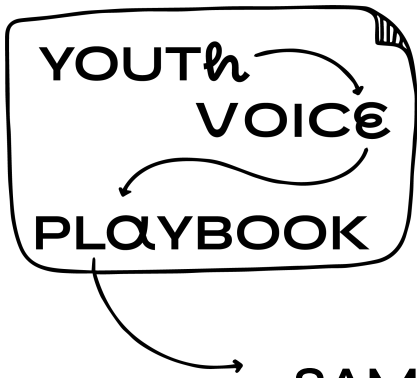

SAMPLE IRB APPLICATION

This example is meant to illustrate the types of questions that an IRB may ask you. Every IRB protocol is slightly different, so make sure you use the one as provided by your IRB.

1 RESEARCH PERSONNEL

1.1 List all co-investigators, collaborators, student researchers. For each, indicate their name, affiliation, and their role in this project.

2 STUDY INFORMATION

Purpose of the Research

2.1 Using lay language, describe the purpose and rationale for the proposed study. State the hypotheses and/or research questions and objectives. Provide the background information and cite relevant literature to contextualize the study.

2.2 Describe the anticipated value and potential benefits of the study and explain how the results will be disseminated (eg. thesis, academic presentations/publications, websites, community organization, etc.)

Location

2.3 Describe the locations (eg. country, city) and settings (eg. lab) where the data collection will take place. Indicate any organization approvals, local legislation, regulations, permissions, or customs that need to be

addressed to conduct this research (eg. school boards). Attach support letters if already obtained.

Participant Description

2.4 Describe in detail the characteristics of the participant population. List and provide justification for all inclusion/exclusion criteria.

2.5 In what language(s) will the research be conducted?

2.6 Given the participant population, is it likely that the participants may have communication difficulties or need special support?

2.7 Does the research involve vulnerable populations?

Methodology / Procedures

2.8 Answer all the points below for each method and procedure used to obtain data:

- **2.8.1** Describe in detail what data is needed to answer the research questions/objectives and what activities and/or procedures will be used to collect the data.
- **2.8.2** For each activity/procedure specify where it will be done, the approximate time commitment and frequency(as applicable).
- **2.8.3** For each activity/procedure, describe the methods to be used (e.g. paper/online surveys, interviews, focus groups, questionnaires, video-recording etc.). List all measures that will be used such as surveys, interview guides, observation guides. If a published scale, the link can be provided. Attachments can be uploaded below.
- **2.8.4** Identify who will do the data collection if not the Principal Investigator.
- **2.8.5** Please upload all relevant methodology documents (eg: measures to be used, surveys, interview guides) in either English OR French only. If more than one, upload as separate documents, identifying by title and version date in file name and on each document.

2.9 Will any participants be photographed or video-recorded?

2.10 Will any participants be audio-recorded?

2.11 Will you collect and use any materials created or provided by the participants such as photos, writings, video-recordings, drawings?

2.12 Will there be participant observation?

3 RECRUITMENT

3.1 Estimate the number of participants needed for each category of participants and methodology (e.g. adults, youth, surveys, focus groups etc.). Provide a rationale for how this was determined.

3.2 Describe in detail how potential participants are identified, contacted and invited to participate in the study. If applicable, describe any screening procedures. Identify who will be doing the recruitment. Attach all documentation to be used.

3.3 Is there a relationship between the study participants and the person recruiting and/or any of the members of the research team?

3.4 Describe any compensation/reimbursement/incentives participants will receive. Describe how compensation will be allocated if they choose to withdraw before completing the study.

3.5 Describe any organizational or community approvals that may be needed to recruit or access the target population (e.g. school board/principal; website manager; camp director). Explain how this will be obtained and attach relevant documentation to be provided to any third parties). Attach support letters if already obtained.

3.6 Please upload all recruitment/permission materials for participants and any third parties (e.g: posters, letters, emails, oral scripts).

4 CONSENT PROCESS

4.1 Will the participant population include those aged 18 and older who are competent to consent?

4.2 Will the participant population include those aged 18 and older who are NOT competent to consent?

4.3 Will the participant population include those under the age of 18?

4.4 Will deception or non-disclosure be used in this study?

4.5 Is there a relationship between the study participants and the person obtaining consent and/or the principal investigators?

4.6 Consent can be withdrawn at any time. Please explain what will happen to participant information if they withdraw. If a participant withdraws consent, the participant can also request the withdrawal of their data. Describe any limitations on the feasibility of the withdrawal of data once collected (e.g., publication of data; when personal information has been anonymized and added to a data pool; etc).

