SUBJECT:	Research & Evaluation	**POLICY NUMBER:**	2-040
SECTION:	Administration	Page 1 of 6	
IMPLEMENTATION:	March 4 1992	**APPROVAL:**	Senior Leadership Team
SPONSOR:	Medical Officer of Health	**SIGNATURE:**	

PURPOSE

To ensure all research and evaluation in which the Health Unit collaborates or participates honours the Middlesex-London Health Unit (MLHU) mission statement.

To support the integration of evidence-informed decision-making with delivery of programs and services.

To ensure that findings from research and evaluation conducted at MLHU are disseminated internally to program staff and managers and broader dissemination through a variety of media is encouraged when appropriate e.g., peer reviewed publications, conferences, social media.

To maximize the impact of resources dedicated to research and evaluation and to the dissemination and uptake of findings.

To ensure appropriate ethical assurances are sought and maintained.

POLICY

The Foundational Standard prescribes that the Board of Health shall have effective partnerships with community researchers, academic partners, and other appropriate organizations to support public health research and knowledge exchange. It also indicates that the Board of Health shall also engage in public health research activities, which may include those conducted by the Board of Health alone or in partnership or collaboration with other organizations.

Research undertaken by the MLHU will be directed towards the determinants of health, public health planning, program evaluation, policy analysis and service delivery. It will be practical, will often involve community, and will be defined by actual and emerging public health issues.

Applied public health research that involves MLHU staff, clients or resources will contribute to the development or refinement of sound public health practice, and meet recognized scientific, methodological, ethical, and protection of privacy standards.

The Research Advisory Committee (RAC) is a standing committee of the Health Unit and reports to the Senior Leadership Team. Senior Leadership Team will ensure the terms of this policy are met. Recommendations made by the RAC panel will be adopted at the discretion of the Director. It is the Manager's responsibility to implement the approved changes.

Research projects do not need to have received RAC approval prior to submission for external funding however they must receive approval prior to commencing any work on the project.

Researchers conducting research through MLHU are expected to disseminate their findings to program staff and managers and more broadly when appropriate.

PROCEDURE

Required Research Advisory Committee (RAC) reviews

Research and Evaluation projects that REQUIRE a RAC review include those that:

- collect, store, access, analyze or share personal information, personal health information or information that could potentially be linked to an identifiable person (See Appendix A: Definitions of Personally Identifiable Information)
- require external partners or researchers to access record level or client data held by MLHU
- require external partners or researchers to access MLHU staff or board member data through individual level records (e.g. personnel files) or information through surveys, focus groups, etc.
- require MLHU to access record level or client data held by an external partner
- collect a biological specimen
- pose a greater than minimal risk of harm[1] to participants (e.g. survey questions that may be upsetting or lead to stigmatization if data was released)
- evaluate, research or make recommendations about a vulnerable population[2] which could pose a potential risk to that population (e.g. stigmatization, power imbalance, coercion through excessive incentives)
- include people who are not competent to provide consent (i.e. age, language, literacy, mental capacity)
- provide an incentive that has a value of $20 or more to participants
- have a methodologically complex study design (e.g. sophisticated sampling strategy beyond convenience sampling, requires a sample size calculation, longitudinal follow-up, randomization of subjects, qualitative methods that involve multiple sources, involves transcription, in-depth thematic analysis)
- have a known conflict of interest

Research and evaluation projects that DO NOT REQUIRE a RAC Review include:

- Routine public health surveillance
- Outbreak investigations
- Requests for assistance in recruiting MLHU clients or partners by external researchers where MLHU is not participating or sponsoring the project. Assistance may include posting a flyer, allowing the researcher to attend a health unit sponsored event to describe the study or including a notice of the study in a health unit mailing. Under these circumstances, the responsible Director/Manager may approve such requests. The standardized form, Appendix B: Request to Recruit Participants for External Research Projects is available as a guide to facilitate decision-making about participation.

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[1] The Tri-Council Policy Statement (TCPS2): Ethical Conduct for Research Involving Humans definition of 'minimal risk': "The research can be regarded as within the range of minimal risk if potential participants can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the participant in those aspects of his or her everyday life that relate to the research."

