has the potential to upset subjects, or identify distressed or disturbed individuals, you must make arrangements to mitigate such effects (e.g. provide access to TRU counselling services). Describe the arrangements you have made.

Illicit drug use is considered an illegal activity and consequently, participants who are users of illicit drugs (i.e., those at-risk for HIV/AIDS) are vulnerable to criminal prosecution. In addition, people with HIV/AIDS may not wish their diagnosis to be shared with others mainly because of the stigmatization of this disease. The research design mediates these risks by: (1) confidentiality measures, (2) scheduling photovoice sessions in "neutral" locations not regularly associated with HIV/AIDS, such as community centre; (3) including the following statement in consent forms: "The information that you give is kept fully confidential. Your answers will not be made available to doctors, treatment providers, police, or other criminal justice people. However, you need to know that there are unusual instances where we would have an obligation to report certain types of information. Some examples are if you tell me that you are going to harm yourself or others, or in a situation where child abuse is suspected, or where there is a court warrant requiring access to the information"; and (4) including in consent forms (and reinforcing verbally at the time of the interview) that the participant should not mention details of his/her personal criminal activity (if it occurs accidentally in photovoice discussions, these will be deleted from tapes and transcripts). In addition, the Project Safety Guidelines (Appendix A) shared with participants will instruct them as to how to avoid documenting an individual's criminal activity (e.g., as injection drug use might be identified as a barrier to meaningful involvement in ASOs, the instructions will include that photos can detail evidence of drug use trade, such as used syringes and needles on the sidewalk, but not people actually injecting drugs). As it is possible that participation in the project may imply to others that the participant has HIV/AIDS, we will not refer to HIV/AIDS in any mailed or e-mailed correspondence to the participant (e.g., the title of the project will be referred to as "Promising Practices in Engaging the Public in Health Care Organizations"; our return address will not indicate our research focus).

26 Estimate of risk:

What level of risk would you assign to this research project? Minimal risk is defined as those risks encountered in normal, everyday life.

Physical risk	<input checked="" type="checkbox"/> minimal risk	<input type="checkbox"/> more than minimal risk
Psychological/Emotional risk	<input checked="" type="checkbox"/> minimal risk	<input type="checkbox"/> more than minimal risk
Social risk	<input checked="" type="checkbox"/> minimal risk	<input type="checkbox"/> more than minimal risk
Employment risk	<input checked="" type="checkbox"/> minimal risk	<input type="checkbox"/> more than minimal risk

If you answered 'more than minimal risk' to any of the above, please describe the manipulations and/or potential risks as well as the safeguards or procedures you have in place. Please provide justification for any potential risks involved and explain why alternative approaches (including revising the types of data collected or the method that data is collected) involving less risk cannot be used.

type here

27	<p>What discomfort or incapacity or perceived degree of coercion are the subjects likely to endure as a result of the research process?</p> <p>It is possible that some participants may become discouraged or angry about the barriers that exist to meaningful involvement in rural ASOs. However, this may also motivate them to advocate for the elimination of such barriers.</p>
28	<p>If monetary or other compensation is to be offered to the subjects, provide details of amounts, reasons for, and payment schedules.</p> <p>An honorarium of \$20 at each of the four meetings (initial workshop, three discussion meetings) will be provided to participants in lieu of costs incurred in participating in the project (e.g., child care, transportation, parking)</p> <p>While the camera may be seen as an inducement, it is a necessary tool for the study. Participants will be told the camera will be provided because not having it may hinder their participation. Participants will be able to keep the digital camera and receive a photo album with a copy of their personal pictures at the end of the study as a way of recognizing their work and the shared ownership of their photos.</p>
29	<p>How much time will a subject have to dedicate to the project?</p> <p>17 hours</p>
30	<p>How much time will a member of the control group (if any) have to dedicate to the project?</p> <p>N/A</p>

DATA

31	<p>Who will have access to the data?</p> <p>Only the researcher will have access to the data</p>
32	<p>How do you plan to handle the requirement of confidentiality and/or anonymity?</p> <p>Participants will be asked to complete a brief Demographic Form (Appendix C) that will be kept locked and separate from the consent forms. Their names will not appear on this form, but an assigned code known only to Dr. Duffy will be given to each participant. The codes will be kept on a hard copy in a secure place and also on Dr. Duffy's password protected computer. Because the analysis will occur in a group setting, each participant will sign a Group Confidentiality Form (Appendix D). The participants may use a pseudonym if desired, especially for dissemination, as they may know each other from previous meetings and may be from the same community. Any RAs or Transcribers will also sign a confidentiality form (Appendix E). Participants will own their photographs and must give consent for their photographs to be used by the research team to be shared publicly (see Appendix F). Even with minimal risk, consent will be ongoing. Reminders of confidentiality, safety, and participant rights will be discussed at the beginning of each participant meeting. Permission to use their photographs will be collected at the end of each meeting and they will know they can withdraw consent for all or part of the study at any time.</p>

