4.0 FACULTY PERSONNEL POLICIES AND PROCEDURES

4.17 RESEARCH AND SCHOLARSHIP

4.17.1 Research and Its Role at Concordia

4.17.1.1 Definitions

Research is a process of inquiry which generates new knowledge. It may involve scholarly, scientific, or creative activities in a field of specialization which results in the development of new insights that are communicated to a broader academic community. It may include the creation, composition, or performance of works.

Members of Concordia in this policy are all academic staff, non-academic staff, sessional instructors, administrators, students, visiting or adjunct scholars and professors, fellows and chairs, emeriti, holders of post-doctoral positions, paid and unpaid research associates and assistants, and any other persons in similar positions. This policy applies to all persons who advance their research or scholarly activities as being connected with Concordia in any way.

Researchers and **scholars** in this policy include all members of Concordia who are involved, to any extent whatsoever, in research and other scholarly and creative activities.

4.17.1.2 Relationship to Teaching

At Concordia, teaching will always have a preeminent role in faculty activity. This is based both on the mission of Concordia and the reality that teaching assignments are significantly above the average for Canadian colleges and universities (Smith Commission Report, 1991).

However, there is widespread consensus among college and university educators that both teachers and students must be learners, and that teaching provided by active scholars instills intellectual curiosity and a free spirit of inquiry in students. Moreover, research is considered to be part of the intellectual development of faculty and a visible demonstration to the broader community of Concordia's commitment to academic excellence.

The importance of both teaching and research, therefore, must be acknowledged. Concordia must recognize and reward excellence in teaching as well as being committed to and fostering research.

4.17.1.3 How Is Research Evidenced?

The design and preparation of courses and literature reviews and the incorporation of new scholarly findings into course materials are an integral part of a faculty member's ongoing teaching responsibilities.

A faculty member's research activity, however, is normally manifested outside the classroom through a process of communication, either with academic peers or a broader public. This may take the form of publication of articles, reviews, critiques, textbooks and the like, as well as active participation in academic conferences or associations where research activities are normally communicated. In the case of artistic works this may include publication, performance, or exhibition.

4.17.1.4 Patents and Copyrights

Researchers and scholars engaged in research at Concordia must adhere to this institution's policies on patents and copyrights: information on these policies is available in the offices of the Vice-President Academic and Provost, and the Dean of Research and Graduate Studies.

4.17.1.5 Research Involving Human Subjects

Any proposal for research involving human subjects must first be submitted for approval Concordia's Research Ethics Board, subject to standards set forth in the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (see 4.17.8).

4.17.1.6 Research Involving Animals

Any proposal for research involving vertebrates must be submitted for approval to an ad hoc committee on animal welfare convened by the Dean of Research and Graduate Studies, subject to guidelines set forth by the Canadian Council on Animal Care (CCAC) (see 4.17.7).

4.17.2 **General Policies**

4.17.2.1 Administration

The Dean of Research and Graduate Studies, who reports to the Vice-President Academic and Provost, is in charge of administering Concordia's research policy. Information regarding Concordia's research policy, the resources for research available at Concordia, and advice as to how to apply for external funding can be obtained in the office of the Dean of Research and Graduate Studies. Pertinent application forms are available from this office.

Moreover, the Dean of Research and Graduate Studies is responsible for promoting research at Concordia by seeking increased sources of internal and external funding. In particular, the Dean of Research and Graduate Studies will endeavour to solicit institutional grants from outside sources for research purposes. The Vice-President Academic and Provost shall oversee the budget allocated to academic research activities. Secretarial assistance will be provided to faculty members for research purposes through the Office of the Vice-President Academic and Provost.

4.17.2.2 Academic Research Council

An Academic Research Council is convened by the Dean of Research and Graduate Studies and includes, in addition to the Dean of Research and Graduate Studies, four faculty members, one from each Division. When necessary, the Dean may invite other individuals as advisory members. This Council is responsible for developing research policies and promoting research activities on campus.

Members of the Council are elected by each Division for a period of two years. Divisions should endeavor to select representatives with research experience to serve on the Council. Meetings are held at a time that is mutually agreeable to Council members; the Chair may call special meetings.

Terms of Reference:

a) To review and make recommendations on policy and mechanisms for encouraging, supporting, and funding research. With sufficient external funding, consideration may be given to the establishment of a research chair and the development of a research publication.
b) To review and make recommendations for institutional arrangements (such as allocation and adequacy of equipment and facilities, secretarial and technical assistance, library collection policy, etc.) to support research at Concordia.
c) To enhance the intellectual life of Concordia as a liberal arts institution by encouraging the presentation and discussion of faculty research activities.
d) To review applications for Concordia research grants and make recommendations to the Vice-President Academic and Provost through the Dean of Research and Graduate Studies.

The Dean of Research and Graduate Studies coordinates the evaluation of applications for research support. Evaluation of each application, establishment of the priority of applications, and recommendation of funding for each research application are the responsibility of the Academic Research Council. Details of the funding of all research projects are on file in the Office of the Dean of Research and Graduate Studies.

4.17.2.3 Publication

The results of research carried out at Concordia are available for publication as determined by the faculty member responsible. Faculty members are encouraged to pursue research in their area of expertise and to publish the results. The Vice-President Academic and Provost, in consultation with the Dean of Research and Graduate Studies, will support these activities by providing facilities and secretarial assistance whenever possible for the production of manuscripts or the preparation of conference materials.

4.17.3 **Internal Research Support**

Concordia provides ongoing support for the promotion and encouragement of research in the form of remuneration of full-time faculty and provision of essential resources such as the library, office space, laboratory space, and secretarial and technical support.

4.17.3.1 Faculty Research Fund

Allocation of funds for research purposes is governed by the following Faculty Research Fund policy:

a) All permanent-stream faculty members shall be eligible to apply for research support from a research fund established for this purpose in the institutional budget. A limited number of grants shall be available each year. The total amount available from the fund for all such grants in any given year shall be limited by the budgeted amount of the fund as approved by the Board of Regents.
b) Research grants shall be awarded on the basis of merit. A system of ranking or rating applications shall be defined by the Council based on faculty input.
c) Research grants for first-time applicants should be given priority when proposals are of equal merit.
d) Grant monies may be used to pay for research assistance, travel directly related to research, charges for publication, or any other items necessary to conduct the research.
e) In evaluating applications, the Academic Research Council may 1) authorize the grant as requested, or 2) authorize a reduced grant, or 3) reject the application. In the event that there is an insufficient number of suitable applications, the research fund may not be allocated entirely in any given year. Awards will normally be limited to a maximum of $5,000. From time to time this limit may be increased. Any funds not used in one year will be added to the budget allocated for research in the next year.
f) The disposition of individual applications and decisions about the allocation of research funds shall be the responsibility of the Academic Research Council. Any Council member who has an application pending will not participate in the discussion and decision on the allocation of funds that year. The Dean of Research and Graduate Studies will approach the Division for an alternate to replace the member who is temporarily withdrawing on grounds of conflict of interest. A fifth advisory member may be appointed to the Council by the Dean of Research and Graduate Studies to consider proposals outside the expertise of existing Council members.
g) Following review procedures established by the Academic Research Council, applications for grants from the research fund should be submitted to the Dean of Research and Graduate Studies before February 15 for the fiscal year beginning July 1, but may be submitted later if the funds have not all been allocated.

4.17.3.2 Teaching Reduction for Externally Funded Research Purposes

In order to encourage externally funded research at Concordia, a faculty member may be granted a reduction in the teaching assignment to facilitate his/her research.

Applications for teaching reduction in order to carry out externally funded research are evaluated by the Academic Research Council using the following criteria:

a) The external grant must provide sufficient funds to hire a teaching replacement for the faculty member.
b) Priority will be given to applicants when the external grant is such that it would be unavailable during a sabbatical leave.
c) Eligibility for full reduction in teaching assignment is limited to full-time faculty in at least the fourth year of their contract. Lesser reductions may be considered for other faculty.
d) Normally the deadline for application for such a teaching reduction shall be November 15 of

the year prior to that in which the reduction is to take place. The application must be accompanied by proof of application to the granting agency, and be submitted in writing through the Dean of Research and Graduate Studies to the Vice-President Academic and Provost. At the discretion of the Academic Research Council, applications presented at other times of the year may also be considered.

e) Faculty receiving this reduction in teaching for research purposes remain in the full-time employ of Concordia. The faculty member's position on the Faculty will not be in jeopardy and the salary will not suffer (i.e., no increments will be lost). Depending on the nature of the particular teaching reduction sought, reduction of committee and advisement responsibilities will be determined by the Vice-President Academic and Provost in consultation with the appropriate Dean. However, the faculty member will not be asked to undertake any new or additional committee work during the reduction in teaching.
f) The faculty member must inform Concordia of any additional remuneration while the teaching assignment is reduced. Concordia will limit its contribution so that the total earned remuneration (net of reasonable related expenses) which the faculty member receives will not exceed 100% of regular salary for the duration of the teaching reduction.
g) Applications for Teaching Reduction for Externally Funded Research Purposes will be considered in conjunction with applications for Reduction in Teaching Assignment for Research Purposes (4.17.3.3).

4.17.3.3 Reduction in Teaching Assignment for Research Purposes

To encourage faculty members to engage in research, Concordia provides a limited number of reduced teaching assignments on a semester-to-semester basis.

a) Reduced teaching assignments are available to permanent-stream faculty members. Reductions in teaching assignments are not available for personal research contracts with personal remuneration.
b) Faculty members whose research projects are underway or nearing completion will be given priority.
c) The maximum teaching assignment reduction per faculty member is twelve hours a year, to be applied to either or both semesters.
d) The maximum institutional teaching assignment reduction is thirty-six hours per year, subject to budgetary considerations
e) Successful applicants will be excused from committee responsibilities.
f) Applications will be evaluated by the Academic Research Council and prioritized on the basis of:
    i. Merit of the proposal.
    ii. Availability of facilities, technical support, and equipment (if they are required for the research)
    iii. Availability of grants from external agencies.
    iv. Commitment from a publisher

    The Academic Research Council will make recommendation to the Vice-President Academic and Provost through the Dean of Research and Graduate Studies.
g) Faculty receiving this reduction in teaching for research purposes remain in the full-time

employ of Concordia. Normal salary increments will apply, and the time involved in the reduced teaching assignment for research will count toward sabbatical leave.

h) The faculty member shall submit a written report to the Dean of Research and Graduate Studies which accounts for his or her use of time during tenure of the teaching assignment reduction.
i) A faculty member may request a reduced teaching assignment for the upcoming academic year to the Dean of Research and Graduate Studies by November 15. Applicants will provide in writing:
    i) The nature of the research project, including a brief description of the goals and methodology of the proposed research.
    ii) A time-line for completion of the research project.
    iii) Plans for sharing the research results, such as via publication, presentation to a scholarly conference or to the public.
    iv) Rationale of the urgency for completion of the research project.
j) Reduced teaching assignment for research requests will be considered by the Academic Research Council. If a member is an applicant, the Dean of Research and Graduate Studies will approach the Division for an alternate from that Division to serve in place of the member. The Academic Research Council makes its recommendation to the Vice-President Academic and Provost through the Dean of Research and Graduate Studies by the end of the first semester.
k) Applicants are informed by the Dean of Research and Graduate Studies of the Academic research Council's recommendation by January 15.
l) The Board of Regents makes a decision on reduced teaching assignments for research, subject to budgetary approval, at the following Board meeting.
m) Faculty members are informed of the Board of Regents action by March 15.

