Public Health Ontario RISK SCREENING TOOL 2.0

LEAD APPLICANT AND PROJECT INFORMATION

Project Title:
First Name:
Last Name:
Position Title:
Lead Program Area/Department and Name of Organization:
If Lead Applicant is a student, please indicate name of supervisor, and name and type of program (Undergrad, Masters, PhD, Post-Doc, Resident):

CONTACT PERSON FOR PROJECT CORRESPONDENCE

☐ Same as Lead Applicant *(if not, then please fill in contact information below)*
First Name:
Last Name:
Position Title:
Lead Program Area/Department and Organization:

OTHER ETHICS BOARD APPROVALS

Will the proposed project be reviewed, or has the proposed project been approved, by another Ethics Review Board or Research Ethics Board?
☐ No (If NO, proceed with completion of form)
☐ Yes (If YES, RST completion may not be required. Please check with the Ethics Office.)

SECTION 1: ADMINISTRATIVE SCREEN

1.1 Is there an administrative reason why this project should receive Ethics Review Board (ERB) review? Select all that apply.

1	☐ Condition of external sponsor/funder. *Please specify name of sponsor/funder:*
1	☐ Required for use or disclosure of personal health information
1	☐ Other. *Please specify:*
0	☐ None of the above

SECTION 2: SENSITIVITY

2.1 Are analyses or reporting planned regarding any of the following potentially vulnerable populations or groups? Select all that apply.

2	☐ Institutionalized individuals
2	☐ Persons engaging in illegal activity
2	☐ Persons associated with or engaged in potentially stigmatizing conditions or activities (e.g., drug use, diagnosed with XDR-TB)
2	☐ First Nations, Inuit or Métis Peoples
1	☐ Named ethnic, faith-based or other groups
1	☐ Identifiable neighbourhoods or communities
1	☐ Other groups for which the findings might create harm (specify):
0	☐ None of the above

2.2 Is it likely that if released or reported, information collected (directly from participants or from existing data sources) could lead to social or psychological harm (e.g., discrimination, harm

0	☐ No
2	☐ Yes
1	☐ Unsure

2.3 Will the project produce test results or findings (e.g., Body Mass Index, lab test results, mental health scores) about identifiable individuals that a reasonable person would want to know (e

0	☐ No
2	☐ Yes

2.4 Will there be any reporting or disclosure of information about identifiable individuals to any of the following? Select all that apply.

2	☐ Participants themselves (e.g., personal test results)
3	☐ Participants' physicians or other health care providers (i.e., health information about individual patients). Does not include reports to health units.
2	☐ Health units (e.g., a reportable condition)
1	☐ Other. *Please specify:*
0	☐ None of the above

SECTION 3: PARTICIPANT SELECTION, RECRUITMENT AND CONSENT

3.1 Will you be identifying or contacting participants/data subjects by accessing non-public information (e.g., health records, non-public lists, referrals from other participants)?

0 ☐ No
☐ Yes - If yes, who will be accessing the records and/or making contact with participants? Select all that apply.
0 ☐ Authorized agent of the information custodian, not the project team member
0 ☐ Project team member, who has authorized access to information
2 ☐ Project team member, not the information custodian
2 ☐ Enrolled participants will provide non-public information about others
1 ☐ Other. *Please specify:*

3.2 Will you be obtaining consent (and assent if applicable) from individual participants (and/or their parents or other substitute decision makers as appropriate)?

0 ☐ No – If No, indicate the reason consent is not required from the list below (select one):
0 ☐ No. Using publically available information
0 ☐ No. Using isolates (e.g., bacteria, viruses) and associated clinical data (if applicable) that are non-identifiable or anonymized
0 ☐ No. Using non-identifiable or anonymized survey data from existing sources
0 ☐ No. Using non-identifiable or anonymized clinical (e.g. medical or dental) records
1 ☐ No. Other reason. *Please specify:*

1 ☐ Yes – If Yes, will you include any of the following groups who might have reduced capacity to provide an informed or voluntary consent? Select all that apply.
2 ☐ Children (0 to< 18 years of age)
2 ☐ Adults (18 or more years of age) with impaired cognitive function
2 ☐ People who, because of their current circumstances, may feel pressured to participate (e.g., client/ patient of project team member, students, employees, institutionalized individuals)
1 ☐ Unsure

3.3 Will there be any deception of participants or incomplete disclosure during the consent process?

0 ☐ No
3 ☐ Yes

SECTION 4: DATA/SAMPLE COLLECTION

4.1 Does this project involve direct participation of individuals or groups?

0 ☐ No
☐ Yes – If yes, what type of interaction will there be with the participant for the purpose of the project? Select all that apply.
1 ☐ Primary data collection (e.g., survey, questionnaire, interview, focus group)
3 ☐ Might questions cause psychological distress or discomfort (e.g., painful memories)?
1 ☐ Photographs
1 ☐ Audio recording
2 ☐ Video recording
2 ☐ Physical measures. *Please specify:*
2 ☐ Biological samples taken
2 ☐ Assignment of participants to an intervention for project purposes
1 ☐ Other. *Please specify:*

For studies involving direct participation, is it anticipated that some participants might be particularly vulnerable to project-related harms including physical, psychological or social harms (e.g., acutely ill, experiencing critical life event)?