[2] The Tri-Council Policy Statement (TCPS2): Ethical Conduct for Research Involving Humans indicates "Individuals or groups in vulnerable circumstances have historically included children, the elderly, women, prisoners, those with mental health issues and those with diminished capacity for self-determination. Ethnocultural minorities and those who are institutionalized are other examples of groups who have, at times, been treated unfairly and inequitably in research, or have been excluded from research opportunities. People or groups whose circumstances cause them to be vulnerable or marginalized may need to be afforded special attention in order to be treated justly in research."

- Data collection by external agencies about their programs (e.g. follow-up survey after webinar)
- Requests for information in the form of environmental scans or other similar surveys from public health colleagues and partners for the purposes of collaboration and knowledge exchange.
- Accreditation processes by an external body where MLHU is seeking accreditation.

The RAC Review process is also available to provide informal consultations or formal review for projects that do not require a formal RAC review but where the project lead would like guidance in methods development, study design, etc.

The Research Advisory Committee

The RAC is composed of staff members from MLHU and, at a minimum, will have representation from the privacy officer, a director, a manager and a member who is competent in relevant public health research and evaluation methods. If possible, at least one member of the committee should have ethics expertise. RAC Committee membership will be for a term of two years. The RAC Chair position will rotate every two years. Senior Leadership Team will appoint the Chair who must be selected from the existing membership of the RAC Committee. Committee members will be recruited by the current RAC Chair. The RAC committee will meet two to four times per year to review the RAC process and all completed reviews to ensure the process is effective and efficient. The RAC Chair retains a copy of the project proposal documents and correspondence related to the proposal. All of the RAC files will be stored together and will be accessible to the current RAC Chair. These documents will be used as part of the RAC process evaluation.

Review of Project Proposals
In planning a project the Project Lead must consult with service area epidemiologist or program evaluator and consider Appendix C: Research and Evaluation Checklist.

During the formulation of the project plans, the Project Lead discusses the project with his or her Manager and the service area epidemiologist or program evaluator to determine if the project requires a RAC review as outlined above.

If the Project Lead is external to MLHU, s/he must connect with the RAC Chair to discuss the project.

If a review is needed, the Project Lead completes Appendix D: Project Summary Form and submits to the Director(s) of the services area(s) which will be involved in the project. The Director(s) will assess the project according to the issues of resource implications and reputational risk for MLHU.

If the Director(s) decides that project will not proceed, s/he will return the original summary to the Project Lead with an explanation for the decision.

If the Director(s) decides that the project will proceed, the Director(s) requests the Project Lead complete Appendix E: Project Review Request Form requesting detailed information on the design of the project. This information is essential for the RAC Review Panel to assess if the project complies with the Research Policy.

The Director(s) forwards Appendix E: Project Review Request Form to the Chair of the RAC.

Proposals submitted to a Research Ethics Board (REB) governed by the Tri-Council Policy Statement (e.g., University, Hospital) are acceptable for submission to RAC. The REB application form and outcomes must be submitted to the Director(s) by the project lead and accompanied by Appendix F: REB Approved Project Review Request Form. The Director(s) will then forward the documents to the RAC Chair.

Upon receipt of a completed Appendix E: Project Review Request Form or Appendix F: REB Approved Project Review Request Form the RAC Chair will be responsible to form a RAC Review Panel which has:

- at least three reviewers who can be internal or external to MLHU
- a Lead Reviewer from current RAC Members
- at least one member who is competent in relevant public health research and evaluation methods
- at least one member who has knowledge of the relevant subject area

To ensure timely review of the proposals:

1. The RAC Review Panel is formed within one week of receipt of the proposal. The RAC Review Panel members review the proposal independently and complete Appendix G: Project Review Form.
2. The RAC Review Panel meets to assess the proposal, within four weeks of receipt of proposal.
3. The Panel will make a joint recommendation whether the project should proceed, proceed with revisions or not proceed. The Lead Reviewer is responsible for compiling feedback on Appendix G: Project Review Form and must send a copy to the Project Lead, Manager, Director(s), Medical Officer of Health and RAC Chair within six weeks of receipt of the request.

The RAC Panel Lead Reviewer may invite the Project Lead to the panel meeting to provide or clarify information about the proposal or the project. Note that only the RAC Review Panel may be present for the discussion about recommendations for the project.