4.17.3.4 Review Procedures

A faculty member can ask for a review in writing to the Dean of Research and Graduate Studies before February 1. The faculty member will be requested to appear at a subsequent meeting of the Academic Research Council. The second decision of the Academic Research Council is final.

4.17.4 **External Research Support**

4.17.4.1 Policy

In recognition of the importance of research in post-secondary education, faculty engaged in research are encouraged to seek support from external agencies such as industry, government, and foundations.

Concordia, on accepting research funding from an external agency, will provide all the resources normally needed to support the project, including equipment, space, and administrative services. Reasonable efforts shall be made to provide for any special facilities that may be required for a research project. Some resources may be designated by the Divisions for research purposes.

4.17.4.2 Regulations

a) An application requesting research support from an external agency must be signed by the applicant and those administrators specified by the granting agency. A copy of each application and any other documents pertaining to the applications shall be kept on record in the Office of the Dean of Research and Graduate Studies.
b) As convenor of the Academic Research Council, the Dean of Research and Graduate Studies, in consultation with the Vice-President Academic and Provost, shall be responsible for the management and allocation of research space and administrative services.
c) The applicant shall submit a copy of the awards notice plus any other documents describing the regulations and/or conditions pertaining to the award to the Office of the Dean of Research and Graduate Studies.
d) For the purpose of external research funding, direct charges may include wages, salaries and benefits for teaching replacements and/or technicians, equipment, consumable supplies, research support (technical and/or clerical), and other services required to complete the project.
e) In order to promote research and increase the acquisition of funding, Concordia will not normally include an overhead allowance on any research budget application.

4.17.4.3 Contract Research

a) Explanation of Contract Research: Contractual research differs from more conventionally funded research grants in four basic aspects. The first important difference is in the nature of the contract. Contract research is normally conducted under the terms of a written legal agreement between two or more parties that clearly specifies the manner in which the work is to be carried out, a budget that itemizes the expenditure of funds, and a schedule of product deliveries and payments. In comparison, conventional research grants, such as those provided by the Natural Sciences and Engineering Research Council (NSERC) and the Social Sciences and Humanities Research Council (SSHRC), have considerably less rigid contractual agreements. Once a grant has been awarded the recipient is essentially free to pursue any aspect of the research topic which falls within the guidelines of the submitted proposal without seeking prior approval from the granting agency.

   Secondly, the two types of research funds differ in the length of time for which funding for a project is provided. Research contracts, the majority of which are sponsored by government agencies, usually provide funds only for short-term projects that have a specified completion date within the fiscal year that ends on March 31. In order to facilitate projects requiring much longer periods of investigation, conventional grants offer funding for from one to three and five years.

   Thirdly, the legal rights to data and publication differ greatly between the two types of research. Whereas the results of the research are the sole property of the grant recipients in the case of conventional awards, ownership of all results generated during the performance of a contract belongs to the contracting agency.

The origin of the research proposal constitutes the last major difference between the two funding sources. In the case of conventional grant applications, the research proposal is the sole inspiration of the researcher. In the case of contracts, the proposal originates with a government or private agency.

Contracts are regarded as a reasonable and substantial source of funding for academic research. Consequently, Concordia fully supports contract research, provided that the research is conducted at a level commensurate with the general expectations of academic research.

Concordia also supports personal research contracts negotiated between an individual faculty member and an external agency, provided that the research project does not infringe on the academic responsibilities of the faculty member. Such research may be carried out with the aid of Concordia facilities on a reasonable cost recovery basis. Hence, the cost of any consumable supplies or support services is the responsibility of the faculty member entering into the contractual agreement.

The same regulations that govern the planning and implementation of externally funded awards shall also apply to research contracts. In addition, the following regulations pertain specifically to contractual agreements.

b) Contracts ordinarily require written approval from the contractor for any changes to either the budget or the work plan. Any proposed changes will normally be made on an informal basis by the principal investigator who may then make a written request to the Vice-President Academic and Provost to negotiate with the contracting agency for an amendment to the contract.
c) Expenditures not listed in the contract budget will not be accepted and the principal investigator shall be held responsible for paying these costs.
d) In order to promote research and increase the acquisition of funding, Concordia will not normally include an overhead allowance on any research budget application. Concordia will absorb the expense of all administrative costs except in the case of personal contracts, in which case all expenses are to be borne by the individual faculty member.
e) Clear, unequivocal evidence of personal contract research negatively affecting a faculty member's teaching responsibilities shall be subject to disciplinary action. Such matters should be dealt with in the same manner as any breach of a faculty member's contract.

4.17.4.4 Institutional Grants

Institutional grants received by Concordia are to be administered by the Dean of Research and Graduate Studies according to the recommendations of the Academic Research Council and, ultimately, the funding agency providing the grant.

4.17.5 Integrity in Research and Scholarship

The present policy conforms to *The Tri-Agency Framework: Responsible Conduct of Research*:

see http://www.rcr.ethics.gc.ca.eng/policy-politique/framework-cadre/ .

Concordia is committed to the highest standards of integrity in research and scholarship. Concordia recognizes that the implementation in practice of ethical research and professional standards is a responsibility of the researcher and scholar and expects that Concordia's researchers and scholars will comply with the ethics guidelines and requirements that apply in their disciplines.

Integrity in research and scholarship includes the understanding by researchers and scholars that research can involve honest error, conflicting data, or valid differences in experimental design or in the interpretation or the judgment of information. Principles of research integrity demand the responsible use of scholarly sources, ethical treatment of both human and animal subjects from whom raw or unformulated data are collected, and financial integrity in the use of research funds.

4.17.5.1 Principles and Responsibilities

Researchers and scholars are responsible for upholding the following principles:

a) Acknowledging the substantive contribution of others, including students, to one's scholarship and research;
b) Using scholarly rigor and integrity in obtaining, recording, and analyzing data, and in reporting and publishing results;
c) Obtaining permission for the use of confidential unpublished material, and using archival material in accordance with the rules of the archival source;
d) Complying with relevant federal or provincial statutes or regulations for the protection and welfare of researchers, human subjects, the public, laboratory animals, and the environment;
e) Using funds designated for research purposes in the prescribed manner;
f) Revealing to sponsors, Concordia, journals, or funding agencies any material conflict of interest, financial or other, that might influence their decisions on whether the researcher/scholar should be asked to review manuscripts or applications, test products, or be permitted to undertake work sponsored by outside sources.

4.17.5.2 Procedures for Promoting Integrity

The Academic Research Council is the institutional body responsible for the review and promotion of ethical standards in research and scholarship. (For policies governing Research Involving Human Participants and Concordia's REB, see 4.17.8). To promote understanding of the relevant issues, this council facilitates the following endeavors:

a) Reviewing and recommending university policies addressing issues of integrity in research and scholarship;
b) Promoting programs for the education of researchers and scholars concerning the principles and practices of research integrity; these educational programs will include appropriate methods of instruction such as workshops, seminars, written materials, and orientations for new employees;

c) Assisting disciplines in establishing and reviewing procedures and practices for informing students of ethical standards appropriate to research in the discipline, and where human or animal subjects will be used, helping disciplines develop and review policies for review of the ethics of the proposed research projects to be conducted by students.

4.17.5.3 Research Data

Scientific and scholarly inquiry is dependent upon the integrity of accurately recorded data. In order to ensure this dependency, a researcher must retain his/her original results in order to respond to questions regarding his/her research. Errors can be mistaken for misconduct if the primary experimental results are not fully accounted for or are unavailable.

Primary data should normally be stored in a secure area of the researcher's department and should remain available and preserved for a minimum of five (5) years following the publication. All collaborators must have free access to the relevant data at all times, and authorization to copy may not be withheld by any team member without valid reason communicated in writing to the Dean of Research and Graduate Studies. The primary research data should be recorded in print form and backed up on secured or protected electronic media. An index with appropriate pagination should be available to ensure easy access to critical areas of the research data. Under no circumstances should any primary data be destroyed or altered while the research is being evaluated or investigated by colleagues, readers, or investigators except where there is a legitimate requirement for confidentiality.

Issues concerning intellectual property rights, ownership and/or location of materials and products, including reproduction and publication of primary data, storage of primary data, research materials, software, and any other relevant circumstances related to conducting the research will be dependent upon the type of research conducted. Prior to any research being conducted, a common understanding of ownership should be reached among collaborators, supervisors, students, and Concordia.

4.17.5.4 Authorship and Publication

It is recognized that authorship implies significant intellectual contribution to the work. *The Tri-Agency Framework: Responsible Conduct of* Research defines “author (including co-author)” as follows: “The writer, or contributing writer, of a research publication or document.”

Anticipated co-authorship and ordering of authors on publications arising from student theses should be reviewed in the understandings and agreements reached prior to the work being undertaken. At the time the writing is undertaken and thereafter prior to submission for publication, the understanding and agreements should be reviewed in light of the actual contributions of the various co-authors to the final manuscript(s).

Although a graduate student may normally expect senior authorship on a publication arising solely from the thesis, patterns of co-authorship will be influenced by considerations of the involvement and contribution of the supervisor and others in a research group. Relevant

contributions to be taken into account include but are not limited to definition of the questions asked and hypotheses tested, development of the research, design and measurement procedures, data collection, organization and interpretation, and the actual writing of the manuscript.

