LOYALIST COLLEGE

(For Office Use) REB File # _____

Application to Participate in Research Form

SECTION A – GENERAL INFORMATION

1. **Title of Research Project:** _____

2. a) **Investigator Information:**

	Name & Position	Dept./Address	Phone No.	Email
Principal Investigator (PI)*				
Faculty: Co-Investigator(s)				
Student Investigator(s)				
Graduate Supervisor				
Other Investigator(s)				

*** The advisor must be listed as PI for any student investigators. Student investigators include faculty/staff who are completing research for educational purposes.**

b) Have you received support to submit your research study from your supervisor?
☐ Yes ☐ No If yes, by who?

c) Have you completed the TCPS2 CORE training and included a copy of your certificate?
☐ Yes ☐ No

3. **Proposed Date:** a) Commencement: _____ b) Completion: _____

Note: The commencement date should be the date the principal investigator (PI) expects to actually begin research investigations (including participant recruitment). The completion date should be the date that the PI expects that all research, including any feedback or follow-up, will be complete.

4. **Indicate the location(s) where the research will be conducted:**

5. **Other Research Ethics Board Approval**
   a) Has any other institutional Ethics Board approved this project? ☐ Yes ☐ No ☐ N/A

      i. If **YES**, please provide the following information:

      ii.

      Title of the project approved elsewhere: _____

      Name of the other institution: _____

      Name of the other Ethics Board: _____

      Date of the decision: _____

      A contact name and phone number for the other Board: _____

      OR

      A copy of the clearance certificate/approval **AND** final copies of all supporting documentation already approved

      iii. Do you plan on submitting to another institution Ethics Board with this project in the future?
      ☐ Yes ☐ No ☐ N/A

6. **Project Funding**
   a) Is this project currently funded? ☐ Yes ☐ No ☐ N/A

      i. If **YES**, please indicate:

      Period of Funding From: _____ To: _____

      Agency or sponsor (funded or applied for):
      ☐ CIHR: _____

      ☐ NSERC: _____

      ☐ SSHRC: _____

      ☐ OCE: _____

      ☐ CFI: _____

      ☐ Other: _____

Note: Please specify the complete title of the funding source. For example, 'NSERC Discovery Grant"

Note: If the funding source changes, or if a previously unfunded project receives funding, you must submit a change/amendment form.

7. **Conflict of Interest**
   a) Will the researcher(s), members of the research team, and/or their partners or immediate family members:

      i. 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 connected to this study? ☐ Yes ☐ No ☐ N/A

      ii. If **YES**, please describe the personal benefits below. (Do not include conference and travel expense coverage, possible academic promotion, or other benefits which are integral to the general conduct of research.)

      iii.

   b) Are there any real, perceived or potential conflicts of interest of which you are aware (for example, researchers who will benefit financially from the research, research which may be in conflict with institutional roles and responsibilities, faculty members who may be responsible for awarding participant grades)? ☐ Yes ☐ No ☐ N/A

If **YES**, please explain:

   c) Are there any restrictions regarding access to or disclosure of information (during or at the end of the study) that the sponsor or institution has placed on the investigator(s)? ☐ Yes ☐ No ☐ N/A

If **YES**, please explain:

d) Is there the possibility of commercialization of the research findings?
☐ Yes ☐ No ☐ N/A

SECTION B – SUMMARY OF THE PROPOSED RESEARCH

8. **Rationale**

a) Describe the purpose and background rationale for the proposed project, as well as the hypothesis(es)/research question(s) to be examined. This needs to be consistent with what is stated in all information letters and consent forms.

Please explain purpose, background, hypotheses and predictions.

9. **Significance of the Research in the Real World**

a) Describe how this research is significant in real-world applications.

10. **Methodology**

a) Describe sequentially, and in detail, all procedures in which the research participants will be involved (e.g., paper and pencil tasks, interviews, surveys, questionnaires, physical assessments, physiological tests, time requirements, etc.).
Note: Attach a copy of all questionnaire(s), interview guides or other test instruments.

b) Does this research involve human participation? ☐ Yes ☐ No

c) Does the nature of the research create vulnerability for any of the groups listed below?
☐ Yes ☐ No ☐ N/A

i. If **YES**, check all that apply:

☐ People with relevant health issues
☐ People in medical emergencies
☐ Indigenous people
☐ People in long-term care
☐ People with mental health issues
☐ Other (please specify):
☐ Children
☐ Elderly people
☐ People in poverty
☐ People in prison
☐ People who are unable to consent

ii. If **YES 10c) above**, please explain your screening process:

Note: Researchers must destroy all information collected during screening in a secure manner as soon as screening is complete.

