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UNIVERSITY OF CALGARY POLICY STATEMENT
ETHICAL CONDUCT FOR RESEARCH INVOLVING HUMANS

CONTEXT OF THIS POLICY STATEMENT

Researchers enjoy important freedoms and privileges, which include freedom of inquiry and the right to disseminate the results thereof, freedom to challenge conventional thought, freedom from institutional censorship, and the privilege of conducting research on human subjects with public monies, trust and support. Along with these freedoms are the responsibilities to ensure that research involving human subjects meets high scientific and ethical standards, is honest and thoughtful inquiry, involves rigorous analysis, respects human dignity, and ensures the application of professional standards. Peer review of research proposals, these freedoms and responsibilities, contributes to accountability, both to colleagues and to society.

At the University of Calgary, the purpose of ethics review of research involving human subjects is a) the protection of research subjects, b) the protection of the University of Calgary, including its academic staff, support staff and students, and c) the education of those involved in research. The following procedures have been designed to meet these three objectives. In addition, they have been designed to a) support research which is beneficial to the University of Calgary, b) use the resources of the University of Calgary in an efficient manner, c) provide an environment that facilitates dialogue on research ethics within the university community, and d) institutionalize and normalize procedures that draw attention to the need to take into consideration ethical issues in training and research. These procedures should complement the educational and research mandate of the University of Calgary and respect the academic freedom of faculty members.

1.0 Requirement for Ethics Review

1.1 All research involving human subjects, conducted by members of the University of Calgary must receive ethics approval from the appropriate University of Calgary Research Ethics Board (REB).

1.1.a Research is defined as the "systematic investigation to establish facts, principles or generalizable knowledge".

1.1.b Research involving human subjects occurs when data is derived from:

- intervention or interaction with a living individual(s)[1];
- secondary sources/non-public sources (e.g., interviews about an individual(s)[2];
- identifiable private information about an individual(s)[3];
- human remains, cadavers, human organs, tissues and biological fluids from individually identified subjects, embryos or fetuses.

1.1.c Certain classes of research involving human subjects are excluded from this requirement, including:

- research conducted by a member of the academic staff as 'Outside Professional Activity'[4];

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[1] This point covers any situation where you as a researcher are directly affecting (even in a small way) a living individual when you do this research. *Intervention* means that you are somehow manipulating the person and/or their environment, or that you are explicitly or implicitly placing them into a situation that you wish to study. *Interaction* means that you are interacting somehow with the living individual (e.g. interviews, questions, observations taken that are noticeable by the individual, etc.). Typical research methodologies covered by this point include controlled experimentation (both field and laboratory) involving humans, written questionnaires, interviews, direct observations of individuals and ethnographic techniques.

[2] If the information that you wish to analyze was gathered by another party, it still requires ethics approval. An example could be a company that automatically tracks phone calls made by their employees. Another example could be student records collected by an educational institute. While the particular institution may have the legal right to collect this information and to make it available to you, you may be on questionable ethical grounds, as the individuals involved have not consented to your use of this information. Therefore, you should submit the research proposal for ethics approval. Similarly, if you gathered the information as a researcher for another purpose, its re-use for a different purpose not covered by the previous approval requires another ethics approval. Secondary use of data refers to the use of data collected for a purpose other than the proposed research itself. Common examples are patient or school records, narrative data or biological specimens originally approved and obtained for one purpose, but which are proposed for use in new research.

[3] If you plan to use information in a private database that identifies individuals and that includes private information about that individual, you need an ethics approval.

[4] If there is a question as to whether your research project is outside professional activity or part of your university activities the Vice President (Research) shall determine whether the research should be classified as

- research undertaken by students outside the auspices of the University of Calgary and/or its academic program, and
- quality assurance studies, performance reviews for organizations or its employees or students within the mandate of the organization, or testing within normal educational requirements, are not subject to REB review unless they contain an element of research, in addition to assessment.[5]

1.1.d Research projects involving humans, conducted by members of the University of Calgary, outside the campus, whether in Alberta, Canada or elsewhere require ethics approval from an appropriate University of Calgary REB. With respect to research conducted, wholly or in part, outside the University of Calgary, researchers are directed to Article 1.14 of the Tri-Council Policy Statement.

1.1e Research involving human subjects conducted by individuals outside the University of Calgary on the University campus or its affiliated institutions/centres requires ethics approval from an appropriate University of Calgary REB.

1.2 Research that involves collection of the following types of data generally does not require an ethics approval:

- information from a public database where aggregated data which cannot be associated with any one individual or group of individuals is obtained[6];
- observations of behavior within a public gathering which cannot be associated with any particular individual or group of individuals[7]; and
- information which is already in the public domain (e.g., autobiographies, diaries or public archives)[8].

1.3 Ethics approval is required for secondary use of data when data can be linked to individuals.[2]

1.4 All course-based research assignments involving human subjects require ethics approval.[9]

1.4.a The criteria applied to determining if an ethics approval is required is "if an activity would be subject to ethics approval in any other context, it is subject to review if it occurs in a teaching and/or training context". Course-based research assignments pose similar risks to research subjects as in other research study.

1.4.b Research projects, which are designed as a learning exercise and/or data collected in supervised laboratory exercises, require ethics approval.

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outside professional activity. If research data collected through outside professional activity is disseminated in the public domain, in association with the University of Calgary, ethics approval is required. It is advisable to request ethics approval if there is a possibility of using the information for research purposes in the future.

[5] If there is a question as to whether the data you are collecting should be classified as a quality assurance study, performance review or testing within normal educational requirements, you should review the project with the appropriate REB Chair.

[6] This statement assumes that the information in the public database was gathered through an honest, ethical process and that the provider has the right to make this information public. This is not always the case. For example, you may find some data published on the WEB that was collected through unethical means or for which the provider may not actually have the right to publicize. If there is any doubt, you should investigate how the material was collected and if the provider has the right to make it public. It is sometimes possible to analyze particular sets of aggregated data in a way that does identify individuals, perhaps through detection of anomalies or by recognizing characteristic patterns. If you plan to do this within your analysis, ethics approval should be obtained.

[7] What constitutes a public gathering is somewhat vague. However, the underlying principle is that neither individuals nor groups can be identified. Typically, you will be making these observations within a time and place generally open to the public, and where the gathering is of random people or of an anonymous group with no known, identifiable membership. If in doubt, apply for ethics approval. A cautionary note is that even when observations do not require ethics approval, the people being observed may take offence to what you are doing. If reasonable, you should clearly indicate what you are doing (e.g. signage) and set things up so that people can opt out of being observed. In essence, this gives participants a limited form of informed consent.

[8] There is an assumption in this statement that the information in the public domain was gathered through an honest, ethical process and that the provider has the right to make this information public. If there is any doubt, you should investigate how the material was collected and if the provider has the right to make it public.

[9] Further clarification of classroom research is provided in the "Guidelines for Ethics Review of Course-Based Research Projects Involving Human Subjects" which can be located on the University's web page for "Ethics in Human Research".

see if the ethical problems can be addressed satisfactorily. If the ethical problems cannot be satisfactorily addressed, the Chair will ask the researcher to submit the proposal for a full ethics review.

4.5.c Where the Chair instructs the researcher to submit the proposal for a full review, and the researcher declines to do so and wishes to appeal the refusal, the relevant Conjoint REB shall hear that appeal at a face-to-face meeting.

5.0 Review of On-Going Research:

5.1 For each protocol that is approved, the principal investigator is required to submit an annual report, a termination report, and such other reports as the REB may require.

6.0 Course-Based Research Projects:[9]

6.1 If a research project is being proposed as part of a course requirement, it must be reviewed using the same criteria as that used in regular or expedited reviews.

6.1.a Research assignments that are repeated across sections and/or semesters may qualify as a "standard protocol".

6.1.a.i The use of a standard protocol is acceptable when the same methodology/research design is used repeatedly and the protocol has received prior approval from the appropriate Faculty /Departmental Ethics Committee.

6.1.b If the research assignment does not follow a standard protocol or varies from previous assignments, it must be reviewed by a Faculty/Departmental Ethics Committee.

6.1.c Departmental level review cannot be used for research in which a student is carrying out research that is part of a faculty member's own research program. Such research must receive ethics approval from the appropriate REB.

7.0 Appeal Process

7.1 If the REB decides against granting ethical approval of a proposal or project, the applicant has the right to appear and to be heard in a meeting with the REB.

7.2 An appeal of a decision of a REB can be made to the Research Ethics Appeal Board.

7.2.a An appeal will be held only on the basis of an error in process, including the potential bias of an appeal board.

7.2.b The decisions of the Research Ethics Appeal Board are final and binding in all respects for any appeal taken by an affected person or group against the decision of a REB.

8.0 Researchers' Procedural Responsibilities

8.1 Submission of Proposals and Projects

8.1.a It is the responsibility of the researcher(s) to obtain ethical approval for any active project, funded or not, involving human subjects and to submit that project with complete documentation to the appropriate REB.

8.1.b In particular, researchers must be aware that ethical review may in the ordinary course take three weeks to complete. Cases involving significant ethical problems may take substantially longer. It is the researchers' responsibility to ensure that there is adequate lead-time available for ethical review in relation to other deadlines.

8.1.c In supervised research, the term "the researcher" must be defined as including both the supervisor and the individual(s) being supervised.

8.2 Sponsored Projects

8.2.a Applications for ethics approval may be made before or concurrently with the submission of proposals to Research Services.

8.2.b The University's Research Services will advise applicants on the need for ethics certification and on University and sponsor requirements and procedures. However, it remains the responsibility of the applicant to provide the REB with complete documentation in adequate time.

8.2.c Ethical approval requires an official statement of acceptance from the appropriate REB chair. Official University endorsement of a research project will be rescinded if an applicant fails to obtain ethics approval. Sponsors may be informed that ethics approval of an application is pending.

8.2.d Project funds will not be accepted and/or released to the project principals until ethics approval is issued and a copy is on file in Research Services.

9.0 Guidelines – Risks and Benefits

9.1 Researchers' Responsibilities

9.1.a The researcher must assess all possible risks involved in and benefits expected from the research.

9.1.b The researcher must be prepared to document all risks and benefits involved.

9.1.c The researcher must be prepared to demonstrate that there is no reasonable alternative methodology that would avoid or reduce possible risks.

9.1.d Where appropriate in light of the risks involved, the researcher may be required to demonstrate successful prior first-hand experience with the methodology proposed and the absence of detriment to the subjects involved.

9.1.e The researcher proposing to use a new methodology must undertake wide consultation and preliminary work, and must be prepared to make the results available to the REB.

9.2 Risks

9.2.a Risks, which go beyond the threshold of minimal risk[17], must be considered.

9.2.b The researcher must be concerned with risks to:

- the subjects involved[18];
- clearly identifiable third parties;
- the researcher personally and any staff involved; and
- broader cultural, ethnic and national interests.

9.2.c The researcher must be concerned with at least the following types of risk:

- physical harm;
- psychological harm;
- injury to reputation or privacy; and
- breach of any relevant law.

9.2.d The researcher must assess not only the likelihood of a given risk, but also the duration and likely reversibility of its impact should it materialize.

9.3 Benefits

9.3.a 'Benefits' include specific advantages to subjects, to third parties or to society or a segment thereof, and any general increase in human knowledge.

9.3.b 'Benefits' include advantages or increases in knowledge both consciously sought by the researcher and likely to arise as byproducts of the research.

9.4 Balancing Risks and Benefits

9.4.a It is always the responsibility of the researcher, and of the REB, to ensure that the projected benefits outweigh the possible risks.

9.4.b The more incalculable the risks or the less tangible the benefits, the more cautious must be the researcher and the REB.

9.4.c The REB must ensure that the research design and proposed implementation procedures are consistent with sound research standards and, where appropriate, with sound standards of professional conduct and practice, in order to be satisfied that there is no unnecessary exposure to risk[19].

9.4.d The REB must always be conscious of the importance of academic freedom for the researcher, particularly where risks are minimal or are the subject of informed consent, or will devolve upon the researcher personally.

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[17] Consistent with Tri-Council Policy the threshold for minimal risk is that potential subjects can reasonably be expected to regard the proability and magnitude of possible harms implied by participation in the research to be no greater than those encountered in everyday life.

[18] Consistent with Tri-Council Policy "certain types of research, particularly in the social sciences and the humanities, may legitimately have a negative effect on public figures in politics, business, labour, the arts or other walks of life, or on organizations. Such research should not be blocked through the use of harms/benefits analysis or because of the potentially negative nature of the findings. The safeguard for those in the public arena is through public debate and discourse, and in extreme, through action in the courts for libel."

[19] Consistent with the Tri-Council Policy research in the humanities and the social sciences which poses, at most, minimal risk shall not normally require a review of scholarly merit.

10.0 Guidelines – Informed Consent

10.1 Nature of Informed Consent: The objective of obtaining informed consent is to ensure adherence to the ethical principle of respect for persons. The elements of consent that must be considered are capacity[20], comprehension[21], and voluntariness[22].

10.1.a The subject or surrogate who is to give informed consent must be given sufficient time and opportunity to consider the information provided, including the opportunity to consult with an advocate or other knowledgeable person, depending on the discipline in question or to the risks involved.

10.1.b The researcher must provide any person who is to give informed consent with at least the following information:

- the individual is being invited to participate in a research project;
- the identity of the researcher;
- a description of the topic being researched;
- a precise description of the subject's involvement;
- a description of the research procedures;
- a description of the possible benefits involved;
- a description of the risks or discomforts involved;
- a description of the extent to which privacy and confidentiality will be protected;
- an assurance that prospective subjects are free not to participate, have the right to withdraw at any time without prejudice to pre-existing entitlements, and will be given continuing and meaningful opportunities for deciding whether or not to continue to participate;
- a contact name, telephone number, and address of an individual in the Research Services Office.

10.1.c Additional information that may be required, depending upon the research protocol, includes:

- a description of likely circumstances of non-participation if the research is therapeutic;
- an assurance that exemplary care will be taken to safeguard the subject;
- a description of how the data will be stored and/or when it will be destroyed;
- an assurance that any new information shall be provided to the subjects in a timely manner whenever such information is relevant to a subject's decision to continue or withdraw from participation;
- the identity of the qualified designated representative who can explain scientific or scholarly aspects of the research;
- information on the appropriate resources outside the research team to contact regarding possible ethical issues in the research;
- an indication as to who shall have access to information collected on the identity of the subjects and descriptions of how confidentiality shall be protected, and anticipated uses of data;
- an explanation of the responsibilities of the subject;
- information on the circumstances under which the researcher may terminate the subject's participation in the research;
- information on any costs, payments, reimbursements for expenses of compensation for injury;
- in the case of randomized trials, the probability of assignment to each option;
- for research which involves health-care interventions, information about (a) foregoing alternative procedures that might be advantageous to the subject, (b) which aspects of the research involve the use of procedures that are not generally recognized or accepted; and

[20]"Capacity" is meant that the individual providing the consent must have the capacity or ability to understand that to which he or she is giving consent, and the researcher has an obligation to ensure the capacity of the consenter.

[21]"Comprehension" indicates that the consent must be presented in such a way, and that the researcher has an obligation to ensure that, the person providing the consent understands that to which he/she is giving consent.

[22]"Voluntariness" implies that consent must be obtained without coercion or undue inducement, and the researcher has an obligation to structure the process in such a way that coercion and/or undue inducement are not perceived by the person giving consent.

(c) particularly in trials of therapeutic interventions, the care provided if the potential subject decides not to consent to participation in the study; and

- the ways in which the research results shall be published, and how the subjects will be informed of the results of the research.

10.1.d When more than minimal risk is involved, the researcher must provide a description of the available mechanisms of compensation, if any, should a risk materialize.

10.1.e The researcher must ensure that prospective subjects understand that their consent may be withdrawn without penalty.

10.2 Format of Consent

10.2.a Consent in any format must demonstrate that there has been compliance with the foregoing requirements.

10.2.b All consents shall be in writing unless an REB specifically authorizes in advance the use of another format in a particular case.

10.2.c Normally, evidence of free and informed consent by the participant or authorized third party should be obtained in writing. Where written consent is culturally unacceptable or where there are good reasons for not recording consent in writing, researchers shall document the procedures used to seek and obtain free and informed consent.

10.2.d Where appropriate to the discipline in question or to the risks involved, a neutral witness should be identified as being present when the consent is given.

10.3 **Special Research Circumstances**

10.3.a 'Special Research Circumstances' include the following:

- therapeutic research in emergency circumstances;
- research capable of impacting physically on a foetus;
- research capable of impacting physically or psychologically on pregnant women;
- research involving human in-vitro fertilization;
- research involving children and mentally incompetent persons;
- research involving prisoners; and
- research involving 'captive groups' such as employees, students, legal wards and the therapeutically dependent[23].

10.3.b In all cases involving 'Special Research Circumstances', the researcher must consult with the REB to obtain details of any specific additional requirements for informed consent.

10.3.c In all cases involving 'Special Research Circumstances', informed consent must be in writing, save that the REB may authorize other formats in cases involving 'captive groups'.

10.3.d In cases involving children or mentally incompetent persons, the written consent must be signed by a person having legal authority to give that consent.

10.3.e In cases involving 'captive groups', informed consent shall be obtained from each individual subject, save that the REB may grant a total or partial exemption from this requirement when it is satisfied:

- that it is impracticable to require that such individual consents be sought;
- that the risks to the subjects involved are minimal; and,
- that informed consent is given by one or more proper persons with responsibility for the 'captive group' in the knowledge that informed consent is not being sought from some or all individual subjects within that group.

10.3.f In cases involving emergency situations consent may be waived if the subject is not competent to consent and a number of conditions are met. The researcher must contact the REB to obtain details of those conditions. If the subject becomes competent he or she must promptly be afforded the opportunity to give free and informed consent concerning continued participation.

10.3.g Compassionate Review – When an individual patient requires urgent treatment that is part of a research protocol, the Chair

[23]The use of class time to collect research data is not considered appropriate unless there is a direct link to the pedagogy or curriculum objectives of that specific course.

or delegate of the Conjoint Health REB may grant approval, provided:

- the treatment is likely to be lifesaving;
- there are no unusual ethical issues identified;
- there is an appropriate consent process;
- the patient's initials/age and date of birth are given;
- a review of the protocol is undertaken by the Chair or delegate;
- one patient only can be included in such a protocol by such mechanism; and
- the decision of the Chair should be reported to the Conjoint Health REB at its next meeting.

Whenever possible, consultation with other, appropriate authorities will be carried out.

10.4 The REB may waive the requirement for consent, if:

- the research involves no more than minimal risk to subjects;
- the waiver is unlikely to adversely affect the rights and welfare of the subjects;
- the research could not be practically carried out without the waiver;
- wherever possible and appropriate subjects will be provided with additional pertinent information after participation; and
- the waived consent does not involve a therapeutic intervention.[24]

11.0 Guidelines – Deception

11.1 Definition of Deception

11.1.a 'Deception' involves any research procedure which does not include, or which alters, some or all of the elements of informed consent as described in section 10.0. Typically this involves either the deliberate withholding of relevant information or the deliberate giving of false information as part of the methodology of research.[25]

11.2 Exceptions to Full and Informed Consent

11.2.a An REB may approve an incomplete and/or deceptive consent procedure if, after rigorous scrutiny, all of the following conditions are satisfied:

11.2.a.i The research involves minimal risk to the participants, and minimal levels of risk are documented.

11.2.a.ii Participant rights and welfare are not adversely affected by the procedure.

11.2.a.iii The research could not practically be carried out without the deception. Researchers must:

- justify their use of the procedure, identifying the manner(s) in which the benefits of the deception outweigh the potential costs;
- demonstrate the inappropriateness of alternative research methods;
- document precedents for using the proposed methodology in their application.

11.2.a.iv Participants must be fully debriefed immediately following their involvement. This debriefing must include all pertinent information in which the exact nature of the deception and its necessity are clearly and fully articulated. A detailed written debriefing scenario, that fully explains the manipulation and its need to the participant, must be submitted as part of the application. Researchers must also provide an explanation of how potential negative effects will be handled.

11.2.a.v Participants must be given the opportunity to withdraw from the study if, after debriefing, they feel they would not have participated had they known about the deception.

11.2.a.vi The proposal does not involve a therapeutic intervention.

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[24] These criteria are consistent with Tri-Council Policy, 1998.

[25] In one sense, almost all research with human participants involves deception—at least to a degree. Actions as simple as not informing participants of the operating hypotheses of a study or asking someone to complete a questionnaire without explaining how it will be scored could be construed as deception. Double blind experiments are not considered deceptive as long as the participant understands the protocol, the procedure can be broken if required and the subject is not led to believe that treatment rather than placebo is being given. As a consequence the REBs must make informed decisions about whether or not the degree of deception in a specific research protocol is or is not acceptable in terms of the costs and benefits that it engenders. Researchers are expected to provide all information required by the REB to make an informed decision. Applications for proposals involving deception require extensive documentation, with no guarantee that a positive decision will result. Each case will be judged on its own merit in the current context of the REB's deliberations.

12.0 Guidelines– Privacy and Confidentiality

12.1 Privacy

12.1.a 'Privacy' involves the right to decide the extent to which personal data that is not already in the public domain may be disseminated.

12.1.b 'Personal data' includes all information relating to a physical or mental condition; personal attitudes, values, concerns, habits or circumstances; social relationships.

12.1.c Privacy must be looked at from the cultural perspective of the subject, not the researcher.

12.1.d It is a requirement of informed consent that a subject be informed both of any anticipated acquisition of personal data by observation or study in a private setting and of the extent to which privacy will be protected.

12.2 Confidentiality

12.2.a 'Confidentiality' involves the preservation of a subject's anonymity and the respecting of guarantees of privacy or confidentiality given to others whose data are to be used.

12.2.b Confidentiality must be preserved when handling the data during the research, when using the data in teaching or for scholarly presentations, and in publication.

12.2.c The research design must include procedures appropriate to securing the degree of confidentiality guaranteed.

12.2.d In the absence of a clear statement to the contrary, it is assumed that confidentiality is guaranteed.

12.2.e It is a requirement of informed consent that any anticipated breach of confidentiality be clearly explained by the researcher to the subject.

12.2.f Appropriate care must be taken to guard against unintended breaches of confidentiality. In particular, where an unintended breach can be anticipated due to the nature or size of a subject population, association or combination of information, the researcher should deal with this risk accordingly.

12.2.g Where the researcher either uses existing data maintained in computerized form or in data banks or institutional records, or proposes to place data in any such system, the researcher must keep in mind that the format may make it impossible to get prior consent for the use of such data.

12.2.h The researcher must always be concerned about risks to third parties arising from the use of confidential material.

12.2.i Researchers are responsible for ensuring the confidentiality of data on human subjects by maintaining such data in secure storage and by limiting access to data to authorized individuals.

12.2.j Upon completion of data analysis, researchers are responsible for ensuring the confidentiality of data on human subjects. This may include destroying, or having suitably destroyed, papers, documents, tapes, questionnaires, etc., that allow identification of individual subjects. If any of the research records are to be held for future analysis, secure storage must be provided.

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