

## Dalhousie University 2003 GUIDELINES for Ethical Review of Faculty and Graduate Thesis Research Involving Humans

## SOCIAL SCIENCES and HUMANITIES RESEARCH ETHICS BOARD

All enquiries regarding ethics review at Dalhousie University should be directed to:

Director, Office of Research Ethics Administration, Room 321, Henry Hicks Academic Administration Building, patricia.lindley@dal.ca ph. 494-1462.

Prepared by:

The Office of Research Ethics Administration Office of the Vice President (Research)

For your information, the following is a list of the questions which the reviewers address when reviewing an ethics submission.

## **Research Protocol**

- Are the objectives of the study clearly described?
- Is the rationale for the study clearly outlined (e.g. reference to similar studies)?
- Is the study design appropriate to the objectives?
- Are the source and number of subjects clearly stated?
- Is the rationale for the sample size clearly stated?
- Are the eligibility criteria (screening, inclusion, exclusion) clearly defined?
- Are the methods / procedures to achieve the intended results clearly described?
- Are the methods/ procedures appropriate to achieve the intended results?
- Is the method of analysis described (including statistical measures for quantitative studies)?
- Does the proposed data analysis address the study's primary objective?
- Do the proposed outcome measures have adequate reliability and validity?
- Is the group of research subjects appropriate?
- Is the procedure for obtaining informed consent appropriate?
- Is the access to subjects and methods of recruitment appropriate?
- Is deception involved and, if so, is it justified and are there appropriate arrangements for debriefing of subjects?
- Has the researcher identified the risks for subjects associated with their participation in the research, and has (s)he described how these will be mitigated or addressed?
- Has the researcher identified the benefits (direct and/or indirect) that may be derived from the research?

## **Consent Form**

- Is the consent form appropriately headed (i.e letterhead, title on front and on signature page)?
- Is the consent form simply written (Gr. 8 comprehension level, no technical jargon)?
- Does the information on the consent form match the protocol?
- Is there an introduction explaining that this is a research study, and that participation is voluntary?
- Is the purpose of the study clearly described?
- Is the study design clearly described?
- Are the conditions of the subjects involvement described (inclusion/exclusion criteria)?
- Are the procedures or tasks that the subjects will be asked to participate in described?
- Is the time that participation will involve described?
- Are the foreseeable risks and benefits described? Are the means to mitigate the risks described?
- If the subjects are to be compensated, are the conditions and amount of compensation described?
- Is there a statement regarding the confidentiality of subject data (i.e. storage of data, access, method of publication?)
- Is there a statement regarding how the anonymity of the subject will be safeguarded?
- Are there special considerations (e.g. mental incompetence, vulnerable population)?
- Is there information about whom the subject may contact regarding the study?
- Are the appropriate signatures requested, in an acceptable format?
- Has the Office of Research Ethics been cited should subjects wish to raise concerns?

APPENDIX 1.