Cairn UNIVERSITY

Institutional Review Board Application

Project Title:

SECTION ONE:

1. Name of Researcher who is submitting this IRB Application:

First Name:	Last Name:
Phone:	Email:
Is this research a requirement for a class at Cairn University?	If yes, which class.
Is this research a requiement for an academic institution other than Cairn University?	If yes, which institution?

2. Faculty Sponsor or Principal Investigator

First Name:	Last Name:
Degree(s):	Title:
School/Department:	City/State
Phone:	Email:

3. List all project personnel including faculty, staff, outside individuals or agencies and their role in the research:

4. Is this research funded? If so, by whom?

Please attach:
Copy of Informed Consent in an Appendix
Copy of Recruitment Script in an Appendix
Copy of Survey Wording in an Appendix

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SECTION TWO: Include a detailed description of each of the following:

1. Purpose

Summarize the purpose of the study and the hypothesis(es) which are to be tested.

2. Background

Describe succinctly and clearly the past findings which led to the plan for this project. A summary of the relevant literature and reports of previous studies may be included. Please limit this section to 3-5 paragraphs.

3. Research Design

Prepare an orderly scientific description of the intended procedures as they directly affect the subject. Describe the various study procedures (interviews completing questionnaires, etc.) including frequency and duration and plans for follow-up. If there is a point at which the study procedures may be discontinued, state how it will be monitored and identified. In an appendix, Include a copy of any questionnaires, surveys or a brief outline of questions to be asked in group settings. If the questionnaires are standardized, please list the names of questionnaires that will be administered. Will data be retained with or without identifiers for use in future research projects (that is, will a database be constructed for future analysis or recruitment)?

4. Subject recruitment and selection:

Summarize the process of obtaining potential subjects, including the description and rationale for the use of the selected subject population or rationale for the use of archive or specimen material to ensure that subject selection is equitable. Include: plans for recruitment and consent of participants and attach a copy of any advertisements or recruiting material. Describe any inducements which will be offered to subjects, such as cash payments, gift certificates, etc. Include copies of all letters to subjects and intermediaries. Indicate all special categories of subjects to be included, such as mentally challenged or disabled, minor, pregnant women, prisoners. If subjects are excluded because of age, gender, economic status, or race, the reason for the exclusion must be documented.

Age:

- Age range of subjects
- Will children and/or adolescents (18 years of age or younger) be included in this research?
- If yes, what is the age range of child and adolescent subjects?
- What is the rationale for the age range chosen, including (if applicable) the justification for including children and adolescents?

5. Duration:

Provide an estimate of the duration of the entire study, including an estimate of the duration of each subject.

6. Location:

Provide the specific name of the organization from which subjects will be recruited and where the research will take place. For locations other than Cairn University facilities, documentation must be submitted that supervisory personnel are aware of and approve the project.

7. Consent Procedures:

Investigators are ethically obligated to inform participants that the study involves research, the research procedures, that the research is voluntary, and provide the participant with information about whom to contact with questions, with information that the research involves interactions with participants, and considerations to minimize coercion and undue influence. Submit proposed consent forms or scripts in appendices.

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8. Protection of Subjects:

Describe procedures (including confidentiality safeguards and provisions for protecting the privacy, interests of participants) for protecting against or minimizing potential risks and assessment of their likely effectiveness, including steps to protect the privacy and/or confidentiality or participants' responses or maintain anonymity of research data. Note: The investigator must take all necessary steps to maintain confidentiality of data. This includes coding data and choosing an appropriate and secure data storage mechanism which will prevent unauthorized access to data. It may be advisable to delete or destroy data at the conclusion of the study.

9. How will the data that you are collecting be protected?

Include your plans to remove identifiers, to keep the data in a safe place, and to delete data at the completion of the study. If identifiers are not removed from the data, explain why and how you plan to keep this data protected.

10. Potential Risks:

Describe and assess any potential risks (physical, psychological, social, economic, monetary, legal, or other) and assess the likelihood and seriousness of such risks. If methods or research create potential risks, describe other methods, to minimize those risks.

11. Potential Benefits:

Assess the potential benefits to be gained by the individual subject, as well as benefits which may accrue to society in general because of the planned work.

12. Risk/benefits ratio:

Analyze the ratio of the benefit to be obtained from the study relative to the risks involved.

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Principal Investigator's Assurance:

I certify that the information provided in this claim of exemption is complete and correct.

I understand that as a Principal Investigator, I have ultimate responsibility for the protection of the rights and welfare of human subjects and the ethical conduct of this research project/protocol. I agree to comply with all Cairn policies and procedures as well as with all applicable federal, state, and local laws regarding the protection of human subjects in research, including but not limited to the following:

- The project will be performed by qualified personnel according to the research project/protocol.
- Maintain a copy of all questionnaires, survey instruments, interview questions, data collection instruments, and information sheets for human subjects for at least three years following the termination of the project, unless otherwise necessary to protect subject confidentiality as described in the project/protocol.
- Obtain necessary review by the Cairn IRB if substantial changes are made in the research project/protocol or if any change is made which may result in the research no longer meeting the criteria exemption.

If the project is federally funded, I will complete the required educational program on ethical principles and regulatory requirements in human subject research prior to initializing the research.

I have read and understand the above Cairn guidelines concerning exempt project/protocols.

X _____

Principal Investigator or Student Conducting Research Printed Name Date

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Faculty Sponsor's Assurance (For students, resident, and fellow projects only)
**The Faculty sponsor must be a member of the standing Cairn faculty. The faculty sponsor is considered the responsible party for legal and ethical performance of the project.*

By my signature as sponsor on this research application, I certify that the student or investigator is knowledgeable about the regulations and policies governing research with human subjects and has sufficient training and experience to conduct this study in accord with the approved project/protocol. In addition,

- I agree to meet with the principal investigator on a regular basis to review study progress.
- Should problems arise during the study, I agree to be available, personally, to supervise the principal investigator in solving them.
- I assure that the principal investigator will complete all required educational programs on the ethical principles and regulatory requirements in human subjects research as required.
- If I will be unavailable, as when on sabbatical, leave on vacation, I will arrange for an alternate faculty sponsor to assume responsibility during my absence, and I will advise the Office Regulatory Affairs by letter of such arrangements.

X _____

Faculty Sponsor* Printed Name Date

Department Head Signature

As a department head, I acknowledge that this research is in keeping with the standards set by our department and I assure that the principal investigator will meet all departmental school requirements for review and approval of this research prior to initiation.

X _____

Department Head Signature* Printed Name Date