If there is any delay in the timeframes outlined above the RAC Chair will inform the Project Lead.

In extenuating circumstances, a special request may be made for an expedited review (where the timelines for the review process are shortened). In these cases the Project Lead will notify the RAC Chair in advance of proposal completion when the completed proposal will be available. The RAC chair will convene a review committee and set dates for review meetings

based on the anticipated proposal completion date. Granting expedited review will be at the discretion of the RAC Chair.

The Lead Reviewer will make him or herself available to Directors and/or the Project Lead to discuss the review results upon request. The RAC Chair will keep a roster of health unit staff and external reviewers who have participated in RAC proposal reviews.

The RAC chair will notify the Senior Leadership Team of the result of all project proposal reviews quarterly. The Senior Leadership Team will determine if further communication about the project proposals with the Board of Health is required.

Ethics Review
RAC may request that a Tri Council Policy Statement 2 compliant ethics review be sought for projects that are submitted to RAC. Proposals may be simultaneously submitted for review by the RAC and a research ethics board.

Data Ownership
Data collected by staff and researchers employed by MLHU will remain the property of MLHU. Data collected by other researchers will remain the property of the principal investigator unless otherwise negotiated.

Dissemination and Uptake of Research Findings
All reports and publications resulting from research conducted at MLHU by health unit staff must be forwarded to the Library. If an external investigator conducted the research, the responsible Service Area Director will ensure that the principal investigator submits one copy of the completed research report to the RAC Chair. The RAC Chair forwards the copy to the MLHU library for cataloguing.

External researchers involving health unit clients or data and MLHU staff conducting research at MLHU will be expected to disseminate findings and practice implications to program staff and managers. Additional dissemination is encouraged which may include Board of Health reports, peer-reviewed articles, media, website, etc. Where possible and appropriate, distribution and release of research reports will follow the presentation of the reports to the Board of Health. The program staff, in consultation with the Communications Manager, should identify a spokesperson(s) for the research prior to the release of any reports.

Inventory of Research Projects
An Inventory of Research Projects will be presented to the Board of Health annually. The Inventory will include research in which MLHU staff were either the lead investigators or collaborated with researchers from other institutions and research projects conducted by students in collaboration with MLHU. The Manager of Strategic Projects will ensure that the Inventory of Research Projects is completed.

APPENDICES
Appendix A: Definitions of Personally Identifiable Information
Appendix B: Request to Recruit Participants for External Research Projects

Appendix C: Research and Evaluation Checklist
Appendix D: Project Summary Form
Appendix E: Project Review Request Form
Appendix F: REB Approved Project Review Request Form
Appendix G: Project Review Form

Definitions of Personally Identifiable Information

The following definitions have been provided to assist you in determining if your research project involves any information that might be covered by privacy legislation. Please note that this is not an exhaustive list. Personal information may include *any* information that could reasonably be expected to identify an individual.

Information and Privacy Commissioner, Ontario

Personal Information
(As defined within the *Municipal Freedom of Information and Protection of Privacy Act* (MFIPPA), 1990.

Personal information means recorded information about an identifiable individual including,

a) Information relating to the race, national or ethnic origin, colour, religion, age, sex, sexual orientation or marital or family status of the individual,

b) Information relating to the education or the medical, psychiatric, psychological, criminal or employment history of the individual or information relating to financial transactions in which the individual has been involved,

c) any identifying number, symbol or other particular assigned to the individual,

d) the address, telephone number, fingerprints or blood type of the individual,

e) the personal opinions or views of the individual except if they relate to another individual,

f) correspondence sent to an institution by the individual that is implicitly or explicitly of a private or confidential nature, and replies to that correspondence that would reveal the contents of the original correspondence,

g) the views or opinions of another individual about the individual, and

h) the individual's name if it appears with other personal information relating to the individual or where the disclosure of the name would reveal other personal information about the individual.

Personal Health Information
(As defined by the *Personal Health Information Protection Act* (PHIPA), 2004.
Personal health information, …means, identifying information about an individual in oral or recorded form, if the information,

a) relates to the physical or mental health of the individual, including information that consists of the health history of the individual's family;

b) relates to the providing of health care to the individual, including the identification of a person as a provider of health care to the individual;

~~c)~~ relates to payments or eligibility for health care, or eligibility for coverage for health care, in respect of the individual;

d) is the individual's health number; or

e) identifies an individual's substitute decision-maker.

