Peter - can you please put all the appendices as files in the AIMSS repo? We also should keep a pdf of this application in the repo, once we are ready to submit

McMaster University | Research Ethics Board

McMaster Research Ethics Board

Choosing the Application Type

1.2 What kind of research ethics application do you wish to create? Click on the info button for an explanation of each application type.

Note: The choices below are for new projects. If you are looking to make an amendment to an existing study then you need to select the already approved (or transferred) study from your work area and use the "create sub-form" action.

Standard MREB Application

1.3 Is this a post-doc, graduate or undergraduate student project? If so, the Faculty Supervisor's contact information will be requested and the Faculty Supervisor must sign the application prior to submission.

- (•) Yes
- ( ) No

If you are an Instructor for a course-based application, please answer NO to this question. For the purposes of this report, as an Instructor, you will be considered to be a Principal Investigator.

Summary of Revisions in Response to MREB Comments

When you respond to the MREB ethics review sent by the MREB Chair, return to this question and select that option. This will allow you to upload your summary of revisions. If this is the initial submission of your application or you are submitting a revised version due to administrative comments from the Research Ethics Officer, then select one of those options instead.

1.4 Please select the status of your application:

- ( ) My revised application in response to ethics review comments from the MREB Chair
- ( ) My revised application in response to the Research Ethics Officer's administrative comments to complete the application
- (•) My initial application submission to MREB

Principal Investigator

2.1 Faculty Supervisor (for PhD, MA, Undergrad Student PI lead projects)

Title	First Name	Surname
Dr.	Spencer	Smith

Organisation	McMaster University
City	Hamilton
Telephone	905-525-9140 ext. 27929
Email	smiths@mcmaster.ca

Supervisors must be registered with MacREM (have logged in with MacID at least once) before they can sign. Ask your supervisor to login to MacREM before you can request their signature. Also make sure all fields are complete on this contact form.

2.2 What is the faculty/department of the Supervisor?

Engineering - Computing and Software

2.3 Student Principal Investigator

Title	First Name	Surname
Mr.	Peter	Michalski

Organisation	McMaster University
City	Hamilton
Telephone	647-462-8052
Email	michap@mcmaster.ca

2.4 What is the faculty/department of the Student Principal Investigator?

Engineering - Computing and Software

2.7 Are there any Co-Investigators?

- (•) Yes
- ( ) No

2.8 Are there any Collaborators?

- ○ Yes
- ◉ No

2.9 Are there any Research Assistants or Coordinators?

- ○ Yes
- ◉ No

2.10 Are there any Student Investigators?

- ◉ Yes
- ○ No

Co-Investigator(s)

2.11 Co-Investigator

Title	First Name	Surname
Dr.	Jacques	Carette

Organisation	McMaster University
Department	Computing and Software
Faculty	Engineering
City	Hamilton
Telephone	905-525-9140 ext. 26869
Email	carette@mcmaster.ca

Student Investigator(s)

2.14 Student Investigator(s)

Title	First Name	Surname
Mr.	Ao	Dong

Organisation	McMaster University
Department	Computing and Software
Faculty	Engineering
City	Hamilton
Telephone	905-525-9140
Email	donga9@mcmaster.ca

2.14 Student Investigator(s)

Title	First Name	Surname
Ms.	Oluwaseun	Owojaiye

Organisation	McMaster University
Department	Computing and Software
Faculty	Engineering
City	Hamilton
Telephone	647-502-5773
Email	owojaiyo@mcmaster.ca

Project Title

3.1 Provide the full title for your research project:

Assessing the Impact of MDE (Model Driven Engineering) and code generation on the Sustainability of SCS (Scientific Computing Software) - State of Practice

3.2 Short Project Title

If your project title is long (more than 15 words), then consider providing a short title below. Otherwise, enter the full title of the project. The title entered below will appear on the project lists in MacREM and a shorter title can save "screen real estate". Please do not use an acronym for the short title.

AIMSS - State of the Practice

Note: If you are completing this application as a Program of Research for a planned series of studies/experiments in your research lab, then add "- Program of Research" to the end of your full title and short title in 3.1 and 3.2 above. The help button to the right contains some guidance on completing the application as a program of research. Please ensure that the ethics office has confirmed a program of research format will work for your series of studies/experiments before completing the application in this way.

Level of Project

3.3 For which Level of Project(s) will the data be used? (Check all that may apply)

- ☐ Faculty Research
- ☐ Post-Doctoral Research
- ☐ Ph.D. Thesis
- ☑ Master's (Major Research Paper - MRP)
- ☐ Master's (Thesis)
- ☐ Graduate Course Project
- ☐ Staff/Administration Research
- ☐ Undergraduate Honour's Thesis
- ☐ Undergraduate (Independent Research)
- ☐ Other

Lay Summary of the Proposed Research

3.4 How would you describe the research activity conducted in this protocol to a lay person unfamiliar with your discipline's methodologies and jargon? (max 250 words)?

define and give at least one example – research software will not be terminology that is familiar to everyone

Research software can be used for tackling important problems in many domains. Given the importance of research software, scientists and engineers are pushing for improved and sustainable development practices. The current state-of-the-practice for research software does not incorporate state-of-the-art software engineering tools and methods, leading to sustainability and reliability problems. To improve this situation, we need to more fully understand the current state of the practice for research software. To understand the current quality of SCS and to assist in developing methods for measuring qualities, this project will identify several domains within SCS and endeavour to summarize the current state of the practice within those domains. This “state of the practice” exercise will build off of prior work on measuring/assessing the state of software development practice in several SCS domains. With the re-boot we will refine a list of software packages within each SCS domain into a short list of the best projects for more detailed measurement. We will use quantitative and qualitative analysis for this. ~~In summary, we will conduct this state of the practice analysis of SCS for~~ the purpose of understanding quality and assisting in future software development.

this study is the of current research software improving

Start and End Dates

3.5 What is the date you plan to begin recruiting participants?

(For secondary use of data, what is the date you plan to receive the dataset, or if applicable, the date you plan to start obtaining consent from individuals to use their data for research?)