Please explain how you will destroy your screening data securely:

11. **Recruitment**

a) How do you plan to recruit participants? (Please check all that apply):

☐ Investigators will approach their own subjects
☐ Investigators will receive referrals from other faculty
☐ Indirect advertising (e.g. poster, email, web-based)
☐ Database of people who consented to future contact
☐ Direct approach (e.g. random digit dialing, blogs and chat room)
☐ Educational records (e.g. academic performance information, student information system)
☐ Other

If **OTHER**, please specify:

b) Do you screen personal health information to identify potential participants?
☐ Yes ☐ No ☐ N/A

c) Does your recruitment plan require you to contact potential participants by:

Telephone	☐ Yes	☐ No	☐ N/A
Personal Email	☐ Yes	☐ No	☐ N/A
Anonymous Email	☐ Yes	☐ No	☐ N/A
Letter	☐ Yes	☐ No	☐ N/A

Note: If you answered YES to any category above, please attach a copy of all telephone scripts and recruitment correspondence.

12. **Informed Consent**

a) Will you be seeking *written* consent from participants? ☐ Yes ☐ No ☐ N/A

i. If **YES**, please attach a copy of the Information Letter and Consent Form for Participants.

Note: Participants should *actively* choose whether or not to participate. A lack of response (i.e. a statement such as "you will be assumed to want to participate unless you indicate otherwise to the researchers") should not be construed to imply consent. Written consent is not required in all circumstances. For example, you could require participants to click a box in an online survey or provide verbal consent.

b) If consent will not be written, please provide details of how you will obtain and document consent in the box below.

c) Will any participants be minors (i.e. ages 0-18)? ☐ Yes ☐ No ☐ N/A

d) Will all participants be competent to consent? ☐ Yes ☐ No ☐ N/A

e) If the participants are minors, or are not competent to consent, describe the proposed alternate source of consent. Please include any permission/information letter to be provided to the person(s) providing the alternate consent.

f) Who will obtain consent to participate for minors or those not competent to consent?

g) When and where will this be done?

h) Do you need to request a waiver of consent? ☐ Yes ☐ No ☐ N/A

i. If **YES**, please explain:

i) Will any of the investigators have a position of power or authority over the participants?
☐ Yes ☐ No ☐ N/A

i. If **YES**, how will you manage and minimize any undue influence?

j) Will continuing consent (for example, research which may continue beyond an academic year) be required during the study? ☐ Yes ☐ No ☐ N/A

i. If **YES**, please explain:

k) Will participants have the option to withdraw from this study? ☐ Yes ☐ No ☐ N/A

i. If **YES**, what do they have to do to withdraw?

l) Indicate what will be done with the participant's data and any consequences for the participant withdrawing from the study.

m) If participants will not have the right to withdraw from the project, please explain the rationale:

n) Will you be using deception in your research? ☐ Yes ☐ No ☐ N/A

i. If **YES**, please explain:

13. **Collection of Personal Information**

a) Please check all types of data which you intend to collect:

☐ Identifying information which identifies a participant through direct identifiers (e.g. full name, medical record number)

☐ Identifiable information which could identify a participant through a combination of indirect identifiers (e.g. DOB plus address)

☐ De-identified/coded information in which identifiers are removed and replaced with a code; the code can be used to re-identify participants

☐ Anonymized information in which all identifiers are removed and no code is kept

☐ Anonymous information in which no identifiers are collected

b) Will all data be treated as confidential? ☐ Yes ☐ No ☐ N/A

i. If **NO**, please explain:

c) Will you collect any Personal Health Information (PHI)? ☐ Yes ☐ No ☐ N/A

Note: The collection, use and disclosure of Personal Health Information (PHI) is regulated by the Personal Health Information Protection Act (PHIPA). Researchers must comply with this legislation. Collection of participant SIN (social insurance number) is prohibited, unless payments to participant exceed $500/year (required for tax purposes). PHI should be collected at the lowest level of identifiability possible (e.g. initials instead of a name, age instead of DOB)

Please detail the specific identifiers required for this study:

	Identifier (Check all that apply)	Why is this necessary?
☐	Full name	
☐	Initials	
☐	Student/Employee number	
☐	Social insurance number	
☐	Health card number	
☐	Medical record number	
☐	Address	
☐	Full postal code	
☐	Partial postal code	
☐	Telephone number	
☐	Email	
☐	Physician	
☐	Date of birth	
☐	Age	
☐	Other (Specify)	

d) How will you record study data?

