



**The University of British Columbia  
Board of Governors**

**Policy No.:**

**89**

**Approval Date:**

March 2002

**Last Revision:**

**Responsible Executive:**

Vice-President, Research

**Title:**

## **Research and Other Studies Involving Human Subjects**

### **Background & Purposes:**

The University recognizes that the use of human subjects is indispensable for progress in many areas of research and other studies. However, all research involving human subjects should be conducted ethically in ways that protect individual subjects and respect their dignity and rights.

This policy is intended to create a research environment in which human subjects are protected, and to ensure responsibilities are discharged according to the relevant ethical standards, by promoting awareness of research ethics amongst faculty, staff and students, establishing an independent research ethics review process, and putting in place mechanisms for the protection of human subjects in ongoing research including monitoring.

It is the intention of the University to ensure that, where a human subject is involved in research:

- respect is shown for the dignity of research subjects;
- selection of subjects is fair;
- vulnerable persons are protected against abuse, exploitation and discrimination;
- standards for privacy and confidentiality are observed with respect to access, control and dissemination of personal information;
- the ethics review process is fair and effectively independent of the University's other academic and administrative decision-making processes;
- foreseeable harms will not outweigh the anticipated benefits;
- research subjects will not be subjected to unnecessary risks of harm, and their participation in research must be essential to achieving scientifically and societally important aims that cannot be realized without the participation of human subjects;
- actual and potential conflicts of interest of researchers and individuals in the review process are made known and dealt with appropriately.

## **1. General**


1.1. This policy applies to all research involving human subjects in any of the following circumstances:

1.1.1. where such research is conducted by members or associated members of the University acting in their University capacity. Members or associated members

of the University include faculty, emeritus faculty, staff, sessional instructors, clinical professors, administrators, students, visiting or adjunct scholars, fellows, paid or unpaid associates and any other person associated with research at the University; or

- 1.1.2. where such research is conducted at the University, including academic space at affiliated teaching hospitals; or
  - 1.1.3. where such research is administered by the University; or
  - 1.1.4. where ethics approval by the University is required for such research pursuant to an affiliation agreement with other agencies.
- 1.2. Research involving human subjects is defined as any systemic investigation (including pilot studies, exploratory studies, and course based assignments) to establish facts, principles or generalizable knowledge which involves:
- 1.2.1. living human subjects;
  - 1.2.2. human remains, cadavers, tissues, biological fluids, embryos or foetuses.
- 1.3. Notwithstanding the above, research involving human subjects does not include:
- 1.3.1. Research about a living individual involved in the public arena, or about an artist, based exclusively on publicly available information, documents, records, works, performances, archival materials or third-party interviews. Such research only requires an ethics review if the subject is approached directly for interviews or for access to private papers.
  - 1.3.2. Quality assurance studies, performance reviews or testing within normal educational requirements, or activities undertaken by the University for administrative or operational reasons.
- 1.4. The University will regulate the conduct of all research involving human subjects in accordance with the most current version of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* and, where applicable to specific research, other relevant national and international standards.
- 1.5. No research to which this policy applies may be undertaken, nor may University services or facilities, including academic space at affiliated teaching hospitals, be used, nor may funds for such purposes be accepted, nor accounts opened by Financial Services unless the research has received formal ethical approval by one of the University Research Ethics Boards before the research proposed begins and the research has received a Certificate of Approval.

- 1.6. Academic units in which research involving human subjects is conducted are to ensure that those who conduct, and those who are being trained to conduct, such research understand their responsibilities for the ethical conduct of such research and receive appropriate training in the skills necessary for the ethical conduct of such research. This includes awareness of policies and other relevant standards (e.g., legal, professional, institutional) pertinent to the particular area of research.

	<b>Policy No.:</b> <b>89</b>	<b>Authorized Procedures</b>	<b>Procedure Version No.:</b> <b>3</b> (since adoption of last policy version)	<b>History since last Policy version:</b> -May 2009 -April 2006 -March 2002 <b>Originating Date:</b> -May 1993 <b>Next Review:</b> TBD
<b>Title:</b> <b>Research and Other Studies Involving Human Subjects</b>				
<b>Related Procedures, Materials, And Notes</b> Pursuant to Policy 1: Administration of Policies, "Procedures may be amended by the President, provided the new procedures conform to the approved policy. Such amendments are reported at the next meeting of the Board of Governors and are incorporated in the next publication of the <i>UBC</i> Policy and Procedure Handbook."				
End of Cover page / Cover Notes				

