

Research Ethics Boards' Application Form

Submission for Research Projects Ethics Evaluation

Please type or print the answers. Please answer all the questions. Use extra paper if you need to include more information or if you need more space to write your answers.

1. Investigators:

Name	Affiliation	Office	Telephone/ fax/email
Lynne MacLean, Ph.D.	Community Health Research Unit (CHRU)	495 Richmond Road, 2 East Ottawa ON K2A 4A4	724-4122, ext. 23574
Alma Estable, MSW	Gentium Consulting	99 Findlay Ave Ottawa ON K1S 3B6	232-1823
Sara Torres, MSW	LAZO (Latin American women's organization)	Centretown Community Health Centre (CCHC) 420 Cooper St. Ottawa ON K2P 2N6	233-4443

3. Research project:

Title of the Research Project:

Building Community Capacity & Equitable Access to Cancer Screening For Ethno-racial Minority women - A Demonstration Project

Funding source (if any):

Joint project of the Centretown Community Health Centre (CCHC), LAZO (Latin American women's organization); Community Health Research Unit; and Gentium Consulting, funded by the Ontario Women's Health Council and (internally) by the Community Health Research Unit.

Brief summary of the Research Project:

This two-year demonstration project assesses the usefulness of adapting a comprehensive, lay health-promoter-based, community capacity building approach, similar to one used in other jurisdictions with disadvantaged, rural, or uninsured populations (US, Latin America) to the specific conditions of a Canadian urban setting. The project focuses on barriers faced by women from one ethnoracial minority (linguistically isolated, Spanish-speaking immigrants from over 20 countries, with few or no ethno-specific services available) in the first year; and explores transferability to other ethnoracial minority communities and settings in the second year. Participatory action research methods will be used to study community capacity building and individual behavioural change in relation to breast and cervical cancer screening. Working out of the Centretown Community Health Centre, 12 Lay Health Promoters will be trained to deliver an educational program to the Hispanic community. Baseline data will be provided by CCHC and the Ontario Breast Screening Program, Ottawa Clinic, on the mother tongue composition of clients (see Appendix A). Quantitative and qualitative data will be collected from program participants.

4. Research Subjects

Describe the Research subjects. Be as specific as possible by indicating the number of subjects, their status, their age, their characteristics, etc.

Data will be collected on 200 Hispanic women prior to and after their participation in the program, to document attitudes and knowledge about cervical and breast cancer, identify barriers to screening, and screening behaviour. Qualitative data will be collected from health service providers to supplement information about barriers and develop useful processes to reduce these.

Number of participants to be involved in the study

The maximum number of participants will be

- a) 200 Hispanic women in Ottawa;
- b) 15 - 30 health service providers participating in focus group(s)
- c) 15 service providers (including health service providers) participating in the Advisory Committee

Indicate how will the subjects will be chosen for this research. Include any poster or advertisement or the text of any method used to recruit research subjects.

- a) Recruitment of a marginalized population is always challenging, and is anticipated to take place on an ongoing basis over many months. Outreach to the Hispanic population to participate in project activities will be concurrent with recruitment to participate in the research aspect of the project.

Multiple methods will be used to recruit participants to project activities, including:

- presentations by lay health promoters (LHPs);
- word-of-mouth through members and activities of LAZO, the Latin American Women's Congress, the Hispanic Congress of Ottawa, other ethnocultural associations;
- announcements at Spanish-speaking community and church events;
- advertisements in Eco Latino (Spanish newspaper);
- Spanish community radio programs;
- posters/presentations at settlement agencies, other community health centres;
- networks of service providers and other agencies in the Advisory Committee, including Health Department; and
- posters at local stores that serve the Spanish-speaking community.

Participants in project activities will be invited to participate in the research aspect of the project at first contact (first home visit, attendance at workshop or information session) through Lay Health Promoters, for both survey questionnaire (see, Appendix B) and in-depth interviews (see, Appendix C). An information letter translated into Spanish will be provided (Appendix D) prior to participating in the interviewing process.

Criteria for inclusion in the research study are:

- female
- Hispanic (mother tongue Spanish)
- 16+
- capable of giving informed consent (consent documents translated/presented verbally if needed, see Appendix E)
- currently living in the City of Ottawa

b) Recruitment to participate in a focus group with health service providers in Ottawa will be accomplished by:

- recruiting primary care staff at CCHC
- using CCHC network of CHC in Ottawa to recruit additional physicians, nurse practitioners, and nurses
- using the CHRU's connection with the City of Ottawa's Health Department to recruit public health nurses
- contacting the mammography clinics directly by phone and in writing
- using already established networks to recruit family physicians

An information letter will be provided prior to participation in the focus group (see Appendix E). Draft focus group questions are outlined (see Appendix F).

c) Advisory committee: a number of service providers already have indicated that they will participate in the Project Advisory Committee (AC) (see Appendix G). Additional members will be actively selected from organizations

for whom this study will be of greatest relevance (other CHC, ethnocultural/settlement organizations, other health services, i.e. mammographic clinics). AC members will be asked to participate in interviews on a voluntary basis towards the end of the project (Fall of 2002) (Appendix H).