33 What are the specific details for storage and disposal of records/data? Provide approximate times/dates.

Identifier codes will be kept in a secure and locked file cabinet or in a computer that can only be entered through a password. The discussion transcripts and tapes will be kept in secure locked storage for seven years, after which they will be destroyed. The hard copies of transcripts will be incinerated and the tapes and the computer files pertaining to the research will be erased in seven years following the completion of the study. The protection of the rights of participants will occur by: 1) full disclosure of the research study's purposes, procedures and intent in the description of the study in letters of invitation and advertisements; 2) assigning codes to maintain confidentiality and not using their name in research reports or presentations (see Informed Consent); 3) informing participants that they may withdraw from the research at any time; 4) obtaining informed consent from all participants (they will be given a copy of the consent for their records); and 5) providing the researchers' contact name, as well as the telephone number of the appropriate persons at each site for participants to pose any questions or concerns about the study.

34 Will any data which identifies individuals be available to persons or agencies outside the Research group? If yes, provide justification and assessment of risk.

No

35 Will your project use: (check)

- ☒ Questionnaires (submit a copy)
- ☐ Interviews (submit a sample of questions)
- ☐ Observations (submit a brief description)
- ☐ Tests (submit a brief description)
- ☐ Review of personal records, including medical

35b. Please attach sample questions

INFORMED CONSENT

36 Who will consent? (check)

- ☒ Subject
☐ Parent/Guardian
☐ Agency Official(s)

In the case of projects carried out at other institutions, the Committee requires written proof that agency consent has been received. Please specify below:

- ☐ Research carried out in a hospital -- approval of hospital research or ethics committee.
☐ Research carried out in a school -- approval of School Board and/or Principal. (Exact requirements depend on individual school boards: check with them.)
☐ Research carried out in a Provincial Health Agency (Name of contact person and title).
☐ Other. Specify: *type here*

If participants will not be fully informed of everything that will be required of them prior to the start of the research session, explain why.

N/A

Are subjects to be debriefed at the end of the research project? If so, explain how this will be done. If not, explain why not.

Participants will receive a written summary of the findings of Stage 1 and 2 (discussion paper) in the mail. They will also be invited to attend a Strategy Workshop in the following year in which the research findings of Stage 1 and 2 will be shared with participants.

A description of the verbal explanation that will be given to subjects before they are asked to consent to participation should be attached. (If not applicable, state why).

The researcher will say, "Please read this over carefully before you sign. You can ask me any questions about it and I will be glad to answer them for you. You are not required to sign it if you do not want to participate in the study. One thing you should know is that even after you sign this, if you decide not to take part in the study, I will not be able to use any information you provided."

To be sensitive to unique situations, including cultural differences, a written consent form may not be appropriate. If there is no consent form, an explanation and details about your alternative procedures to ensure that consent is obtained and recorded is required.

N/A

How and when are the subjects informed of the right to withdraw? What procedures will be followed for subjects who wish (or who exhibit signs that they wish) to withdraw at any point during the study?

See above for verbal explanation. This is also in the informed consent

CONSENT CHECK LIST

37 Written subject consent (Form #1) is required in all cases other than questionnaires which are completed by the subject. (See item #36 for questionnaire consent requirements.) Please check each item in the following list to ensure that the written consent form attached contains all necessary items. If your research involves contact by telephone, you need not fill out this section. Written correspondence should be on TRU letterhead.