Jan/11/2021 ← update

Your anticipated start date should account for the ethics review process, which can take about four weeks from the point of submitting the application.

3.6 What is the estimated last date for data collection with human participants?

Mar/31/2021

Funding and Granting Agencies

4.1 Is this project currently being funded?

- ○ Yes
- ◉ No

4.5 Is funding or additional funding being sought?

- ○ Yes
- ◉ No

4.7 Are you requesting ethics clearance for a research project that was not originally designed to collect data from human participants or their records (i.e., your research project originally did not involve collecting data from humans or their records but you now intend to do so)?

- ○ Yes
- ◉ No

Location of the Research

5.1 Select the location(s) where research will be conducted.

- [x] McMaster University
- [ ] Community
- [ ] Hospital
- [x] Outside Canada
- [ ] School Boards
- [x] Online
- [ ] Other

5.1.5 Specify Outside Canada

We will be conducting video-conferencing interviews with software developers. The location of these developers will be predominantly in the US and Europe.

Note:

EOHSS requires all McMaster researchers engaging in off-campus research to complete a risk management form. This requirement is independent of the ethics review process. For more information go to https://hr.mcmaster.ca/employees/health_safety_well-being/our-safety/field-trip-research-activity-and-student-placements/

Review by Other Research Ethics Boards

5.2 Has any other Research Ethics Board(s) or equivalent already cleared this project?

- ○ Yes
- ◉ No

5.4 Will any other Research Ethics Board(s) or equivalent be asked for clearance?

- ○ Yes
- ◉ No

5.5 Has a version of this study been disapproved or rejected by any Research Ethics Board/Committee?

- ○ Yes
- ◉ No

International Research

5.6 Research in a foreign country requires review by the appropriate REB or equivalent. Where there is no appropriate local review body, MREB usually requires a local reviewer to conduct a review of the application. A local reviewer is a person, usually an academic, who has expertise in the country/culture and area of research. The person could be living in the host country or elsewhere, and should not have a conflict of interest with your research.

5.7 Name countries and or places where the research will take place:

The specific countries are unknown at this time but it will be predominantly in the US and Europe. Participation with developers in these countries will be conducted online.

5.8 Is there a local REB or equivalent that will conduct an ethics review of your research project?

- ○ Yes
- ◉ No

5.10 Provide title, name, and email address of the local reviewer and which country they will be able to comment on in terms of the ethical appropriateness of your research. MREB recommends providing contact information for more than one local reviewer, just in case the first choice is unable to complete the review.

I contacted the MREB Secretariat and was advised, that for now, it is not necessary to provide local reviewer information. This is because the participants are professional software developers recruited for an online interview to discuss topics related to their profession, and ad hoc review considering the local cultural context may not be necessary. Furthermore, at this point the exact locations of the software developers is not known, as we have yet to conduct the first phase to determine the software programs we want to research.

Research Involving Canadian First Nations, Inuit and Metis Peoples

6.1 Will your research involve collecting data from a Canadian Indigenous community(ies) and/or will the data pertain to Indigenous identity or knowledge?

- ○ Yes
- ◉ No

If you answer No, but are not sure, please answer Yes to see the criteria statements, or contact the Research Ethics Office for more information.

Conflicts of Interest

7.1 What are the relationships (if any) between the investigator(s) and participant(s)? Select all that might apply:

- ☐ Instructor (Teaching Assistant)-Student
- ☐ Manager-Employee
- ☐ Family Member
- ☐ Friend(s)
- ☐ Student Peers
- ☐ Fellow Club Members
- ☑ No Relationship
- ☐ Business/Work Colleagues or Clients
- ☐ Other

7.2 Do any researchers conducting this study have multiple roles with potential participants that may create real, potential, or perceived conflicts of interest? Or could multiple roles create situations of undue influence, power imbalances, or coercion, which could affect participant decision-making processes such as consent to participate? Examples of dual roles include acting as both researcher and therapist, health care provider, family member, caregiver, teacher, advisor, consultant, supervisor, student peer, work colleague, and/or employer.

- ○ Yes
- ◉ No

7.5 Will the researcher(s), members of the research team, and/or their partners or immediate family members receive any personal benefits (for example a financial benefit such as remuneration, intellectual property rights, rights of employment, consultancies, board membership, share ownership, stock options etc.) as a result of or being connected to this study?

- ○ Yes
- ◉ No

7.7 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 investigator(s)? These restrictions could come from a study sponsor, community partners, an organization being researched, or another group involved in the study.

- ○ Yes
- ◉ No

Description of the Project

8.1 Describe concisely and in plain language the study background of the proposed research project (e.g., context of the research, previous research, importance of this area of study, etc.).

The context of this research is to explore ways to improve the sustainability of research software. Software continues to be an integral part of research, which spans diverse fields. Despite the technological advancements and its acknowledged benefits, many research software project failures have been documented. The complexity and volatility of software have manifested in difficulty in reproducing and replicating scientific methods resulting in several retractions and cascading retractions. Issues of maintenance and productivity still traverse research software development. As software evolves, maintenance cost becomes more expensive, especially if there are no adequate software engineering practices to support maintenance activities. The issues of maintainability, reproducibility, productivity point to sustainability issues. Research software consists of computer programs or systems used by scientists to investigate unknown areas. They include software for data analysis, modeling, forecasting, and so on.

increase

an example would be good + acceptable & could on a structure, or spread of a virus

the definition should be given in the lay summary

8.2 Describe concisely and in plain language the specific purpose / research question for the proposed study.

What are the attitudes and actions of research software developers towards software quality?

via simulation and analysis of mathematical models of physical systems numerical

Participants

If researching several sub-populations, use a heading for each population and provide details for each. Answer the next questions for each type of study population that you may have.