0 ☐ No
2 ☐ Yes

4.2 Does this project involve the use of existing, non-publically available data about human participants/data subjects (e.g., health records, administrative databases, reportable disease registries)?

0 ☐ No
☐ Yes – If Yes, who will retrieve records?
0 ☐ Accessed by authorized agent of information custodian and shared with project team in secure, non-identifiable format
0 ☐ Accessed by authorized agent of information custodian who is a project team member, and working with an extracted dataset that is not identifiable
2 ☐ Accessed by authorized agent of information custodian (who may be project team member) and shared with project team in identifiable format

4.3 Does the project involve the use of human tissue or biological materials derived from human tissue (e.g., bacteria, viruses)?

0 ☐ No
☐ Yes - If Yes, please specify nature of use. Select all that apply.
☐ f yes, what type of use?
2 ☐ Long-term storage of samples for future unspecified use (i.e., new storage initiated for project, not routine storage related to clinical use)
2 ☐ Genetic (DNA or RNA) analysis
1 ☐ Other
☐ Use of existing banked or cultured isolates (e.g., bacteria, viruses). If yes, which of the following apply?
0 ☐ No clinical or patient demographic information will be used in analysis
0 ☐ Non-identifiable clinical or patient demographic information will be used in the analysis (e.g., sex, age, vaccination status, region)
1 ☐ Indirectly identifying (including potentially identifying) clinical or patient demographic information will be used in analysis (e.g., postal code, diagnostic codes, treatment
2 ☐ Identifiable patient information will be linked to isolates (e.g., name, OHIP number)
1 ☐ New extraction and use of isolates (e.g., bacteria, viruses) from human tissue specifically for the current project (does not include routine extraction for clinical use)

4.4 Does this activity involve direct observation of individuals?

0 ☐ No
☐ Yes – If yes, what type of observation? Select all that apply.
2 ☐ Direct observation by an individual
2 ☐ Observation through a camera or equivalent
3 ☐ Monitoring through some form of device or sensor (e.g., wireless tracking device)
1 ☐ Other. *Please specify:*

4.5 Does this activity involve access to private property (e.g., homes, private businesses)?

- [ ] No (0)
- [ ] Yes (1)

4.6 Does this activity involve analysis of documents (e.g., guidelines, policies, memos, e-mails) that are not in the public domain? Does not apply to documents where the project team memb

- [ ] No (0)
- [ ] Yes, organizational guidelines, policies, manuals, etc. are provided by an authorized representative of the organization (0)
- [ ] Yes, other. *Please specify:* (1)

SECTION 5: IDENTIFIABILITY AND PRIVACY RISK

5.1 Will there be collection or use of directly identifying personal information (e.g., name, address, email, telephone number, health insurance number)?

- [ ] No (0)
- [ ] Yes, for contact or consent, but data cannot be linked to identifiers (0)
- [ ] Yes, to collect or pull the data, but the working data set will not contain direct identifiers (1)
- [ ] Yes, for linking data sets only, then de-identified prior to analysis (1)
- [ ] Yes, individuals will be identifiable during the analysis (2)
- [ ] Yes, results will be linked to an identifiable individual (2)

5.2 Will there be collection or use of indirectly identifying personal information about individuals?

- [ ] No (0)
- [ ] Yes. Select all that apply.
  - [ ] Dates (e.g., date of birth, admissions, treatments, procedures) (1)
  - [ ] Full postal code or dissemination area (1)
  - [ ] Partial postal code (forward sortation area), region, health unit or census tract (0)
  - [ ] Any uncommon characteristic where there is a reasonable risk of re-identification (1)
  - [ ] Other. *Please specify:* (1)

5.3 Will there be collection or use of data that would identify communities, neighbourhoods or other groups or organizations (e.g., schools, institutions, programs)?

- [ ] No (0)
- [ ] Yes, but publically available information (0)
- [ ] Yes, not publically available information (1)

5.4 Will there be any linkage of two or more data sources at the individual record level (i.e., to amass more data about particular individuals)?

- [ ] No (0)
- [ ] Yes , linkage will be done by information custodian within a secure system and results will be released to the project team only in aggregate (0)
- [ ] Yes , linkage will be done by information custodian within a secure system and individual level results will be released to study team (1)
- [ ] Yes, linkage likely to produce identifiable information (2)

SECTION 6: COMMERCIAL INTERESTS

6.1 Does this activity involve? Select all that apply.

- [ ] Private sector partnerships or funding (1)
- [ ] Financial interests (potential commercializable products or intellectual property interests) (1)
- [ ] None of the above (0)

SECTION 7: ADDITIONAL COMMENTS (NOTE: COMPLETION OF THIS SECTION IS OPTIONAL)

7.1 Is there anything else not yet mentioned in this form that you feel is relevant to an appreciation of the risk associated with the project? (1)

OVERALL SCORE

0 No risks identified

LEGEND:

Missing Response