- a. ☒ Title of project
- b. ☒ Identification of investigators (including a telephone number)
- c. ☒ Brief but complete description IN NONTECHNICAL LANGUAGE of the purpose of the project and of all procedures to be carried out in which the subjects are involved.
- d. ☒ Assurance that identity of the subject will be kept confidential and description of how this will be accomplished.
- e. ☒ Statement of the total amount of time that will be required of a subject.
- f. ☒ Details of monetary or other compensation, if any, to be offered to subjects.
- g. ☒ An offer to answer any inquiries concerning the procedures to ensure that they are fully understood by the subject and to provide debriefing, if appropriate.
- h. ☒ A statement of the subject's right to refuse to participate or withdraw at any time and a statement that withdrawal or refusal to participate will not jeopardize further treatment, medical care or influence class standing as applicable. **NOTE:** This statement must also appear on letters of initial contact.
- i. ☒ A place for signature of subject **CONSENTING** to participate in the research project, investigation or study.
- j. ☒ A statement acknowledging receipt of a copy of the consent form including all attachments.
- k. ☐ Parental consent forms must contain a statement of choice providing an option for refusal to participate. (e.g. "I consent/I do not consent to my child's participation in this study." (Form #2)
- l. ☒ Contact information for relevant Dean and for Chair of REC-HS.
- m. ☒ Statement as to what the information will be used for (presentation, publication etc.)
- n. ☒ Statement as to how the subject can receive a copy or executive summary of completed project and, where appropriate, receive updated information during the course of the research.
- o. ☒ Description of the likelihood of any discomforts and/or conveniences associated with the participation and known or suspected short and long-term risks, and factors which might lead to refusal to participate.

QUESTIONNAIRE/SURVEY CHECK LIST

38 Questionnaires should contain an introductory paragraph or cover letter which includes the following information. Please check each item in the following list before submission of this form to insure that the introduction contains all necessary items.

- a. ☐ Title of Project.
- b. ☐ Identification of investigators (including a telephone number).
- c. ☐ A brief summary that indicates the purpose of the project, including potential presentation and publication if applicable.
- d. ☐ The benefits to be derived.
- e. ☐ A full description of the procedures to be carried out in which the subjects are involved.
- f. ☐ A statement of the subject's right to refuse to participate or withdraw at any time without jeopardizing further treatment, medical care or class standing as applicable. **NOTE:** This statement must also appear on explanatory letters involving questionnaires.
- g. ☐ The amount of time required of the subject must be stated.
- h. ☐ The statement that if the questionnaire is completed it will be assumed that consent has been given.
- i. ☐ Assurance that identity of the subject will be kept confidential and description of how this will be accomplished.
- j. ☐ For surveys circulated by mail submit a copy of the explanatory letter as well as a copy of the questionnaire.

ATTACHMENTS CHECK LIST

39 Check items attached to this submission, if applicable, incomplete submissions will not be reviewed.

- a. ☐ Letter of initial contact (item 19)
- b. ☒ Advertisement for volunteer subjects (item 19)
- c. ☒ Subject consent form (Form #1, see item 36)
- d. ☐ Subject feedback form (Form #3)
- e. ☐ Control group consent form (if different from c. above)
- f. ☐ Parent/guardian consent form (if different from c. above) (Form #2)
- g. ☐ Agency consent (item 35) (letter of consent)
- h. ☒ Questionnaires, tests, interviews, etc. (item 34)
- i. ☐ Explanatory letter with questionnaire (item 37)
- j. ☐ Description of debriefing if deception is involved
- k. ☐ Deception Form (Form #5)
- l. ☐ Telephone Form (Form #4)
- m. ☐ Description of verbal explanation given to subjects before consenting to participation
- n. ☐ Other permissions/approvals required where the research will be conducted
- o. ☐ Graduate degree-granting institution ethical board approval letter attached (if not attached, please explain why).
- p. ☒ Other. Specify:

ADDITIONAL INFORMATION

40 Use this space to provide information which you feel will be helpful to the ethics committee OR to continue any item for which sufficient space was not available.

There are more consents needed for a photovoice study than the subject informed consent. Consequently, Appendix F is a consent for the use of participants' photographs, Appendix G is a consent by people who were photographed for their photos to be shared with the research team, and Appendix H is consent to be photographed or videoed during the workshop or discussion meetings. Because the analysis will occur in a group setting, each participant will sign a Group Confidentiality Form (Appendix D). The participants may use a pseudonym if desired, especially for dissemination, as they may know each other from previous contacts and may be from the same community.

The demographic form will be used by the research assistant when potential participants telephone the toll free number to indicate interest in the study. It will be used as a means of determining whether the person meets the inclusion criteria for the study. Only the demographic information of people agreeing to volunteer as participants, later providing informed consent, and who meet the inclusion criteria will be kept by the research team; information pertaining to others who do not volunteer for the study or who do not meet the inclusion criteria will be erased/shredded and not considered as research data.