☐ Case report form

☐ Other, please specify:

14. **Storage and Protection of Information**

Note: PHIPA Requirements

- **Paper files with identifiable information must be kept in a locked cabinet within a locked office (but not at home)**
- **Electronic files with identifiable information may be stored on a password-protected computer on a secure network (i.e. Virus protection, file backup, firewall) or they must be encrypted**

- **Electronic files with identifiable information may be stored on mobile devices (e.g. laptop, CD, USB, PDA), but no alternative method of storage; these files must be encrypted**
- **Identifying and/or identifiable PHI cannot be transmitted by email unless it is encrypted**

Note: Coding

- **Identifying and/or identifiable PHI should be protected by a coding system**
- **The code (study ID and identifiable PHI) must be isolated from study data and stored in a secure manner**

a) Will you use a coding system to protect identifiable information?
☐ Yes ☐ No ☐ N/A

i. If **NO**, please explain:

b) How will you store and protect the study code (or other data with identifiers)?

Type of Record	Required Protection	Location (ex. building, room)
Paper File	☐ Locked cabinet in locked institutional office	
	☐ Password protected computer on a secure network	
	☐ Encrypted (specify software used):	
	☐ Identifiers and participant data are stored separately	

c) How will you store and protect data without identifiers?

d) Do you plan to anonymize the study data? ☐ Yes ☐ No ☐ N/A

i. If **YES**, at what point in the study?

Note: You are required to destroy identifiers or links at the earliest possible time.

e) How long will you keep the study data?

Note: If this study requires Health Canada approval, records must be retained for 25 years. For all other studies, the REB recommends seven years. Sponsors and institutions may set out other requirements.

f) Do you plan on physically moving the data? ☐ Yes ☐ No ☐ N/A

i. If **YES**, how will the data be secured while in motion?

f) What What will you do with the study data after this period?

Note: Use of data for purposes other than those for which the data were originally collected is considered to be secondary use of data and requires the participant's permission.

15. **Transmission of Data**

a) Will the research data be move outside its original location of collection ((for example, sent for transcription or uploaded to a central data repository)? ☐ Yes ☐ No ☐ N/A

b) If **YES**, do these data to be transmitted include identifiers? ☐ Yes ☐ No ☐ N/A

i. If **YES**, please provide details on the data transfer agreement:

ii. If **YES**, where will the data be sent?

Note: Data sent to the United States, or uploaded to American servers (e.g. Survey Monkey), are open to access by American regulatory bodies. Researchers must inform study participants of this possibility.

c) Please list the names and affiliations of persons outside of your research team who will have access to the identifiable data.

Name	**Institutional Affiliation**

Note: If you require outside sources to have access to participant data, you need to ensure that mechanisms are in place to ensure data security, confidentiality and anonymity.

d) How will the data be transmitted?

☐ Fax
☐ Email **(Note: Encryption protocol must be attached)**
☐ Private Courier **(Note: Delivery must be traceable)**
☐ Canada Xpresspost **(Note: Regular mail may not be used)**
☐ Other, please explain:

16. **Secondary Use of Data**

a) Will you combine your research data with any other data sets? ☐ Yes ☐ No ☐ N/A

i. If **YES**, please specify:

Identify the dataset: Explain how the linkage will occur: Provide a list of data items contained in the dataset:

b) Will your data be entered into another database for future use? ☐ Yes ☐ No ☐ N/A

i. If **YES**, please specify:

Where it will be stored? Who will be the custodian? Who will have access to the database? What security measures will be in place?

17. **Experience**

a) What is your experience with this kind of research?

Note: It is strongly recommended that researchers complete the free online TCPS training, available at: www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/. Please attach a copy of the certificate if you have completed the training.

18. **Compensation**

a) Will participants receive compensation for participation?

a. Financial ☐ Yes ☐ No ☐ N/A

b. Non-Financial ☐ Yes ☐ No ☐ N/A

b) If **YES** to **either** i) or ii) above, please provide details, including when compensation is to be paid.

c) If participants choose to withdraw, how will you deal with compensation if already provided?

SECTION C – DESCRIPTION OF THE RISKS AND BENEFITS OF THE PROPOSED RESEARCH

19. **Possible Risks to Participants**

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

Physical risk (including any bodily contact or administration of any substance)?	☐ Yes	☐ No	☐ N/A
Psychological risks (including feeling demeaned, embarrassed worried or upset)?	☐ Yes	☐ No	☐ N/A
Social risks (including possible loss of status, privacy and/or reputation)?	☐ Yes	☐ No	☐ N/A
Economic risks (including incurring expenses, loss of incentive)?	☐ Yes	☐ No	☐ N/A
Academic risks (including loss of bonus marks or course standing)?	☐ Yes	☐ No	☐ N/A
Potential access to personal data	☐ Yes	☐ No	☐ N/A
Are any possible risks to participants greater than those the participants might encounter in their everyday life?	☐ Yes	☐ No	☐ N/A

b) If you answered **YES** to any of the risks above, please explain the risk.

c) Please comment on the magnitude of harm participants are likely to encounter, i.e. would you assess it as minimal, substantial, transient or longer lasting?

d) Please comment on the probability that participants will encounter harm, i.e. would you assess it as low, medium or high?

e) Describe how the risks will be managed (including an explanation as to why alternative approaches could not be used).