Outline what the subjects will be required to do. Indicate the number and length of sessions that each subject will participate in. Submit a copy of protocols, questionnaires or other material distributed or administered to the subjects. Do not submit mechanical apparatus. Where scientific instruments involving covert or physical contact are to be used, provide a description of the apparatus, its function and how it will be used (e.g. Electrodes, sensory devices, etc.).

a) Hispanic Women

The development and testing of suitable instruments, specific to the Ontario health system and the Hispanic-Canadian community, is part of the demonstration project. It is estimated (Pasick et al, 1996) that a realistic time frame for developing and translating a final instrument of approximately 100 items across languages/cultures is three to six months. This process will be undertaken as part of the demonstration project. A 101 core-question instrument, covering demographics, health beliefs and practices, and cultural values, which has been used in cross-cultural baseline surveys of intervention trials related to improving early detection of breast and cervical cancer (the "Pathways" project), validated in the United States, is available in Spanish from Pasick et al (1996). Some items from the Pasick instrument may be adapted, and included and/or substituted for those in the draft questionnaires appended.

- written survey: Participants will be asked to complete a written questionnaire (Appendix B) that would take them about 30 minutes to complete. The interviewers will administer the questionnaire.
 - interviews: Interviews will be conducted in Spanish or English (participant choice) by trained lay health promoters. Interviews will be conducted at CCHC, the woman's home, or another place chosen by the interviewee where she feels most comfortable. Each interview will take about one hour (Appendix C). Interviews will be audiotaped with consent of participant.
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- b) Focus Group(s): Focus Groups will be conducted at CCHC. They will be about 2-3 hours in length (Appendix F). Notes will be taken and discussions audiotaped with consent of participants (Appendix I).
- c) Advisory Committee: members of the Advisory Committee will be interviewed towards the end of the project (Fall, 2002). Interviews will be conducted at a site chosen by Advisory Committee member. Each interview will take approximately one hour (Appendix H). Interviews will be audiotaped with consent of participants (Appendix J).

5. Free and Informed Consent (Chapter 2 of the Statement)

Indicate how you will obtain the free and informed consent of the research subjects and, where applicable, of authorized representatives of subjects who are not competent to give consent. Append a copy of the consent form or information sheet to be given to the research subjects.

All research subjects will be informed, verbally and in writing, in Spanish and/or English, that their refusal to participate in the interviews, focus group, or questionnaire will not result in denial of services from CCHC or any other organization involved in the project; and will not result in their exclusion from the educational and support activities of the program.

- a) Informed consent from individual participants will be obtained as follows:
- Spanish-speaking participants will receive a written letter (in English and/or Spanish) explaining the project at recruitment (see Appendix E).
 - Written consent forms, in English and Spanish, will be provided for participants to sign prior to interview or filling out surveys (see Appendix D)
 - Verbal consent will be obtained from participants who are not literate, by reading the consent form and asking participants to consent verbally. Their verbal consent will be recorded on audio tape, for interviews; and noted by the interviewer, for survey questionnaires. The verbal will be read in English and/or Spanish, according to the preference of the participant.
- b) Focus group with health service providers: Informed consent (see, Appendix I) will be obtained prior to participation in the focus group.
- c) Interviews with Advisory committee members: Informed consent (see, Appendix J) will be obtained prior to participation in the interviews.

6. Proportionality of Harms and Benefits (Parts C and D of Chapter 1 of the Statement)

Indicate if the methods used on the research subjects risk causing harm. Describe the nature of such harms or the potential consequences on any legal, physical, psychological or social aspect associated with each procedure in the research or the methods used.

- a) Hispanic women: No legal, physical, or social risks are anticipated. Possibly a very low psychological/emotional risk could result if participants feel uncomfortable to address issues related to breast self examination or cervical cancer. If they desire, they will be referred to appropriate health services. It is also possible that participants may, as a result of their participation, acquire knowledge and skills that will lead to practicing breast or cervical cancer screening- and may, in turn, lead to the eventual detection of illness, in the longer run, and consequent psychological/emotional stress during discovery, diagnosis, and treatment. This type of risk is inherent in any intervention that is aimed at increasing screening behaviour. The immediate psychological/emotional stress will be minimized as much as possible by:

6

- providing information in their own language/language of preference
- providing correct information about steps to follow;
- providing supportive listening (through Lay Health Promoters) so participants can share concerns in own language
- offering referral to appropriate health resources.

b) Focus group: No legal, physical, or social risks are anticipated, given that all participants are professionals and are accustomed to participate in similar discussions about service barriers. Focus groups will be facilitated by the PIs and research staff with extensive experience in leading discussions of this nature.

c) Advisory committee: No legal, physical, or social risks are anticipated. The interviews will focus on working relationship and project accomplishments with little or no anticipated psychological/emotional stress for AC members. Interviews will be conducted by the PIs and research staff with extensive experience in qualitative data collection and interviewing.