NOTE: the legislation also contains a number of exceptions. Contact the Privacy and OHS Manager to assist you in determining if the information you are working with is considered to be personally identifiable information.

Request to Recruit Participants for External Research Projects

In the event that your Service is contacted by **external researchers** to recruit research participants and **MLHU is not participating in or sponsoring the project,** the following criteria are offered:

- to assist in assessing the suitability of the request, and
- in documenting the project in the event that queries are received.

Please note that the Research Advisory Committee does not review these requests but is available for consultations if requested. ***We recommend that you keep this form on file for future reference.***

Title of Project:	
Purpose of the Project:	
Principal Investigator(s)	
Academic Institution	
If student, Faculty Supervisor	
Contact Person:	
Phone	
Ethics Review: YES ☐ NO ☐ If yes, by whom:	

Expectations of MLHU ***(please circle applicable)*** e.g. - post flyers - provide access to clients - contact potential recruits - other ***(please describe)***	
Timeline/Time Required	
Consistency with MLHU/Service mission, mandate and philosophy	
Additional Comments	
Assessment of Potential Risk or Benefit to: - MLHU - HU Clients	

Health Unit Use Only

Decision: Allow Recruitment ☐ Recruitment Declined ☐

Date: _____ ***Manager/Director*** Signature: _____

Title:

Research and Evaluation Checklist

☐ **Is the program you want to research or evaluate clearly defined?**
- Have you defined your program goals, population of interest, and outcome objectives?
- Have you defined your activities and outputs?
- Have you identified measurable outcome indicators?

☐ **What is the purpose of the research or evaluation project?**
- What would be most helpful to know?
- What are your evaluation questions**?**

☐ **Have you engaged stakeholders?**
- Do you understand stakeholders' interests and expectations?
- Are stakeholders participating in the process?
- Are research or evaluation questions based on program goals and objectives and stakeholders' interests/expectations)

☐ **Do you have the resources to conduct this research or evaluation?**
- Do you have staff with the necessary skill sets and time?
- Do you have money allocated?

☐ **Have you clearly articulated your design?**
- What is the research design?
- Is this a formative (needs assessment), process, outcome or developmental evaluation?
- Do you have a written plan?
- Have you considered the privacy and ethical issues (see Appendix A: Definitions of Personally Identifiable Information)?

☐ **Can you clearly describe your methodology?**
- What kind of study are you implementing?
  (e.g. literature review, survey of experts, interviews/survey of target population, analysis of administrative data, pre/post outcome measures)
- Is this a qualitative, quantitative or mixed-methods study design?
- Are you using a previously developed data collection tool or are you developing your own? Can you justify your choices? Have you pilot tested your instruments?
- Do your methods allow you to collect the information you need?
- Have you clearly described your sampling strategy?
- Do you have an analysis plan?

☐ **Do you have a clearly articulated work plan, budget and timeline?**
- Have you identified individuals responsible for specific tasks and roles including data collection, analysis, reporting, and implementing the results?
- Have you allocated the appropriate amount of time and resources for these tasks?
- Have you articulated the timelines?

For more information or support in answering these questions, please contact your service area Epidemiologist or Program Evaluator.

Research/Evaluation Proposal: Summary Form

Purpose/Objectives of the study:

-

Methodology:

Study Design

-

Data Source (clients, records, etc)

-

Sampling Considerations (i.e. sampling strategy, sampling procedure, sample size)

-

Procedure for Data Collection

-

Analysis Procedure

-

Resource Implications for MLHU (i.e. what MLHU Services are needed)

-

Organizational risk/benefit to MLHU (e.g. finances, human resources, legislation, reputation)

-

General Timeframe (include proposed start date)

-

How do you propose to share the results of this research?

Research Advisory Committee
Project Review Request Form

Instructions:
1. Determine if your project requires a Research Advisory Committee (RAC) review in accordance with section 1.1 of the Research Policy (Policy # 2-040).
2. If RAC review is required, download this form and complete it on your computer. Hand written applications will not be accepted.
3. Submit one electronic copy and one hard copy of this completed and signed form with all attachments to the RAC Chair.

