Agenda No. 4.2

THE UNIVERSITY OF BRITISH COLUMBIA

FOR INFORMATION ONLY

FORWARDED TO: BOARD OF GOVERNORS ON RECOMMENDATION OF PRESIDENT STEPHEN J. TOOPE

APPROVED FOR SUBMISSION:

STEPHEN J. TOOPE

Date: 13/01/12.

PRESENTED BY: Hubert Lai, University Counsel
John Hepburn, Vice President, Research

DATE OF MEETING: February 2, 2012

SUBJECT: Amendments to Policy #89 (Research Involving Human Participants) and associated Procedures

DECISION REQUESTED: FOR INFORMATION ONLY (No action required)

Background

The Board of Governors adopted Policy #89 in March 2002 and most recently approved a revision of the Procedures associated with Policy #89 in May 2009. A copy of the Policy and Procedures currently in effect (the "**Current Policy**") is attached as Attachment 2.

UBC receives approximately $200 million per annum from the Tri-Council granting agencies (consisting of the Canadian Institutes for Health Research, the Natural Sciences and Engineering Research Council and the Social Sciences and Humanities Research Council). This amounts to more than 35% of UBC's total research budget.

The Current Policy was created in order for UBC to become compliant with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans which was issued in 1998 ("**TCPS**") so that UBC would continue to be eligible to receive funding from the Tri-Council granting agencies. In January 2011, the Tri-Council issued a second, revised edition of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans ("**TCPS2**") which is a significant expansion over TCPS. The Current Policy is not compliant with TCPS2.

The Current Policy has also proven to be incompatible with the changing realities of contemporary research. For instance, under the Current Policy, UBC was unable to enter into collaborative research arrangements with other institutions.

Objectives

The Office of the University Counsel constituted a Policy #89 Review Committee (the "**Review Committee**") to review the Current Policy and to propose a revised version of Policy #89 and its associated Procedures (the "**Revised Policy**") with a view to achieving the following goals:

1. ensure the Revised Policy is compliant with TCPS2 and other relevant current ethical standards;

2. ensure that the research environment at UBC continues to be one in which human participants are properly protected and to establish the following core ethical principles (the "**Core Ethical Principles**") to be applied by all UBC-sanctioned research ethics boards ("**REBS**"):

    a. respect for persons;
    b. concern for welfare of human participants; and
    c. justice;

3. permit and facilitate collaborative research partnerships involving researchers, data or human participants from more than one institution;

4. ensure the Revised Policy and associated Procedures are sufficiently flexible for practical application; and

5. restructure and simplify the Revised Policy and associated Procedures so that they are user-friendly.

Proposal

The Review Committee met on four occasions in October and November 2011 and developed a proposal for a Revised Policy which is attached as Attachment 3. The Review Committee unanimously believes that the Revised Policy achieves the objectives set out above. The Review Committee was made up of the individuals listed in Attachment 4.

The Revised Policy is supported by the University Counsel. An itemized list of the amendments contained in the Revised Policy is attached as Attachment 1. At 12 pages in length, the Revised Policy is considerably shorter than the Current Policy which was 21 pages long.

Next Steps

Subject to feedback from the Board of Governors, the Office of the University Counsel will publish the Revised Policy with a public call for comments.

The comment period will remain open for approximately 6 weeks, after which the Review Committee will reconvene to consider any feedback that has been received.

The Review Committee will make any amendments to the Revised Policy that they consider warranted.

It is anticipated that the Revised Policy will then be submitted to the Board of Governors towards the end of April 2012 with a request for final approval, effective June 5, 2012.

Attachments

Attachment 1 – Summary of Amendments contained in the Revised Policy
Attachment 2 – Current Policy #89, as adopted in March 2002
Attachment 3 – Revised Policy #89
Attachment 4 – Composition of the Policy #89 Review Committee

Attachment 1
Summary of Amendments Contained in the Revised Policy

Policy:

1. The Review Committee proposes to simplify the Background and Purposes section in the Revised Policy so that it focuses on providing an overview of what UBC is trying to achieve with this Policy instead of serving as an index of the contents of the Policy, as is the case in the Current Policy.

2. Consistent with other UBC policies, the Review Committee proposes to add a section following the Background and Purposes section of the Revised Policy that will direct readers to other policies and documents that are relevant to research involving human participants.