Evaluate the level of physical or emotional harms that the research risk to create for the research subjects (None, low, moderate or high).

a) No legal, physical, or social discomforts are anticipated. The level of psychological/emotional discomfort for this study is expected to be very low or nonexistent. Conducting the interviews in Spanish for Spanish-speaking participants will also help alleviate discomfort (see above).

b) Focus group: No legal, physical, or social risks are anticipated, given that all participants are professionals and are accustomed to participate in similar discussions about service barriers. Focus groups will be facilitated by the PIs and research staff with extensive experience to lead discussions of this nature.

c) Advisory committee: No legal, physical, or social risks are anticipated. The interviews will focus on working relationship and project accomplishments with little or no anticipated psychological/emotional stress for AC members. Interviews will be conducted by the PIs and research staff with extensive experience in qualitative data collection and interviewing.

Indicate the measures you have taken to minimize such harms.

Any discomfort encountered by participants will be minimized through participant anonymity, their ability to withdraw at any time without reprisal, their right of refusal to answer any particular question, and their ability to censor what they choose to relate to us.

7. Privacy and Confidentiality (Chapter 3 of the Statement)

Specify how you will ensure the anonymity of the research subjects and the confidentiality of data. Explain how the subjects will be protected if you are not using

pooled data. Where subjects are interviewed, state whether the interviewees will be quoted, and if so, how their anonymity will be ensured. If anonymity cannot be guaranteed, explain why and mention it on the consent form or information sheet given to the subject.

Questionnaires will be assigned anonymous unique codes known only to the researchers. Interviews will be audio taped with consent. All interviews with Hispanic women will be coded with an anonymous unique code known only to the researchers. This unique code will be used with all transcripts, tape labels, translation (Spanish to English) and quotations used in subsequent documents. Questionnaires, tapes, transcripts, and identification codes will be stored in locked facilities and only researchers will have access to them. Permission for anonymous quotations will be obtained from participants, and all efforts will be made to reduce identifying information in the quotations.

Anonymity will be maintained for all Advisory Committee member interviews. Interviews will be audio taped with consent. All interviews with Advisory Committee members will be coded with an anonymous unique code known only to the researchers. Complete confidentiality of Advisory Committee members might not be possible in all cases. AC members might be identifiable through their affiliation with their organizations (e.g., there is only one Ontario Breast Screening Program Clinic in Ottawa) and it might be necessary to highlight specific achievements, or changes made within the organization as a result of participation in this research project. Interviewees, therefore, will be informed of this risk at the beginning of the interview. At the end of the interview, they will be asked whether they would like to withdraw their interview, or sections of their interview, from the data. If yes, they will be given the choice of erasing sections then and there, or they will be given the tape of the interview to keep, in which case, no interview information will enter the records.

8. Attestation

I agree to abide by the ethical guidelines and procedures of the University of Ottawa Research Ethics Boards, of the Tri-Council Policy Statement, of my profession or discipline, as well as of the institution in which the research is undertaken. I am aware of my responsibility to be familiar with these standards. I further agree to notify the appropriate Research Ethics Board of any substantive change in the use of human subjects in this research and to comply with requests made by such Board during the life of this research.

Name	Signature	Date
Lynne MacLean		
Alma Estable		
Sara Torres		

I agree to abide by the guidelines, ethical principles and code of ethics adopted by the UHREC and its subcommittee, and where applicable, by those of the granting agency to which this proposal is being submitted, and by those of my profession or discipline, as well as by those of the facility or institution in which the research is undertaken. I am aware of my personal responsibility to be familiar with these standards. I further agree to notify the UHREC and the Human Research Ethics Committee of the Faculty of Health Sciences of any substantive changes in the use of human participants in this research and to comply with requests by UHREC or its subcommittee for other information/documentation during the life of this research.

SIGNATURE OF PRINCIPAL INVESTIGATOR(S)

_____ DAY _____ MONTH _____ YEAR _____

_____ DAY _____ MONTH _____ YEAR _____

_____ DAY _____ MONTH _____ YEAR _____

List of Appendices

NB: All information letters, consent forms, and questionnaires used in this project will be translated to Spanish and back-translated to English, to ensure that concepts and constructs are accurately conveyed and questions are phrased in a culturally appropriate way. Therefore, the specific wording of the final Spanish versions may vary from the English. In addition, in accordance with participatory methodologies used in this project, all data collection tools are in draft format and will be reviewed and adapted taking into account the input of the project participants (AC members, Lay Health Promoters).

Appendix A - Mother tongue/ethnicity question

Appendix B - Survey questionnaire For Women Participants

Appendix C - Interview questions with women participants

Appendix D - Consent Form: Women Participants

Appendix E - Information Letter to focus group participants (service providers)

Appendix F - Focus Group Questions

Appendix G - List of the Advisory Committee

Appendix H - Interview questions for Advisory Committee members

Appendix I - Consent Form: Focus Group With Service Providers

Appendix J - Consent Form: Interviews With Advisory Committee Members