9.1 What is the approximate number of participants required for this study? Where applicable, also provide a rationale for your choice in sample size and/or the sample size calculation (e.g., to explain how a low sample size will still provide meaningful results, or to justify the number of participants needed in research that includes significant risks).

Up to 60. We will be studying two SCS domains. For each domain we plan to analyze about 30 software packages. We will try to interview one developer of each of these packages. We will likely not receive a response or agreement to interview from some of them, or succeed in contacting them.

Say how you come up with the list of software → borrow from the methodology document.

9.2 What are the salient participant characteristics (e.g., age, gender, location, affiliation, etc.)? Describe any specific inclusion/exclusion criteria (e.g., BMI > 30, immigrated to Canada in the past year, etc.)

None. These will be developers of the software packages of interest.

Categories of Participants

9.3 Categories of Participants: (Check all that may apply)

- ☐ Children - not school aged
- ☐ Adolescents
- ☐ School children/pupils
- ☑ Adults
- ☐ Pregnant women
- ☐ Older adults
- ☐ Canadian Indigenous people
- ☐ McMaster students
- ☐ Hamilton community
- ☐ Mental Health Patients (Non-HHS or SJHH)
- ☐ Prisoners
- ☑ International Participants
- ☐ Other

If you are doing research in foreign countries you may need ethics clearance in the host country or you may need a local reviewer. If applicable, return to Question 5.1 and check "Outside Canada" for study location, if not already selected.

9.4 Will your study include participants who are not fluent in the English language?

- ○ Yes
- ◉ No

Recruitment

If researching several sub-populations, use a heading for each study population and provide details for the type of participant or group and who does the recruiting. Refer to the Menu above Help – Templates to find the "How to Unpack the Recruitment Details" worksheet and other sample documents you may modify.

10.1 How will each type of participant be recruited?

The developers of the software packages of interest will be contacted via email using the contact address that is listed on the webpages of their software packages.

10.2 Who will recruit each type of participant?

Student Investigator (Peter Michalski or Ao Dong)

10.3 Will you require permission to conduct any of the above recruitment strategies? (e.g., permission from an employer to recruit employees on site).

- ○ Yes
- ◉ No

Participant Recruiting Methods

10.6 Identify the documents that will be used during recruitment (select all that apply):

There are sample recruitment documents in the Help - Templates section in the menu above.

- ☐ Recruitment brochure
- ☐ Recruitment poster
- ☐ Video/audio recording
- ☐ Social media (e.g. Instagram, Twitter, etc.)
- ☐ Website Post or Online Advertisement
- ☐ SONA ad
- ☐ Telephone Recruitment Script
- ☐ In-person Recruitment Script
- ☐ Hardcopy Letter – e.g. sent via mail
- ☑ Email script (sent direct to participant) and reminder emails (if applicable)
- ☐ Email script (sent from holder of participant contact) and reminder emails (if applicable)
- ☐ Crowd sourcing platform (e.g. MTurk, Prolific, etc.)
- ☐ Recruitment for follow up interview
- ☐ Snowball recruitment script
- ☑ Appreciation letter/certificate/thank you card
- ☐ Not Applicable (e.g. study only involves secondary use of data)
- ☐ Other

10.6.7 Upload your email script(s) sent directly to participants and reminder emails.
Upload in PDF format
The document file name should clearly indicate type of document, as the file name will appear on the clearance certificate.

If uploading a revised document,
1) use track changes so the revisions can be easily verified
2) delete the previous version of the document from this upload question.

Documents

Type	Document Name	File Name	Version Date	Version	Size
Recruiting Materials	RecruitingScript	RecruitingScript.pdf	Dec/10/2020	Version 3	36.4 KB

10.6.12 Upload your appreciation letter/certificate thank you card for participants.
Upload in PDF format
The document file name should clearly indicate type of document, as the file name will appear on the clearance certificate.

If uploading a revised document,
1) use track changes so the revisions can be easily verified
2) delete the previous version of the document from this upload question.

Documents

Type	Document Name	File Name	Version Date	Version	Size
Recruiting Materials	ThankYouScript	ThankYouScript.pdf	Dec/10/2020	Version 1	31.4 KB

10.7 Will potential participants answer screening questions to determine eligibility to participate in the study?

- ○ Yes
- ◉ No

Research Methods

11.1 Describe sequentially, and in detail all data collection procedures in which the research participants will be involved (e.g., paper and pencil tasks, interviews, focus groups, lab experiments, participant observation, surveys, physical assessments etc. —this is not an exhaustive list). Include information about who will conduct the research (include tasks done by assistants, translators, transcriptionists etc.), how long it will take, where data collection will take place, and the ways in which data will be collected (e.g., computer responses, handwritten notes, audio/video/photo recordings etc.).

The interviewer (a Student Investigator, or Principal Investigator, or Co-Investigator) will conduct a video-conference interview with each interviewee using McMaster's Microsoft Teams. Around 20 technical questions will be asked. The answers will be transcribed into text using Microsoft Teams. The process should take less than 2 hours per interview.

11.2 Describe your data analysis methods, (e.g. statistical analysis, textual analysis, NVIVO, etc.)?

Textual/content analysis. We will be looking for patterns between the answers of all interviewees.

We should say we will also be looking for correlation with independently collected data on each project — like the types of documentation provided for the project, number of lines of code, etc.