4.17.6 **Research Misconduct**

Research misconduct does not include those factors intrinsic to the process of academic research, such as honest error, conflicting data, or valid differences in method of interpretation.

4.17.6.1 Definition

Misconduct in academic research means:

a) Fabrication, falsification, or plagiarism;
b) Failure to formally acknowledge the substantive contributions of others, including students;
c) The use of the unpublished work of other researchers without permission, or the use of archival material in violation of the rules of the archival source;
d) Material failure to comply with relevant federal or provincial statutes or regulations for the protection and welfare of researchers, human subjects, the public, laboratory animals, or the environment;
e) Material failure to meet other relevant legal requirements that relate to the conduct or reporting of research;
f) The intentional misuse of funds designated for research purposes;
g) Failure to reveal any material conflict of interest to sponsors or to those who commission work, or when asked to undertake reviews of research grant applications or manuscripts for publication, or when asked to test products for sale or distribution to the public;
h) Failure to reveal to Concordia any material financial interest in an organization that contracts with the university college to undertake research, particularly research involving the organization's products. Material financial interest includes ownership, substantial stock holding, a directorship, significant honoraria, or consulting fees but does not include minor stock holding in a large publicly-traded company.

4.17.6.2 Report of Allegations

All allegations of misconduct or fraud in research shall be written, signed, dated, accompanied by appropriate evidence, and directed to the relevant adjudicator. Anonymous allegations will not normally be considered; however, if compelling evidence is received anonymously by the adjudicator, the investigation process may be initiated.

Where the accused is a student in an undergraduate program, the adjudicator is the Dean of the Faculty in which the offense is alleged to have occurred, and the associate adjudicator is the Discipline Officer. Where the accused is a student in a graduate program, the adjudicator is the Dean of the Faculty of Graduate Studies, and the associate adjudicator is the Discipline Officer. Academic wrongdoing by students under the present policy shall be treated as Academic

Dishonesty and falls under the authority of the Academic Honesty policy as published in the Concordia Calendar. In cases in which a student is a co-accused together with a faculty member or researcher/scholar in any other category, the student's case shall fall under the authority of the Academic Honesty policy as published in the Concordia Calendar. The case of the co-accused researcher/scholar in all other categories shall fall under the authority of the present policy.

Where the accused is a member of Concordia other than a student, the adjudicator is the Vice-President Academic. Complaints received by any party other than the Vice-President Academic should be channeled to the Office of the Vice-President Academic. In the event that the Vice-President is either the complainant or the respondent, the President shall appoint a designate to serve in the place of the Vice-President for the investigation of the allegation.

In order to determine if a formal investigation is warranted, the Vice-President or designate shall request in writing a meeting with the respondent (the person against whom the allegation is made). The notice of this meeting shall inform the respondent of the purpose of this meeting, and of his/her right to be accompanied by an individual of the respondent's choice as well as legal counsel. Any statements made during these discussions shall be strictly without prejudice and, as such, in any subsequent proceedings related to the allegation statements shall be presented *de novo*.

Commentary: During both the initial investigation of the allegations and any subsequent formal investigation, the individual who accompanies the respondent to meetings can assist the respondent in assessing the allegation, evaluating the evidence, and formulating a response. Before selecting an individual to accompany him/her to meetings, the respondent may want to seek legal counsel and/or speak with the Chair of the Faculty Personnel Committee. The accompanying individual could be another faculty member, a member of Concordia's staff, or a professional colleague from another institution. In addition, legal counsel may be present.

The Vice-President or designate, in consultation with the Department Coordinator or Division Chair, will decide if a formal investigation is warranted. If the Vice-President or designate decides that a formal investigation is not warranted, he or she will inform the complainant in writing of this decision. The complainant will have five (5) working days to challenge this decision. If there is no challenge, the allegation(s) shall be dismissed and no action taken. The Vice-President or designate shall inform the respondent and the complainant of this decision in writing. In this event, no reference to the complaint shall be placed or retained in the official file of the respondent.

If the complainant challenges the decision, the matter will be reviewed by the President, in consultation with the relevant Faculty Dean. The President's decision to conduct a formal investigation or to dismiss the allegations shall be considered final and shall be communicated in writing to the Vice-President Academic or designate.

Within ten (10) working days of the meeting with the respondent, the Vice-President or designate shall advise the respondent in writing whether or not a formal investigation is warranted.

If the Vice-President or designate finds that a formal investigation is warranted, s/he shall give written notice to the respondent and the complainant that a Committee of Inquiry is to be established. The written notice shall include a copy of the allegation(s) and shall inform the respondent of his/her rights to participate in the selection of a Committee of Inquiry and to be accompanied to all meetings with the committee by someone of his/her choice.

4.17.6.3 The Formal Investigation

The formal investigation process commences when the respondent has received the written notice of the formal investigation specified in 4.17.6.2 above.

The formal investigation shall be conducted by a Committee of Inquiry composed of the Vice-President Academic (or designate in a case where the Vice-President is either the complainant or respondent), two impartial faculty members agreeable to both the complainant and the respondent, and one external member who has no current affiliation with Concordia. To avoid perceived conflicts of interest, the two faculty members should not be directly affiliated with the respondent's academic department; these members should be chosen on the basis of the nature of the complaint and the respondent's area of expertise. During the investigation, the Committee of Inquiry shall provide the complainant and the respondent full opportunity to submit their versions of the facts of the case. The Committee of Inquiry shall maintain a formal record of all proceedings; all materials pertaining to the investigation (including minutes, written records of interviews, audio or video tapes, and relevant documents) shall be kept on file in the Office of the President for a minimum of five (5) years to a maximum of ten (10) years. The Committee of Inquiry shall conduct a full investigation of the allegation(s), determine whether the act(s) of the respondent constitute research misconduct according to the definition of the policy, and recommend appropriate remedies and/or sanctions to the President.

The Committee of Inquiry has the authority to decide on matters of misconduct. Its decision is binding on the institution.

The Committee of Inquiry shall investigate the allegation(s) promptly, fairly, judiciously, and confidentially. The Committee of Inquiry is not a court of competent jurisdiction and is not bound by the rules of evidence. It shall, within the context of this policy, establish its own procedures and will conduct its process in compliance with the rules of natural justice. It shall be free to accept any oral or written evidence that, in its discretion, it considers proper, whether admissible in a court of law or not. The Committee shall ensure that the respondent has adequate opportunity to know any evidence presented and to respond to that evidence if s/he chooses to do so.

No person consulted by the Committee of Inquiry concerning the allegation(s) shall be appointed to an appeal committee (Faculty Handbook 4.8) in any subsequent proceedings dealing with the allegation(s) against the respondent.

The Committee of Inquiry, subject to the agreement of the respondent as to any extension, shall submit a written report to the President no later than sixty (60) calendar days from the

respondent's receipt of the written notice specified in 4.17.6.2 above. The report shall include a copy of the signed allegation(s), the written response, if any, of the respondent, the composition of the investigating committee and an explanation of the selection process, and the Committee of Inquiry's finding and decision; it should also identify a follow-up process, to be developed by the Vice-President. In its decision, the Committee of Inquiry shall indicate the appropriate disposition of the complaint, in what respects (if any) research misconduct as articulated in this policy has occurred, and what sanctions (if any) it considers fitting. A copy of this report shall be sent to the respondent and the complainant. The complainant and the respondent may submit a written comment on the draft report within five (5) working days of their receipt of the report. At the end of those five days, the Committee of Inquiry shall submit its final report to the Vice-President, who will then make it available to the complainant and the respondent. If the respondent disagrees with the recommendation of the Committee of Inquiry, s/he may initiate appeal procedures outlined in Faculty Handbook 4.8.

The Committee of Inquiry may recommend to the President:

a) Inclusion of the Committee's decision in the respondent's personnel file;
b) Barring the respondent from access to internal research funds for a specified period of time;
c) Informing government agencies, archival sources, academic journals, or such other external organizations as may need to know of the Committee's decision;
d) Suspension;
e) Pursuit of legal action to recover misappropriated funds from internal sources; and/or
f) Any other action of restitution that the Committee of Inquiry determines to be appropriate.

4.17.6.4 Protection of Federal Agency Funds

Should misconduct be found to have occurred, Concordia will independently, or at the Agency's request, take the necessary measures to ensure the protection of Agency funding, including freezing the funding until the matter has been resolved if the situation warrants such action.

4.17.6.*5* Outcome of the Formal Investigation

Within five (5) working days following the receipt of the Committee of Inquiry's report, the President shall notify the respondent in writing of the outcome of the inquiry, including any actions or sanctions imposed on the respondent. The President also shall inform the complainant in writing of the outcome of the inquiry.

Any decision on disciplinary action imposed on a member of the Concordia faculty for research misconduct shall be subject to appeal procedures (Faculty Handbook 4.8).

If Concordia decides after a formal investigation not to take disciplinary action against the respondent, or if an appeals committee decides in favor of the respondent, all documentation concerning the allegation(s) shall be removed from the respondent's official file.

Concordia will make every effort to restore the reputation of those unjustly accused.

Concordia will take such steps as may be necessary and reasonable to protect the rights, positions, and reputations of individuals who in good faith make allegations of research misconduct, or whom it calls as witnesses in the formal investigation.

Concordia will take disciplinary action against those who make allegations of misconduct in research which are reckless, malicious, and/or not in good faith. The Vice-President Academic retains a confidential record of allegations, and the President retains final reports of committees of inquiry in order to protect faculty from such harassment. These records will be retained for a minimum of five (5) years to a maximum of ten (10) years. Access to these records is limited to the President, the Vice-President Academic (except in those cases in which the Vice-President Academic is an interested party), and those to whom the President has provided specific permission.

