Protection of Human Research Subjects

Introduction

CBC has a responsibility to protect the rights and welfare of human subjects recruited to participate in research activities (broadly defined) under its auspices. The Institutional Review Board (IRB) was created to insure this protection and to insure that all human subject research is in compliance with federal regulations pertaining to human subjects review (e.g., 45 CFR Part 46 and all subparts). The IRB also assists researchers in conducting safe and ethically sound research involving human subjects.

Scope of the IRB

The CBC IRB can approve, require modifications to, or disapprove all research activities involving:

- Individuals affiliated with CBC (including faculty, staff, or students) who intend to conduct a research project involving CBC faculty, staff, or students.
- Individual not affiliated with CBC, but who want to conduct research at CBC involving faculty, staff, students, use college records or data, or the use of campus facilities.
- Research activities under the direction of CBC faculty or staff that involve human subjects not affiliated with CBC (e.g., K-12 students).

Definitions of Research and Human Subjects

- Research is defined as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge" (34 CFR 97.102d). Research includes other activities that meet this definition, whether or not they are considered "research" in a strict sense. For example, a grant-funded program that provides services to CBC students and collects data for evaluation purposes is considered research in this context.
- A human subject is defined as a "living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or obtains identifiable private information" (34 CFR 97.102f).

Purpose of IRB Review

Federal law and CBC policy require that <u>all</u> projects conducted by CBC faculty, staff, and students using human subjects be reviewed. That is, the review includes student class projects that involve participants outside of that particular class, pilot studies, theses and dissertations, and programs and interventions involving data collection. The goals of the IRB review process are to minimize risks to subjects, determine that risks to subjects are reasonable in relation to anticipated benefits, and determine that the selection of subjects is equitable. The IRB process will ensure that participant informed consent is obtained and

documented and that the data collection methodology maintains participants' safety and confidentiality. As a result, in all research conducted at CBC, subjects will be well-treated physically, psychologically, and socially so as to minimize embarrassment and stress, and to avoid harm or negative effects to individuals or the institution. Although confidentiality is an important aspect of research conducted at CBC, confidential information may be disclosed in some special circumstances. Such disclosure might appropriate, for example, if release of information is needed to protect either the participant or others from harm. Although confidential information may be revealed in such circumstances, the identity of the participant providing the information will not be revealed without their consent. In addition, it is possible that confidential information, as well as the identity of the participant, could be released as a result of legal action. The informed consent forms signed by research participants should include the possibility that confidential information may be released in either of these circumstances.

IRB Membership

The IRB is composed of the CBC President; the Vice Presidents for Instruction, Student Services, Human Resources, and Diversity; and the Dean for Institutional Effectiveness. The Vice President for Administration will be included in the decision-making process where the proposed research potentially involves the use of CBC facilities or equipment. The Dean of Institutional Effectiveness will serve as the committee Chair. Other CBC administrators may be asked to serve in an advisory or consultant role on an ad hoc basis. For example, the Director of Institutional Research could be included in the event that the research proposes to acquire student- or faculty-related data from existing CBC databases. The CBC Registrar would be consulted if there are FERPA-related concerns about the data confidentiality. If a research proposal has the potential to impact CBC faculty members or their classrooms in any way, the affected Dean(s) will be consulted before a decision is made.

The Review Process

The following steps are to be followed in completing the IRB review process:

1. The researcher will submit a completed Human Subjects Review Form (Appendix A) to the Dean of Institutional Effectiveness. The Human Subjects Review Form asks for detailed information about the purpose of the project, a description of number and characteristics of intended participants, a summary of the research methodology or intervention approach, a description of the type of data to be collected, and an assessment of the risks and likely benefits of the study. The Consent Form to be completed by participants will also be submitted by the researcher.
2. Copies of the completed Human Subjects Review Form and Consent Form will be provided to the IRB committee members for their review. The members will consider the following issues in their review:

a. ***Appropriateness of the study design***, to the extent that there are impacts on the rights and welfare of human subjects. Some determination of the validity of the research design may also be made. For example, according to Protecting Human Subjects, Institutional Review Board Guide Book (NIH, 1993), "if a research study is so methodologically flawed that little or no reliable information will result, it is unethical to put subjects at risk or even inconvenience them through participation in such a study." In general, however, the IRB will seek to honor the principles of academic freedom.

b. ***Risks and benefits***. The IRB will review possible risks to the participants of participating in the study, whether the risks are physical or psychological as well as possible risks to the institution. Benefits of the study will also be examined. Benefits can include those to participants, the college, society, or benefits due to new knowledge that is created. These benefits should clearly justify any possible risks to students or to CBC.

c. **Equitable selection of subjects.** Subjects should be selected in a fair and reasonable fashion, free of any coercion. The review will focus closely on any research involving Native Americans or vulnerable subject populations (e.g., limited English proficiency, children).