3. Throughout the Revised Policy, the Review Committee proposes to use the term "human participant" instead of the term "human subject" which is used in the Current Policy. This is proposed because the TCPS2 uses the term "human participant" in order to reflect the fact that individuals who choose to participate in research play a more active role than the term "human subject" conveys. Also, TCPS2 indicates that the term "human participant" better reflects the range of research covered by the TCPS2 and the varied degree of involvement by human participants – from undergoing an invasive procedure, to providing a saliva sample, to completing a survey – depending on the type of research being conducted.

4. Section 1 sets out that the Revised Policy generally applies to research that is conducted under the auspices of UBC and that involves human participants or human biological materials.

5. In Section 2 of the Revised Policy, the Review Committee proposes to confirm that UBC is committed to upholding the Core Ethical Principles which are set out in TCPS2. This is proposed because the Core Ethical Principles are the principles that inform the entire TCPS2 and, therefore, should also inform the research environment at UBC.

6. In Section 3.1 of the Revised Policy, the Review Committee proposes to mandate the REBs not only to review but also to maintain ongoing oversight of the ethical acceptability of research involving human participants that is conducted under the auspices of UBC and to apply the Core Ethical Principles in so doing. The Review Committee proposes that the REBs be given such a mandate in the Revised Policy in order to better protect human participants involved in current and future research.

7. Sections 3.3 and 3.4 of the Revised Policy set out the responsibilities of the Vice President, Research and International (the "**Responsible Executive**") in relation to the REBs. The Review Committee proposes to add these sections in order to make clear UBC's commitment to enabling the REBs to discharge their duties properly.

8. Sections 3.5 and 3.6 of the Revised Policy set out that the REBs are independent in their decision making, yet are accountable to the Responsible Executive for their research ethics review processes.

The Review Committee proposes to add these sections in order to safeguard public trust in the integrity of the research ethics review process.

9. In Section 4.1 of the Revised Policy, the Review Committee proposes to establish that an ethics approval issued by one REB be recognized by all other REBs, and that a research project conducted by one researcher or group of researchers at one UBC site shall require ethics approval from only one REB. The Review Committee proposes to add this section in order to increase efficiency in the conduct of research involving human participants that is carried out under the auspices of UBC.

10. Sections 4.2 and 4.3 of the Revised Policy set out what may not be done by a researcher who has not received research ethics approval for a particular research project involving human participants. Sections 4.4 and 4.5 set out what may and may not be done by UBC Financial Services in respect of a particular research project involving human participants that has not received research ethics approval. The Review Committee proposes to add these sections with a view to limiting the activities that may be undertaken by a researcher in relation to a particular research project if research ethics approval has not been granted for such project.

11. In Section 4.6 of the Revised Policy, the Review Committee proposes to clarify that receipt by a researcher of research ethics approval from a REB in respect of a particular research project does not necessarily mean that such research project may be commenced or continued. The Review Committee wanted to emphasize to researchers that in the case of certain research projects, in addition to seeking REB approval, researchers must also seek approvals from other UBC officials or committees or from other agencies.

12. In Section 5 of the Revised Policy, the Review Committee proposes to enable UBC to enter into alternative ethics review agreements with other institutions in order to facilitate collaborative research projects involving researchers, data or human participants from more than one institution. The Review Committee proposes to add this section in order to bring the Revised Policy up-to-date with the realities of contemporary research, since contemporary research often involves collaborative partnerships among researchers from multiple institutions.

13. Section 6 of the Revised Policy sets out the ways in which UBC's core values and organizational structure serve to ensure that research activities that take place under UBC's auspices are undertaken with integrity, in a manner consistent with the Core Ethical Principles, and free from undue interference. The Review Committee proposes to add this section in order to confirm UBC's commitment to academic freedom and independent research.

14. In Section 7 of the Revised Policy, the Review Committee proposes to provide a list of definitions of the defined terms which are used throughout the Revised Policy. This is proposed for the sake of clarity, as placing all definitions in one and the same section is a more reader-friendly approach than having definitions embedded in the text at various locations throughout the Revised Policy.

Procedures:

15. Section 1 of the Procedures associated with the Revised Policy sets out the responsibilities that researchers have when planning to conduct research involving human participants as well as when carrying out research that has received REB approval. The Review Committee proposes to add this

section in order to enumerate the key responsibilities of researchers with respect to research involving human participants.