A. Project Lead

If there is more than one Project Lead, provide their name(s) and contact information below in Section B, Other Project Team Members.

Name: Title/Position:

Phone: Service Area:

Team:

B. Project Information

Project Title:

Anticipated Start Date (yyyy/mm/dd): Anticipated End Date (yyyy/mm/dd):

Specify any known interim deadlines:

Consulting Epidemiologist/Program Evaluator (if applicable):

Other Project Team Members (Include co-investigators, students, employees, volunteers, community organizations. The form will expand.)

Contact Name	Role in Project	Institutional Affiliation	Email or Phone

Source(s) of Project Funding	Amount

Is approval required by some other agency, community group, local governments, etc.?

☐ Yes ☐ No

If yes, please indicate the type and list the name of each organization:

FOR RAC USE ONLY	Primary Reviewer:	Date Received:	Date Review Completed:

Have you or do you plan to submit this to a Research Ethics Board?

☐ Yes ☐ No

If yes, you can attach the REB submission form and complete section A, B and C only.

C. Description of Project

Does the project (check all that apply):

☐ collect, store, access, analyze or share personal information, personal health information or information that could potentially be linked to an identifiable person (See Appendix A: Definitions of Personally Identifiable Information)?

☐ require external partners or researchers to access record level or client data held by MLHU?

☐ require external partners or researchers to access MLHU staff or board member data through individual level records (e.g. personnel files) or information through surveys, focus groups, etc.

☐ require MLHU to access record level or client data held by an external partner?

☐ collect a biological specimen?

☐ pose a greater than minimal risk of harm[3] to participants (e.g. survey questions that may be upsetting or lead to stigmatization if data was released)?

☐ evaluate, research or make recommendations about a vulnerable population[4] which could pose a potential risk to that population (e.g. stigmatization, power imbalance, coercion through excessive incentives)?

☐ include people who are not competent to provide consent (i.e. age, language, literacy, mental capacity)?

☐ provide an incentive that has a value of $20 or more to participants?

☐ have a methodologically complex study design (e.g. sophisticated sampling strategy beyond convenience sampling, requires a sample size calculation, longitudinal follow-up, randomization of subjects, qualitative methods that involve multiple sources, involves transcription, in-depth thematic analysis)?

☐ have a known conflict of interest?

If any of the above are checked, a RAC review is required.

A RAC review can be requested, even if it is not required, in circumstances such as:

☐ Request guidance on study design, particularly when it comes to statistical or methodologically complex issues

☐ Request guidance on cost-effectiveness of a large time or resource intensive projects

☐ Other, specify:

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[3] The Tri-Council Policy Statement (TCPS2): Ethical Conduct for Research Involving Humans definition of 'minimal risk': "The research can be regarded as within the range of minimal risk if potential participants can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the participant in those aspects of his or her everyday life that relate to the research."

[4] The Tri-Council Policy Statement (TCPS2): Ethical Conduct for Research Involving Humans indicates "Individuals or groups in vulnerable circumstances have historically included children, the elderly, women, prisoners, those with mental health issues and those with diminished capacity for self-determination. Ethnocultural minorities and those who are institutionalized are other examples of groups who have, at times, been treated unfairly and inequitably in research, or have been excluded from research opportunities. People or groups whose circumstances cause them to be vulnerable or marginalized may need to be afforded special attention in order to be treated justly in research."

What are the relevant objectives and outcomes of the PROGRAM you are evaluating or studying?

What are the research or evaluation questions you would like answered by this evaluation/research PROJECT?

Please summarize or attach a summary of background information you have collected related to the project from a literature review, other health units, and other sources.

D. Study Design

What study design will be used?
Check all that apply
☐ Pre and post-test
☐ Post-test only
☐ With control/comparison group
☐ Cross-sectional without intervention (e.g. needs assessment)
☐ Analysis of secondary data
☐ Focus groups
☐ Key informant interview
☐ Document Analysis
☐ Other, specify:

E. Study Population

Briefly describe the study population(s) (e.g. age, gender, ethnicity, socio-economic status, single parents, students, clients vs. potential clients, etc.).

Why is this population of interest?

In what way have the research subjects been involved in the study design (e.g. defining problems, recruitment, developing research designs, considering implications of findings)?

F. Recruitment and Selection of Participants

Attach all relevant recruitment materials in an appendix (i.e. information letter, consent form).