3. IRB members will complete a Reviewer Feedback Form, in which they rate the extent to which the researcher clearly explained the research purpose, methodology, data collection process, and potential risks and benefits. They will also rate the degree of linkage between the research and CBC's Mission and Vision, the likely impacts on CBC resources, potential legal risks, and the degree of interest CBC will have in the results of the research. Members may provide additional comments on the research and to indicate an overall vote for approval or disapproval of the study.
4. The Dean of Institutional Effectiveness will compile all ratings and comments. If all ratings and comments are favorable and reviewers conclude the project is of low risk, the project will be approved without further action. If there are moderate or substantial risks or concerns, the full IRB committee will be convened to discuss the research and reach consensus on approval or disapproval
5. The researcher will be notified of the IRB decision within 10 working days of submitting the Human Subjects Review Form.
6. After approval of the research by the IRB, the researcher will require participants to complete the Consent Form, which will be kept on file by the researcher.

In accordance with federal regulations, the following types of research are exempted from the IRB review process:

1. Classroom research conducted by the instructor or by students under the supervision of the instructor.
2. Student assessments conducted by instructors or by the college.
3. The collection and analysis of secondary data which do not contain individually identifiers.
4. Research conducted by the Institutional Research office in order to gather data on the college's effectiveness. However, all such activities will be conducted in compliance with accepted standards of research and professional ethics.

Appendix A: CBC Human Subjects Review: Internal Request Form

I. Background Information

1. Principal Investigator/Grant Administrator: _____
2. Phone #: _____ 3. email: _____
4. Title: _____
5. Division/Department: _____
6. Campus Building and Room: _____
7. Campus mailing address: _____

II. Description of Proposed Research

A. Project Title:

B. Abstract/Summary of Proposed Research (purpose, research design, procedures, description of activities proposed for subjects):

C. Type of Research

__ Educational research. This includes research conducted in an educational setting, involving normal education practices. Research is intended to improve educational practice)
__ Study of public behavior. May involve surveys, questionnaires, interviews, observation, etc. but does not involve "sensitive" topics (e.g., criminal behavior, sexual behavior, drug/alcohol use)
__ Study of sensitive behavior. May involve surveys, questionnaires, interviews, observations, etc., but includes sensitive topics (e.g., criminal behavior, sexual behavior, drug/alcohol use)
__ Archival research. Involves the collection or study of existing data, documents, or records.
__ Marketing research. May involve surveys, questionnaires, interviews, observations, etc. focusing on consumer attitudes or behaviors.
__ Program evaluation. Research whose goal is to evaluate the effectiveness and benefit of programs designed to benefit CBC students or employees.

D. Data Collection Methods

1. Describe data collection methodology

2. Type of data to be collected (check all that apply)

__ Survey. How will it be administered (e.g., one on one, group, mail, phone) Attach a copy of the survey

__ Interview. How will it be conducted (e.g. one on one, focus group)? Attach a copy of the interview or focus group guide

__ Observation of public behavior. Describe how this will be accomplished.

__ Examination of archival data or records. Describe type of data to be examined.

__ Experimental manipulation. Describe how the manipulation will be performed (e.g., psychological, biomedical)

3. Status of data after collection:

__ Anomymous

__ Confidential

__ Individuals to be identified

4. Type of informed consent to be obtained:

__ Written. (attach consent form)

__ Verbal. (attach consent script)

__ Implied (describe)

__ Seek waiver of consent (attach explanation)

5. Data storage/maintenance

a. How will data be stored or maintained? List sites where data might be stored.

b. Who will have access to the data?

c. How long will the data be stored?

D. Description of the sample/population

1. How many subjects will be used?

2. How will subjects be selected or recruited? How will they be contacted?

3. Will subjects be compensated or receive extra credit?

4. What is the age range of subjects? Will any be under 18 years old?

5. Will any specific ethnic group or gender be excluded from the study? If so, please explain the reason for exclusion.

6. Will this study involve subjects who are not fluent in English? If yes, attach English and translated versions of consent forms, surveys, etc.

7. Does this study involve the use or creation of protected health information? If yes, please describe the information to be collected.

E. Deception
1. Will any deception of subjects be used in the study? If yes, please describe why this is necessary and when/how subjects will be debriefed.

III. Risks and Benefits of Proposed Research
A. Risks
1, Describe any potential risks to the subjects (including stress, discomfort, embarrassment, legal risks, invasion of privacy, side effects)

2. If any of these risks were to occur, how would they be addressed?

3. Describe any potential risks to CBC

B. Benefits
1. Describe the expected benefits to either the individual or those to society

2. Describe any potential benefits to CBC