16. In Section 2 of the Procedures, for the sake of clarity, the Review Committee proposes to set out the proper composition of each REB and provide a procedure which shall be undertaken by a REB member if he or she has any real, potential or perceived conflict of interest with respect to certain research being reviewed by such member's REB.

17. The appointment of REB Chairs is provided for, and the key roles and responsibilities of REB Chairs are described in Section 3 of the Procedures. The Review Committee proposes to add these sections to the Procedures to clarify the key roles and responsibilities of the REB Chairs.

18. Section 4 of the Procedures describes the key responsibilities of REBs and the way in which they must discharge such responsibilities. The Review Committee proposes to add these sections in order to ensure that REB meetings are carried out in accordance with the requirements of TCPS2.

19. In Section 5 of the Procedures the Review Committee proposes to establish the ability of a researcher to request a reconsideration of a decision made by a REB.

20. In Section 6 of the Procedures, the Review Committee proposes revisions that:

    (a) establish the ability of a researcher to make a written request to the Responsible Executive to appeal a decision of a REB if such researcher is not satisfied with the outcome of the reconsideration process;

    (b) describe the appointment of individuals by the Responsible Executive to a research ethics appeal committee to hear such appeals;

    (c) describe details such as the membership requirements of the research ethics appeal committee;

    (d) set out in general terms the way in which the appeal process should occur; and

    (e) establish that decisions made by the research ethics appeal committee shall be final.

Attachment 2
Current Policy

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.

	Policy No.: 89	Authorized Procedures	Procedure Version No.: 3 (since adoption of last policy version)	History since last Policy version: -May 2009 -April 2006 -March 2002 Originating Date: -May 1993 Next Review: TBD

Title:

Research and Other Studies Involving Human Subjects

Related Procedures, Materials, And Notes

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 *UBC* 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 than 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:

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

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.[1]
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*[2]; or
    b) referred to it by another body under the *Policy*[3].
10. The appropriate *REB* must read and evaluate each complete application[4] 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;[5]
    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:[6]
        a) this *Policy 89*[7];

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[1] Face-to-face meetings are to be the norm.
[2] N.B. This includes enactments under it.
[3] N.B. This includes enactments under it.
[4] N.B. An application is not complete if it is missing any attachments or other documents required.
[5] The 2 essential components are stated in the *TCPS* at B. on i.4.
[6] See *TCPS* Article 2 regarding free and informed consent.
[7] 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*[8];

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: [9]

a) another *REB*, which may be a *Departmental REB*, with the appropriate expertise[10]; 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.[11] 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.[12]

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*.[13]

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[8] N.B. this includes these procedures, *UBC Ethics Directives,* and other enactments under them.
[9] Responds to *TCPS* Articles 1.6 and 1.13.
[10] N.B. Policy 11 "Radiation Safety" also applies if radioactive material is involved coordination may be necessary.
[11] This is a paraphrase of *TCPS* Article 1.5(a).
[12] This responds to *TCPS* requirement at Article 1.5.
[13] This responds to *TCPS* requirement at Article 1.5.

Multicentred and Extrajuridictional 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:[14]

        a) compliant with *Policy 89*;[15] 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.

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[14] Responds to *TCPS* Article 1.14.

[15] 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.[16]

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[17] 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);[18] and

        d) all other documentation relevant to *REB* decisions;

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

[17] N.B. An application is not complete if it is missing any attachments or other documents required.

[18] 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*,[19] or affiliated institutions;[20]

b) exchange reports and notices as needed;[21] 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

[19] This may include bodies such as the *UBC* Conflict of Interest Committee or equivalent.
[20] This responds to *TCPS* requirement at Article 1.4.
[21] This responds to *TCPS* requirement at Article 1.4.

beyond the minimum of 5 members, the number of community representatives should also increase.[22]

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:

[22] 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:[23]

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.