## PROCEDURES

### Definitions in Schedule

1. A schedule to these procedures establishes the definitions of terms that apply to these procedures.

### Responsibility to Refer for *REB* Review

2. Each researcher is responsible to:
  - 2.1. Read and be aware of all *UBC* policies related to research, including without limitation this *Policy 89* (which includes procedures, and any other enactments under the *Policy* or procedures).
  - 2.2. Bring to the attention of the Head of his/her department any research or other study proposed by him or her, or proposed by a student working under his or her direction, that could be defined as a study involving human subjects.
  - 2.3. Present sufficient information to the Head to enable a judgment to be made by him or her as to whether the project comes within the definition of research involving human subjects.
  - 2.4. Submit *Behavioural Research* for *REB* review in the form and with the content specified in the *UBC Ethics Directives*.
  - 2.5. Submit *Clinical Research* for *REB* review in the form and with the content specified in the *UBC Ethics Directives*.

- 2.6. Include as part of each *REB* application a process for continuing review appropriate to the project.
- 2.7. Promptly inform the *REB* that is considering, or will consider, an application by the researcher for any similar or equivalent proposal to:
  - a) other *REBs*;
  - b) funding agencies or regulatory bodies; or
  - c) research ethics boards, or the like, of other institutions.
- 2.8. Maintain any issued *Certificate of Approval* in good standing during the research project.
- 2.9. Promptly notify the *REB* that issued a *Certificate of Approval* of any change in the research involving human subjects as proposed and when the project concludes.
- 2.10. Ensure that informed consent, when required, is obtained from research participants prior to their enrolment into the research project in a form and manner prescribed by *TCPS*, *UBC Ethical Directives* and other relevant national and international standards or condition of funding, where applicable.
- 2.11. Report all serious and unexpected study related events to the applicable *REB* in accordance with applicable regulations and guidelines.
- 2.12. Ensure that any amendments to the study personnel, funding, protocol, consent form or any recruitment procedures are approved by the applicable *REB* prior to implementation, except where necessary to eliminate apparent immediate hazards to human subjects.
- 2.13. Promptly notify the applicable *REB* of any unexpected incident, experience or outcome, or any new research knowledge that could impact the conduct of the study or alter the *REB*'s approval or favourable opinion to continue the study.
3. Each Department Head is responsible to ensure that research that involves human subjects is submitted to a *REB* before the research is begun. The Head may wish to appoint a Departmental Advisory Committee to assist in this oversight.

### **UBC Ethics Directives**

4. The *Responsible Executive* shall issue and maintain directives ("*UBC Ethics Directive*") to regulate the conduct of all research involving human subjects in compliance with *Policy 89* (which includes procedures, and any other enactments under the *Policy* or procedures and with the requirements of:
  - a) the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*;
  - b) any other governmental funding agency; and
  - c) other relevant national and international standards or condition of funding, where applicable to specific research.

5. *UBC Ethics Directives* may be issued as linear electronic documents that may include hyperlinks, or as context sensitive electronic documents. Where advice or guidance is included within *UBC Ethics Directives* the distinction between mandatory and nonbinding text must be clear and readily apparent by formatting or other visual markers.

### **Research Ethics Boards**

6. All research involving human subjects must be reviewed by one of the *REBs* before the research begins. The *REBs* and their jurisdictions are as follows:

<b><i>REB</i></b>	<b>Type of Research</b>	<b>Location of Research</b>
<i>UBC – Behavioural Research Ethics Board, Panels A &amp; B.</i>	<i>Behavioural Research</i>	All locations not captured below or as specified by the <i>Responsible Executive</i>
<i>UBC – Clinical Research Ethics Board</i>	<i>Clinical Research</i>	All locations not captured below or as specified by the <i>Responsible Executive</i>
<i>UBC – BC Cancer Agency Research Ethics Board</i>	<i>Behavioural Research</i> <i>Clinical Research</i>	BC Cancer Agency site(s)
<i>UBC Okanagan Research Ethics Board</i>	<i>Behavioural Research</i>	<i>UBC Okanagan campus</i>
<i>UBC – Providence Health Care Research Ethics Board</i>	<i>Behavioural Research</i> <i>Clinical Research</i>	Providence Health Care site(s)
<i>UBC-Children’s &amp; Women’s Research Ethics Board</i>	<i>Behavioural Research</i> <i>Clinical Research</i>	Oak Street campus site and associated Provincial Health Services Authority agencies and Institutes
Any other ethical review board appointed or authorized by the <i>Responsible Executive</i>	<i>Behavioural Research</i> <i>Clinical Research</i>	As directed by the <i>Responsible Executive</i>