What type of selection process or sampling method will be used?
☐ Simple random sample (sample represents the population of interest)
☐ Complex sample (stratified or cluster)
☐ Convenience sample (sample may not represent the population)

☐ Census (entire population of interest)
☐ Purposeful sample (sample deliberately selects particular segments of a population)
☐ Other, specify:

Describe how recruitment will be done (e.g. in person, by telephone, letter, email, advertisement, web-based, social media).

What source(s) will participants will be recruited from?

Do you have the appropriate permissions or mandate to recruit participants from the data source?

What are the participant inclusion/exclusion criteria?

What is the sample size?

How did you determine the sample size?

What strategies will be used to increase response rate (if applicable)?

Will it be clearly communicated to participants that their participation is entirely voluntary with no negative consequences to service provision if participation is declined or withdrawn after consenting?

G. Data Collection Methods and Tools

Which of the following methods will be used to collect data?
Check all that apply.
☐ Face-to-face interview
☐ Telephone interview
☐ Focus groups
☐ Paper survey
☐ Online survey
☐ Observing participants
☐ Collecting environmental samples (e.g., air, water, soil)
☐ Using human biological samples (e.g., urine, blood, hair)
☐ Analyzing secondary data (data previously collected for another purpose)
☐ Other, specify:

Will the participants be audio or video recorded?
☐ Yes ☐ No

If interviewing participants, who will be doing the interviews (e.g. hired research assistant, clinic staff, program evaluator)?

If interviewing participants, will interviewers be receiving any type of research interview training?
☐ Yes ☐ No, please explain

Are your data collection and assessment tools:
☐ Existing tools
☐ Adapted from existing tools
☐ Newly developed for this project

List and attach copies of all data collection and assessment tools (e.g. questionnaires). Provide the source information of all questions adapted from existing tools.

To what extent have your tools been pre-tested or validated?
☐ Has not been pre-tested, validated or used by others
☐ Don't know
☐ Pre-tested
☐ Used in another study
☐ Formally validated tool

Provide details on results of any pre-testing completed.

H. Data Entry and Analysis

Describe your data entry plan? (Who will be doing it? What software program will be used? What are your data validation procedures?)

Outline your data analysis plan (include the type of statistical tests (quantitative) or thematic analysis (qualitative) that will be completed)

I. Results

How will the results of this research project be used to influence program planning?

What are your product/deliverables of this project (e.g. report, Board Report, summary report, presentation, video)

How will the results be disseminated? (e.g. directly to participants, shared internally, media, publications, social media)

J. Possible Benefits, Inconveniences, Risks and Harms

The Tri-Council Policy Statement (TCPS) definition of "minimal risk" is as follows:

> *"The research can be regarded as within the range of minimal risk if potential participants can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the participant in those aspects of his or her everyday life that relate to the research."*

Based on this definition, do you believe your research or evaluation qualifies as "minimal risk"?

☐ Yes ☐ No

Identify and explain any potential or known benefits to participants, society or state of knowledge, associated with participation.

Identify and describe any known or potential inconveniences to participants or others (e.g. time devoted to the research, travel)

What are the risks to participants? (e.g. physical, emotional, psychological, economic, legal, etc.)

What are the potential inconveniences or risks for MLHU? (e.g. service disruption as a result of data collection, increased program costs, risk management issues).

What will you do to minimize or prevent the risks or inconveniences outlined above?

How will you respond if harm occurs?

K. Compensation

Is there any compensation for participating in the research? (e.g., gifts, money, bonus points)

☐ Yes ☐ No

If yes, what is the nature and value of the compensation and why do you consider it to be necessary:

L. Free and Informed Consent

The following questions address the competence of participants to give consent, the process used in your research to obtain consent, ongoing consent, and the participants' right to withdraw.

Will consent be obtained?
☐ Yes ☐ No, please explain.

If yes, describe prospective participants.
Check all that apply
☐ Adults (18 and older)
☐ Youth (14-17)
☐ Children (< 14 years of age)
☐ Institutionalized (e.g. inmates, institutionalized patients, wards of the state)
☐ Mental health issues
☐ Low literacy
☐ Non-English speaking or English as a second language

From whom will consent be obtained? (Check all that apply)
☐ Participant
☐ Family/authorized representative
☐ Parent or guardian

How will consent be obtained? (Check all that apply and attach copies of all consent materials.)
☐ Signed consent form

☐ Verbal consent, specify how you will document that the individual has provided their consent.

