ADMINISTRATIVE BULLETIN

TO: Deans, Directors, Department Heads & Grantees

UNIVERSITY OF MANITOBA

THE UNIVERSITY OF MANITOBA (the "University") **No. 79 Issued June 29, 2001**

Subject: Policy 1406 The Ethics of Research Involving Human Subjects Guidelines: Administrative Research, Interviews and Surveys

Introduction

In ***University Policy 1406, The Ethics of Research Involving Human Subjects,*** the University commits to ensuring respect for principles of ethical treatment of humans in support of The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans. Policy 1406 requires Research Ethics Board review of all research undertaken in association with the University. While quality assurance studies, performance reviews, or testing within normal educational requirements is not subject to Research Ethics Board review they do require respect of ethical treatment of participants, of relevant University Policy and of other applicable standards of conduct.

In some cases, administrative information gathering activity my constitute research requiring Research Ethics Board approval.

Purpose of these Guidelines

These guidelines will clarify the difference between information gathering techniques, undertaken in the normal course of administering University operations, and administrative research, falling under the purview of University Policy 1406 and requiring Research Ethics Board approval. These guidelines will also identify minimum standards to be maintained in administration of client interviews and surveys.

Responsibility

It is the responsibility of the individual administering the information gathering techniques to ensure that appropriate judgement has been reached in regard to the requirement for Research Ethics Board approval. Further the individual must ensure that, in all cases, the University remains in respect of the principles of ethical treatment of humans, of all relevant University Policy, and of any other applicable standards of conduct associated with the activities or profession of practice. Individuals may find it useful to acquire management authorization for their specific information gathering activity. Deans, Directors, managers, and other administrators may find it necessary to require management authorization. At a minimum, the ethical standards outlined in these guidelines must be met.

Application for Research Ethics Board Approval

Administrators who are uncertain whether the information gathering procedures require Research Ethics Board Review should consult the chair of the REB designated for the review of administrative research under Policy #1406, i.e., either the Joint-Faculty Research Ethics Board (JFREB) in the case of central administrative research or the discipline-relevant REB in the case of unit-based administrative research.

If it is deemed that Research Ethics Board approval is required, University Policy #1406 must be followed with the required submissions completed from the perspective of the survey or research administrator serving as the "principal investigator", and the protocol submitted to the appropriate REB for review and approval.

Appended Guidance:

Appendix 1: Minimum Ethical Standards in Conducting Interviews, Surveys and Administrative Research.

Appendix 2: Determining if Administrative Information Gathering Activities Require Research Ethics Board Approval

Appendix 3: Guidance and Checklist for Establishing Informed Consent

APPENDIX 1

Minimum Ethical Standards in Conducting Interviews, Surveys and Administrative Research

1. Ensure that there is no more than minimal risk associated with the study. That is, risk of harm anticipated in the proposed research is not greater nor more likely, considering probability and magnitude, than that ordinarily encountered in everyday life, including that encountered during the performance of routine physical and psychological examinations or tests.

2. Ensure sensitivity to participant's physical, emotional and mental well-being and ensure respect of University Policy 236 Human Rights.

3. Ensure that the study is valid and/or is appropriate in that the study achieves its purpose in accessing necessary data. Also ensure that the study is cost-effective in terms of time, effort and risk to be incurred by the University and its participants. Note that Policy 1406 states that: scientifically invalid research, or research that is unnecessarily intrusive, is unethical.

4. For studies involving active participation, ensure that there is informed consent from all participants and ensure that such consent is documented. Documentation should ensure: that the purpose for which the information is collected is clear to the participant; that the legal authority for collection is secure; and finally, that the title, business address and telephone number of an officer or employee of the University is provided for participant inquiry. (For further information see: **Guidelines and Check list for Establishing Informed Consent**, as appended.)

5. Ensure confidentiality and appropriate retention and destruction of data obtained from participants and ensure respect of the University Policy regarding FIPPA/PHIA.

6. Ensure that if there is any uncertainty about whether the activity constitutes research, the appropriate Research Ethics Board Chair is consulted in respect of University Policy 1406 The Ethics of Research Involving Human Subjects.

7. Ensure that University Administration and the appropriate Research Ethics Board is made aware of any unanticipated negative reactions by subjects or other unexpected events that may arise from the study which involve an ethical issue.