### **Authority of the UBC Research Ethics Boards**

7. Each *REB* is established and empowered to ensure that all research conducted under the auspices of the University is designed and conducted in such a manner that it protects the rights and welfare and privacy of research subjects. Each *REB* has the authority to suspend or terminate research:
- 7.1. that is not being conducted in accordance with its requirements; or
  - 7.2. that has been associated with unexpected serious harm to subjects; or
  - 7.3. when the principal investigator is found to be non-compliant with *REB*, University, statutory or regulatory requirements or other relevant national and international standards or condition of funding, where applicable.

The *UBC REBs* are further specifically authorized to observe, or have a third party observe any research or consent processes related to the research.

### **Review Scope and Standards**

8. Normally, *REB* meetings shall be face-to-face but, where circumstances require members may attend, and meetings may be held, by a communications medium if all members participating in the meeting, whether by telephone, by other communications medium or in person, are able to communicate with each other.<sup>1</sup>
9. Each *REB* will meet regularly to review applications for *Certificates of Approval*:
  - a) received and within its jurisdiction provided that the application has not been delegated to another body under the *Policy*<sup>2</sup>; or
  - b) referred to it by another body under the *Policy*<sup>3</sup>.
10. The appropriate *REB* must read and evaluate each complete application<sup>4</sup> and decide for the relevant proposed or ongoing research whether to:
  - a) approve it;
  - b) require modifications (provisos) to it;
  - c) defer it to be re-submitted with significant amendments;
  - d) reject it.
11. Each *REB* must:
  - 11.1. determine whether it is the appropriate *REB* and whether to refer the application to another *REB* with the appropriate jurisdiction or expertise;
  - 11.2. consider and may scrutinize scientific or technical quality of the research as necessary to assess risks and benefits of the research as proposed;
  - 11.3. determine whether research proposals are acceptable on ethical grounds including 2 essential components, which are:
    - a) the selection and achievement of ethically acceptable ends; and
    - b) the ethically acceptable means to those ends;<sup>5</sup>
  - 11.4. determine the level and frequency of continuing review of proposed research appropriate to the degree of risk, provided it is not less than once per year; determine that free and informed consent will be obtained and maintained in accordance with:<sup>6</sup>
    - a) this *Policy 89*<sup>7</sup>;

<sup>1</sup> Face-to-face meetings are to be the norm.

<sup>2</sup> N.B. This includes enactments under it.

<sup>3</sup> N.B. This includes enactments under it.

<sup>4</sup> N.B. An application is not complete if it is missing any attachments or other documents required.

<sup>5</sup> The 2 essential components are stated in the *TCPS* at B. on i.4.

<sup>6</sup> See *TCPS* Article 2 regarding free and informed consent.

<sup>7</sup> N.B. this includes these procedures, *UBC Ethics Directives*, and other enactments under them.

- b) the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*;
  - c) the applicable *UBC Ethics Directives, if any*;
  - d) requirements issued by the applicable *REB*;
  - e) other relevant national and international standards or condition of funding, where applicable to specific research.
- 11.5. determine whether the research complies with:
- a) this *Policy 89*<sup>8</sup>;
  - b) the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*;
  - c) the applicable *UBC Ethics Directives, if any*;
  - d) requirements issued by the applicable *REB*;
  - e) other relevant national and international standards or condition of funding, where applicable to specific research.

### **Intensity of Review**

#### **Proportionate Review**

12. The *REBs* must scrutinize applications proportionate to the magnitude and probability of potential harm to the human subject inherent in the research under review, and if appropriate referring the application to:<sup>9</sup>
- a) another *REB*, which may be a *Departmental REB*, with the appropriate expertise<sup>10</sup>; or
  - b) the full *REB* if a subgroup is conducting the review.