☐ Implied consent, specify the steps taken to ensure implied consent model is valid for this project

☐ Other means, specify

☐ Consent will not be obtained, explain why not:

Have the project and associated risks been adequately explained?

If understanding the consent could be difficult for the participant please describe how you will mitigate the difficulty (e.g. translation, verbal explanation, ensuring appropriate literacy level*)*

M. Anonymity and Confidentiality

Complete this section, only if you indicated under Section C that your project will "collect, access, analyze, or store personal information, personal health information or information that could potentially be linked to an identifiable person."

Are you collecting, accessing, analyzing or storing personal information or personal health information that could be characterized as "sensitive"[5]?

☐ No
☐ Yes. Please specify

At what level is the personal information that is used within your projected able to be linked to an identifiable individual?

☐ Identifying information: The information identifies a specific research participant through direct identifiers (e.g., name, address, social insurance number or personal health number).
☐ Identifiable information: The information could be used to re-identify a participant through a combination of indirect identifiers (e.g., date of birth, place of residence or unique personal characteristic) using reasonably foreseeable means.
☐ De-identified/coded information: Identifiers are removed and replaced with a code. Depending on access to the code, it may be possible to re-identify specific research participants (e.g., participants are assigned a code name and the principal investigator retains a list that links the code name with the participant's actual name so data can be re-linked if necessary.) Researchers who have access to the code and the data have identifiable information.
☐ Anonymized information: Information is irrevocably stripped of identifiers, and a code is not kept to allow future re-linkage.
☐ Anonymous information: Information never had identifiers associated with it (e.g., anonymous surveys).

Describe how the personal information of the participants will be protected against theft, loss, unauthorized access, unauthorized disclosure and unauthorized modification? Note, safeguards and security measures should be relative to the level of identifiability and sensitivity of the personal information. Include information on the following:

Means of storing data (e.g., a locked filing cabinet, password protected computer files):

Location of storing data:

Who will have access to data and for what purposes? Describe the measures you've taken to limit or restrict access to any personal information about an identifiable individual?

Duration of data storage:

[5] The ***CIHR Best Practices for Protecting Privacy in Health Research*** - September 2005, indicates that the "sensitivity of personal data is related to the potential for harm or stigma that might attach to the identification of an individual because of the nature of the information. "The type of information that an individual may consider sensitive could relate to: sexual attitudes, practices and orientation; use of alcohol, drugs, or other addictive substances; illegal activities; suicide; sexual abuse; sexual harassment; an individual's psychological well-being or mental health; some types of genetic information (e.g. information that predicts future illness or disability and raises concerns around future employability or insurability; and any other information that, if released, might lead to social stigmatization or discrimination (p. 30).

Methods of destroying data:

During dissemination:

Other:

N. Researcher-related Risks

Are you or any of your co-researchers in any way in a position of authority or influence over participants? Examples of this situation include inspectors-restaurant owners, therapists-clients, supervisors-employees and possibly researcher-relative or researcher-close friend.

☐ Yes ☐ No ☐Varies

If yes or varies, describe below:

1. The nature of the relationship.
2. Why it is necessary to conduct research with participants over whom you have power.
3. What safeguards (steps) will be taken to minimize inducement, coercion or potential harm.
4. How the dual-role relationship and the safeguards will be explained to potential participants.

Are you or any of the research team members in a perceived, actual or potential conflict of interest with regard to this research project? (e.g. in relation to participants, partners in research, private interests in companies or other entities)

☐ Yes ☐ No

If yes, please provide details of the conflict and how you will manage it.

Does this research study pose any risks to the researchers, assistants and data collectors?

If there are any risks, explain the nature of the risks, how they will be minimized, and how they will be responded to if they occur.

