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

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

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

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

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 liP8.1 ChildrenliP8.1 Ch6sren andu0.00027 Tw(uy(lns 8T.0028 Tw(incapable of gnroTj20

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 p(confidentntnPs’, the)TTEMC by the publ6ghctut the

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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

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.