#### **Peer Review (Scholarly Review)**

13. Each *REB* shall satisfy itself that the design of a research project that poses more than minimal risk is capable of addressing the questions being asked in the research.<sup>11</sup> It shall determine whether peer review is a requirement arising from *Policy 89*, or traditionally for the discipline and if so whether the requirement has been satisfied appropriate to the discipline, the subjects, and the research proposed.<sup>12</sup>
14. By *UBC Ethics Directive*, or of a *REB*'s own accord, a permanent or temporary peer review committee may be created, reporting to the *REB*.<sup>13</sup>

<sup>8</sup> N.B. this includes these procedures, *UBC Ethics Directives*, and other enactments under them.

<sup>9</sup> Responds to *TCPS* Articles 1.6 and 1.13.

<sup>10</sup> N.B. *Policy 11 "Radiation Safety"* also applies if radioactive material is involved coordination may be necessary.

<sup>11</sup> This is a paraphrase of *TCPS* Article 1.5(a).

<sup>12</sup> This responds to *TCPS* requirement at Article 1.5.

<sup>13</sup> This responds to *TCPS* requirement at Article 1.5.

**Multicentred and Extrajurisdictional Review**

15. In case of research involving human subjects that is located on or involves several *UBC* campuses, other institutions, or other jurisdictions the following shall apply:
- 15.1. If the multicentre research located on several *UBC* campuses, or involving both *UBC* and other institutions, the appropriate *UBC REB* may coordinate its review with other *UBC REBs* or the equivalents specified by the other institution, as the case may be.
- 15.2. If the research is to be conducted other than at *UBC* or an affiliated institution the researcher must undergo prospective ethics review by:
- a) the appropriate *UBC REB* (which may coordinate its review with the following); and
  - b) the research ethics board, if one exists, that has the legal responsibility and equivalent ethical and procedural safeguards in the jurisdiction where the research is done.
- 15.3. In no case may a *Certificate of Approval* be issued by a *REB* for research under this section unless the research is:<sup>14</sup>
- a) compliant with *Policy 89*;<sup>15</sup> and
  - b) conditional upon compliance of the research regarding human subjects with the equivalent ethical and procedural safeguards of the institution where research is to be done.

**Delegated Review**

16. The full *REB* will review most applications involving human subjects, but a review by a subgroup of the *REB* or a designated individual member may be specified at the discretion of the applicable *REB* Chair. In this case of a *Delegated Review* the *REB* Chair or designate(s) for this review will constitute the *REB* and review the application for ethical acceptability and a *Certificate of Approval* will be issued when appropriate.
17. *Delegated Reviews* of both initial and continuing review applications are permissible when the research activities present no more than minimal risk to human subjects or minor changes in approved research.
18. Applications for new research proposals that undergo a *Delegated Review* by the Chair or designate(s) must be reported to the full *REB*.

**Approval or Reasons**

19. When a *REB* is considering a negative decision, it should provide the researcher with its reasons for doing so and give the researcher an opportunity to reply before making a final decision.

---

<sup>14</sup> Responds to *TCPS* Article 1.14.

<sup>15</sup> N.B. This includes enactments under the Policy.

**Certificate, Terms of Approval, and Amendment**

20. If a *REB* determines that the application and the research as proposed is acceptable it shall direct the issuance of a *Certificate of Approval* compliant with the applicable granting agency standards.
21. A *Certificate of Approval* may impose conditions and require scheduled or event driven reporting by the researcher to the *REB* or another person. The rigour of the conditions and any reporting requirements shall, at least, be proportionate to the ethics assessment required.<sup>16</sup>
22. The *REB* issuing a *Certificate of Approval* retains a continuing interest in the project, at issue and may withdraw or modify a *Certificate of Approval* at any time. The *REB* will notify applicants in writing of any imposed conditions or modifications which are imposed. Normally, if a *REB* is considering withdrawing or modifying a *Certificate of Approval*, the researcher will be given an opportunity to make a submission to the *REB*.
23. Provided there is no modification of procedures, a completed *Certificate of Approval* will be valid for **one** year from the date of the decision of the *REB* or the Delegated reviewer, prior to which time an application for renewal must be submitted to the *REB* if research-related procedures involving humans are to continue.
24. If at any time a researcher wishes to modify the research study, the researcher must submit an application for amendment of the *Certificate of Approval* to the *REB*, and comply with the requirements of the *REB*. Amendments to a *Certificate of Approval* do not alter the expiry date for the validity of a *Certificate of Approval*.

**Records, Reports and Communication of REBs**

25. Each *REB* should make its standard operating procedures available to researchers.
26. Each *REB* must:
  - 26.1. convey its decision and reasons to the applicant; and
  - 26.2. keep available for the duration of the applicable research and for a further 5 years thereafter a copy of:
    - a) the application<sup>17</sup> made to it;
    - b) minutes of its meetings;
    - c) issued decisions and reasons, including any issued dissenting decision and reasons (if issued separately from the minutes);<sup>18</sup> and
    - d) all other documentation relevant to *REB* decisions;

---

<sup>16</sup> This responds to *TCPS* Article 1.6 and 1.13 re proportionality and ongoing oversight with/via reporting requirements.

<sup>17</sup> N.B. An application is not complete if it is missing any attachments or other documents required.

<sup>18</sup> This responds to *TCPS* requirement at Article 1.8 regarding recording of dissent.

which shall be made available to:

- e) the University;
- f) the other *REBs*; and
- g) the researchers, funding agencies, and other relevant authorities involved in the research

27. The *REBs* report to the *Responsible Executive*:

27.1. on any matter requested by the *Responsible Executive*; and

27.2. should provide annual reports on their activities to:

- a) the *Responsible Executive*; and
- b) the other *REBs*.

28. The *REBs*, their respective Chairs, and any permanent peer review committee shall:

- a) maintain open lines of communication between them and other relevant bodies of *UBC*,<sup>19</sup> or affiliated institutions;<sup>20</sup>
- b) exchange reports and notices as needed;<sup>21</sup> and
- c) regularly communicate with the designated *REB* coordinator as specified in the *UBC Ethics Directives* or failing such designation then to the *Responsible Executive*.

### **Reconsideration and Appeal Procedures**

29. A researcher may request reconsideration of a decision made by the *REB*. The *REB* will reconsider its decisions upon receipt of a written request, and the researcher may submit additional information and/or attend the *REB* meeting in person to present information. If, after the completion of the *REB*'s reconsideration the researcher is still not satisfied with the decision, the researcher may make a written request to the *Responsible Executive* for review by the *UBC* Research Ethics Appeal Board ("*REAB*").

30. The *REAB*'s composition, terms of membership and quorum requirements must satisfy the *REB* requirements outlined below. No person can serve as a member of the *REAB* with respect to a review of a *REB* decision if that person was a member of the *REB* that made or reconsidered the decision.

### **Research Ethics Board Membership, Quorum, Voting, and Reports**

31. Appointments to the *REBs* will be made by the *Responsible Executive*, in consultation with the appropriate Deans of the Faculties and the Vice-Presidents of Research, or equivalent, at institutions affiliated with *UBC*. Normally appointments will be for 3-year terms. Terms of individual members should be staggered to ensure continuity of the *REB* expertise. Normally, as the size of the *REB* increases

---

<sup>19</sup> This may include bodies such as the *UBC* Conflict of Interest Committee or equivalent.

<sup>20</sup> This responds to *TCPS* requirement at Article 1.4.

<sup>21</sup> This responds to *TCPS* requirement at Article 1.4.

beyond the minimum of 5 members, the number of community representatives should also increase.<sup>22</sup>

32. Each *REB* should have enough members to ensure that the ethical review process has input from a multi-disciplinary membership with relevant expertise and experience. All members of the University community, including students, are eligible to serve.
33. The *Responsible Executive* will appoint:
  - a) the Chair of each *REB*, which normally will be for a 3-year term; and
  - b) one or more Associate Chair(s) for each *REB*.
34. Quorum for meetings of the *REBs* will consist of at least 5 members, including both men and women, of whom:
  - a) at least 2 members have broad expertise in the methods or in the areas of research that are covered by the *REB*;
  - b) at least one member is knowledgeable in ethics;
  - c) for biomedical research, at least one member is knowledgeable in the relevant law; this is advisable but not mandatory for other areas of research; and
  - d) at least one member has no affiliation with the institution, but is recruited from the community served by the University.
35. It is preferred that decisions of *REBs* be made by consensus. Where consensus is not achieved the decision will be made by majority vote.
36. Members of *REBs* must act with integrity and adhere to the highest ethical standards at all times. Where a member of *REB* has an actual, perceived or potential conflict of interest in the research under review, that member must disclose the conflict of interest to the Chair of the *REB*. If the Chair determines that a conflict of interest exists, the member must not be present when the *REB* is discussing or making a decision concerning the research project.