O. Agreement and Signatures

Project Lead, Manager and Director affirm that:

- *I have read this application and it is complete and accurate.*

- I attest that all persons named in Section B of this document as well as program managers and service area director(s) have reviewed the contents and are in agreement with the project information and
  protocols as submitted;
- *The research will be conducted in accordance with the Middlesex-London Health Unit regulations, policies and procedures governing the ethical conduct of research involving human participants.*
- *The research will not commence until approval has been granted.*

Project Lead

_____
Signature

_____
Print Name

_____
Date

Manager

_____
Signature

_____
Print Name

_____
Date

Director

_____
Signature

_____
Print Name

_____
Date

Additional Manager (if applicable)

_____
Signature

_____
Print Name

_____
Date

REB Approved Project Review Request Form

If you have received approval from a Research Ethics Board (REB) you must complete this form. Please forward this form along with your completed REB form and approval to the appropriate Director.

Title:

-

Purpose of the project:

-

Contact:

Principal Investigator(s), Academic Institution

Contact Person, Phone

-

Expectations of MLHU (describe what resources will be needed from MLHU)

-

Organizational risk/benefit to MLHU (e.g. finances, human resources, legislation, reputation)

-

Timeline/Time Required

-

Assessment of Potential Risks or Benefits to MLHU and study participants

-

Additional Comments

-

Agreement and Signatures

Project Lead, Manager and Director affirm that:

- *I have read this application and it is complete and accurate.*
- *The research will be conducted in accordance with the Middlesex-London Health Unit regulations, policies and procedures governing the ethical conduct of research involving human participants.*
- *The research will not commence until approval has been granted.*

Project Lead	**Manager**
_____	_____
Signature	*Signature*
_____	_____

This form has been adapted from the Durham Region Health Department Research Project Review Request Form

Print Name	Print Name
Date	Date
Director	**Additional Manager or Director (if applicable)**
Signature	*Signature*
Print Name	Print Name
Date	Date

Research Advisory Committee
Project Review Form

Project Description:

Project Title:	
Project Lead:	
Phone:	
Program Area:	
Anticipated Start Date:	
Required Signatures Included:	☐

Public Health Impact	Yes	No	Provide explanation or suggestions for improvement, where applicable:
Is the project relevant or important to Public Health, the health unit or community?	☐	☐	

Methodological Review:	Yes	No	Provide explanation or suggestions for improvement, where applicable:
Is/Are the research question(s) clearly stated?	☐	☐	
Is the relationship to the program objectives and/or outcomes clearly identified?	☐	☐	
Does the Project Lead seem to be familiar with current work in the area?	☐	☐	
Will the study design address the research question(s)?	☐	☐	
Is it clear who is being studied?	☐	☐	
Is the sampling methodology appropriate?	☐	☐	
Is the recruitment strategy appropriate?	☐	☐	
Are the data collection tools appropriate?	☐	☐	
Is the analysis plan appropriate?	☐	☐	
Is there an appropriate plan for the use and dissemination of the results?	☐	☐	
Does the research team have the	☐	☐	

required skills to complete the project?			
Are there any other methodological concerns?	☐	☐	

Risk Assessment:	Yes	No	N/A	Provide explanation or suggestions for improvement, where applicable:
Have the risks to participants been adequately minimized?	☐	☐	☐	
Are there adequate plans to address potential risks to participants?	☐	☐	☐	
Is compensation appropriate?	☐	☐	☐	
Is the consent process appropriate?	☐	☐	☐	
Will the personal or personal health information be adequately protected?	☐	☐	☐	
Have issues of power-over and/or conflict of interest been addressed?	☐	☐	☐	
Have the risks to researchers been adequately minimized?	☐	☐	☐	
Does the activity set up any inequities (i.e. treatment, intervention) and is it being dealt with adequately?	☐	☐	☐	
Is there potential impact on the client–service provider relationship if the participant refuses to participate?	☐	☐	☐	
Does this project require a tri-council policy ethics review?	☐	☐	☐	
Has there been a tri-council policy ethics review?	☐	☐	☐	
Is the biological sampling process safe and appropriate?	☐	☐	☐	

Is there potential organizational risk in the dissemination of messages?				
Are there other potential organizational risks as they relate to methodology, ethics, or privacy?	☐	☐	☐	
Is there a plan to address the organizational risks identified above?	☐	☐	☐	

Comments/ issues for further discussion:

Review completed by:

Lead Reviewer _____

Signature: _____

Date: _____

Recommendations of the Panel:

Proceed	Proceed with revisions	Do not proceed

Required Revisions: