THE UNIVERSITY OF WESTERN ONTARIO

RESEARCH ETHICS BOARD
FOR
NON-MEDICAL RESEARCH INVOLVING
HUMAN SUBJECTS
(NMREB)

GUIDELINES

DOCUMENT REFERENCE 3-G-001

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1.0 INTRODUCTION

It is the responsibility of the Research Ethics Board for Non-medical Research Involving Human Subjects (NMREB) to review protocols for non-medical research involving human subjects for The University of Western Ontario and its affiliated hospitals and research institutes. In conducting these activities the committee complies with guidelines promulgated through the Tri-Council Policy Statement: Ethical Conduct for Research Involving Human Subjects as mandated by the Natural Sciences and Engineering Research Council (NSERC), the Social Sciences and Humanities Research Council (SSHRC) and the Canadian Institutes of Health Research (CIHR) and the Good Clinical Practice: Consolidated Guideline (GCP) of the International Conference on Harmonization which has been adopted by Health Canada. The NMREB also endeavours to facilitate compliance with the human subject requirements of two U.S. federal agencies: The Food and Drug Administration and the Office for Human Research Protections in the U.S. Department of Health and Human Services.

The NMREB's primary responsibility is the protection of subjects from undue risk and from deprivation of personal rights and dignity while ensuring that participants are participating in scientifically valid projects. This protection is best assured by consideration of two issues which are the touchstones of ethical research: 1) that voluntary participation is assured, indicated by free and informed consent; and 2) that an appropriate balance exists between potential benefits of the research to the participant or to society and the risks assumed by the participant.

At times the issues are quite clear; at times they are extremely difficult to resolve. Researchers themselves must begin the process by examining their own projects with all the conscience and candour they can summon as they prepare to seek NMREB approval. The NMREB, in turn, brings to bear its collective experience in reviewing each proposal - always conscious of its primary responsibility to protect the rights of human participants against exploitation, but within the context of the need for continued scientific - and therefore human - discovery.

2.0 METHODOLOGY

It is not specifically the role of this NMREB to evaluate and review the research methodology being proposed for any study submitted for consideration. Most research projects will be scrutinized by colleagues and peers in that subject area, and the validity of the design and the value of the research will be assessed during that process.

However, as a member of the research community, the NMREB has the right and the responsibility to monitor the methodology being proposed. With any research study involving people, the investigator enters into an ethical and moral contract, not only with the scientific and subject discipline communities, but also with the study participants themselves. In exchange for that specific information from the participants, the investigator agrees to work to extend scientific knowledge. If the research is poorly considered, in its design, execution or analysis, it is unlikely to meet this commitment.

Thus, the NMREB takes the view that it is unethical to perform any research which

through seriously flawed design fails to demonstrate an adequate research methodology, and it may then deny approval solely on methodological grounds. The benefit of the doubt will ordinarily be given to the investigator; however, the NMREB will ultimately act in the best interests of the study participants.

3.0 ENSURING EQUITABLE PARTICIPANT SELECTION (Inclusion of Women in Research)

"The research subject/participant population should be as representative of the patient population as possible. It follows that women must be included in research in adequate number. Mere inclusion, however, is not sufficient. There must also be valid gender (and otherwise) subgroup analysis of the research data otherwise women (and members of other under-researched populations) may be included in the research and yet remain invisible. Also, as appropriate, the research design must consider variability created by hormonal fluctuations." (Baylis; The Journal of Clinical Ethics Vol 7, Number 3 p232)

Research, that excludes women as research subjects/participants or ensures their underrepresentation should not receive REB approval unless the investigators provide a compelling justification of the decision to exclude, or limit the participation of women.

4.0 RISK-BENEFIT CONSIDERATIONS

The key feature for determining whether research is ethically acceptable is a balance between risk and benefit. When the participant assumes risk, it is not enough that he/she be informed of the risk involved. The NMREB must also perceive that the participant, or society in general, stands to benefit in proportion to the degree of psychological or physical risk involved. The more incalculable the risk, the more cautious should be the researcher and the REB in permitting the study to be carried out. Where research procedures involve short-term behavioural changes, as in some psychological research, approval from the NMREB is dependent upon assurances of their reversibility. There must also be safeguards against risks to individuals not involved in the study (third party risks), as might be found in some business or educational research. For this reason, the NMREB at times draws on the expertise of the scientific community in general (by external peer review), when the study involves technical issues not within the body of knowledge held by NMREB members themselves.

5.0 DECEPTION

Prospective participants normally must be fully informed about the purpose of the study before being asked to agree to participate. Use of deception requires that certain aspects about the purpose of the study are either misrepresented or withheld and thus, conflicts with the requirement for provision of informed consent. There may be legitimate reasons however, for needing to withhold specific details about a study. In this situation, it is the researcher's responsibility to provide sufficient detail on the application form about the nature of the deception as well as a rationale for why it is necessary. A study involving deception will not receive ethics clearance if it is felt that a participant would not have agreed to participate if full information about the study had

been provided. Participants in a study involving deception must be involved in a debriefing session at the end of their participation. This debriefing session serves as an opportunity to provide participants with an explanation (orally and as a written hand-out) for why deception was required; to answer any questions in regard to the use of deception, and to seek their written consent to use all information obtained in the course of their participation in the study.

Under most circumstances, the NMREB will follow the principle that no deception should be involved in research. Therefore, if the research involves the practice of deception where participants are purposely misled as part of the research project, it must be justified as important and as the only alternative. Further there should be no foreseeable risk of harm or potential for the perception of harm or embarrassment by the subject and there must be a full explanation and "debriefing" soon after completion of the experiment.

6.0 PRINCIPLES OF CONSENT

One of the most difficult problems in any research involving human participants is assurance of free and informed consent. Any person considering participation in research should understand, as completely as possible, the specific research activities in which he/she will be involved, and also the personal benefits and risks that the research may entail. Under some circumstances, participants may be incapable of understanding the nature of the proposed research. The specific issue of research involving these individuals is dealt with in a subsequent portion of this document (Section 8.0). For participants capable of understanding the nature of the research, consent must be freely given, without pressure or inducement.

The informed consent of participants must be documented by a signed Consent Form. This item features prominently in NMREB review. The NMREB must verify that this document explicitly describes the voluntary nature of choosing to participate in the research.

The concept of informed consent is extended to those studies in which participants are not able to give personal consent. Here the consent documents are addressed to those legally responsible for the well-being of the participant, for example the parents, when the participant is a child. The NMREB is concerned with verifying that the documents are likely to assist legal guardians in making a prudent decision that is in the best interest of the participants in question.

In general, the NMREB may approve a protocol involving significant risk if the participant is well informed, appreciates the risk, and is under no duress or coercive pressure to participate. Where appropriate, the investigator must demonstrate that the study has a sound scientific (including statistical) base. If the study is seriously flawed in concept or design, it would not be considered ethical to proceed with an investigation involving human subjects.

The REB exercises special care when considering participants with diminished capacity to give free and informed consent, for example children and mentally incompetent participants. Other groups which require special care to ensure that there is no

coercion and that consent is freely given include students, hospital or university employees, and prisoners. The process of obtaining consent in these situations is discussed in detail in following sections.

7.0 INFORMED CONSENT

In order that research involving human participants conform to ethical standards which respect the autonomy of the participant, ideally that participant must give free and informed consent to participation in the research protocol. In addition to consent from the subjects themselves, informed consent of appropriate authorities always must be obtained.

Generally informed consent can be obtained by ensuring that the participant is given information, in language that he or she is capable of understanding about the nature of the study, the risks to which he or she might be exposed and the potential benefits that might result both to the participant and to society in general as a result of the research. Generally, informed consent will require a written form, which will be read by the participant, or in the case of a participant not able to give consent, by the person giving consent for him/her, for example a parent, guardian, or designated other. Exceptions will be considered for telephone surveys where it is not possible to provide a copy of the information document to the potential participant. NMREB approval of protocols involving guardian consent is contingent upon a highly favourable risk-benefit ratio. Information and consent documentation must adhere to the Guidelines for Information/Consent Documentation in Appendix 1.

With regard to the written Information Consent documentation, it should be designed to inform the research participant, in order to permit him/her to make an intelligent, voluntary decision prior to participation in the study. For this reason,

a) the form must be written in a straightforward fashion, well-organized and succinct,
b) technical terms should be explained in simple language,
c) the language used must be grammatically correct, and
d) in most cases be understood by a research participant at a grade 8 reading level.

If necessary, when English is not the primary language of the research subject, an interpreter must be provided to guarantee that the participant understands the details involved in participation.

Investigators have the option of using separate Letters of Information and Consent Forms or a combined Information/Consent document. A copy of the Letter of Information or the combined Information/Consent Form must be provided to the participants to be retained by them.

In presenting information, it is important to avoid characterizations of the research project that are in any way coercive. The language of consent forms, as well as the circumstances of recruitment, must attempt to ensure that potential participants have a genuine choice about their involvement. Consent should not be sought under

conditions of emotional or physical stress, but rather, if at all possible, consent should be sought, prior to the period of physical or emotional stress.

The Information Letter or Information/Consent documentation, should contain a statement that this participant agrees to be involved in the "research project" (or "research investigation" or "study") described; has had the project explained; has had all questions answered to his/her satisfaction; provides a place for the participant's signature, and where appropriate, a place for the signature of the participant's parent, guardian, or designated other.

8.0 PARTICIPANTS INCAPABLE OF GIVING INFORMED CONSENT

It is recognized that occasionally important studies could not be undertaken without using participants who are incapable of giving consent, particularly studies which are designed to benefit those very participants. In such circumstances, participants who are incapable of giving consent may be used provided that there is no significant risk or discomfort to the participant or that any risk or discomfort that does exist is outweighed by the probability and degree of benefit that may accrue to that individual participant, or, to the group of which the participant is a member.

Participants who may be incapable of giving consent fall into two broad categories: children and the mentally incompetent.

8.1 Children

Children should not be exposed to greater risks than they face in their everyday lives and that, while parents may consent to inspection of their children's records for research and may approve the collection and analysis of collected excreted materials, the method of collection must cause no pain or embarrassment.

Research protocols involving children that do not expose the children to any risks that are not faced in daily life may be submitted for expedited review. Where there are risks the protocol must be submitted for full review and will be subject to the same rigorous review as applies to incompetent adults. The consent of parent or guardian is normally required at all ages up to 18. If the NMREB determines that a research protocol is designed for conditions or subject populations for which parental or guardian permission is not a reasonable requirement to protect the participants, it may waive such requirement, provided an appropriate mechanism for protecting the participating children is substituted. The choice of an appropriate mechanism should depend upon the nature and purpose of the activities described in the protocol, the risks and anticipated benefit to the research participants, and their age, maturity, status and condition. Furthermore, in all cases for research involving children, the child's assent must be sought in simple language that the child is capable of understanding, from the age of 7 upwards, in order to ensure that there is no coercion. If appropriate the child should sign either the Consent form or a special Assent form as described in Appendix 2.

A child's objection to participation in research should be binding unless the

intervention holds out a prospect of direct benefit that is important to the health or well being of that child and is available only in the context of research. The above conditions will hold for those protocols involving no greater than minimal risk.

In addition, the NMREB will take into account any potential for embarrassment and psychological risk as part of its evaluation. If the protocol involves greater than minimal risk from either an intervention or monitoring procedure, the risk must be justified by the anticipated benefit to the participant or similar persons, and the relation of anticipated benefit to such risk must be at least as favourable to the participants as that presented by alternative research methodologies, if any exist, capable of answering the research questions.

Investigators should as well:

a) devote sufficient time to explaining the projects to parents and to child participants, preferably in the presence of a non-involved professional colleague, for example, the child's teacher, and to listening to the anxieties that will often arise,
b) monitor whether research procedures produce any emotional or behavioural disturbances in the child participant,
c) deal promptly with any emotional disturbance that does arise, either themselves or by appropriate referral and,
d) devote sufficient time to explaining their projects to staff involved with the child participants and their parents, and to discussing any problems that may arise from research procedures.

In general, research procedures on neonates, infants and children should not be undertaken in such a way as to keep parent and child apart; where possible, parent(s) should be encouraged to be present.

No financial or other inducement should be offered to parents or guardians to persuade them to enter their children into a research project; any reasonable expenses incurred, however, should be reimbursed (e.g., transportation costs).

There may be circumstances in which a responsible adult may not give consent to the participation of a child in research where the child himself/herself desires to participate. In such cases the competence of the potential participant must be carefully assessed to determine if the child is capable of independently authorizing participation in the study. Indication must be provided that a third party will be available to counsel the child in the event there is later difficulty with parent or guardian and this third party must be named by the investigator on the protocol submission. Indeed in some situations it may be an invasion of the child's privacy to seek parental consent, for example, where the child has received treatment for a venereal disease at a public clinic and is invited to participate in a study designed to improve the educational services offered in the clinic. Similar observations may be made with respect to research in which the investigator seeks to recruit children for research involving drug abuse. In these cases, at least, consent for participation should be obtained from the child in the absence of parents or guardian, and ongoing support, as indicated above, made

available to the child.

8.2 Incompetent Adults

Considerations similar to those presented for children will prevail with respect to research involving mentally incompetent individuals, both children and adults. Again, a restrictive approach to the circumstances in which such research could be conducted would deter and prevent investigators from pursuing important and potentially beneficial research. Thus, the NMREB may approve protocols involving incompetent adults where ample justification is provided for their inclusion as participants and the risk/benefit ratio is appropriate. Further, assent must be sought and obtained from the participant where possible and full information provided except for the single waiver that where the intervention proposed holds out a significant prospect of direct benefit and is available only in the context of research. Written authorization for this, and, all cases involving research on incompetent adults, excluding acute illnesses, must be obtained from the next-of-kin or designated proxy prior to the research project being initiated in individual participants. In general, in the absence of designated proxy or next-of-kin, research must not be performed.

9.0 COERCION

The requirement that consent be freely given and be well-informed dictates that those from whom consent is sought not be vulnerable to exploitation or open to coercion or inducement. The invitation to a prospective research participant must be made in a way that allows the individual freedom of choice. It should be noted that advertisement of REB and/or institutional approval should not be used as an inducement to participate.

Another important consideration to take into account in protecting the voluntary nature of the consent is the manner by which, and the time at which, a participant is approached to participate. Generally participants should not be recruited at a time of stress or when their ability to comprehend the proposed procedure is impaired. Moreover, they should be given sufficient opportunity and time to consider and reflect upon the request made of them before being required to make their decision.

There are a number of groups of potential participants who, because of their status and/or their relationship with the investigator, are vulnerable to undue influence and are at risk that any consent they may give is not freely given. These groups include, but are not restricted to, students, employees, patients, persons in institutions (e.g., correctional institutions or facilities for the aged, developmentally handicapped, blind or deaf) and persons whose financial position is such as to render them prone to consenting to research as an aid in obtaining income. Persons in each of these groups are to varying degrees, vulnerable to influence. Consequently much care should be taken to ensure that the subject's independence is maintained.

Subjects who are welfare dependents, involved in court proceedings, and similarly vulnerable, would also be regarded as members of a captive or dependent population. In research using such subjects and in studies often designed to benefit those very participants, great care must be exercised to balance risks and benefits and to prevent

subtle pressures being brought to bear on a captive subject.

Frequently, research is conducted by investigators who are also in a position of authority over the participant (e.g., teachers responsible for the grading of the student's work). In this, and similar situations, considerable care must be taken to avoid any undue influence on the participant which will undermine the voluntary character of the consent. Where possible, the approach to the participant inviting participation in a research project should be made by someone not in a position of authority over the subject, preferably one who has no direct responsibility for the participant's future employment or educational standing. Normally, as well, the person in authority should remain blind to the identity of those who chose to participate and those who did not, for as long as (s)he is in a position of authority over the participant pool.

Consequently, care should be taken to ensure that the participant's independence is maintained. It should be made clear to participants who are vulnerable to influence that those invited to participate may refuse to participate and that those who agree to participate may withdraw at any time with no effect on their present or future care. Students must be assured that withdrawal will not result in any academic penalty; employees must be assured that withdrawal will not lead to any adverse employment consequences.

Similarly, care must be taken not to induce consent by the promise of reward. Thus, for example, students should not be promised academic reward; and employees should not be promised employment advancement.

Research participants participate voluntarily in research studies. However, there are circumstances in which it is appropriate to offer financial compensation to participants for their participation in research. Such remuneration should be limited to compensation for expenses actually incurred, e.g., travel costs, child care. In addition some reimbursement for time committed to the study and nconvenience associated with participation in the study is acceptable provided that it is not of such a magnitude as to constitute an inducement to enter the study. Justification for compensation must be included in the protocol submission. There is no compensation for lost wages as a result of study participation. It is not possible to specify exactly what amount of compensation will be appropriate. Each case must be determined on its own merits, should be consistent with the principle of volunteerism.

10.0 INTERVIEWS WITH PERSONS WHO HOLD OR HAVE HELD POSITIONS OF RESPONSIBILITY

As well, scholarly research which primarily probes the personal or private affairs of persons who hold or have held positions of responsibility, or which depends on aggregate data from formal questionnaires may, at the discretion of the NMREB, not be required to adhere to the usual requirements of the REB

Scholarly research which is comprised of semi-structured interviews of competent subjects who are primarily relating their experiences in public or private office (e.g., politicians, government officials, senior executives), may satisfy the ethical standards in a less formal way. The interviews must be sought from persons who are competent,

who share control of the interview and who are primarily recounting experiences or relating knowledge emanating from their roles in public or private offices. In general, the appropriateness of such less formal compliance with ethical standards is directly proportional to the degree to which participants are immune to any potential vulnerability associated with the study.

Such individuals must be informed of the nature and purpose of the research in writing so that their consent to an interview is well informed. They also must agree to subsequent use of the information provided and to the manner of its disposition. An interviewee may wish specific controls on interview material and, if the interviewer should agree, such stipulations are to be added to the letter of acknowledgement. The interviewer should keep copies of all such correspondence.

These guidelines should not be interpreted to suggest that the interviewee can tell the researcher what to say or supecede the findings. The researcher should retain the freedom to honour the data.

The NMREB suggests that the relaxed standards can be met in the following way:

a) once an interview has been set, a letter should be written to the interviewee confirming the date and time of the interview, outlining the purpose of the research, the use to which any information provided may be put, provision for the security of any resulting records and their long term disposition, and contact information (e.g., address, telephone or fax number or email address of the interviewer) with an offer to provide more information
b) after the interview, an acknowledgement letter should be sent which includes a precise statement of the use to be made of the information, any special understandings reached with the interviewee, provisions for its security and long term disposition, and an offer to have the interviewee review any material from the interview to be attributed when published (if appropriate).

11.0 CROSS-CULTURAL RESEARCH

Cross-cultural research involving human subjects must also be approved by the NMREB. In doing so the NMREB recognizes that methods must be tailored to local practice. Researchers must be sensitive to the political situation, culture, ethnicity, family norms, and religion of the research subjects in regard to both the informed consent process and the assessment of harms and benefits. Researchers must conform to the usual ethical standards and must also ensure that the subjects are treated with respect and dignity in their own context. Research must not begin until permission is obtained from the appropriate authorities in a subject's community. The researcher is responsible for acquiring the consent of all levels as appropriate. The risk(cost)-benefit test for cross-cultural research requires that the subject population benefit from the results of the research in proportion to the risks(costs) placed on them. Once cannot justify cross-cultural research on the basis of benefit to the researchers and cost to the subject's community.

12.0 HUMANITIES RESEARCH AND CULTURAL ISSUES

Research ethics are not restricted to particular disciplines or methodologies but are

involved wherever and whenever an investigator intervenes in the lives of others. The scholar in the humanities as well as in social sciences should be alert to the possibility of ethical conflict. Historical investigations may pose problems of confidentiality or invasion of privacy if living persons are likely to be affected by the publication of private materials. The biographer, particularly of a living person, whether the interest be artistic or historical, must exercise care not to infringe on the rights of a subject.

Researchers acquiring and using cultural properties (e.g., totems, religious objects etc.) should consult the Social Sciences and Humanities Research Council of Canada guidelines on the acquisition and exhibition of such properties. Investigators must consider and be prepared to discuss the variations in ethical principles, communication problems, informed consent difficulties and similar issues for research on cultures, countries, and different ethnic groups. Cultural or ethnic research places significant responsibility on the researchers (and the NMREB) to be sensitive to socio-cultural circumstances and to build added safeguards into their methods to protect participants.

In conducting research for the biography of a recently deceased person, the researcher must always get permission from the executor (or representative) of the estate to examine or distribute any papers and private documents previously belonging to the deceased.

When publishing material from interviews that derive from research in 'oral history', the researcher must, if the interviewee is directly or indirectly to be identified in the published material, obtain consent from the interviewee for the publication and give the interviewee the opportunity to see those parts of the interview that will be published. The general rule in research is that confidentiality cannot be breached without the participant's consent.

13.0 DISCLOSURE OF RESULTS

In all cases, where data have been obtained, research participants have the right to request and receive the results and interpretation of the grouped data. Specific results that apply to them individually, if these are discernible and appropriate for release, must be made available by the researcher if requested. The investigator has a responsibility to present individual data accurately, sensitively, and in a language comprehensible by the participant (e.g., the interpretation of psychometric testing). Furthermore, the investigator must provide for the possibility of more extensive counselling or professional referral if necessary. In research involving children in which possible physical, sexual or emotional abuse is noted, duty-to-report legislation requires disclosure of the suspicion to proper authorities (e.g., police, Children's Aid). Research participants should be informed of such reporting obligations in the letter of information describing the study.

14.0 CONFIDENTIALITY & ANONYMITY

The general rule in research is that confidentiality cannot be breached without the participant's consent. This requires that care be taken at a number of stages in the research project: at the stage where the investigator is attempting to identify participants who will be suitable for the research; during the conduct of the research on

the participants; and during the period that the data obtained are studied, analyzed and reported.

In the hospital setting, where patients are to be recruited as subjects of research, it is inappropriate to identify potentially suitable subjects by a random audit of patients' medical charts. Rather, the investigator should approach a member of the health care team treating patients who possess the characteristics for inclusion in the study to identify prospective subjects. The initial approach to the patient to determine whether or not the subject is willing to participate should be made by the attending physician or member of the health care team and not by the investigator (where the investigator is not the participant's physician). If the subject consents to being approached, the investigator may then proceed to contact the subject and explain the research to the subject and seek consent.

Where subjects give consent to research, access to personally identifying information and its use in research should be carefully guarded. Identifiable data should be coded at the earliest possible time. A minimum number of research staff, all of whom must be instructed about confidentiality requirements, should be involved. Where, in the conduct of research, it is necessary to consult a subject's personal records e.g., school transcripts, the consent of the participant should be obtained. It is recognized, however, that for some types of studies, e.g., epidemiological studies involving examination of hospital records, it may not be feasible to obtain the consent of participants.

Where participants are offered the protection of confidentiality, care should be taken to inform subjects that, while the investigator will not voluntarily breach confidentiality, research records may well be subject to subpoena, to disclosure by operation of law, and in some cases, to the sponsoring agency, including for monitoring purposes, and where applicable Health Canada, and the Food and Drug Administration in the USA.

Data once obtained should be kept secure from theft, copying, interception and/or casual release. Records should be kept in locked cabinets to which access is restricted to as few members of the research team as is reasonably possible. Similarly, data which are stored on computerized data bases should be rendered secure from access by other users of the system. The method of disposal of research data must be clearly described.

Where the research is of such a nature as to require contact with relatives (or others such as teachers, physicians, supervisors, colleagues etc) of the subject, access to relatives must in principle be controlled by the subjects themselves. No approach for research purposes can be made without a subject's consent. If subjects consent, they should approach family members first because individuals must not be approached by strangers, bearing intimate information.

Confidentiality requires that when researchers publish their results, they preserve the anonymity of the subjects used in that research. In cases where disclosure of the identity of the subject should not or cannot be avoided (e.g., an interview with a public figure), consent to such disclosure and/or direct quotation must be obtained.

15.0 COMPOSITION OF THE NMREB

The NMREB is administered by the Office of Research Ethics. The Research Ethics Board shall comprise 9 members (all voting).

- A Chairperson - ex officio;
- The Vice-President Research (or designate) - ex officio ;
- One lay representative with no current ties whatsoever to the University, affiliated hospitals or research institutes appointed by the Vice President (Research)
- Three members appointed by the Vice President (Research), from faculties other than Social Sciences
- Three members appointed from the Faculty of Social Sciences .

An alternate is named for each member at the time of appointment. The NMREB members have overlapping three-year terms, to preserve experience and continuity in the function of the NMREB.

If a researcher, whose protocol is before the board, is also a member of the board, that member must not be present when the REB is deliberating and making its decision. That person may be called before the REB as a researcher however, if the REB so requests.

Whenever a protocol raises issues with which the NMREB members are not familiar, the Chairperson, at his/her discretion, or upon the request of any member of the NMREB may co-opt additional members to advise on that particular protocol, or consult externally, and confidentially.

16.0 JURISDICTION OF THE RESEARCH ETHICS BOARD

COMMENCING RESEARCH WITHOUT THE PRIOR WRITTEN AND SIGNED APPROVAL OF THE RESEARCH ETHICS BOARD IS UNACCEPTABLE AND WILL RESULT IN PENALTIES.

Research refers to the generation of data about persons, using methodologically valid protocols, through intervention or otherwise, that goes beyond that necessary for the individual person's immediate well-being. Intervention is not just medically defined, but includes acts which affect a participant's interests in, for instance, physical, psychological, intellectual and behavioural integrity, and privacy.

The NMREB must review <u>all</u> non-medical research protocols involving human participants, in which the research is to be carried out by a full-time or part-time member of the University or by an undergraduate or graduate student of the university or any research conducted within the University and affiliated Hospitals or Institutes. In any case in which the research is to be carried out by a student, a Faculty Advisor must be involved in the research and be named on the protocol submission as the principal investigator. Investigators are required to submit their protocol on UWO approved forms. (see Office of Research Ethics website www.uwo.ca/research/ethics).

The NMREB strongly recommends waiting to apply for ethics approval until after a project submitted for funding has received notification that the funding has been approved. It is very wasteful of the researcher's and the REB's time to prepare/review a protocol that may not proceed or may require significant revision and re-review as a result of receiving less funding than anticipated or because of the outcome of peer review.

Investigators involved in multicentre studies require the specific approval of the UWO NMREB for the component carried out under UWO jurisdiction. In addition, the NMREB, at its discretion, may review protocols from outside the University, upon request submitted to the Office of Research Ethics.
The NMREB reserves the right to redirect a protocol submission to another UWO REB that it feels is better qualified to review the protocol.

Once a protocol has been approved by the NMREB, the Investigator will receive a signed notice documenting such approval. The title on the approval form will be identical with that on the approved protocol.

17.0 CONDUCT OF MEETINGS

The NMREB meets to consider protocols monthly. A quorum of 5 voting members is required to make decisions. The NMREB may hold additional meetings, as required by the volume of protocols, or to consider specific issues. The NMREB may request that a researcher or research team attend a meeting, to discuss certain aspects of the protocol. Investigators may make a request to appear before the NMREB.

It is the investigator's responsibility that all requests for approvals and documentation are made sufficiently in advance of any deadlines for such documentation.

A majority decision with at least 4 affirmative votes are required for approval of protocols. The proceedings and minutes of NMREB deliberations are to be kept strictly confidential. In general, the NMREB strives to reach decisions by sufficient discussion to reach a consensus.

All decisions made by the NMREB will be communicated to the Principal Investigator within 7 working days of the NMREB meeting/decision. Correspondence or communication to the NMREB by the Investigators should be made to the Office of Research Ethics.

18.0 DELEGATED AUTHORITIES AND EXPEDITED REVIEW

Please note that the term "expedited" as used in this section refers to specific categories of research that may be approved outside a meeting of the full NMREB and not the alacrity with which the proposal is considered and approved.