### **Departmental Review of Course-based Undergraduate Research**

37. Research involving human subjects that is undertaken by undergraduate students as part of their course requirements may be reviewed at the department level, instead of by a *REB*. This does not include research conducted by an undergraduate student that is part of a faculty member's research program. A department level review may take place only if the department is empowered by a directive of the *Responsible Executive* to do so, and has, in consultation with the Office of Research Services, created a formal *Departmental REB* and developed a departmental process that complies with the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*. Each *Departmental REB* must:

---

<sup>22</sup> This complies with *TCPS* Article 1.3 by matching the explanatory text.

- a) maintain records of research proposals to the *Departmental REB*, and of its proceedings and decisions;
  - b) set criteria for which categories of course-based undergraduate research are suitable for review at the departmental level and what research should be reviewed by a *REB*; and
  - c) file a written report of each of its decisions to the appropriate *REB*.
38. *Departmental REBs* are accountable to the *REBs* and must comply with any directions from them regarding their procedures or individual decisions.

**Education**

39. Academic units shall at the request of the *Responsible Executive* demonstrate how they address the ethical training of researchers in their units, in the curriculum for students, and in other forms appropriate for faculty and staff.
40. The *REB* Chairs shall jointly coordinate with the *Responsible Executive* the holding of:<sup>23</sup>
- a) general meetings;
  - b) educational and consultation retreats; and
  - c) education workshops;
- in which *REB* members may:
- d) take advantage of educational opportunities that may benefit the overall operation of the *REB(s)*;
  - e) discuss general issues arising out of any *REB* activities; or
  - f) recommend revision of policies, procedures, *UBC Ethics Directives* or guidance notes.

<b><u>Approval of Procedures</u></b>	
<p>“<i>Stephen Toope</i>” (signature or seal)</p>	May 28, 2009
	<b>Date Approved</b>
<b>President</b>	May 28, 2009
	<b>Date Signed/Sealed</b>

<sup>23</sup> Responds to *TCPS* Article 1,4 re coordination and Article 1.7 re: education.

**Schedule of Definitions**  
**to Procedures for Policy 89**

**Definitions**

1. In these procedures the following terms have the meaning defined below unless the context requires otherwise:

<b>Term</b>	<b>Definition</b>
a. <i>Behavioural Research</i>	means research which is carried out by a person subject to <i>UBC</i> policies and procedures and involves humans in procedures that involve the potential invasion of privacy and may involve asking subjects to participate in studies that use, for example, questionnaires, interviews, focus groups, observation, secondary use of data, deception, testing, video and audio taking.
b. <i>Certificate of Approval</i>	means an approval issued by a <i>REB</i> that an application with its research proposal is acceptable on ethical and moral grounds while it is in good standing and unexpired.
c. <i>Clinical Research</i>	means research which is carried out by a person subject to <i>UBC</i> policies and procedures and involves human subjects in clinical procedures as follows: <ul style="list-style-type: none"> <li>• surgery</li> <li>• administration of drugs</li> <li>• medical imaging or other diagnostic techniques</li> <li>• biopsies</li> <li>• taking of blood or other specimens</li> <li>• review of clinical medical records</li> <li>• any invasive procedure involving an element of risk.</li> </ul> <p>The term does not include research consisting entirely of <i>Behavioural Research</i>.</p>
d. <i>Delegated Review</i>	means a review assigned in accordance with section 16 and these procedures.
e. <i>Departmental REB</i>	means a research ethics board of a department that is created and empowered in accordance with these procedures.
f. <i>Policy 89 or the Policy</i>	means Policy 89 and its procedures and any other enactments under them unless such enactments are necessarily excluded by the context.
g. <i>REAB</i>	means the independent research ethical review board appointed by the <i>Responsible Executive</i> to hear appeals.
h. <i>REB</i>	means a board appointed by the <i>Responsible Executive</i> under <i>Policy 89</i> and these procedures to conduct research ethics reviews.

i. <i>Responsible Executive</i>	means: <ol style="list-style-type: none"> <li>1) the individual(s) specified by the President to be responsible for <i>Policy 89</i> and</li> <li>2) any person delegated to fulfill that person(s) role except to the extent that delegation is specifically excluded.</li> </ol>
j. <i>Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, or TCPS</i>	means the “Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans” as amended from time to time.
k. <i>UBC Ethics Directives</i>	means mandatory requirements issued from time to time by the <i>Responsible Executive</i> to regulate the conduct of research involving human subjects.

## Ethics Directive

This Ethics Directive is issued under the authority of Policy 89 and section 4 of its Procedures.