Guiding Ethical Principles

The approach taken in this framework is to guide and evoke thoughtful actions based on principles. The principles that follow are based on the guidelines of the Councils over the last decades, on more recent statements by other Canadian agencies, and on statements from the international community. The principles have been widely adopted by diverse research disciplines. As such, they express common standards, values and aspirations of the research community.

Respect for Human Dignity: The cardinal principle of modern research ethics, as discussed above, is respect for human dignity. This principle aspires to protecting the multiple and interdependent interests of the person – from bodily to psychological to cultural integrity. This principle forms the basis of the ethical obligations in research that are listed below.

In certain situations, conflicts may arise from application of these principles in isolation from one another. Researchers and Research Ethics Boards must carefully weigh all the principles and circumstances involved to reach a reasoned and defensible conclusion.

Respect for Free and Informed Consent: Individuals are generally presumed to have the capacity and right to make free and informed decisions. Respect for persons thus means respecting the exercise of individual consent. In practical terms within the ethics review process, the principle of respect for persons translates into the dialogue, process, rights, duties and requirements for free and informed consent by the research subject.

Respect for Vulnerable Persons: Respect for human dignity entails high ethical obligations towards vulnerable persons – to those whose diminished competence and/or decision-making capacity make them vulnerable. Children, institutionalized persons or others who are vulnerable are entitled, on grounds of human dignity, caring, solidarity and fairness, to special protection against abuse, exploitation or discrimination. Ethical obligations to vulnerable individuals in the research enterprise will often translate into special procedures to protect their interests.

Respect for Privacy and Confidentiality: Respect for human dignity also implies the principles of respect for privacy and confidentiality. In many cultures, privacy and confidentiality are considered fundamental to human dignity. Thus, standards of privacy and confidentiality protect the access, control and dissemination of personal information. In doing so, such standards help to protect mental or psychological integrity. They are thus consonant with values underlying privacy, confidentiality and anonymity respected.

Respect for Justice and Inclusiveness: Justice connotes fairness and equity. Procedural justice requires that the ethics review process have fair methods, standards and procedures for reviewing research protocols, and that the process be effectively independent. Justice also concerns the distribution of benefits and burdens of research. On the one hand, distributive justice means that no segment of the population should be unfairly burdened with the harms of research. It thus imposes particular obligations toward individuals who are vulnerable and unable to protect their own interests in order to ensure that they are not exploited for the advancement of knowledge. History has many chapters of such exploitation. On the other hand, distributive justice also imposes duties neither to neglect nor discriminate against individuals and groups who may benefit from advances in research.

Balancing Harms and Benefits: The analysis, balance and distribution of harms and benefits are critical to the ethics of human research. Modern research ethics, for instance, require a favourable harms-benefit balance – that is, that the foreseeable harms should not outweigh anticipated benefits. Harms-benefits analysis thus affects the welfare and rights of research subjects, the informed assumption of harms and benefits, and the ethical justifications for competing research paths. Because research involves advancing the frontiers of knowledge, its undertaking often involves uncertainty about the precise magnitude and kind of benefits or harms that attend proposed research. These realities and the principle of respect for human dignity impose ethical obligations on the prerequisites, scientific validity, design and conduct of

research. These concerns are particularly evident in biomedical and health research; in research they need to be tempered in areas such as political science, economics or modern history (including biographies), areas in which research may ethically result in the harming of the reputations of organizations or individuals in public life.

Minimizing Harm: A principle directly related to harms-benefits analysis is non-maleficence, or the duty to avoid, prevent or minimize harms to others. Research subjects must not be subjected to unnecessary risks of harm, and their participation in research must be essential to achieving scientifically and societally important aims that cannot be realized without the participation of human subjects. In addition, it should be kept in mind that the principle of minimizing harm requires that the research involve the smallest number of human subjects and the smallest number of tests on these subjects that will ensure scientifically valid data.

Maximizing Benefit: Another principle related to the harms and benefits of research is beneficence. The principle of beneficence imposes a duty to benefit others and, in research ethics, a duty to maximize net benefits. The principle has particular relevance for researchers in professions such as social work, education, health care and applied psychology. As noted earlier, human research is intended to produce benefits for subjects themselves, for other individuals or society as a whole, or for the advancement of knowledge. In most research, the primary benefits produced are for society and for the advancement of knowledge.