Certain protocols, depending on the nature of the research, may be eligible for an expedited review (non-interventional minimal risk studies). The NMREB will consider some delegation of responsibility for the appraisal of undergraduate- and graduate-student projects, theses, dissertations, and minor, unfunded faculty pilot investigations,

case study preparations etc to formally constituted faculty or departmental ethics committees or a subcommittee of members of the NMREB. The composition and procedures of such committees must be approved by the NMREB, the subcommittee membership must include a member appointed by the NMREB ex-officio, and the NMREB must be assured that all questionable or dubious studies will be referred to it for review.

Where the expedited committees have concerns about a specific protocol, the protocol should be directed to the NMREB for a Full Board review. All other investigations involving human subjects, including all research involving substance administration, DNA banking and research on incompetent or vulnerable participants, must be submitted to the NMREB for Full Board review.

Documentation authorizing the delegation of responsibility must be approved by the NMREB and be maintained on file in the Office of Research Ethics. Annual reports of the work of these committees must be filed with the Office of Research Ethics and chairs of the reporting subcommittees may be required to discuss the activities of the reporting committee before the NMREB.

19.0 PROTOCOL DOCUMENTATION

All applications for review of protocols must be on the appropriate UWO form available on the Office of Research Ethics web site. (Appendix 4) Investigators are encouraged to call the Office of Research Ethics with any questions. The principal investigator must sign the application form attesting to the fact that the principal investigator and all listed co-investigators have reviewed the protocol as submitted and are in agreement with the protocol.

On receipt of the protocol in the Office of Research Ethics, the Ethics Officer will check the protocol. If the protocol is deemed by the Ethics Officer to be incomplete, it will be returned to the Investigator without review, with comments made as to which items remain outstanding.

Sponsoring agency documents are received and retained solely as resource documents as outlined in Appendix 3 – Sponsor Documents. It is expected that all the relevant material in those documents will be incorporated succinctly by the Principal Investigator into the UWO protocol.

21.0 APPROVAL FORMS

RESEARCH CANNOT COMMENCE WITHOUT WRITTEN AND SIGNED APPROVAL. FROM THE OFFICE OF RESEARCH ETHICS. Once a protocol has been approved, the Office of Research Ethics will provide an approval notice to the investigator documenting such approval. The title on the approval form will be identical to that on the approved protocol. The Office of Research Ethics does not sign sponsoring agency approval forms.

22.0 REVISIONS TO APPROVED PROTOCOLS

During the course of the research, no deviations from, nor changes to, the protocol or consent form may be initiated without prior written approval from the NMREB except when necessary to eliminate immediate hazards to the participant or when the change(s) involve on logistical or administrative aspects of the study (e.g., change of staff, telephone number). An investigator must complete a Request for Changes to an Approved Protocol form and submit it along with the relevant documentation to the Office of Research Ethics. Expedited review of minor change(s) will be considered.

23.0 ADVERSE EVENTS AND/OR INCREASES IN RISKS TO PARTICIPANTS

Investigators must promptly report to the Office of Research Ethics:

a) all adverse and unexpected experiences or events that are both serious and unexpected
b) new information that may adversely affect the safety of the participants or the conduct of the study and
c) changes increasing the risk to the participant(s) and/or affecting significantly, the conduct of the study. If these events or changes require a revision of the consent form and/or recruitment advertisement, a newly revised consent form and/or advertisement must accompany the report.

24.0 ONGOING SURVEILLANCE

It is expected that investigators will conduct their own monitoring of ongoing studies as an aspect of their own personal ethical and professional behaviour. If the investigator finds information which indicates a cognitive or health impairment detrimental to the participant's well-being, and, that information is unknown to the participant, the investigator has an obligation to make the participant aware of the problem.

All protocols will require the completion of the Surveillance Report form at least annually and a final completion report, which should include a brief summary of the results of the research. When a protocol is submitted, the researcher must propose, a continuing review process appropriate to the protocol. The Office of Research Ethics will send out reminders when the surveillance reports are due. Failure to respond in a complete and timely manner may result in suspension of the NMREB approval until the documentation is complete.

25.0 STANDARD OPERATING PROCEDURES

As general and day-to-day operating policies and procedures are required and evolve, the Office of Research Ethics will issue Standard Operating Procedures (SOPS) and append them, on an ongoing basis, to these guidelines.