4.7 Please upload all Consent/Assent/Debriefing forms. If using an oral consent procedure , please upload the oral scripts which must contain the same elements as a written consent.

5 RISK / BENEFIT ASSESSMENT

5.1 Describe any known or reasonably foreseeable harms or discomfort, if any, that the participants or others might be subject to during or as a result of the research. Harm is anything that has a negative effect on the welfare of individuals or groups and may include psychological, physical, emotional, social, economic, or political harms.

5.2 Assess the potential risk of harms considering the expected magnitude or seriousness of a harm and the likelihood of someone actually experiencing harm. Consider the potential vulnerability of the participants within the specific research context. Detail the steps that will be taken to manage, reduce or eliminate potential harms or discomforts.

5.3 Describe the potential benefits (if any) of the research to the individual study participants or the population/community being researched (note that compensation/incentives are not a benefit). Explain why

these potential benefits may justify any risks that were identified above.

6 CONFIDENTIALITY & DATA SECURITY

Important definitions:

Anonymous information	The information never had identifiers associated with it (e.g., anonymous surveys), and risk of identification of individuals is low or very low.
Anonymized information	The information is irrevocably stripped of direct identifiers, a code is not kept to allow future re- linkage, and risk of re-identification of individuals from remaining indirect identifiers is low or very low.
Coded information	Direct identifiers are removed from the information and replaced with a code. Depending on access to the code, it may be possible to re-identify specific participants (e.g., the principal investigator retains a list that links the participants' code names with their actual name so data can be re-linked if necessary).

6.1 Describe how the identity of research participants will be protected during recruitment and data collection and after the research, including how participants will be identified on data collection instruments and in publications. Indicate if participants may be identified by name or otherwise (e.g. organization, job title) in any reports and indicate why this would be an appropriate option for participants to agree to. Explain if participant confidentiality is not applicable (e.g. anonymous survey).

6.2 Describe how and where all identifiable study materials (e.g. consent forms, study data, contact information) will be kept secure during the conduct of the study, both in the field (if applicable) and at your institution (e.g. password protection, encryption, unique codes). As applicable, describe how physical or electronic materials will be securely transported or transmitted between data collection and data storage sites and/or amongst the research team. If data is shared with other collaborators, will they employ the same data security measures?

6.3 Who will have access to identifiable study materials including data, consent forms, audio/video recordings, code keys etc.?

6.4 If third party data collection or storage services will be used (e.g. cloud storage, online surveys, mobile apps) indicate which one(s), and include details on security and confidentiality of data including final disposition of the data.

6.5 Are there any reasonably foreseeable disclosure requirements (e.g. duty to disclose abuse or neglect of minors) considering the population and the nature of the research?

6.6 Is it expected that any clinically relevant results may be generated (e.g. high scores on depression measures, blood test results, poor vision)?

6.7 Are there any other factors which may limit the confidentiality of participants due to context or procedures (e.g. sample size, focus groups, location, recruitment, use of translator or transcriptionist)?

6.8 Will any bio specimens (e.g. blood, urine, saliva, hair) be collected?

6.9 Describe how the study data and other materials (e.g. consent forms) will be stored at study completion. Include details of the storage location, storage conditions (e.g. encrypted external hard drive, cloud storage, locked drawer) and how long the materials will be retained. Specify if, and what, identifiable information will be retained once data collection is complete, and explain why retention of identifiable information is necessary. Indicate if someone other than the PI will store the data and describe what data is involved.

6.10 Identifiable or anonymized data collected as part of a research project can only be shared or used in the future with the explicit consent of participants. In current best practices in many fields of research, electronic data is to be preserved for future use in open access initiatives. Data is normally uploaded to an online repository and/or provided to other qualified researchers, stripped of any information that could identify participants (e.g., names, email addresses, audio recordings), to ensure confidentiality. If data will be shared with other researchers or users, please describe how, and indicate any restrictions that will be made regarding access.

7 CONFLICTS OF INTEREST

7.1 Will the researcher(s), members of the research team, and/or their partners or immediate family members receive any personal benefits, financial or otherwise (outside of expected standard salary/conference/expenses) directly related to this study?

7.2 Are there any restrictions regarding access to or disclosure of information (during or at the end of the study) that have been placed on the researcher(s) including any publication restrictions by any third parties.

7.3 Does any member of the research team have a dual role or any other relationship, financial or non-financial, that may be, or could be seen to be, a conflict of interest in relation to the study participants or any aspect of the research (e.g. teaching or clinical relationship, family member, supervisory relationship)?

7.4 Are there any other issues or information that need to be considered by the Research Ethics Board in the review of this application?