4.17.6.6 Reporting Requirements

a) Subject to any applicable laws, including privacy laws, Concordia shall advise the relevant Agency or the Secretariat on Responsible Conduct of Research (SRCR) immediately of any allegations related to activities funded by the Agency that may involve significant financial, health and safety, or other risks.
b) Concordia shall write a letter to the SRCR confirming whether or not the Institution is proceeding with an investigation where the SRCR was copied on the allegation or advised as per Section 4.17.6.6.a. If a breach is confirmed at the inquiry stage, reporting requirements outlined in Section 4.17.6.6.c apply.
c) Concordia shall prepare a report for the SRCR on each investigation it conducts in response to an allegation of policy breaches related to a funding application submitted to an Agency or to an activity funded by an Agency. Subject to any applicable laws, including privacy laws, each report shall include the following information:
    i. the specific allegation(s), a summary of the finding(s) and reasons for the finding(s);
    ii. the process and time lines followed for the inquiry and/or investigation;
    iii. the researcher's response to the allegation, investigation and findings, and any measures the researcher has taken to rectify the breach; and
    iv. the institutional investigation committee's decisions and recommendations and actions taken by the Institution.

    Concordia's report should not include the following:

    i. Information that is not related specifically to Agency funding and policies; or
    ii. Personal information about the researcher, or any other person, that is not material to the Institution's findings and its report to the SRCR.

d) Inquiry letters and investigation reports should be submitted to the SRCR within two and seven months, respectively, of receipt of the allegation by Concordia. These timelines may be extended in consultation with the SRCR if circumstances warrant, and with monthly updates provided to the Agency until the investigation is complete.

e) Concordia and the researcher may not enter into confidentiality agreements or other agreements related to an inquiry or investigation that prevents Concordia from reporting to the Agencies through the SRCR.
f) In cases where the source of funding is unclear, the SRCR reserves the right to request information and reports from Concordia.

4.17.7 Science Research

Concordia has one level-2 Biology laboratory which complies with the Health Canada Laboratory Biosafety Guidelines http://www.hc-sc.gc.ca/pphb-dgspsp/ols-bsl/lbg-ldmbl/index.html.

No research is currently conducted involving radioactive materials, or research in the Yukon, the Northwest Territories, or Nunavut. Should this change, the institution will promptly inform NSERC.

As of May 2012, research involving animals is not conducted at Concordia. However, since Concordia intends to be able, in the future, to allow its members to conduct research involving animals, it will apply for a Canadian Council on Animal Care Certificate of Good Animal Practice (GAP). Concordia will inform NSERC as soon as it is granted a GAP certificate.

4.17.8 Research Involving Human Subjects

4.17.8.1 Introduction

1.1 Purpose:

The purpose of this research policy is to ensure that the rights of human subjects participating in research are respected and that the highest ethical standards are applied to all research involving human participants conducted by members of the community of Concordia University of Edmonton (referred to as Concordia in this document), regardless of where the research is conducted. This policy also applies to research conducted on Concordia premises by researchers who are not members of the Concordia community.

Concordia fully subscribes to the principles detailed in the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS 2: 2010) and has established a Research Ethics Board (REB) in compliance with those principles. The official version of the TCPS 2 on which the present policy is based can be found on-line at http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/

This policy is based on the following core principles, as listed in Article 1.1 of TCPS 2:

a) Respect of persons
b) Concern for welfare
c) Justice

1.2 Definition of research

For the purposes of this policy, Concordia accepts the TCPS 2 definition of "research" (Article 2.1) as "an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation." Accordingly, research involving human participants in this policy refers to an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation involving human subjects as participants.

4.17.8.2 Research Requiring Ethics Review (TCPS 2, chapter 2)

Concordia's REB shall comply with the following requirements of the TCPS 2:

(TCPS 2, Article 2.1) The following requires ethics review and approval by an REB before the research commences:

a) Research involving living human participants;
b) Research involving human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individuals.

(TCPS 2, Article 2.2) Research that relies exclusively on publicly available information does not require REB review when:

a) The information is legally accessible to the public and appropriately protected by law; or
b) The information is publicly accessible and there is no reasonable expectation of privacy.

(TCPS 2, Article 2.3) REB review is not required for research involving the observation of people in public places where:

a) It does not involve any intervention staged by the researcher, or direct interaction with the individuals or groups;
b) Individuals or groups targeted for observation have no reasonable expectation of privacy; and
c) Any dissemination of research results does not allow identification of specific individuals.

(TCPS 2, Article 2.4) REB review is not required for research that relies exclusively on secondary use of anonymous information, or anonymous human biological materials, so long as the process of data linkage or recording or dissemination of results does not generate identifiable information.

(TCPS 2, Article 2.5) 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, do not constitute research for the purposes of this Policy, and do not fall within the scope of REB review.

(TCPS 2, Article 2.6) Creative practice activities, in and of themselves, do not require REB review. However, research that employs creative practice to obtain responses from participants that will be analyzed to answer a research question is subject to REB review.

(TCPS 2, Article 2.7) As part of research ethics review, the REB shall review the ethical implications of the methods and design of the research. As traditions for scholarly review vary among the disciplines, the REB must take into account the extent of scholarly review that is required for each discipline.

(TCPS 2, Article 2.8) Following initial REB review and approval, research ethics review shall continue throughout the life of the project in accordance with Article 6.14, which reads as follows:

The REB shall make the final determination as to the nature and frequency of continuing research ethics review in accordance with a proportionate approach to research ethics review. At minimum, continuing research ethics review shall consist of an annual status report (for multi-year research projects), and an end-of-study report (projects lasting less than one year).

4.17.8.3 Free, Informed, and Ongoing Consent (TCPS 2, chapter 3)

Research that is governed by this policy may begin only if the participants have given their consent. The following requirements must be met:

3.1 Consent shall be given voluntarily (TCPS 2, Article 3.1)

a) Consent shall be given voluntarily.
b) Consent can be withdrawn at any time.
c) If a participant withdraws consent, the participant can also request the withdrawal of their data or human biological materials.

3.2 Consent shall be informed (TCPS 2, Article 3.2)
Researchers shall provide to prospective participants, or authorized third parties, full disclosure of all information necessary for making an informed decision to participate in a research project.

3.3 Consent shall be an ongoing process (TCPS 2, Article 3.3)
Consent shall be maintained throughout the research project. Researchers have an ongoing duty to provide participants with all information relevant to their ongoing consent to participate in the research.

3.4 Incidental findings (TCPS 2, Article 3.4)
Researchers have an obligation to disclose to the participant any material incidental findings discovered in the course of research.

3.5 Consent shall precede collection of, or access to, research data (TCPS 2, Article 3.5)

Research shall begin only after the participants, or their authorized third parties, have provided their consent.

3.6 Critical inquiry (TCPS 2, Article 3.6)
Permission is not required from an organization in order to conduct research on that organization. If a researcher engages the participation of members of an organization without the organization's permission, the researcher shall inform participants of any foreseeable risk that may be posed by their participation.

3.7 Alteration of consent in minimal risk research (TCPS 2, Article 3.7)
The REB may approve research without requiring that the researcher obtain the participant's consent in accordance with sections 10.1 to 10.5 where the REB is satisfied, and documents, that all of the following apply:

a) The research involves no more than minimal risk to the participants;
b) The lack of the participant's consent is unlikely to adversely affect the welfare of the participant;
c) It is impossible or impracticable to carry out the research and to answer the research question properly, given the research design, if the prior consent of the participant is required;
d) Whenever possible and appropriate, after participation, or at a later time during the study, participants will be debriefed and provided with additional pertinent information in accordance with Articles 3.2 and 3.4, at which point they will have the opportunity to refuse consent in accordance with Article 3.1; and
e) The research does not involve a therapeutic intervention, or other clinical or diagnostic interventions.

3.8 Consent for research in individual medical emergencies (TCPS 2, Article 3.8)
Subject to all applicable legal and regulatory requirements, research involving medical emergencies shall be conducted only if it addresses the emergency needs of the individuals involved, and then only in accordance with criteria established in advance of such research by the REB. The REB may allow research that involves medical emergencies to be carried out without the consent of participants, or of their authorized third party, if all of the following apply:

a) A serious threat to the prospective participant requires immediate intervention;
b) Either no standard efficacious care exists or the research offers a realistic possibility of direct benefit to the participant in comparison with standard care;
c) Either the risk is not greater than that involved in standard efficacious care, or it is clearly justified by the prospect for direct benefits to the participant;
d) The prospective participant is unconscious or lacks capacity to understand the risks, methods and purposes of the research project;
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 participant is known to exist.
When a previously incapacitated participant regains capacity, or when an authorized third

party is found, consent shall be sought promptly for continuation in the project, and or subsequent examinations or tests related to the research project.

3.9 Capacity (TCPS 2, Article 3.9)
Capacity refers to the ability of participants to understand a research project and to appreciate the consequences of participating in the research project.

For research involving individuals who lack the capacity, either permanently or Temporarily, to decide for themselves whether to participate, the REB shall ensure that, as a minimum, the following conditions are met:

a) The researcher involves participants who lack the capacity to consent on their own behalf to the greatest extent possible in the decision-making process;
b) The researcher seeks and maintains consent from authorized third parties in accordance with the best interests of the persons concerned;
c) The authorized third party is not the researcher or any other member of the research team;
d) The researcher demonstrates that the research is being carried out for the participant's direct benefit, or for the benefit of other persons in the same category. If the research does not have the potential for direct benefit to the participant but only for the benefit of the other persons in the same category, the researcher shall demonstrate that the research will expose the participant to only a minimal risk and minimal burden, and demonstrate how the participant's welfare will be protected throughout the participation in research; and
e) When authorization for participation was granted by an authorized third party, and a participant acquires or regains capacity during the course of the research, the researcher shall promptly seek the participant's consent as a condition of continuing participation.

3.10 Third-party consent
Where an authorized third party has consented on behalf of an individual who lacks legal capacity, but that person has some ability to understand the significance of the research, the researcher shall ascertain the wishes of that individual with respect to participation. Prospective participants' dissent will preclude their participation.

3.11 Signed directives
Where individuals have signed a research directive indicating their preferences about future participation in research in the event that they lose capacity or upon death, researchers and authorized third parties should be guided by these directives during the consent process.

3.12 Documentation of consent
Evidence of consent shall be contained either in a signed consent form or in documentation by the researcher of another appropriate means of consent.

4.17.8.4 Fairness and Equity in Research Participation (TCPS 2, chapter 4)

4.1 Appropriate Inclusion (TCPS 2, 4.1)
Taking into account the scope and objectives of their research, researchers should be inclusive in selecting participants. Researchers shall not exclude individuals from the opportunity to participate in research on the basis of attributes such as culture, language, religion, race, disability, sexual orientation, ethnicity, linguistic proficiency, gender or age, unless there is a valid reason for the exclusion.

4.2 Inappropriate Exclusion (TCPS 2, Article 4.2)
Women shall not be inappropriately excluded from research solely on the basis of gender or sex.

4.3 Inappropriate Exclusion (TCPS 2, Article 4.3)
Women shall not be inappropriately excluded from research solely on the basis of their reproductive capacity, or because they are pregnant or breastfeeding.

4.4 Research Involving Children (TCPS 2, Article 4.4)
Children shall not be inappropriately excluded from research solely on the basis of their age or developmental stage. The inclusion of children in research is subject to section 4.6 (TCPS 2, Article 4.6).

4.5 Research Involving the Elderly (TCPS 2, Article 4.5)
Elderly people shall not be inappropriately excluded from research solely on the basis of their age.

4.6 Research Involving Participants Who Lack the Capacity to Consent for Themselves
Subject to applicable legal requirements, individuals who lack capacity to consent to participate in research shall not be inappropriately excluded from research. Where a researcher seeks to involve individuals in research who do not have capacity to consent for themselves, the researcher shall, in addition to fulfilling the conditions in Articles 3.9 and 3.10, satisfy the REB that:

a) The research question can be addressed only with participants within the identified group; and
b) The research does not expose the participants to more than minimal risk without the prospect of direct benefits for them; or
c) Where the research entails only minimal risk, it should at least have the prospect of providing benefits to participants or to a group that is the focus of the research and to which the participants belong.

4.7 Participants' Vulnerability and Research (TCPS 2, Article 4.7)
Individuals or groups whose circumstances may make them vulnerable in the context of research should not be inappropriately included or automatically excluded from participation in research on the basis of their circumstances.

4.8 Equitable Distribution of Research Benefits
Researchers should ensure that the benefits of research are distributed to participants. And the results of research should be made available to participants in a culturally appropriate and meaningful format.

4.17.8.5 Privacy and Confidentiality (TCPS 2, chapter 5)

5.1 Ethical Duty of Confidentiality (TCPS 2, Article 5.1)
Researchers shall safeguard information entrusted to them and not misuses or wrongfully disclose it. Concordia shall support its researchers in maintaining promises of confidentiality.

5.2 Disclosure (TCPS 2, Article 5.2)
Researchers shall describe measures for meeting confidentiality obligations and explain any reasonably foreseeable disclosure requirements:

a) In application materials they submit to the REB; and
b) During the consent process with prospective participants.

5.3 Safeguarding Information (TCPS 2, Article 5.3)
Researchers shall provide details to the REB regarding their proposed measures for safeguarding information, for the full life cycle of information: its collection, use, dissemination, retention and/or disposal.

5.4 Security Safeguards (TCPS 2, Article 5.4)
Researchers shall consult with their supervisors regarding security protocols at Concordia and shall abide by those protocols.

5.5 Consent and Secondary Use of Identifiable Information (TCPS 2, Article 5.5)
Researchers who have not obtained consent from participants for secondary use of identifiable information shall use such information only for these purposes if the REB is satisfied that:

a) Identifiable information is essential to the research;
b) The use of identifiable information without the participants' consent is unlikely to adversely affect the welfare of individuals to whom the information relates;
c) The researchers will take appropriate measures to protect the privacy of individuals, and to safeguard the identifiable information;
d) The researchers will comply with any known preferences previously expressed by individuals about any use of their information;
e) It is impossible or impracticable to seek consent from individuals to whom the information relates; and
f) The researchers have obtained any other necessary permission for secondary use of information for research purposes.

If a researcher satisfies all the conditions in sections 5.5(a) to (f), the REB may approve the research without requiring consent from the individuals to whom the information relates.

5.6 REB Approval (TCPS 2, Article 5.6)
When secondary use of identifiable information without the requirement to seek consent has been approved under Article 5.5, researchers who propose to contact individuals for additional information shall, prior to contact, seek REB approval of the plan for making contact.

5.7 Data Linkage (TCPS 2, Article 5.7)
Researchers who propose to engage in data linkage shall obtain REB approval prior to carrying out the data linkage, unless the research relies exclusively on publicly available information as discussed in Article 2.2 (see 4.17.8.2). The application for approval shall describe the data that will be linked and the likelihood that identifiable information will be created through the data linkage.

Where data linkage involves or is likely to produce identifiable information, researchers shall satisfy the REB that:

a) The data linkage is essential to the research; and
b) Appropriate security measures will be implemented to safeguard information.

4.17.8.6 Research Ethics Board (REB)

There is one REB at Concordia, and it is solely responsible for all ethics review regarding human participants carried out at Concordia or by members of the Concordia community. No research is permitted to begin until the review process has been completed. Departmental ethics reviews are allowed only for review of undergraduate research within course requirements. Departmental reviews should not be used for research in which an undergraduate student is carrying out research that is part of a faculty member's own research program.

6.1 Authority of the REB (TCPS 2, Articles 6.1, 6.2, & 6.3)
Concordia's Research Ethics Board is appointed and mandated by the President of Concordia to approve, reject, propose modifications to, or terminate any proposed or ongoing research involving human participants that is conducted within, or by a member of, Concordia, using the considerations set forth in the TCPS 2 as the minimum standard. The President will ensure that the REB has the appropriate financial and administrative independence to fulfill its primary duties.

6.2 Membership of the REB (TCPS 2, Article 6.4)
The REB shall consist of at least five members, including both men and women, of whom

a) At least two members have expertise in relevant research disciplines, fields, and methodologies covered by the REB;
b) At least one member is knowledgeable in ethics;

c) At least one member is knowledgeable in the relevant law (but that member should not be the institution's legal counsel or risk manager). This is mandatory for biomedical research and is advisable, but not mandatory, for other areas of research; and
d) At least one community member who has no affiliation with Concordia.

It is advisable that each member be appointed to formally fulfill the requirements of only one of the above categories.

To ensure the independence of REB decision making, institutional senior administrators shall not serve on the REB.

These basic membership requirements are designed to ensure the expertise, multidisciplinary, and independence essential to competent research ethics review by the REB. In any review in which the regular members of the REB do not possess all of the expertise required to assess a project, the REB Chair shall nominate appropriate ad hoc members for the duration of the review (TCPS 2, Article 6.5).

REB members normally serve for a two-year term and may be re-appointed. The Chair is elected by the REB on a two-year appointment. The term of appointments of REB members should be arranged to balance the need to maintain continuity with the need to ensure diversity of opinion and the opportunity to spread knowledge and experience gained from REB membership throughout Concordia and the community (TCPS 2, Article 6.6).

6.3 REB Chair (TCPS 2, Article 6.8)
The REB Chair is responsible for ensuring that the REB review process conforms to the requirements of this policy.

6.4 REB Quorum (TCPS 2, Article 6.9)
The REB shall require a quorum of 50% plus one of the membership representation outlined in section 6.2. Decisions requiring a full review should be adopted only if the members in attendance possess the range of background and expertise needed to conduct the review(s).

6.5 Meetings and Attendance (TCPS 2, Article 6.10)
The REB shall have regular meetings and shall normally meet face to face to review proposed research that is not assigned to delegated review.

6.6 Procedures for REB Review: Initial Research Ethics Review (TCPS 2, Article 6.11)
Researchers shall submit their research proposals, including proposals for pilot studies, for REB review and approval of its ethical acceptability prior to the start of recruitment of participants, access to data, or collection of human biological materials. REB review is not required for the initial exploratory phase, which may involve contact with individuals or communities intended to establish research partnerships or to inform the design of a research proposal.

6.7 Procedure for REB Review: Determining the Level of Research Ethics Review (TCPS 2, Article 6.12
In keeping with a proportionate approach to research ethics review, the selection of the level of REB review shall be determined by the level of foreseeable risks to participants: the lower the level of risk, the lower the level of scrutiny (delegated review); the higher the level of risk, the higher the level of scrutiny (full board review).

6.8 Review Process

Step 1: The Principal Researcher completes and submits an "Application for Research Involving Human Subjects" to the Chair of the REB (TCPS 2, Article 6.11).

Step 2: The REB assesses the design of the research project to determine the level of proportionate ethics assessment (TCPS 2, Article 6.12).

Full board review by the REB is the default requirement for all research involving human subjects.

If the Chair of the REB determines that a delegated review is not appropriate, or if the applicant elects a full review, the application will be copied and distributed to the members of the REB for consideration at its next scheduled meeting. A full REB review must take place in a face-to-face meeting of the REB. The applicant may be present to discuss the proposed research and answer questions about the research, but the applicant may not be present when the REB is making its decision.

Delegated review is permitted in certain instances, listed below:

a) Research protocols that involve no more than minimal risk;
b) Annual renewals of approved projects in which there has been little or no change in the ongoing research;
c) Affirmations that conditions laid down by the REB as a condition of approval have been met.

If the Chair of the REB determines that the proposed research will involve a minimal risk to the research subjects, and if the applicant has not indicated a preference for a full review, a sub-committee of the REB consisting of the Chair and one other member will determine whether the proposed research is (a) acceptable as submitted, or (b) acceptable with minor modifications, in which case it shall be returned to the applicant with a request for modification. The sub-committee may also determine that the proposed research must undergo a full review. The applicant will be notified in writing of the decision of the review within 10 working days of the submission of the application. Approval of delegated research proposals will be reported to the REB at its next scheduled meeting. An application cannot be rejected without a consideration by the full REB.

Delegated Review of Student Course-Based Research: In all courses in which undergraduate students are required to carry out research on human subjects as part of their course work, the

instructor must report the nature of this research to the Department Coordinator. The Coordinator and one additional appropriate Faculty member will constitute a Departmental Ethics Review Committee, which will assess the proposed research and determine if it meets ethics requirements. The Departmental Ethics Review Committee will report its conclusions to the Chair of the REB before the undergraduate research project is scheduled to begin. The Chair of the REB may decide to accept the recommendation of the Departmental Ethics Review Committee or to forward the matter to the REB for REB assessment.

Step 3: The REB provides one of the following responses to the applicant:

a) The proposed research is acceptable as submitted, in which case approval will be granted and the Chair of the REB will sign the application form;
b) The proposed research is acceptable with modifications, in which case the application will be returned to the applicant with a request for modification; or
c) The proposed research is unacceptable, in which case the applicant will be advised in writing with reasons for the rejection, and in which case the applicant will have the right to reconsideration of the application.

Step 4: Any request by the REB for modification of proposed research shall include an explanation of the reason for the modification request. The REB should consult with the researcher to assist him or her in planning research that meets ethics requirements. Once the research plan has been modified to comply with the REB requests, and reviewed by the Chair of the REB and one other member, the Chair will issue approval and notify the members of the REB. If the modifications do not meet REB requests, the applicant will be invited to the next REB meeting for assistance in amending the application.

Step 5: Upon approval of the REB, the principal investigator must ensure that all participants are informed of the nature of the research and their participation, understand the risks and benefits of the research, and provide their consent to participate in writing by signing the "Informed Consent Form for Research Participants." Where written consent is culturally unacceptable or where there are good reasons for not recording consent in writing, the procedures used to seek free and informed consent must be clearly documented and reviewed by the REB Chair prior to the start of the research. Original consent forms must be kept by the department responsible for the research.

Step 6: Reports on the research program must be submitted annually at a minimum to the department responsible, with a copy to the Office of Research and Graduate Studies. Funded programs of research must follow the reporting requirements of the funding agency.

6.9 Decision Making (TCPS 2, Article 6.13)

In conducting its review, the REB shall do the following:

a) Review fully-detailed research proposals or, where applicable, progress reports.
b) Be fair, impartial, and equitable.

c) Allow for reasonable requests from researchers to participate in discussions about their proposals. Researchers may not, however, be present when the REB is making its decision.
d) When the REB is considering a negative decision, provide the researcher with the reasons for the negative decision and allow the researcher an opportunity to reply before the final decision is made.

6.10 Review Procedures for Ongoing Research (TCPS 2, Article 6.14)

Ongoing research shall be subject to continuing ethics review. The rigor of the review shall be in accordance with a proportionate approach to ethics assessment. As part of each research proposal submitted for REB review, the researcher shall propose to the REB the continuing review process deemed appropriate for that project. Normally, continuing review should consist of at least the submission of a succinct annual status report to the REB. The REB shall be promptly notified when the project concludes.

In accordance with the principle of proportionate review, research that exposes subjects to minimal risk or less requires only a minimal review process. The continuing review of research that exceeds the threshold of minimal risk shall require, in addition to an annual review, one or more of the following:

a) Formal review of the process of free and informed consent;
b) Establishment of a safety monitoring committee;
c) Periodic review by a third party of the documents generated by the study;
d) Review of reports of adverse events;
e) A random audit of the process of free and informed consent.

Other models of a continuing ethics review may be designed by researchers and the REB to fit particular circumstances.

6.11 Changes to Research

Researchers must report to the REB any unanticipated changes that have ethical implications and may affect participants' welfare (TCPS 2, Article 6.15). Researchers must also submit to the REB any requests for substantive changes to their originally approved research (TCPS 2, Article 6.16).

6.12 Record Keeping (TCPS 2, Article 6.17)

The minutes of all REB meetings shall be prepared and maintained by the REB. The minutes shall clearly document all REB decisions and any dissents, and the reasons for them. The minutes must be accessible to authorized representatives of Concordia, its researchers, and the funding agencies.

6.13 Reconsideration (TCPS 2, Article 6.18)

Researchers have the right to request, and the REB has an obligation to provide, reconsideration of decisions affecting a research project. In reconsidering its decision, the REB should be guided by the principles of natural and procedural justice in its decision making. Such principles include providing a reasonable opportunity to be heard, an explanation of the reasons for opinions or decision, the opportunity for rebuttal, fair and impartial judgment, and reasoned and written grounds for the decisions. The applicant will be invited to be present to discuss the application with the REB prior to decision making. The decision of the REB shall be made in writing to the applicant, with reasons for the decision, and shall be issued in a timely manner. If the decision of the REB, on reconsideration, remains negative, the applicant may appeal the decision to the Concordia Research Ethics Appeal Board.

6.14 Appeals (TCPS 2, Articles 6.19 & 6.20)

In cases in which the researchers and the REB cannot reach agreement through discussion and reconsideration, Concordia REB's decision may be reviewed by the Concordia Research Ethics Appeal Board (REAB). If the applicant wishes to appeal a negative decision of the REB following reconsideration, he or she must do so within 30 days of receipt of the written decision of the REB. The appeal must be made in writing to the Chair of the Concordia Research Ethics Appeal Board and include all supporting documents. The applicant has the right to appear before the REAB, although he or she may not be present when the REAB is making its decision.

The Concordia Research Ethics Appeal Board may sustain, modify, or reverse a decision of the REB. The decision of the REAB is final and will be communicated in writing promptly to the applicant.

The membership of the Concordia Research Ethics Appeal Board shall mirror that of the REB and shall operate under the same reporting and administrative practices as the REB. Current members of the REB shall not be eligible for membership on the REAB.

6.15 Research Ethics Review during Publicly Declared Emergencies
Concordia's REB will develop preparedness plans for emergency research ethics review. Research ethics review during publicly declared emergencies may follow modified procedures and practices (TCPS 2, Articles 6.21, 6.22, & 6.23).

4.17.8.7 Conflicts of Interest (TCPS 2, chapter 7)

7.1 Institutional Conflicts of Interest

Concordia respects the autonomy of the REB and will ensure that the REB has the appropriate financial and administrative independence to fulfill its primary duties. The REB shall maintain an arm's-length relationship with Concordia so as to avoid and manage real or apparent conflicts of interests.

7.2 Conflicts of Interest Involving Researchers (TCPS 2, Article 7.3)

Researchers and REB members shall disclose actual, perceived, or potential conflicts of interest to the REB. When a significant real or apparent conflict of interest is brought to the REB's attention, it will require the researcher to disclose this conflict to the prospective subjects during the process of free and informed consent. Research subjects should be fully informed of a researcher's potential or actual conflict of interest. To identify and address conflicts properly, the REB should be provided with details on the research project, budgets, commercial interests, consultative relationships, and other relevant information.

The REB shall manage cases of conflict of interest in a proportionate manner. In cases in which the conflict of interest is so pervasive that it is not enough merely to disclose it, the REB may require that the researcher abandon one of the interests in conflict. In other cases, the REB might conclude that the identified conflict of interest does not warrant specific actions.

7.3 Conflicts of Interest by REB Members

Researchers shall disclose in research proposals they submit to the REB any real, potential or perceived individual conflicts of interest, as well as any institutional conflicts of interest of which they are aware that may have an impact on their research. Upon discussion with the researcher, the REB shall determine the appropriate steps to manage the conflict of interest.

Members of the REB must withdraw from the committee when they are in conflicts of interests such as the following:

a) When their own research projects or projects in which they have a personal interest are under review;
b) When they have been in direct academic conflict or collaboration with the researcher whose proposal is under review;
c) When they accept undue or excessive honoraria for their participation in the REB (e.g., on commercial REBs).

4.17.8.8 Multi-Jurisdictional Research (TCPS 2, chapter 8)

8.1 Review of Research Involving Multiple Institutions and/or Multiple REBs
(TCPS 2 Article 8.1)

In cases in which a project is being conducted at Concordia and at another institution or institutions, and is therefore subject to the ethics review of more than one REB, Concordia's REB may approve alternative review models for research involving multiple REBs and/or institutions, in accordance with this policy. Concordia's REB remains responsible for the ethical acceptability and ethical conduct of research undertaken within its jurisdiction or under its auspices irrespective of where the research is conducted.

8.2 Selection of a Research Ethics Review Model Relevant to the Research Project

(TCPS 2, Article 8.2)

When planning a research project involving multiple institutions and/or multiple REBs, researchers and the REB should select the most appropriate research ethics review model from among those authorized by Concordia.

8.3 Ethics Review of Research Conducted outside of Concordia (TCPS 2, Article 8.3)

a) Where research conducted under the auspices of Concordia and performed in whole or in part outside of Canada has been approved under a research ethics review model involving multiple institutions and/or REBs consistent with this policy, the terms of that model apply.
b) Subject to section 8.2(a), research conducted under the auspices of Concordia and conducted outside its jurisdiction, whether elsewhere in Canada, or outside Canada, shall undergo prior research ethics review by both:
   i. the REB at Concordia, under the auspices of which the research is being conducted; and
   ii. the REB or other responsible review body or bodies, if any, at the research site.

8.4 Researcher's Report (TCPS 2, Article 8.4A)

a) The information to be provided to the Concordia REB will be determined by the provisions of the research ethics review model.
b) When conducting research outside the jurisdiction of Concordia, whether at a site abroad, or in Canada, researchers shall provide Concordia's REB with:
   i. The relevant information about the rules governing research involving humans and the ethics review requirements at the research site, where any exist;
   ii. The names and contact information for the relevant REBs or comparable ethics bodies, if known, that will review the proposal at the research site; and
   iii. Relevant information about the target populations and circumstances that might have a bearing on the research ethics review by Concordia's REB.

4.17.8.9 Research Involving the First Nations, Inuit and Métis Peoples of Canada

When research involves Aboriginal individual, researchers and the REB should consider the following:

9.1 Requirement of Community Engagement in Aboriginal Research (TCPS 2, Article 9.1)
Where the research is likely to affect the welfare of an Aboriginal community, or communities, to which prospective participants belong, researchers shall seek engagement with the relevant community. The conditions under which engagement is required include, but are not limited to:
a) Research conducted on First Nations, Inuit or Métis lands;
b) Recruitment criteria that include Aboriginal identity as a factor for the entire study or for a subgroup in the study;
c) Research that seeks input from participants regarding a community's cultural heritage, artifacts, traditional knowledge or unique characteristics;

d) Research in which Aboriginal identity or membership in an Aboriginal community is used as a variable for the purpose of analysis of the research data; and
e) Interpretation of research results that will refer to Aboriginal communities, peoples, language, history or culture.

9.2 Nature and Extent of Community Engagement (TCPS 2, Article 9.2)
The nature and extent of community engagement in a project shall be determined jointly by the researcher and the relevant community, and shall be appropriate to community characteristics and the nature of the research.

9.3 Respect for First Nations, Inuit, and Métis Governing Authorities (TCPS 2, Article 9.3)
Where a proposed research project is to be conducted on lands under the jurisdiction of a First Nations, Inuit or Métis authority, researchers shall seek the engagement of formal leaders of the community, except as provided under sections 9.5, 9.6 and 9.7. Research ethics review by the institutional REB and any responsible community body recognized by the First Nations, Inuit or Métis authority (see sections 9.9 and 9.11) is required in advance of recruiting and securing consent of individuals.