Types of Research Methodology

11.3 In addition to describing your methods above, also check the following boxes that apply to study design and the methods used in this research. The checklist allows for accurate reporting of the types of methods reviewed by MREB. (Check all that apply)

- [ ] Ethnography/participant observation
- [ ] Autoethnography
- [ ] Surveys/questionnaires (paper and pen)
- [ ] Online Survey
- [ ] Interviews (face-to-face)
- [x] Interviews (telephone / Skype)
- [ ] Focus groups
- [ ] Community Engagement
- [ ] Delphi
- [ ] Online Research (e.g. social media, online forums)
- [ ] Participatory action research/CBPR
- [ ] Secondary use of data (e.g. employee records, non-public data from another research study)
- [ ] Photovoice
- [ ] Video recording
- [ ] GIS/GPS
- [ ] Physical assessments/exercise
- [ ] Auditory tests
- [ ] EEG / FNIRS
- [ ] EMG/ECG
- [ ] Eye tracking
- [ ] Cortisol
- [ ] Motion Capture (Optical or Magnetic Tracking)
- [ ] Standardized test instruments (e.g. PANAS)
- [ ] High Risk test instruments (e.g. Beck Depression Inventory)
- [x] Quantitative
- [x] Qualitative
- [ ] Mixed Methods
- [ ] Pilot study/proof of concept
- [ ] Cross-sectional
- [ ] Longitudinal
- [ ] Randomized
- [ ] Observational
- [ ] Pedagogical
- [ ] Research includes QA/QI component
- [ ] Other

11.4 Are you using an online survey or data collection tool?

- ○ Yes
- ◉ No

Community Based Research

11.6 Are you doing community based research? Click on the info icon to the right for a definition of community based research.

- ○ Yes
- ◉ No

Test Instruments and Interview Guides

11.14 Select and upload copies of all questionnaires, interview guides (i.e., lists of questions), tests, or data collection instruments, etc.

- ☐ Demographic Form
- ☐ Instructions for Participants (e.g. how to perform a task in an experiment, instructions for a Photovoice project, etc.)
- ☑ Interview Guide (face to face, telephone, Skype, etc.)
- ☐ Focus Group Guide (questions for focus group)
- ☐ Questionnaire or Survey
- ☐ Rating scales/inventories/assessment instruments
- ☐ Role-play simulation scripts
- ☐ Stimuli used to elicit responses
- ☐ Pictures (or diagrams) of what the participant will experience in the study, such as wearing equipment (e.g. EEG) or doing physical tasks
- ☐ LIVELab SOPs
- ☐ Not Applicable (e.g. study only involves secondary use of data)
- ☐ Other

11.14.5 Upload your Interview Guide - (Questions for face to face, telephone, internet/email interview).
Upload in PDF format
The document file name should clearly indicate type of document, as the file name will appear on the clearance certificate.

If uploading a revised document,
1) use track changes so the revisions can be easily verified
2) delete the previous version of the document from this upload question.

Documents

Type	Document Name	File Name	Version Date	Version	Size
Interviews	InterviewGuide	InterviewGuide.pdf	Dec/02/2020	1	46.3 KB

Secondary Use of Data

12.1 In this current research project are you planning to use secondary data that was originally collected for another purpose?

- ○ Yes
- ◉ No

Research Database

12.32 Does your research involve the creation and/or modification of a research database (databank) containing human participant information? A research database is a collection of data maintained for use in future research. The human participant information stored in the research database can be identifiable or anonymous.

- ○ Yes
- ◉ No

A research database is a formal collection of data maintained and administered by you for use in future research by you and other researchers. This is different from simple data storage of your research data for your own future use. Big Data or databank projects most likely would need to select Yes but most researchers collecting data can select No. Contact the ethics office if not sure.

Incentives

This section asks different questions for incentives, reimbursement and compensation as each are considered different forms of payment.

13.1 Will participants receive an incentive for participation?

- ○ Yes
- ◉ No

Reimbursements

13.5 Will participants be reimbursed for expenses related to participating in the research (e.g., transportation, parking, childcare, taking unpaid leave from work)?

- ○ Yes
- ◉ No

Compensation

The application section of Article 3.2 in the TCPS notes participants should be informed about any compensation they may be entitled to for research-related injuries. This is only applicable if your study has a genuine likelihood of causing physical injury or financial harm (e.g. job loss) to participants. This will not apply for most studies reviewed by MREB.

13.8 Will participants be entitled to any compensation for research-related injuries?

- ○ Yes
- ◉ No

Risks and Benefits Inherent in the Research

Indicate if the participants might experience any of the following risks:

Physical Risks

14.1 Physical risks (including any bodily contact or administration of any substance)?

- ○ Yes
- ◉ No

Psychological Risks

14.3 Psychological risks (including feeling demeaned, embarrassed, worried or upset)?

- ◉ Yes
- ○ No

14.4 Provide the following;

a) Description of the potential psychological risk(s).

b) Explanation of how the psychological risk(s) will be managed or minimized.

c) If the study includes significant psychological risk, then explain why alternative approaches with less psychological risk cannot be used.

a) There is very little or no risk associated with our study. The interviewee might feel that their work is being scrutinized.
b) We have assured that our interview questions are objective and technical. The questions will not suggest that a specific course of (technical) action is better than another. Our questions focus on what was done and not why it was done.
c) The potential psychological risk is very minimal, and there are no alternatives with lesser risks.

Social Risks

14.5 Social risks (including possible loss of status, privacy and / or reputation as well as economic risks)?

- ◉ Yes
- ○ No

14.6 Provide the following;

a) Description of the potential social risk(s).

b) Explanation of how the social risk(s) will be managed or minimized.

c) If the study includes significant social risk, then explain why alternative approaches with less social risk cannot be used.

a) Social risk is very minimal. The participants face the social risk of privacy breach if someone deduces their identity and sees their interview responses. We will identify by name the software packages in our research.
b) While we list the software packages in our research, interviewee names will never be shared. Neither will the interview answers for any specific interview (software package). We will only share an overall qualitative analysis of the specific software domain, which encompasses all interviewees. Interviewee answers will only be known to be associated with a specific software package internally in our investigation team. Interviewee names and their answers will be secured and confidential, as detailed in Section 15 of this application.

Community Counselling or Support Services

14.7 Do you have a list of community counselling or other support services to give participants if they were to become distressed during participation in your research?

- ○ Yes
- ◉ No

Deception and Partial Disclosure

14.9 Is there any deception or partial disclosure involved in this research?

- ○ Yes
- ◉ No

Benefits

14.18 Discuss any potential benefits to the participants, scientific community and/or society that justify involvement of participants in this study.

The answers to these interview questions will help us analyze the current state of practice of software development in a domain, and provide insight into common or best practices for the benefit of future software development.

Experience with the Research

14.19 What is your experience with this kind of research? Include information on the experience of all individual(s) who will have contact with the research participants or their data. If this is student research, include the experience of your supervisor. Mention your familiarity with:

(a) the proposed methods
(b) the study population(s) and/or
(c) the research topic.

a) The Principal Investigator (Smith) has expertise in software engineering methods applied to Scientific Computing software, as this has been the focus of his research since the year 2000. Smith has conducted two studies at McMaster that required ethics approval: one surveying the attitudes of scientific software developers and another, where student participants assessed the effectiveness of a computer game for teaching computing.
The Co-Investigator (Carette) also has experience with multiple empirical studies related to game design involving interviewing human participants. They are both extensively familiar with the ethical consideration of using human participants in research.
b) The study population is scientific computing software developers and the principal investigator and co-investigator are well familiar with this population as they have professional academic experience in this field and familiarity with similar software developers.
c) The Principal Investigator and Co-investigator have conducted research in this area for over ten years combined. They have several publications related to this research area. The student investigators have been working on this research area for over a year and have at least that many years of related experience in software engineering

Researchers are strongly encouraged to take the TCPS2: Course on Research Ethics tutorial prior to conducting their study. Especially student researchers and researchers new to human participant research. If you have already completed the TCPS2: CORE tutorial, then you can include that training as part of your experience with human participant research in 14.19 above. Completion of the tutorial is not a requirement of the research ethics review process.

Confidentiality and Data Security

The level of confidentiality and anonymity promised to participants can vary during different stages in the life cycle of the research (e.g., recruitment, consent, data collection, providing compensation or incentives, data preparation and analysis, data transfer/movement, data storage, dissemination of research findings and the final disposition of study documents [archiving or secure destruction, as applicable]). This section of the application covers the responsibility of researchers to describe their measures for meeting confidentiality obligations and for safeguarding participant information, per the TCPS2, Articles 5.1, 5.2 and 5.3.

Confidentiality concerns the responsibility for the protection, privacy and security of information entrusted to researchers.

Anonymity concerns whether participant identities are known or not.

Please check the new MREB Data Storage and Security Tools documents in the Help - Templates menu above for best practices to secure electronic and hard copy versions of data and study documents.

Confidentiality and Security of Personal/Contact Information Collected for Administrative Purposes

15.1 Are you collecting personal information for administrative purposes during the recruitment, screening or consent phases of the study and/or to provide participants with incentives, reimbursements or study results?

Some examples of administrative documents with personal information include:

- Signed consent forms
- Email addresses for contacting participants
- Payment log
- Screening form
- Linking Document (has both participant identities and study ID)

(•) Yes

( ) No

Note that this series of questions is asking about personal information collected for administrative purposes, not research data. The confidentiality and security of research data is covered in the next section below.

15.2 What identifiable personal/contact information will be collected? (Check all that apply.)

- [x] Name/signature
- [x] Email addresses
- [ ] Phone number
- [ ] Mailing address
- [ ] Other

15.2.2 Describe the administrative purpose(s) for which this information is required (e.g. setting appointments, consent forms, consent log, distributing incentives, follow-up with participants for further research, sharing research results, etc.)

For our study, we will collect the first name, last name, and email address. The data will be used strictly for recruitment and correspondence.
The data will be available only to the Student Investigators, Principal Investigator, and Co-Investigator. The names/ email information will be stored in the password protected email accounts of the Student Investigators, Principal Investigator, and Co-Investigator.
During the interview and throughout the entire study, only the above will be aware of the participants' identity.

15.3 Describe below the security procedures for the personal information collected for administrative purposes (e.g., consent forms, contact information). Keeping this information secure and confidential reduces potential risks for participants and is a requirement of privacy legislation (e.g., FIPPA). Refer to the MREB Data Storage and Security Tools for recommendations and requirements for data security (go to Help - Templates in the above menu).

15.3.1 Please describe:

a) Who will have access to the personal information collected for administrative purposes (including people outside of the research team).

b) If your answer to (a) includes people outside of the research team, then describe the information they have access to, why they need access, and what measures are in place so that participant confidentiality is maintained.

Note: Participants should consent to their personal information being shared outside the research team.

a) Only the Student Investigators, Principal Investigator, and Co-Investigator.
b) Not Applicable

15.3.2 How will the personal information be collected securely and how will it be kept secure during storage? If multiple members of the research team are collecting and storing the personal information, provide details on all collection and storage procedures, and how the personal information will be shared with other team members.

The names and emails will be stored, and when needed shared, on password protected email accounts of the Student Investigators, Principal Investigator, and Co-Investigator.

↳ where will the information be stored? student investigators password protected computer?

15.3.3 How will the personal information be transported securely from the field to the storage location, between McMaster and a home office, or other scenarios requiring the movement of the personal information? This could be hard copy documents (e.g., consent forms) or electronic (e.g., a laptop containing files with contact information).

Personal information will not be transported. It will be stored on password protected email accounts.

↳ It might be if it is on a laptop?

15.4 Provide details on the retention of personal information for administrative purposes (e.g., consent forms, contact information). Please include:

a) Length of time you plan on retaining the administrative documents containing personal/contact information. If some documents will be kept longer than others, please specify.

b) The reason why you need to retain the documents for the length of time stated in (a).

c) Details on how the documents will be destroyed at the end of the retention period.

d) If the procedures for longer term storage of personal information are different than what is described in 15.3, please provide the details.

Unless there is a reason to contact participants later, then contact information should be destroyed.

The retention period will span the length of the project so that all correspondence can be completed. It will be deleted upon the completion of the project.

Confidentiality and Security of Research Data

15.5 Are you collecting any research data that directly identifies participants (e.g., audio or video recording) or that could indirectly identify participants (e.g., a combination of demographic variables - date of birth, postal code, occupation, ethnicity, etc.)?

In this section "research data" refers to information collected from participants for analysis or to describe the sample.

- (•) Yes
- ( ) No

15.8 Will there be a separate file with a unique code or pseudonym linking the participant name/contact information to the data (e.g., linking data between multiple sessions within a study, linking data in the current study to a future study)?

- ( ) Yes
- (•) No

15.10 Select all (potentially) identifiable data that will be collected for this study and explain why each type of identifiable data is necessary to conduct the research. (Select all that apply)

- ☐ Full Postal Code
- ☐ Partial Postal Code
- ☐ Full Date of Birth
- ☐ Partial Date of Birth
- ☐ IP Address (ensure this function is turned off in online platforms if not collecting IP addresses)
- ☑ Audio Recording
- ☐ Video Recording
- ☐ Photographs
- ☐ Indirectly Identifying Variables (ethnicity, program of study, occupation, gender, etc.)
- ☐ Direct Quotes
- ☑ Other

15.10.6 Explain why it is necessary to audio record participants:

Audio recording will be required when conducting our interviews to capture all information accurately and also for the analysis of data. We will use Microsoft Teams' audio recording feature. The audio recording will be stored in our online password-protected data repository.

More details:
The audio recorded meeting will be automatically transcribed via the Student Investigator's, Principal Investigator's, or Co-Investigator's McMaster Microsoft Stream account. Microsoft Team and Microsoft Stream are linked, thus the meeting is automatically stored on Microsoft Stream. Transcription is done automatically in Microsoft Stream and the transcription file will be downloaded immediately after the interview is completed. The data on Microsoft Teams and Microsoft Stream are private data and not available to the public.
The interviewer will log into the McMaster Microsoft stream account to download the original interview audio recording, and the transcribed file, then save on our online password-protected data repository for security and privacy. Only the Student Investigators, Principal Investigator, and Co-Investigator will have access to the stored data.

After the original interview recording and the transcribed text have been securely stored on our online password-protected repository, we will permanently delete copies of the data from Microsoft Teams and Microsoft Stream immediately.

15.10.11 Specify the other identifiable data and explain why it is necessary to collect this information.

Transcribed data for interview sessions
Audio recording will be transcribed using Microsoft Teams transcription feature. The transcribed data is necessary to prepare data for analysis. Transcribed data will be stored alongside its corresponding audio data in our password protected data repository.

The participant's names and contact information (email address) will be known to only the Student Investigators, Principal Investigator, and Co-Investigator. This is necessary for the interviews. However, this information will be kept strictly confidential.

Details about the proposed transcription process:
The interview meeting will be conducted using McMaster's Microsoft Teams account. The meeting is recorded and then automatically transcribed via the Student Investigator's, Principal Investigator's, or Co-Investigator's McMaster Microsoft Stream account. Microsoft Team and Microsoft Stream are linked, thus the meeting is automatically stored on Microsoft Stream. Transcription is done automatically in Microsoft Stream and the transcription file will be downloaded immediately after the interview is completed. The data on Microsoft Teams and Microsoft Stream are private data.
The interviewer will log into their McMaster Microsoft stream account to download the original interview audio recording, and the transcribed file, then save on our online password-protected data repository for security and privacy. Only the Student Investigators, Principal Investigator, and Co-Investigator will have access to the stored data.

After the original interview recording and the transcribed text have been securely stored on our online password-protected repository, we will permanently delete copies of the data from Microsoft Teams and Microsoft Stream immediately.

+ we will connect the answers to their questions to their software — this is potentially identifying them

15.11 Describe below the data security procedures that will be used to keep the research data private and secure during data collection and analysis. Refer to the MREB Data Storage and Security Tools for recommendations and requirements for data security (go to Help - Templates in the above menu).

15.11.1 How will the research data be collected securely, to ensure participant privacy and confidentiality during the data collection phase of the study? If an online survey platform, video-conferencing platform, or similar will be used to collect the data, then provide information on how that service protects the data (this could include a link to the service's privacy policy).

The Student Investigators, Principal Investigator, and Co-Investigator will be collecting and storing research data. Interview data will be collected via Microsoft Teams App using audio recording. The interview will then be transcribed immediately after completion of the interview using McMaster's Microsoft Stream App. Microsoft Stream and Microsoft Teams are linked, hence there will be no need to manually transfer data. Transcription is automatically done in Microsoft Stream. When the transcription is completed, the interviewer will upload the audio interview recording and the corresponding transcribed data to our online password-protected data repository where only the Student Investigators, Principal Investigator, and Co-Investigator can access it. No other party will be able to access the data. The original audio recording on Microsoft Team and Microsoft Stream will be deleted permanently from the cloud servers and the transcribed data will also be deleted permanently from the Microsoft Stream cloud server.

15.11.2 How will research data be stored (e.g. digital files, hard copies, audio recordings, etc.)? Specify the physical and/or online storage location(s) and how data will be secured to minimize the risk of a data breach. If multiple members of the research team are storing the research data, provide details on all storage procedures and how the research data will be shared between team members.

Note: The TCPS2 advises that identifiable data obtained through research and kept on a computer that is connected to the Internet, should be encrypted. Generally, MREB requires researchers to follow this guidance for identifiable research data. In some cases, sensitive identifiable data, even if not on a device connected to the Internet, may need to be encrypted to protect participant privacy and mitigate social risk. See the application section of TCPS2 Article 5.3.

Only the Student Investigators, Principal Investigator, and Co-Investigator will be collecting and storing data. All research data will be stored on our private password-protected data repository (Computing and Software Department Gitlab server) which can only be accessed by the Student Investigators, Principal Investigator, and Co-Investigator.

We will download the interview audio recording and transcribed text and store securely on our online password-protected data repository. The interviewer will delete the data permanently from the local machine or McMaster Microsoft Teams or Microsoft Stream account as applicable.

15.11.3 How will the research data be transported securely from the field to the storage location, between McMaster and a home office, or other scenarios requiring the movement of the research data (e.g. sending to a translator, downloading data from an online platform)? This could include both hard copy documents and electronic files.

All research data will be stored on our password-protected data repository (Computing and Software Department Gitlab server). We will download the interview audio recording and transcribed text and store securely on our online password-protected data repository. The interviewer will delete the data permanently from the local machine or McMaster Microsoft Teams or Microsoft Stream account as applicable. All data will be collected electronically, no hard copy required.

15.11.4 Please describe:

a) Who will have access to the research data (including people outside of the research team, e.g. translator, transcription service).

b) If your answer to (a) includes people outside of the research team, then describe the information they have access to, why they need access, and what measures are in place so that the data is kept secure.

a) Only the Student Investigators, Principal Investigator, and Co-Investigator will have access to audio recordings and transcribed data.

b) Not Applicable

15.11.5 Will you be asking anyone who has access to research data, access to other study documents (e.g. contact lists), and/or knowledge of who participated in the study, to sign an oath of confidentiality?

Note: This is more common when someone outside the research team has access to confidential information (e.g. translator), or when some participants will know that other participants were in the study or what they said (e.g. in a focus group). But it may also include research team members in a study with high social risk for participants. The need for an oath of confidentiality depends on the study context, the sensitivity of the data, and the risk to participants if there was a loss of confidentiality.

- ○ Yes
- ◉ No

Transfer of Study Records to Another Institution/Organization

15.12 Will any research data and/or study related documents be transferred to another institution or organization (e.g. to a research partner organization, to a separate research team at another university requesting use of the data)?

- ○ Yes
- ◉ No

Dissemination of Findings and Final Disposition of Research Data

15.18 How will the data from study participants be reported in the dissemination of research results (e.g., aggregated data, identifiable descriptors, de-identified descriptors, etc.)?

Recruitment:
• The participants will be known to the investigators (Student Investigators, Principal Investigator, and Co-Investigator).
Data Collection:
• For interviews: The participants will be known to the investigators.
Data Storage:
• The data will be known to the investigators.
Dissemination:
• The participants will be anonymous. They will not be identified by name.
• Their work will be generalized so that it cannot be identified as belonging to them.
• Data will be aggregated.

software development process details
the ~~feedback~~ will be linked to their software project – we do not identify who provided the information

15.19 Provide details on the retention of research data. Please include:

a) Length of time you plan on retaining data. If some parts of the data will be kept longer than others, please specify.
b) The reason why you need to retain the research data for the length of time stated in (a).
c) If applicable, details on how the research data will be destroyed at the end of the retention period.

a) Data will be retained for 3 years after the study.
b) This should provide adequate time for analysis, the publication of results response to questions that may arise from published work.
c) The data will be removed i.e deleted permanently from our online password-protected repository thus it will be deleted permanently from the server.

15.20 Will you be retaining identifiable and/or coded research data long-term (i.e. beyond the initial data analysis phase)? Coded data refers to a de-identified data set that can be re-identified with a document linking participant ID numbers to names.

- ○ Yes
- ◉ No

15.21 State at what point the data will be anonymized, or specify if the data was anonymous at the point of collection (e.g. an anonymous online survey).

Interview and project log data will be anonymized during dissemination and all data will be aggregated.

15.23 Will longer term storage procedures used for keeping research data secure differ from the storage procedures used during data collection and initial analysis described above in 15.11.2?

- ○ Yes
- ◉ No

15.25 Do you have plans to have identifiable data professionally archived? (e.g. interview recordings kept in a library archive)

- ○ Yes
- ◉ No

15.27 Will someone other than the Principal Investigator be retaining the study data long-term? In the case of student research, will someone other than the Student Investigator and/or Faculty Supervisor be retaining the data long-term?

- ○ Yes
- ◉ No

15.29 Do you plan to post research data to a database accessible by other researchers and/or the general public, or to make data available to other researchers upon request? (e.g. some journals require sharing of data for verification purposes as a condition of publication)

- ○ Yes
- ◉ No

Informed Consent

16.1 Describe the process the investigator(s) will use to obtain informed consent from participants with the capacity to provide consent. For participants lacking capacity to consent see the question below.

Please include;

a) How participants will be informed of the study details prior to consenting (e.g. information letter via email, in-person by the researcher, reading letter online before a survey, etc.).

b) How consent will be documented (e.g. signed consent form, verbal consent log) or if there will be no documentation (e.g. online survey where proceeding with the survey implies consent).

c) Which member(s) of the research team will be handling the informed consent process, if applicable.

d) Any unique consent details, for example if the study involves consent in multiple stages or an ongoing consent process.

a) Letter of Information containing research study details will be sent to participants via email.
b) Consent will be documented by each participant electronically by signing the letter of information/consent.
c) The Student Investigators will be handling the informed consent process.
d) No

(Mention that you will verbally ask for consent when you start the interview
- mention that there will be a table that is filled in to track consent → I'll send an e-mail about this.

Alternative Consent Processes

16.2 Do any individuals lack the capacity, in the context of your study, to make an informed choice to participate in the research (e.g. children, people with cognitive impairments)?

- ○ Yes
- ◉ No

16.4 Are you seeking an exception to the requirement that researchers seek consent from participants prior to the collection of data?

- ○ Yes
- ◉ No

Informed Consent Documents

16.6 Select the document(s) that will be used in the consent process. There are sample consent documents in the Help - Templates section in the menu above.

- ☑ Letter of Information / consent - Participants
- ☐ Online survey preamble and consent options.
- ☑ Oral / telephone consent script
- ☑ Oral consent log
- ☐ Letter of Information / consent - Parent(s) or Guardian(s)
- ☐ Letter of Information / Assent form - Minors
- ☐ Letter of Information / consent - Substitute Decision Maker
- ☐ Not Applicable (e.g. study only involves secondary use of data)
- ☐ Debriefing document for educational purposes only (e.g. post-experiment information sheet for students recruited through SONA)
- ☐ Other

16.6.3 Upload your Letter of Information / consent - Participants. Multiple data collection methods and/or participant groups may require multiple letters of information.

Upload in PDF format

The document file name should clearly indicate type of document, as the file name will appear on the clearance certificate.

If uploading a revised document,
1) use track changes so the revisions can be easily verified
2) delete the previous version of the document from this upload question.

Documents

Type	Document Name	File Name	Version Date	Version	Size
Consent Forms	Letter-of-Information-Consent-Form	Letter-of-Information-Consent-Form.pdf	Dec/02/2020	1	56.9 KB

Providing Participants with Study Results

16.7 Will participants be able to learn about the study results (e.g., mailed/emailed brief summary of results in plain language; posting on website or other appropriate means for this population)?

- (•) Yes
- ( ) No

16.9 Explain how participants will learn about study results:

The participants will learn about the study results through the research paper. The paper should be complete by May 2020. If desired, a copy will be sent to each requester.

Participant Withdrawal

16.10 Will participants have the right to withdraw from the study during their data collection (e.g. during an interview, during a lab session)?

- (•) Yes
- ( ) No

16.10.1 Describe:

a) how the participants will be informed that they can withdraw during the data collection process, and
b) the procedures which will be followed to allow participants to exercise this right.

a) The Letter of information/consent explicitly states their right to withdraw.
b) All that would be required to withdraw would be an e-mail to a Student investigator who will acknowledge the email in response to the withdrawal, or verbally at the point of contact.

make this part of your oral script

16.10.2 For a participant who withdraws during the data collection process, describe:

a) what will be done with any data collected up to the point of withdrawal, and
b) consequences withdrawal might have on the participant, including any effect that withdrawal may have on the participant(s) incentive/reimbursement or continuation of services (if applicable).

a) If a participant withdraws, all of their data will be deleted, if they so wish.
b) There is no compensation for participation.

16.11 Will participants have the right to withdraw their data from the study after their data has been submitted/collected?

- (•) Yes
- ( ) No
- ( ) Both Yes and No (e.g. due to multiple data collection methods)

16.11.1 Describe:

a) at what point/date after data collection it will no longer be possible to withdraw data from the study,
b) how participants can request data be removed before this point/date, and
c) if there will be any consequences for participants withdrawing their data.

Be sure to include these details in the Letter of Information.

a) Participants are able to withdraw data from the study at any time before the data has been analyzed into the study.
b) Participants can request data to be removed by sending an email to a Student investigator.
c) There will be no consequences for withdrawing.

Your informed consent letter says this?
They can also withdraw at the ~~the~~ during the interview if they so wish

Incidental Findings and Third Party Disclosure

16.13 Is there a potential of material incidental findings resulting from your research? See the info button for further details (most studies reviewed by MREB will not have incidental findings).

- ( ) Yes
- (•) No

16.15 Is there a reasonable possibility the researcher will obtain information from participants that will require the researcher to break confidentiality and report details to a third party? This could be a legal or ethical requirement (e.g. suspected child abuse, imminent self-harm or harm to others). See the info button for further details.

- ( ) Yes
- (•) No

Additional Information

18.1 Do you have any additional information or documents relevant to this project that you wish to provide to the Research Ethics Board?

- ○ Yes
- ◉ No

Posting of Approved Protocols on the Research Ethics Website

18.4 Public posting your research title

It is the policy of MREB to post a list of cleared protocols on the Research Ethics website. Posted information usually includes: title, name of principal investigators, principal investigator department, type of project (i.e. Faculty; PhD; Masters, Undergraduate etc.)

Do you request that the title be deleted from the posted information?

- ○ Yes
- ◉ No

Supervisor Assurance for Graduate or Undergraduate Student Research:

Investigator Assurances

I understand that the following all constitute violations of the McMaster University's Research Integrity Policy:

- failure to obtain research ethics clearance;
- carrying out research in a manner that was not cleared by one of the university's REBs (see TCPS, Art. 6.11);
- failure to submit an **Amendment** to obtain ethics clearance prior to implementing substantive changes to a cleared study (see TCPS, Art. 6.16);
- failure to submit an **Annual Report** in advance of the yearly anniversary of the original ethics clearance date; (see TCPS, Art. 6.14).

Additionally, researchers are required to report **Adverse Events** (i.e., an unintended negative consequence or result affecting participants) to the MREB secretariat and the MREB Chair as soon as possible, and no more than 3 days after the event occurs (see TCPS, Art. 6.15). A privacy breach affecting participant information should also be reported to the MREB secretariat and the MREB Chair as soon as possible. The **Reportable Events** form is used to document adverse events, privacy breaches, protocol deviations and participant complaints.

I confirm that I have read the McMaster University Research Integrity Policy, and I agree to comply with this and other university policies, guidelines and the Tri-Council Policy Statement (TCPS) and the guidelines of my profession or discipline regarding the ethical conduct of research involving humans.

20.4 Signature of Student Investigator (Student Principal Investigator) for Supervised Projects

20.5 **Signature of Faculty Supervisor of Student Research**

I am the supervisor for this proposed student research and have read this ethics application and supporting documents and deem the project to be valid and worthwhile. I will provide the necessary supervision of the student researcher(s) throughout the project, will ensure that the project will be conducted as cleared, and will make myself available should problems arise during the course of the research.

Supervisors must be registered with MacREM (have logged in with MacID at least once) before they can sign. Make sure the supervisor has logged into MacREM before you Request their signature. Also click the Share tile to give supervisors permissions to access the form.

A MacID is required to sign the form. A temporary MacID can be obtained for an external Faculty Supervisor. Contact the ethics office at x23142 or ethicsoffice@mcmaster.ca.