BRIERCREST

APPLICATION FOR REVIEW BY RESEARCH ETHICS BOARD
FOR RESEARCH WITH HUMAN PARTICIPANTS

Application Information

Application Date:_____ Proposed Research Start Date:_____

Application Status: ___ New ___ Renewal
___ Addendum to Application dated _____

Investigator Information

Principal Investigator:_____
___Faculty ___Staff ___Student ___Other (explain):_____
Email Address: :_____ Phone:_____

Investigator:_____
___Faculty ___Staff ___Student ___Other (explain):_____
Email Address: :_____ Phone:_____

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Investigator:_____
___Faculty ___Staff ___Student ___Other (explain):_____
Email Address: :_____ Phone:_____

If more than six investigators are involved in this project, include their information on a separate sheet of paper and attach it to this application.

Investigator's Agreement

I certify that the information provided in this application is correct and complete.
I understand that, as Principal Investigator, I have ultimate responsibility for the conduct of the study, the ethics performance of the project and the protection of the rights and welfare of human participants. I agree to comply with the Tri-Council Policy Statement and all Briercrest policies and procedures governing the protection of human participants in research, including, but not limited to:

- ensuring that those performing the project are qualified and appropriately trained
- implementing no changes to the REB approved protocol or consent form/statement without notification to the REB of the proposed changes and their subsequent approval;
- promptly reporting significant adverse effects to the REB within five (5) working days of occurrence; and
- submitting, at minimum, a progress report annually or in accordance with the terms of certification.

Principal Investigator's Signature: :_____ Date:_____

Investigator's Signature: :_____ Date:_____

Investigator's Signature: :_____ Date:_____

Investigator's Signature: :_____ Date:_____

Investigator's Signature: :_____ Date:_____

Investigator's Signature: :_____ Date:_____

Project Details

Title of Research Project:_____

Type of Project (check one): ___Faculty research ___Student research
___Other (specify):_____

Research Sponsor:

Status of Funding: ___Applied for ___Held ___No funding required

Summary of Proposed Research

A. State the purpose of the research.

B. Describe in detail what will be done to participants. Attach a copy of any questionnaires or test instruments.

C. Describe your experience with this kind of research.

D. Do any of the procedures involve contact with the body (e.g., touching, physical attachment to instruments, collection of biological specimens?) ___Yes ___No

E. Does the study involve the administration of any drugs? ___Yes ___No

Participants

A. Describe the salient characteristics of the participants (number, age range, gender, institutional affiliation, location)

B. Describe how participants are recruited.

C. Describe the relationship(s) between the participants and the investigator(s).

D. What inducements will be offered to participants?

Risks of Proposed Research

A. In your estimation, might the participants be harmed in any way?	___Yes	___No
B. Will you deceive them in any way?	___Yes	___No
C. Are there physical risks?	___Yes	___No
D. Are there any psychological risks? Might the participants feel demeaned, embarrassed, worried, or upset?	___Yes	___No
E. Are there any social risks (possible loss of status, privacy, and/or reputation)?	___Yes	___No

IF THE ANSWER IS "YES" TO ANY OF THE ABOVE, EXPLAIN WHY ALTERNATIVE APPROACHES INVOLVING LESS RISK CANNOT BE USED. PROCEDURES FOR REVERSING REVERSIBLE HARM SHOULD BE STATED. ATTACH ANSWERS TO FORM.

Benefits of Proposed Research

What are the proposed benefits to the participants, the scientific community, and/or society that would justify asking participants to participate?

Informed Consent

A. Describe the explanation to be given to participants before they agree to become participants in the project. In the case of mail surveys, attach a copy of the explanatory letter that participants will receive. *(See Appendix A for details/elements which normally would be addressed in an information letter to prospective participants)*

B. Are participants competent to give consent? ___Yes ___No

If "No," describe the alternate source of consent.

If participants are minors, describe the procedure to be used.

C. Do participants have the right to withdraw at any time during (and even after) the project? ___Yes ___No

D. Are participants informed of this right? ___Yes ___No

If the answer to "C" or "D" is "No," please explain.

E. What procedures will be followed for participants who wish to withdraw at any point during or after the project?

Confidentiality of Data

A. Will the data be treated as confidential? ___Yes ___No

If "Yes," explain the steps that will be taken to ensure confidentiality. If "No," explain why not.

B. Where will the data be stored and who will supervise access to the data?

Debriefing

Will participants be debriefed at the end of the project? ___Yes ___No

If "Yes," explain how this will be done. If "No," explain why not.

APPENDIX A: GUIDELINES FOR INFORMATION LETTER TO PROSPECTIVE PARTICIPANTS

In order to obtain free and informed consent, researchers should inform prospective participants in regard to details about the study as well as the procedure to be used. A copy of the letter to be used in this process must be appended to the application for ethics review. Normally participants who are being asked to participate in other than a study involving use of a questionnaire, must be asked to provide their consent in writing. Two copies of the information-consent letter must be signed. The researcher retains one and the other is provided to the participant for his/her records. It is understood that all participants will provide free and informed consent, voluntarily given, without manipulation, undue influence or coercion. A number of important details/elements must appear in the Information Letter in order to ensure that the participants have been adequately informed. An acceptable information letter normally would include:

- name of faculty investigator (and student investigator(s), where applicable);
- departmental affiliation(s) with local telephone extension and/or e-mail address for each;
- information that the individual is being invited to participate in a research project;
- a statement of the research purpose in plain language, the identity of the funder or sponsor, the expected duration and nature of participation, a description of research procedures, and an explanation of the responsibilities of the participant;
- a plain language description of all reasonably foreseeable risks and potential benefits, both to the participants and in general, that may arise from research participation;
- an assurance that prospective participants:
    - are under no obligation to participate and are free to withdraw at any time without prejudice to pre-existing entitlements;
    - will be given, in a timely manner throughout the course of the research project, information that is relevant to their decision to continue or withdraw from participation; and
    - will be given information on the participant's right to request the withdrawal of data, including any limitations on the feasibility of that withdrawal;
- information concerning the possibility of commercialization of research findings, and the presence of any real, potential or perceived conflicts of interest on the part of the researchers, their institutions or the research sponsors;
- the measures to be undertaken for dissemination of research results and whether participants will be identified directly or indirectly;
- the identity and contact information of a qualified designated representative who can explain scientific or scholarly aspects of the research to participants;
- the identity and contact information of the appropriate individual(s) outside the research team whom participants may contact regarding possible ethical issues in the research;
- an indication of what information will be collected about participants and for what purposes; an indication of who will have access to information collected about the identity of participants, a description of how confidentiality will be protected, a description of the anticipated uses of data; and information indicating who may have a duty to disclose information collected, and to whom such disclosures could be made;
- information about any payments, including incentives for participants, reimbursement for participation-related expenses and compensation for injury;
- a statement to the effect that, by consenting, participants have not waived any rights to legal recourse in the event of research-related harm; and
- in clinical trials, information on stopping rules and when researchers may remove participants from trial.