APPENDIX 2

Determining if Administrative Information Gathering Activities Require Research Ethics Board Approval:

Most administrative information gathering procedures and practices are not undertaken in the context of research nor are they necessarily embedded in a research framework. Rather, they are undertaken for the purpose of evaluating choices, assessing client satisfaction, identifying product or service enhancements and so forth. As an example, the University Bookstore may choose to conduct a client survey to gather information about customer satisfaction with merchandise and services. Similarly, Student Affairs may conduct a client survey to assess satisfaction with the services provided. In this context of supporting normal administration of University operations, the information gathering procedures do not constitute research studies requiring Research Ethics Board approval. Nonetheless, individuals administering these information gathering procedures must ensure that the highest ethical standards are maintained and that the anonymity of respondents is protected.

It is important to note that there will be cases where information gathering procedures undertaken by University Administration are subject to Research Ethics Board approval. Administrators who are uncertain whether the information gathering procedures require Research Ethics Board Review should consult the Chair of the Research Ethics Board designated to that operation under Policy 1406. The following criteria should be useful in determining whether Research Ethics Board approval is required for information gathering procedures undertaken in the context of University administrative activities.

Criteria for Considering Applicability of Policy #1406

Information gathering activities **may constitute research requiring Research Ethics Board approval when** they meet one or more of the following characteristics:

- The primary aim of the data collection is to produce conceptual knowledge or expand existing published theory
- There is an expectation to share the results or findings within a professional community through professional community through publication, articles, conference papers, etcetera.
- Participants may be manipulated or exposed to certain conditions without their awareness as a part of their research participation;
- It involves the active participation of "at-risk" participants such as children or other vulnerable populations, or involves the collection of personally sensitive information.
- If it is possible to identify individual respondents so that confidentiality cannot be assured.

Information gathering procedures **may be classed as "in support of general administration of the University" when** they exhibit none of the above-noted characteristics, and

- The primary aim of the activity is to diagnose problems, identify appropriate solutions, provide advice for operation management, or assess performance.

- The data collection is primarily designed to affect the operations of the University simply through affirming satisfaction with the status quo or leading to quality improvements.

APPENDIX 3

Guidance and Checklist for Informed Consent

Out of respect for the idea that persons should have the autonomy to make choices on matters which affect them, free and informed consent by all subjects is required before research can be undertaken.

There are four elements necessary for consent to be free and informed: disclosure of information; comprehension of information; competency of consent; and voluntary to consent. Verbal or written consent is normally required.

Written Consent

Written consent should be recorded on University letterhead in a simple, direct style, using terms and language which can be understood by the prospective subject. This information should be discussed with the subject as well, whenever possible. When written consent is required, two (2) copies have to be signed by the respondent and the researcher (or their representatives). One signed copy has to be given to the respondent and the other is to be retained by the researcher.

A written consent form should contain the following information:

1. The identity of the researcher(s), the University unit, the phone number of the researcher and the unit administration in the event that the subject wishes to contact the researcher;

2. A statement of the general purpose of the study, including what the unit hopes to learn;

3. A description of the procedures involving the subject, including their purpose, nature, frequency and duration;

4. A description of risk (i.e., potential harm greater than that which one might experience in the normal conduct of one's everyday life);

5. A description of any recording devices to be used;

6. A statement of confidentiality;

7. A statement of whether or not the findings will be available to the subjects;

8. Details of any scheme of remuneration; An explicit statement that participation is voluntary and that subjects have the right to withdraw from the study at any time and/or refrain from answering whatever questions they prefer to omit, without prejudice or consequence;

9. A concluding statement in the first person, summarizing the information the subject has received, the consent given, and incorporating the date and the subject's signature, which is witnessed by the researcher or research staff; and

10. If a substitute decision-maker is giving consent for a subject incapable of doing so for her/himself, the consent form should indicate the relationship to the subject and the rationale for giving consent (assent of the subject should also be sought, and this should be indicated in the consent form).

11. A statement that any complaint regarding the study may be reported to the Vice-President (Administration) 474-9777 or the Human Ethics Secretariate 474-7122.

Verbal Consent

A researcher may choose to acquire verbal rather than written consent. Any free and informed consent required that the following issues be discussed with the prospective participants:

1. Identify yourself, and the University unit.

2. Make a statement of the general purpose of the study identifying what the unit hopes to learn.

3. Provide a description of the procedures involving the participants, including their purpose, nature, frequency and duration.

4. Ask for permission if you want to use any recording devices.

5. Explain the issue of confidentiality and assure that anonymity will be respected.

    (a) In most instances, the participants information will be grouped together with others and names will be omitted from the presentation of the research findings. If names are used, and/or the number of participants is so small that they can be identified, a written consent form will be required.

    (b) Tell your participants your method of storage and disposal of the collected information.

6. Explain the purpose of the use of the information gathered to the participants, that is: report, publication, general planning information etc.

7. If you intend to contact the participants for further sessions, they have to be told at the first contact.