### **Title & Definitions**

1. This Ethics Directive may be referred to as the “Ethics Directive on Informed Consent”.
2. The terms defined in Policy 89 and its procedures apply in this *Ethics Directive* unless the context requires otherwise.

### **Free and Informed Consent**

3. Research involving human subjects that is governed by *UBC* policies and for which free and informed consent is required may only include research subjects if they, or their authorized third parties, have provided their free and informed consent and that consent has been maintained throughout their participation in the research.
4. Research subjects must have freely agreed to take part in the research study on the basis of well-understood information about the objectives of the research and the nature of their participation. Research subjects must be fully informed of any and all known or reasonably foreseeable risks of harm associated with the research, as well as possible benefits of their participation. They must have the opportunity to evaluate the relative weight of any risks and benefits.
5. Free and informed consent must be voluntarily given, without manipulation, undue influence, or coercion. There shall not be incentives offered that are so large as to become an undue influence and undermine the voluntary nature of their participation. Researchers must take care to avoid problems of informed consent based on a special relationship between researcher and research subject, so that such relationship does not unduly influence the research subject’s free and informed consent.

### **Withdrawal of Consent and Concern or Complaint**

6. Research subjects may withdraw their consent at any time during the research program, and such withdrawal shall not result in penalty or harm or loss of promised benefits that are not inherently dependent on completion of their participation.
7. Where any research subjects express significant concern about the nature of the informed consent or the use of the research, the researcher should report the concerns to the *REB*.

**Form of Consent**

8. Free and informed consent should normally be provided in writing in a form specified under the authority of the Policy. If written consent is not culturally acceptable, or where there are good reasons for not recording consent in writing, the procedures used to seek free and informed consent must be documented for review by the *REB*.

**Altered or Waived Elements of Consent**

9. The *REB* may approve a consent procedure that does not include, or alters some or all of the elements of informed consent as noted above, or waives the normal requirements for informed consent, provided that the *REB* decides and documents that:
- a) the research involves no more than minimal risk to the research subjects;
  - b) the waiver or alteration is unlikely to adversely affect the rights and welfare of the subjects;
  - c) the research could not practicably be carried out without the waiver or alteration;
  - d) whenever possible and appropriate, the subjects will be provided with additional pertinent information after participation; and
  - e) the waiver or altered consent does not involve a therapeutic intervention.
10. In studies that include randomized consent or blinding in clinical trials, neither the research subjects nor those responsible for their care know which treatment the subjects are receiving before the project begins. Such research is not regarded as a waiver or alteration of the requirements for consent if the subjects are informed of the probability of being randomly assigned to one part of the study or another.

**Naturalistic Observations**

11. *REB* review is normally required for research involving naturalistic observation, except for observation of research subjects in public meetings, demonstrations, political rallies or like activities where research subjects are expected to be seeking or are aware of public visibility. Naturalistic observation is used to study behaviour in a natural environment. If the naturalistic observation does not allow for the identification of the subjects, and is not staged, then the research will normally be considered as of minimal risk. Research involving naturalistic observations will normally be reviewed by the *REB* to ensure that concerns of privacy and the dignity of those being observed are handled appropriately.

**Procedures for Free and Informed Consent**

12. Researchers shall provide to prospective research subjects, or to their authorized third parties, full and frank disclosure of all information relevant to their free and informed consent. Throughout this process, the researcher must ensure that prospective research subjects, or to their authorized third parties, are given adequate opportunities to discuss and contemplate their participation.
13. Researchers shall provide at a minimum the following information:
  - a) information that the person is being invited to participate in a research project;
  - b) a comprehensible statement of the research purpose, the identity of the researcher and their affiliation to *UBC*, the expected duration and nature of participation, and a description of the research procedures;
  - c) a comprehensible description of the known or reasonably foreseeable risks and benefits that may arise from participation in the research, as well as the likely consequences of non-action, particularly in research related to treatment, or where invasive methods are involved, or where there is a potential for physical or psychological harm;
  - d) assurance that the prospective research subjects are free not to participate, and are able to withdraw at any time without prejudice;
  - e) assurance that the research subjects have ongoing opportunities to decide whether or not to continue to participate during the course of the research;
  - f) the potential of commercialization of research findings, and the presence of any apparent, actual, or potential conflict of interest on the part of the researchers, sponsors, or institutions; and
  - g) the name, and contact information for a person(s) who may be contacted for information on the nature of the research, or in the case of concerns, complaints, or consequences.
14. Researchers may be required by a *REB* to provide additional information, depending on the nature of the research project, including:
  - a) assurance that new information will be provided to the research subjects in a timely manner whenever such information is relevant to the research subject's decision to continue or withdraw from the research;
  - b) information on the resources available outside the research team to contact regarding concerns with the research;
  - c) an indication as to who will have access to the information collected on the identity of research subjects, descriptions of how confidentiality will be protected, and the anticipated uses of the data;
  - d) an explanation of the responsibilities of the research subject;