Approval of Procedures	
	May 28, 2009
"Stephen Toope"	**Date Approved**
(signature or seal)	May 28, 2009
President	**Date Signed/Sealed**

[23] 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:

	Term	Definition
a.	*Behavioural Research*	means research which is carried out by a person subject to *UBC* 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.	*Certificate of Approval*	means an approval issued by a *REB* that an application with its research proposal is acceptable on ethical and moral grounds while it is in good standing and unexpired.
c.	*Clinical Research*	means research which is carried out by a person subject to *UBC* policies and procedures and involves human subjects in clinical procedures as follows: • surgery • administration of drugs • medical imaging or other diagnostic techniques • biopsies • taking of blood or other specimens • review of clinical medical records • any invasive procedure involving an element of risk. The term does not include research consisting entirely of *Behavioural Research*.
d.	*Delegated Review*	means a review assigned in accordance with section 16 and these procedures.
e.	*Departmental REB*	means a research ethics board of a department that is created and empowered in accordance with these procedures.
f.	*Policy 89* or the *Policy*	means Policy 89 and its procedures and any other enactments under them unless such enactments are necessarily excluded by the context.
g.	*REAB*	means the independent research ethical review board appointed by the *Responsible Executive* to hear appeals.
h.	*REB*	means a board appointed by the *Responsible Executive* under *Policy 89* and these procedures to conduct research ethics reviews.

i.	*Responsible Executive*	means: 1) the individual(s) specified by the President to be responsible for *Policy 89* and 2) any person delegated to fulfill that person(s) role except to the extent that delegation is specifically excluded.
j.	*Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, or *TCPS*	means the "Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans" as amended from time to time.
k.	*UBC Ethics Directives*	means mandatory requirements issued from time to time by the *Responsible Executive* 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. Fee 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.

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

Attachment 3
Revised Policy

The University of British Columbia Board of Governors	**Policy No.:** **89**	**Approval Date:** March 2002 **Last Revision:** June 2012 [Anticipated]
	Responsible Executive: Vice President, Research and International	

Title:

Research Involving Human Participants

Background & Purposes:

The University is committed to promoting research as a fundamental human endeavour deriving from the wish to understand and improve the collective global condition. The University recognizes that the use of Human Participants is indispensable to progress in many areas of research. However, all research involving Human Participants must be conducted in accordance with the highest ethical standards in ways that protect, and respect the dignity and rights of all Human Participants involved.

The purpose of this Policy is to create a research environment in which the University's responsibilities towards Human Participants involved in research are discharged in accordance with the highest ethical standards; to promote awareness and understanding of such standards among members or associated members of the University; to articulate clearly the Core Ethical Principles applicable to research in a manner consistent with the most current version of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans and with international best practices; and to establish an independent research ethics review process.

Related Policies, Materials and Notes

Related Policies:
Policy 87 – Research

Defined terms are capitalized in this Policy and can be found in Section 7 at the end of this Policy.

1. Scope

1.1. This Policy applies to all Research Involving Human Participants.

2. Core Ethical Principles

2.1. Over and above the legal obligations to which all researchers and the University are bound to adhere, a fundamental imperative of Research Involving Human Participants is the respect for human dignity. The University adopts the Core Ethical Principles as principles that will not only guide the conduct of all Research Involving Human Participants but will also guide REBs when they are reviewing the ethical acceptability of such research.

3. Mandate and Authority of Research Ethics Boards

3.1. REBs are mandated to review and maintain ongoing oversight of, on behalf of the University, the ethical acceptability of all proposed or ongoing Research Involving Human Participants by applying the Core Ethical Principles to such review and oversight.

3.2. The University shall authorize such number of REBs as is determined to be appropriate from time to time by the Responsible Executive.

3.3. The Responsible Executive is responsible for determining the financial and administrative resources that are necessary to enable the REBs to fulfill their duties and shall ensure that such resources are provided.

3.4. The Responsible Executive or his or her delegate is responsible for:

3.4.1. keeping the REB Chairs informed of all ethics requirements of the Tri-Councils and of all other provincial, national and international laws, regulations, policies, standards (e.g. legal, professional, institutional), and guidelines that are relevant to research ethics review; and

3.4.2. communicating to the REB Chairs any changes in such requirements, laws, regulations, policies, standards and guidelines.

3.5. The REBs are accountable to the Responsible Executive for their research ethics review processes.

3.6. However, in conducting their research ethics reviews, the REBs must operate in an impartial manner, without interference, and the decisions of the REBs with respect to any given Research project are not subject to review by the Responsible Executive or any other person except to the extent that such decisions may be appealed pursuant to the Procedures to this Policy.