20. **Possible Risks to Researchers**

Please describe any risks to researchers which you anticipate.

21. **Possible Benefits to Participants**

a) Discuss any potential direct benefits to the participants from their involvement in the project. Comment on the (potential) benefits to the scientific community/society that would justify involvement of participants in this study.

22. **Possible Benefits to Researchers**

a) Discuss any potential direct benefits to the researchers from their involvement in the project.

SECTION D – PARTICIPANT FEEDBACK

23. Explain what feedback/ information will be provided to the participants after participation in the project. (For example, a more complete description of the purpose of the research, or access to the results of the research). Indicate when results will be available and, if they will be made available on the internet, the URL to be used to access the results:

Note: Feedback should be provided in a way which is accessible to participants. For example, some participants may not have access to a computer, so uploading results to a website may not be sufficient.

SECTION E – MONITORING ONGOING RESEARCH

24. **Annual Review and Adverse Events**

a) Protocol review requires the completion of a "Renewal/Completed Status Report" at least annually. Indicate whether any additional monitoring or review would be appropriate for this project.

Note: It is the principal investigator's responsibility to notify the REB when the project is completed, or if it is cancelled, using the appropriate form.

b) **Adverse events** (i.e. unanticipated negative consequences or results affecting participants) must be reported to the Research Ethics Board and the Research Ethics Coordinator as soon as possible using the form available on this website.

25. **Dissemination of Findings**

a) Do you plan to publish or present the findings outside of the College/institution?
☐ Yes ☐ No ☐ N/A

i. If **YES**, please explain dissemination strategy.

ii. If **NO**, the only use of the data will be for course/program decision making. All ethics principles must be met, however, REB approval may not be required.

26. **Additional Information**

SECTION F – SIGNATURES

Principal Investigator (PI) Assurance:

I, _____ [PLEASE PRINT] have the ultimate responsibility for the conduct of the study described in this application including my responsibilities as an advisor to any students involved in this project. I have read and am responsible for the content of this application. The information provided is complete and accurate. I understand that, as Principal Investigator, I will be the primary link with the REB, other researchers involved with this project, and the research participants. I agree to conduct the research in accordance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans and by the Policies and Procedures at Loyalist College for Ethical Conduct of Research.

I also understand that if I make any additional changes whatsoever to the sample documents provided with this application (including, but not limited to, the recruitment scripts, information and consent letters, survey questions, interview or focus group questions), I need to complete a change request form and submit this to the REB for review. I further understand that these changes, if determined to be substantive by the REB, may require a new application if they constitute new research. If any changes are made in the above arrangements or procedures, or if adverse events are observed, I will bring these to the attention of the Research Ethics Coordinator immediately.

I understand that if I fail to advise the REB of any changes or adverse events, or fail to comply with research protocols outlined in this application, or make any unauthorized changes to any document submitted with this application, the Certificate of Ethical Acceptability may be rescinded by the REB.

_____ _____

Signature of Principal Investigator **Date**

Please email a copy with signature to:

Kurstin Salisbury - Research Ethics Board Coordinator
ksalisbury@loyalistcollege.com

Loyalist College Applied Arts and Technology
376 Wallbridge-Loyalist Road
P.O Box 4200
Belleville, ON
K8N 5B9
(613) 969-1913, ext. 2275

If your study is determined to be high risk and requires a full board review, you will be asked to provide the following:

<u>Original Copy + Five additional copies</u> of the following DOCUMENTS	✓ if applicable
Recruitment Materials • Letter of invitation • Verbal script • Telephone script • Advertisements (newspapers, posters, etc.) • Electronic correspondence guide	☐ ☐ ☐ ☐ ☐
Consent Materials • Consent form • Assent form for minors • Parental/third party consent • Transcriber confidentiality agreement	☐ ☐ ☐ ☐
Data Gathering Instruments • Questionnaires • Interview guides • Tests	☐ ☐ ☐
Feedback Letter	☐
Letter of Approval for research from cooperating organizations, school board(s), or other institutions	☐
Any previously approved protocol to which you refer	☐