- e) information on the circumstances under which the researcher may terminate the subject's participation in the research;
  - f) information on any costs, payments, reimbursement for expenses, or compensation for injury;
  - g) in the case of randomized trials, the probability of the research subject's assignment to each of the options;
  - h) the ways in which research results will be published, and how the research subjects will be informed of the results of the research.
15. It is the responsibility of the researcher to collect and retain documentation of written consent for at least 5 years from the conclusion of the research study. If consent has been waived or the consent is not recorded in writing then the researcher must retain appropriate documentation evidencing this.
16. Researchers must ensure that they comply with all applicable federal and provincial legislative requirements and the legislative requirements of the jurisdiction in which participation takes place.

**Competence**

17. The competence of the potential research subjects to provide free and informed consent is an important factor in the validity of the consent. Competence refers to the ability to understand the information presented about the research, to appreciate the potential consequences of a decision, and to provide free and informed consent to participate in a specific research project. Competence is not an all or nothing condition. The prospective research subjects do not need to have the capacity to make every kind of decision, but they should be able to make an informed decision about participation in the specific research.
18. Individuals who are not legally competent to participate in the proposed research shall only be asked to become research subjects when:
- a) the research question can only be addressed using the identified group(s); and
  - b) free and informed consent is sought from their authorized representatives, such as parents or legal guardians; and
  - c) the research does not expose them to more than minimal risk without the potential for direct benefits for them.
19. For research involving individuals who are not competent, the *REB* shall ensure that, as a minimum, the following conditions are met:
- a) the researcher shall show how:
    - i) the free and informed consent will be sought from the authorized third party; and
    - ii) how the research subject's best interests will be protected;

- b) the authorized third party is not the researcher or any other member of the research team;
  - c) the continued free and informed consent of the authorized third party is required in order for the continuation of the participation of the legally incompetent person in the research project, as long as the person remains incompetent; and
  - d) if the incompetent research subject becomes competent during the research project, his or her informed consent will be sought as a condition of continuing participation.
20. If the free and informed consent has been obtained from an authorized third party, and the legally incompetent research subject understands the nature and consequences of the research, the researcher must seek to determine the wishes of the research subject. Should the potential subject dissent then such dissent will preclude participation.

**Research in Emergency Health Situations**

21. Subject to all applicable legislative and regulatory requirements, research involving emergency health situations shall be conducted only if it addresses the emergency needs of individuals involved, and then only in accordance with criteria established in advanced of such research by the *REB*. The *REB* may allow research that involves health emergencies to be carried out without the free and informed consent of the research subject or of his or her authorized third party if ALL of the following apply:
- a) a serious threat to the prospective subject requires immediate intervention;
  - b) no standard efficacious care exists or the research offers a real possibility of direct benefit to the subject in comparison to the standard of care;
  - c) either the risk of harm is not greater than that involved in standard efficacious care, or it is clearly justified by the direct benefits to the subject;
  - d) the prospective subject is unconscious or, for any reason, lacks capacity to understand risks, methods and purposes of the research (and this lack of capacity may arise by the nature of the emergency diminishing capacity);
  - e) third party authorization cannot be secured in sufficient time, despite diligent and documented efforts to do so; and
  - f) no relevant prior directive by the subject is known to exist.

22. If a previously incapacitated subject of research, involving emergency health situations, regains capacity, or when an authorized third party is found, the free and informed consent of the subject or authorized third party shall be sought promptly for the subject's continuation in the project and for subsequent examinations or tests related to the study to be conducted.

<b><u>Approval of Ethics Directive</u></b>	
	April 21, 2006
<i>"John Hepburn"</i>	<b>Date Approved</b>
Vice-President, Research (signature or seal)	April 21, 2006
<b>Responsible Executive</b>	<b>Date Signed/Sealed</b>