9.4 Engagement with Organizations and Communities of Interest (TCPS 2, Article 9.4)
For the purposes of community engagement and collaboration in research undertakings, researchers and the REB shall recognize Aboriginal organizations, including First Nations, Inuit and Métis representative bodies, and service organizations and communities of interest, as communities. They shall also recognize these groups through representation of their members on ethical review and oversight of projects, where appropriate.

9.5 Complex Authority Structures (TCPS 2, Article 9.5)
Where alternatives to securing the agreement of formal leadership are proposed for research on First Nations, Inuit or Métis lands or in organizational communities, researchers should engage community processes and document measures taken, to enable the REB to review the proposal with due consideration of complex community authority structures.

9.6 Recognizing Diverse Interests within Communities (TCPS 2, Article 9.6)
In engaging territorial or organizational communities, researchers should ensure, to the extent possible, that they take into consideration the views of all relevant sectors – including individuals and subgroups who may not have a voice in the formal leadership. Groups or individuals whose circumstances make them vulnerable may need or desire special measures to ensure their safety in the context of a specific research project. Those who have been excluded from participation in the past may need special measures to ensure their inclusion in research.

9.7 Critical Inquiry (TCPS 2, Article 9.7)
Research involving Aboriginal peoples that critically examines the conduct of public institutions, First Nations, Inuit and Métis governments, institutions or organizations or persons exercising authority over First Nations, Inuit or Métis individuals may be conducted ethically, notwithstanding the usual requirement of engaging community leaders.

9.8 Respect for Community Customs and Codes of Practice (TCSP 2, Article 9.8)
Researchers have an obligation to become informed about, and to respect, the relevant customs and codes of research practice that apply in the particular community or communities affected by their research. Inconsistencies between community custom and this Policy should be identified and addressed in advance of initiating the research, or as they arise.

9.9 Institutional Research Ethics Review Required TCPS 2, Article 9.9)
Research ethics review by community REBs or other responsible bodies at the research site will not be a substitute for research ethics review by Concordia's REB, and will not exempt researchers affiliated with Concordia from seeking Concordia's REB approval, subject to section 8.1. Prospective research and secondary use of data and human biological materials for research purposes is subject to research ethics review.

9.10 Requirement to Advise the REB on a Plan for Community Engagement (TCPS 2, Article 9.10)
When proposing research expected to involve First Nations, Inuit or Métis participants, researchers shall advise their REB how they have engaged, or intend to engage, the relevant community. Alternatively, researchers may seek REB approval for an exception to the requirement for community engagement, on the basis of an acceptable rationale.

9.11 Research Agreements (TCPS Article 9.11)
Where a community has formally engaged with a researcher or research team through a designated representative, the terms and undertakings of both the researcher and the community should be set out in a research agreement before participants are recruited.

9.12 Collaborative Research (TCPS 2, Article 9.12)
As part of the community engagement process, researchers and communities should consider applying a collaborative and participatory approach as appropriate to the nature of the research, and the level of ongoing engagement desired by the community.

9.13 Mutual Benefits in Research (TCPS 2, Article 9.13)
Where the form of community engagement and the nature of the research make it possible, research should be relevant to community needs and priorities. The research should benefit the participating community (e.g., training, local hiring, recognition of contributors, return of results), as well as extend the boundaries of knowledge.

9.14 Strengthening Research Capacity (TCPS 2, Article 9.14)
Research projects should support capacity building through enhancement of the skills of community personnel in research methods, project management, and ethical review and oversight.

9.15 Recognition of the Role of Elders and Other Knowledge Holders (TCPS 2, Article 9.15)
Researchers should engage the community in identifying Elders or other recognized knowledge holders to participate in the design and execution of research, and the interpretation of findings in

the context of cultural norms and traditional knowledge. Community advice should also be sought to determine appropriate recognition for the unique advisory role fulfilled by these persons.

9.16 Privacy and Confidentiality (TCPS 2, Article 9.16)
Researchers and community partners shall address privacy and confidentiality for communities and individuals early on in the community engagement process. The extent to which limited or full disclosure of personal information related to the research is to be disclosed to community partners shall be addressed in research agreements where these exist. Researchers shall not disclose personal information to community partners without the participant's consent, as set out in section 3.2.

9.17 Interpretation and Dissemination of Research Results (TCPS 2, Article 9.17)
Researchers should afford community representatives engaged in collaborative research an opportunity to participate in the interpretation of the data and the review of research findings before the completion of the final report, and before finalizing all relevant publications resulting from the research.

9.18 Intellectual Property Related to Research (TCPS 2, Article 9.18)
In collaborative research, intellectual property rights should be discussed by researchers, communities, and Concordia. The assignment of rights, or the grant of licenses and interests in material that may flow from the research, should be specified in a research agreement (as appropriate) before the research is conducted.

9.19 Collection of Human Biological Materials Involving Aboriginal Peoples(TCPS 2, Article 9.19)
As part of community engagement, researchers shall address and specify in the research agreement the rights and proprietary interests of individuals and communities, to the extent such exist, in human biological materials and associated data to be collected, stored and used in the course of the research.

9.20 Secondary Use of Information or Human Biological Materials Identifiable as Originating from Aboriginal Communities or Peoples (TCPS 2, Article 9.20)
Secondary use of data and human biological material identifiable as originating from an Aboriginal community or peoples is subject to REB review. Researchers shall engage the community from which the data or human biological materials and associated identifiable information originate, prior to initiating secondary use where:

a) Secondary use has not been addressed in a research agreement and has not been authorized by the participants in their original individual consent; or
b) There is no research agreement; and
c) The data are not publicly available or legally accessible.

Individual consent for the secondary use of identifiable information is required unless the REB agrees that either sections 5.5 or 5.6, or sections 12.3 or 12.4 may apply.

9.21 (TCPS 2, Article 9.21):
Where research relies only on publicly available information, or on legally accessible information as defined in section 4.17.8.2 (Article 2.2), community engagement is not required. Where the information can be identified as originating from a specific community or a segment of the Aboriginal community at large, seeking culturally informed advice may assist in identifying risks and potential benefits for the source community.

9.22 (TCPS 2, Article 9.22):
REB review is required where the researcher seeks data linkage of two or more anonymous datasets or data associated with human biological materials and there is a reasonable prospect that this could generate information identifiable as originating from a specific Aboriginal community or a segment of the Aboriginal community at large.

4.17.8.10 Research Ethics Review of Qualitative Research (TCPS 2, chapter 10)

10.1 Timing of the REB Review (TCPS 2, Article 10.1)
Researchers shall submit their research proposals, including proposals for pilot studies, for REB review and approval of its ethical acceptability prior to the start of recruitment of participants, or access to data. Subject to the exceptions in section 10.5, REB review is not required for the initial exploratory phase (often involving contact with individuals or communities) intended to discuss the feasibility of the research, establish research partnerships, or the design of a research proposal (see section 6.11).

10.2 Modalities of Expression of Consent (TCPS 2, Article 10.2)
Researchers shall explain in their research design the proposed procedures for seeking consent and the strategies they plan to use for documenting consent.

10.3 Observational Studies (TCPS 2, Article 10.3)
In research involving observation in natural environments or virtual settings where people have a reasonable or limited expectation of privacy, the researcher shall explain the need for an exception to the general requirement for consent. The REB may approve research without requiring that the researcher obtain consent from individuals being observed on the basis of the justification provided by the researcher and appropriate privacy protection.

10.4 Privacy and Confidentiality in the Dissemination of Research Results (TCPS 2, Article 10.4)
In some research contexts, the researcher may plan to disclose the identity of participants. In such projects, researchers shall discuss with prospective participants or participants whether they wish to have their identity disclosed in publications or other means of dissemination. Where participants consent to have their identity disclosed, researchers shall record each participant's consent.

10.5 Qualitative Research Involving Emergent Design (TCPS 2, Article 10.5)
In studies using emergent design in data collection, researchers shall provide the REB with all the available information to assist in the review and approval of the general procedure for data collection. Researchers shall consult with the REB when, during the conduct of the research,

changes to the data collection procedures may present ethical implications and associated risks to the participants.

4.17.8.11 Clinical Trials (TCPS 2, chapter 11)

Key concepts:

a) Risk and Proportionate Approach:
Clinical trials are subject to a proportionate approach to research ethics review.
b) Clinical Equipoise:
All research involving clinical trials conducted by members of the Concordia community or at Concordia shall respect the principle of clinical equipoise: that is, a genuine uncertainty on the part of the expert research community about the comparative therapeutic merits of each arm of a clinical trial. This tenet of clinical equipoise provides a clear moral foundation to the requirement that the health care of subjects not be disadvantaged by research participation.
c) Duty of Care, Therapeutic Misconception, and Dual Roles
    i. The duty of care in a medical context is the obligation of clinicians to act in the best interests of patients. In the context of clinical trials, researchers are concerned with the welfare of individual participants, but are also focused on the generation of new knowledge that may or may not confer direct benefits on participants.
    ii. Therapeutic misconception occurs when trial participants do not understand that research is aimed primarily at producing knowledge and may not provide any therapeutic benefit to them.
    iii. Researchers should take all necessary measures to separate their role as research from their role as clinician. It is important that the REB appreciate the potential conflicts between these roles and the possible impact on the welfare of prospective participants.

11.1 Clinical Trial Design and Registration (TCPS 2, Article 11.1)
In the design and review of a clinical trial, researchers and REBs shall consider the type of trial (e.g., pharmaceutical, natural health product, medical device, psychotherapy), its phase (if appropriate) and the corresponding particular ethical issues associated with it, in light of the core principles of this policy.

11.2 Placebo-Controlled Trials (TCPS 2, Article 11.2)

a) A new therapy or intervention should generally be tested against an established effective therapy.
b) As with all alternative choices of a control, a placebo control is ethically acceptable in a randomized controlled clinical trial only if:
    i. Its use is scientifically and methodologically sound in establishing the efficacy or safety of the test therapy or intervention; and
    ii. It does not compromise the safety or health of participants; and
    iii. The researcher articulates to the REB a compelling scientific justification for the use of the placebo control.
c) For clinical trials involving a placebo control, the researcher and the REB shall ensure the general principles of consent are respected and that participants or their authorized third parties are specifically

informed (see section 3.2):

i. About any therapy that will be withdrawn or withheld for purposes of the research; and
ii. Of the anticipated consequences of withdrawing or withholding the therapy.