4. Ethics Approval

4.1. For each Research project, there shall be one REB of record such that an Ethics Approval issued by one REB shall be recognized by all other REBs and a Research project conducted by the same researcher or researchers at more than one University site shall require Ethics Approval from only one REB.

4.2. If a researcher has made application to a REB seeking review and approval of the ethical acceptability of Research Involving Human Participants but approval is not obtained, such researcher may not withdraw his or her application and submit it to another REB with respect to the same Research Involving Human Participants unless authorized to do so by the first REB.

4.3. Unless proposed Research Involving Human Participants has first been granted Ethics Approval, a researcher must not:

4.3.1. commence or continue to carry out such research;

4.3.2. use University services or facilities, including academic space at affiliated teaching hospitals, for such research; or

4.3.3. accept or use any funds made available to such researcher for such research.

4.4. Unless Financial Services has received notification that Ethics Approval has been granted to certain Research Involving Human Participants, Financial Services must not, with respect to such Research Involving Human Participants:

4.4.1. open research accounts; or

4.4.2. authorize spending on a research account.

4.5. If a REB rescinds or terminates an Ethics Approval, the REB may give notice and direction to Financial Services. Upon receipt of such notice and direction from a REB, Financial Services must freeze or close the relevant research account as appropriate.

4.6. A Research project may require a number of different approvals from various officials or committees of the University and other relevant agencies. Ethics Approval and all other required approvals with respect to such Research project must be obtained before the Research project is undertaken.

5. Ethics Review Agreements with Other Institutions or Organizations

5.1. In order to facilitate collaborative research projects involving researchers, data or participants from more than one institution, and in order to avoid a duplication of efforts with respect to research ethics reviews, the University through its authorized signatories may enter into Ethics Review Agreements.

5.2. An Ethics Review Agreement may be limited to a specific type of Research.

5.3. Prior to entering into an Ethics Review Agreement with another institution, the University shall:

5.3.1. take into account the manner in which the other institution's research ethics board conducts research ethics reviews; and

5.3.2. consult with the Chairs of the REBs.

6. Institutional Conflicts of Interest in Relation to Research

6.1. The University has many diverse objectives. From time to time these objectives may appear to be, or may actually be in conflict with one another. For example, the University has an interest in enhancing its investment returns, fundraising activities and operational efficiencies in order to achieve its mission and to serve the people of British Columbia, Canada and the world. However, regardless of any other interest it may have, the University has an overriding interest in ensuring that Research activities are undertaken with integrity and in a manner that is consistent with the Core Ethical Principles. To the extent that there is a conflict between this overriding interest and any other interest the University may have, any decisions made by the REBs shall be consistent with this overriding interest.

6.2. In addition, academic freedom is one of the University's core values. As a result, no person at the University may interfere with Research unless the Research is contrary to applicable legal requirements or University policies. Furthermore, the University's administrative structure is organized in such a manner as to create separation between Research activities and the financial and other operations of the University. Due to the University's limited ability to interfere with Research and the University's organizational separation, the risk of the University's operational interests influencing or compromising the Core Ethical Principles is minimized.

6.3. In the unlikely event that a conflict arises between the Core Ethical Principles and the University's other objectives that cannot be adequately managed by the structural separation described in Section 6.2, the Responsible Executive will be charged with the responsibility of reviewing the matter and reporting to the President of the University and any external agencies as may be appropriate. Any person who has a concern that such a conflict may exist is encouraged to bring it to the attention of the Responsible Executive. All concerns submitted pursuant to this Section 6.3 will be taken seriously. The anonymity of the person raising a concern will be maintained, and the University will protect personal information of all parties involved as required under the Freedom of Information and Protection of Privacy Act. The University will not tolerate any retaliation, directly or indirectly, against anyone who, in good faith, raises a concern

pursuant to this Section 6.3, gives evidence or otherwise participates in a process under this Policy.

7. Definitions

7.1. "Anonymous", when used to describe information, data or materials, means information, data or materials that has never had personal identifiers associated with it (e.g. anonymous surveys) where the nature of the information, data or materials is such that it would be extremely unlikely that the persons having access to the information, data or materials could determine the identities of individuals by combining such information, data or materials with information, data or materials that are publicly available or that would otherwise be expected to be in their possession. For the purposes of this Policy, genetic material shall not be considered Anonymous unless a REB determines otherwise.

7.2. "Core Ethical Principles" means the following principles:

7.2.1. Respect for Persons: This principle requires the recognition of the intrinsic value of human beings and the respect and consideration that they are due, whether they are involved in research directly as subjects, or whether they are involved solely by virtue of their data or human biological materials being used in research. This principle also incorporates the requirement that all Human Participants give their free, informed and ongoing consent as a prerequisite for participation in research.

7.2.2. Concern for Welfare: This principle requires that the welfare of Human Participants in research be protected and promoted, and the recognition that the welfare of a person is the quality of that person's total experience of life, which consists of the impact caused, among other things, by factors such as his or her physical, mental and spiritual health, as well as his or her physical, economic and social circumstances.

7.2.3. Justice: This principle requires that all Human Participants in research be treated fairly and equitably so that individuals or groups are not inappropriately included in or excluded from participation in research on the basis of attributes such as culture, language, religion, race, disability, sexual orientation, ethnicity, linguistic proficiency, gender, age, developmental stage, reproductive capacity, capacity to consent, or presumed vulnerability. Instead, the question of participation should be based on inclusion and exclusion criteria that are required in order to carry out the research project. Also, the principle of justice requires that researchers consider ways to ensure the equitable distribution of any benefits of participation in research (e.g. amelioration of a health condition for an individual as a result of experimental therapy; the establishment of health care or beneficial services in a community which has been involved in research).

For further information, reference may be made to the most current version of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans.

7.3. "Ethics Approval" means the research ethics approval granted by a REB in accordance with this Policy.

7.4. "Ethics Review Agreement" means an agreement between the University and another research institution or organization that authorizes an alternative model or models for ethics review of Research Involving Human Participants. Such agreements may or may not be reciprocal in nature.

7.5. "Human Biological Materials" means human tissues, organs, blood, plasma, serum, DNA, RNA, proteins, cells, skin, hair, nail clippings, urine, saliva and other body fluids, embryos, fetuses, fetal tissues, reproductive materials and stem cells.

7.6. "Human Participants" means individuals whose data, or responses to interventions, stimuli or questions by a researcher are gathered or utilized for the purposes of a Research project.

7.7. "REB" means a research ethics board authorized by the University.

7.8. "Research" means any disciplined inquiry or systemic investigation (including pilot studies) intended to extend knowledge or to establish facts or principles that is:

7.8.1. conducted by members or associated members of the University acting in their University capacity, including but not limited to 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;

7.8.2. conducted within space that is under the administration of the University, including in academic space at affiliated teaching hospitals; or

7.8.3. in need of research ethics review by the University pursuant to the terms of an affiliation agreement with another agency;

but does not include:

7.8.4. quality assurance and quality improvement studies, program evaluation activities and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes. For greater certainty, where data is collected for purposes set out in the preceding sentence but later proposed to be used for research purposes, such use may be considered Secondary Use of information not originally intended for research, which would require research ethics review in accordance with this Policy.

7.9. "Research Ethics Appeal Committee" means the committee which the Responsible Executive may from time to time create for the purpose of hearing appeals of decisions made by the REBs.

7.10. "Research Involving Human Participants" means Research involving

7.10.1. Human Participants; or

7.10.2. Human Biological Materials;

but does not include:

7.10.3. Research that relies exclusively on publicly available information when such information: (i) is made accessible to the public through legislation and regulation, and is therefore appropriately protected by law, or (ii) is disseminated in the public domain (e.g. through print or electronic publications), may contain identifiable information, and for which there is no reasonable expectation of privacy;

7.10.4. Research involving the observation of individuals or groups in public places so long as: (i) the research does not involve any intervention staged by the researcher or any direct interaction between the researchers and the individuals or groups; (ii) the individuals or groups being observed have no reasonable expectation of privacy; and (iii) the dissemination of research results from such observation does not allow identification of specific individuals; and

7.10.5. Research that relies exclusively on Secondary Use of Anonymous information or Anonymous materials, so long as the process of data linkage or recording or dissemination of the Research results does not generate information about an identifiable individual.

7.11. "Secondary Use" means the use in Research of information or Human Biological Materials originally collected for a purpose other than the purpose of the current Research.

7.12. "University" means The University of British Columbia.

PROCEDURES

Approved: May 2009
Revised: June 2012 [anticipated]

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 UBC Policy and Procedure Handbook."

1. Researcher Responsibilities

1.1. A researcher who plans to conduct Research Involving Human Participants is required to:

1.1.1. be familiar with all University policies relating to research, including without limitation Policy 89, these Procedures, and the most current version of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans;

1.1.2. bring to the attention of the Head of such researcher's department, or where the researcher is in a non-departmentalized faculty, the Dean or the Dean's designate, any research project proposed by such researcher, or proposed by a student working under the direction of such researcher;

1.1.3. if the research project referred to in Section 1.1.2 constitutes Research Involving Human Participants, submit a proposal for such research project to the appropriate REB for review and approval of its ethical acceptability prior to the start of recruitment of human participants, access to data, or collection of Human Biological Materials, and include in such proposal such details as are reasonably required by the appropriate REB in order to enable such REB to discharge its duties as set out in Section 3.1 of Policy 89;

1.1.4. if there is any doubt as to whether such research project constitutes Research Involving Human Participants, consult the appropriate REB to obtain a determination as to whether such research project requires research ethics review;

1.1.4. conduct all REB-approved Research Involving Human Participants in accordance with:

1.1.4.1. any determinations respecting such research made by the REB that has continuing oversight of such research and comply with and maintain in good standing any Ethics Approval issued by such REB for as long as is required by such REB;

1.1.4.3. the Core Ethical Principles;

1.1.4.4. the most current version of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans;

1.1.4.5. all applicable policies and procedures of the University; and

1.1.4.6. other relevant provincial, national and international laws, regulations, policies, standards (e.g. legal, professional, institutional) and guidelines, where applicable to a particular area of research or to the funding of such research;

1.1.5. promptly report to the relevant REB the occurrence of any unanticipated issue or event during the course of the implementation of the approved research project that may result in an increased level of risk to Human Participants involved in the research project, or that has other ethical implications that may affect the welfare of such Human Participants;

1.1.6. promptly submit to the REB that has continuing oversight of the research project any proposed changes to the research project and notify such REB when the research project concludes; and

1.1.7. ensure that any proposed changes to an approved research project are approved by the REB that has continuing oversight of such research project prior to implementation of the changes, except when such changes are required to be made in order to eliminate immediate hazards to Human Participants involved in such research project or to implement minor logistical changes.

2. Composition of REBs

2.1. The Responsible Executive shall make appointments to the REBs.

2.2. Any REB constituted by the Responsible Executive under Section 4 of Policy 89 will consist of at least 5 members, including both men and women, of whom:

2.2.1. at least 2 members shall have broad expertise in the methods or in the areas of research that are covered by the relevant REB;

2.2.2. at least one member shall be knowledgeable in ethics;

2.2.3. at least one member shall be knowledgeable in law; and

2.2.4. at least one member shall have no affiliation with the University, but shall be recruited from the community served by the University.

2.3. Members of REBs shall normally serve in one capacity only for each of the membership categories listed in Section 2.2.

2.4. Terms of appointment of individual members shall be established at the time such appointments are made and should be staggered to allow for continuity of the research ethics review process.

2.5. A REB member shall disclose to the REB in question the nature of any real, potential or perceived conflict of interest such member may have with respect to any Research project being reviewed by such REB. If the REB member chooses to recuse himself or herself from all discussion or decisions regarding such Research project or group of Research projects, such recusal shall be recorded in the minutes of the REB proceedings. If the REB member does not recuse himself or herself, the conflict of interest disclosure shall be recorded in the minutes of the REB proceedings and the REB Chair and remaining REB members shall reach agreement on an appropriate course of action by majority vote. If the REB Chair is the individual disclosing a real, potential or perceived conflict of interest, the Associate Chair shall perform the duties of REB Chair during all discussion or decisions regarding such conflict of interest, or if the Associate Chair is conflicted, unable to act, or not present, such non-conflicted REB member as may be selected by the majority of the non-conflicted REB members, shall perform the duties of REB Chair during all discussion or decisions regarding such conflict of interest.

3. REB Chairs

3.1. The Responsible Executive will appoint a Chair to each REB and may also appoint to each REB one or more Associate Chair(s).

3.2. The Chair of each REB is responsible for ensuring that the research ethics review process adhered to by his or her REB conforms to the requirements of the Core Ethical Principles and all other relevant requirements, laws, regulations, policies, standards and guidelines that are relevant to research ethics review.

3.3. The role of each REB Chair is to:

3.3.1. provide leadership for the relevant REB;

3.3.2. facilitate the research ethics review process, based on University policies and procedures and the most current version of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans;

3.3.3. oversee decisions of the relevant REB for consistency;

3.3.4. ensure that REB decisions are recorded accurately and communicated clearly to researchers in writing as soon as possible by the Chair or his or her designate; and

3.3.5. ensure appropriate quorum requirements are met for each Research project being reviewed.

4. Responsibilities of REBs

4.1. REBs shall conduct initial reviews of the ethical acceptability of all proposed Research Involving Human Participants and continuing review of all previously approved Research Involving Human Participants over which they have ongoing oversight, and may, where applicable, approve, reject, propose modifications to, terminate or suspend such research.

4.2. In discharging their responsibilities described in Section 4.1 above, REBs shall:

4.2.1. have regular meetings and shall normally meet face to face;

4.2.2. function impartially, provide a fair hearing to the researchers involved, and provide reasoned opinions and decisions;

4.2.3. make the final determination as to the nature and frequency of continuing research ethics review of approved research projects;

4.2.4. communicate to researchers in writing all approvals and refusals of, all proposed modifications to, and any requirements they may impose on proposed or ongoing Research Involving Human Participants; and

4.2.5. prepare and maintain comprehensive records, including all documentation related to the research projects submitted to REBs for review, attendance at all REB meetings, and accurate minutes reflecting REB decisions, as well as any dissents and the reasons for them. Where a REB denies approval for a Research project, the minutes shall clearly document the reasons for this decision. Providing reasons for REB decisions is optional when approval is granted.

5. Reconsideration of REB Decisions

5.1. A researcher may request reconsideration of a decision made by a REB. The relevant REB will reconsider its decision upon receipt of a written request, and the researcher may submit additional information and/or attend the REB meeting in person to present information.

6. Appeal of REB Decisions

6.1. If, after the completion of the relevant REB's reconsideration, a researcher is still not satisfied with the decision made by a REB, such researcher may make a written request to the Responsible Executive to appeal such decision.

6.2. If the Responsible Executive grants a request for an appeal of a decision made by a REB, the Responsible Executive shall appoint individuals to a Research Ethics Appeal Committee to hear such appeal.

6.3. The composition of the Research Ethics Appeal Committee, as well as its terms of membership and quorum requirements, must satisfy the REB requirements in Section 2 of these Procedures.

6.4. No person can serve as a member of the Research Ethics Appeal Committee with respect to a review of a decision made by a REB if such person was a member of the REB that made or reconsidered such decision.

6.5. The Research Ethics Appeal Committee shall function impartially, provide a fair hearing to those involved, and provide reasoned and appropriately documented decisions and reasons for such decisions.

6.6. Both the appealing researcher and a representative of the REB whose decision is being appealed shall be granted the opportunity to address the Research Ethics Appeal Committee, but neither shall be present when the Research Ethics Appeal Committee deliberates and makes a decision.

6.7. When reviewing decisions made by a REB with respect to a Research project, the Research Ethics Appeal Committee may approve, reject or request modifications to such Research project.

6.8. The decision made by the Research Ethics Appeal Committee on behalf of the University shall be final and should be communicated in writing to the relevant researcher and to the REB whose decision was appealed.

Attachment 4
Policy #89 Review Committee

Name	Dept/Faculty/Campus
Hubert Lai	University Counsel and Chair of the committee
Helen Burt	Associate VP - Research & International
Ruth Elwood Martin	Clinical Professor, Postgraduate Residency Program Lead, Faculty for Research Family Practice, Faculty of Medicine
Laurel Evans	Associate Director, Ethics Research Services
David Klonsky	Assistant Professor, Department of Psychology
Marc Levine	Professor & Acting Co-Chair, Clinical Pharmacy, Faculty of Pharmaceutical Sciences
Peter Loewen	Associate Professor, Faculty of Pharmaceutical Sciences
Bill McKellin	Assistant Professor, Department of Anthropology
Cynthia Nicol	Associate Professor, Curriculum and Pedagogy, Faculty of Education
Christine Oberti	Associate, Farris, Vaughan, Wills & Murphy LLP, external legal counsel to UBC
Carlos Teixeira	Associate Professor, Geography UBCO Barber Arts &Sciences, Unit 1