11.3 Clinical Trial Registration (TCPS 2, Article 11.3)
All clinical trials shall be registered before recruitment of the first trial participant in a recognized and easily web-accessible public registry.

11.4 Assessing Safety and Minimizing Risk (TCPS 2, Article 11.4)
Researchers and the REB should ensure that the foreseeable risk to participants in clinical trials is: (a) justified by the potential benefits to be gained; and (b) appropriately minimized.

11.5 (TCPS 2, Article 11.5):
When describing the foreseeable risks and potential benefits of research involving participants who are undergoing high-risk therapies, researchers should clearly indicate which risks are attributable to the research (including cumulative risks), and which risks the participants would normally be exposed to in the course of their clinical care. In their evaluation of risk, REBs should ensure that they are evaluating only those risks that are attributable to the research (including cumulative risks), and not compounding them with the risks attributable to clinical care.

11.6 (TCPS 2, Article 11.6)
The REB and clinical trial researchers should be conscious of the phenomenon of therapeutic misconception, and ensure that procedures for recruitment and consent emphasize which specific elements of a clinical trial are required for research purposes, as well as the differences between research and the standard clinical care patients might otherwise receive.

11.7 Monitoring Safety and Reporting New Information (TCPS 2, Article 11.7)
Researchers shall provide the REB with an acceptable plan for monitoring the safety of participants, including a plan for the tabulation, analysis and reporting of safety data, and the sharing of other new information in a form that permits the REB to interpret and respond appropriately.

11.8 (TCPS 2, Article 11.8)
Researchers shall promptly report new information that may affect the welfare or consent of participants, to the REB, and to other appropriate regulatory or advisory bodies. When new information is relevant to participants' welfare, researchers shall promptly inform all participants to whom the information applies (including former participants). Researchers shall work with their REB to determine which participants must be informed, and how the information should be conveyed.

11.9 (TCPS 2, Article 11.9)
The REB shall develop procedures to review safety reports and other new information arising from clinical trials that may affect the welfare or consent of participants, and to take

appropriate steps in response.

11.10 Financial Conflicts of Interest: Sponsored Research (TCPS 2, Article 11.10)
Researchers and the REB should be aware of and consider the possibility of financial conflicts of interest. They should ensure that clinical trials are designed to meet appropriate standards of participant safety in accordance with the core principles of this policy. Financial considerations shall not affect these standards or the scientific validity and transparency of trial procedures.

11.11 Clinical Trial budgets (TCPS 2, Article 11.11)
REBs shall ensure that clinical trial budgets are reviewed to ensure that conflicts of interest are identified and minimized, or otherwise managed.

11.12 Analysis and Dissemination of Clinical Trial Outcomes (TCPS 2, Article 11.12)
With respect to research findings:

a) Institutions and REBs should take reasonable measures to ensure that sponsors, researchers and institutions publish or otherwise disseminate the analysis of data and interpretation of clinical trial results in a timely manner without undue restriction.
b) Any prohibition or undue limitation on the publication or dissemination of scientific findings from clinical trials is ethically unacceptable.
c) Institutions should develop reasonable written policies regarding acceptable and unacceptable clauses in clinical trial research contracts relating to confidentiality, publication and access to data.

4.17.8.12 Human Biological Materials, Including Materials Related to Human Reproduction (TCPS 2, chapter 12)

12.1 Collection of Human Biological Materials
Research involving collection and use of human biological materials requires REB review and:

a) Consent of the participant who will donate biological materials; or
b) Consent of an authorized third party on behalf of a participant who lacks capacity, taking into account any research directive that applies to the participant; or
c) Consent of a deceased participant through a donation decision made prior to death, or by an authorized third party.

12.2 (TCPS 2, Article 12.2)
To seek consent for use of human biological materials in research, researchers shall provide to prospective participants or authorized third parties, applicable information as set out in section 3.2 as well as the following details:

a) The type and amount of biological materials to be taken;
b) The manner in which biological materials will be taken, and the safety and invasiveness of the procedures for acquisition;
c) The intended uses of the biological materials, including any commercial use;

d) The measures employed to protect the privacy of and minimize risks to participants;
e) The length of time the biological materials will be kept, how they will be served, location of storage (e.g., in Canada, outside Canada), and process for disposal, if applicable;
f) Any anticipated linkage of biological materials with information about the participant; and
g) The researchers' plan for handling results and findings, including clinically relevant information and incidental findings.

12.3 Consent and Secondary Use of Identifiable Human Biological Materials for Research Purposes (TCPS 2, Article 12.3)
Researchers who have not obtained consent from participants for secondary use of identifiable human biological materials shall only use such material for these purposes if the REB is satisfied that:

a) Identifiable human biological materials are essential to the research;
b) The use of identifiable human biological materials without the participant's consent is unlikely to adversely affect the welfare of individuals from whom the materials were collected;
c) The researchers will take appropriate measures to protect the privacy of individuals and to safeguard the identifiable human biological materials;
d) The researchers will comply with any known preferences previously expressed by individuals about any use of their biological materials;
e) It is impossible or impracticable to seek consent from individuals from whom the materials were collected; and
f) The researchers have obtained any other necessary permission for secondary use of human biological materials for research purposes.

If a researcher satisfies all the conditions in section 12.3(a) to (f), the REB may approve the research without requiring consent from the individuals from whom the biological materials were collected.

12.4 (TCPS 2, Article 12.4)
When secondary use of identifiable human biological materials without the requirement to seek consent has been approved under section 12.3, researchers who propose to contact individuals for additional biological materials or information shall, prior to contact, seek REB approval of the plan for making contact.

12.5 Storage and Banking of Human Biological Materials (TCPS 2, Article 12.5)
Concordia and researchers, in the event that they that maintain biobanks:

a) Shall ensure that they have or use appropriate facilities, equipment, policies and procedures to store human biological materials safely, and in accordance with applicable standards; and
b) Shall establish appropriate physical, administrative and technical safeguards to protect human biological materials and any information about participants from unauthorized handling.

12.6 Research Involving Materials Related to Human Reproduction (TCPS 2, Article 12.6)

In addition to requirements in this chapter that apply to all research involving human biological materials, the following guidelines apply to research involving materials related to human reproduction:

a) Research using materials related to human reproduction in the context of an anticipated or ongoing pregnancy shall not be undertaken if the knowledge sought can reasonably be obtained by alternative methods.
b) Materials related to human reproduction for research use shall not be obtained through commercial transaction, including exchange for services.

12.7 Research Involving Human Embryos (TCPS 2, Article 12.7)
Research on in vitro embryos already created and intended for implantation to achieve pregnancy is acceptable if:

a) The research is intended to benefit the embryo;
b) Research interventions will not compromise the care of the woman, or the subsequent fetus;
c) Researchers closely monitor the safety and comfort of the woman and the safety of the embryo; and
d) Consent was provided by the gamete donors.

12.8 (TCPS 2, Article 12.8)
Research involving embryos that have been created for reproductive or other purposes permitted under the *Assisted Human Reproduction Act*, but are no longer required for these purpose*s*, may be ethically acceptable if:

a) The ova and sperm from which they are formed were obtained in accordance with section 12.7;
b) Consent was provided by the gamete donors;
c) Embryos exposed to manipulations not directed specifically to their ongoing
d) Normal development will not be transferred for continuing pregnancy; and
e) Research involving embryos will take place only during the first 14 days after their formation by combination of the gametes, excluding any time during which embryonic development has been suspended.

12.9 Research Involving Fetuses and Fetal Tissue (TCPS 2, Article 12.9)
Research involving a fetus or fetal tissue:

a) Requires the consent of the woman; and
b) Should not compromise the woman's ability to decide whether to continue her pregnancy.

12.10 Research Involving Pluripotent Stem Cells (TCPS 2, Article 12.10)
Researchers who intend to conduct research to derive or use pluripotent stem cells shall follow the *Guidelines for Human Pluripotent Stem Cell Research*, as amended from time to time and published by the Canadian Institutes of Health Research.

4.17.8.13 Human Genetic Research (TCPS 2, chapter 13)

13.1 Application of Core Principles to Genetic Research (TCPS 2, Article 13.1)
Guidance regarding a proportionate approach to research ethics review, consent, privacy, confidentiality, research with human biological materials and other ethical guidance described in earlier chapters of this policy apply equally to human genetic research.

13.2 Plans for Managing Information Revealed through Genetic Research (TCPS 2, Article 13.2)
Researchers conducting genetic research shall:

a) In their research proposal, develop a plan for managing information that may be revealed through their genetic research;
b) Submit their plan to the REB; and
c) Advise prospective participants of the plan for managing information revealed through the research.

13.3 (TCPS 2, Article 13.3)
Where researchers plan to share findings with individuals, researchers shall provide participants with an opportunity to:

a) Make informed choices about whether they wish to receive information about themselves; and
b) Express preferences about whether information will be shared with biological relatives, or others with whom the participants have a family, community or group relationship.

13.4 Genetic Counselling (TCPS 2, Article 13.4)
Where researchers plan to share results of genetic research with participants, the research proposal should make genetic counselling available at that time, where appropriate.

13.5 Genetic Research Involving Families (TCPS 2, Article 13.5)
Researchers who seek to recruit members of a family to participate in genetic research shall:

a) Ensure recruitment processes respect privacy and other personal interests of family members; and
b) Seek consent from individual family members.

13.6 Genetic Research Involving Communities and Groups (TCPS 2, Article 13.6)
Where researchers intend to recruit participants for genetic research based on their membership in specific communities or groups, it may be appropriate for researchers to discuss the research with community or group members, and/or their leaders, in addition to seeking consent from individual participants. In these cases, researchers shall provide details to the REB about their proposed methods for engaging in discussion.

13.7 Genetic Material Banks (TCPS 2, Article 13.7)

a) Researchers who propose research involving the collection and banking of genetic material shall indicate in their research proposal, and in the information they provide to prospective participants, how they plan to address the associated ethical issues, including confidentiality, privacy, storage, use of the data and results, possibility of commercialization of research findings and withdrawal by participants as well as future contact of participants, families, communities and groups.
b) Researchers who propose research involving the secondary use of previously collected and banked genetic material shall, likewise, indicate in their research proposal how they plan to address associated ethical issues.