# GUIDE TO APPENDICES

**The appendices are designed to facilitate the implementation of the FGS Human Participants Research Guidelines. Please <u>do not</u> submit a copy of all of the guidelines and the appendices when submitting research proposals or annual reports, but submit ONLY materials pertinent to the task.**

| APPENDIX | TITLE | FUNCTION | SUBMIT TO |
|---|---|---|---|
| A | Sample language for inclusion on course outline | For use by Course Directors in preparing course outlines | N/A |
| B | Informed Consent Document Checklist for Researchers (Form TD3) | a) For use by students in the preparation of Informed Consent Documents<br>b) For use by Ethics Committees in the review of research | a) Students must submit the checklist with their proposals<br>b) Ethics Committees may use the checklist to review proposals. |
| C | Graduate Program Directors' reporting form for courses involving human participant research | For use by Graduate Program Directors to report annually on activity within the program | Submit to Faculty of Graduate Studies |
| D | Graduate Program Directors' reporting form for MRPs involving human participant research | For use by Graduate Program Directors to report annually on activity within the program | Submit to Faculty of Graduate Studies |
| E | Table outlining procedures for each type of proposal | N/A | N/A |
| F | Statement of Relationship between Proposal and an Existing HPRC Approved Project (Form TD4) | For use by students in submitting proposals funded by faculty research grants | Submit to Faculty of Graduate Studies |

**APPENDIX A**
**RESEARCH ETHICS**
**SAMPLE TEXT FOR INCLUSION ON COURSE OUTLINE**

Students who conduct a research study using human participants must submit the following for approval prior to the conduct of research:

1. two copies of a proposal outlining the purpose of the research and the methodology to be used
2. two copies of the Faculty of Graduate Studies Human Participants Research Protocol Form, and
3. two copies of the Written Informed Consent form **or** a script of Verbal Informed Consent (Verbal Informed consent is permissible only in extenuating circumstances, where written communication is not feasible).
4. one copy of the TCPS completion certificate, dated within the past two years, to be placed in their graduate programme file

This material will be reviewed by a committee of the Graduate Program. Reviews will take no more than 2 weeks from the date of submission. If the research is not approved ***prior to*** the conduct of the research, then the research will not have received research ethics clearance and will be deemed unacceptable for submission as a component of this course. Information regarding the use of human participants in research studies may be found on the Faculty of Graduate Studies webpage http://www.yorku.ca/grads/polc/ethics.htm.

Students are advised that all human participants in the research must have either signed a written consent form or have provided oral consent for their participation in the research. Students also are advised that the consent forms will be retained by the Principal Investigator for two years following the completion of the research.

**APPENDIX B**
***FORM TD3***
**INFORMED CONSENT DOCUMENT CHECKLIST FOR RESEARCHERS**

| YES | NO | N/A | DESCRIPTION |
|---|---|---|---|
| | | ----- | Have you included a brief description of the purpose/rationale of the study? |
| | | ----- | Have you included a brief description of the study design? |
| | | | If the research involves a questionnaire or a survey, have you provided the questionnaire or survey? |
| | | ----- | Have you indicated the time commitment required of participants? |
| | | ----- | Have you indicated whether and what incentives are offered to participants and why? |
| | | ----- | Have you included a brief description of risks/benefits and mitigation methods? |
| | | | If the study involves any type of physiological assessment or procedure (such as those studies undertaken by Kinesiology and/or psychology researchers), have you provided the following information in the Informed Consent Document?:<br>i. Information about the expertise of the researchers conducting the study (i.e., if it involves giving an injection, that the researcher is competent to do so)<br>ii. Notification to participants that are being taken to safeguard their person<br>iii. Notification to participants of any potential risks and/or impacts to their person due to their participation<br>iv. Information for participants on any anticipated circumstances arising from their participation in the study<br>v. Notification to participants of any benefits<br>vi. Contact information for participants regarding resources available to them should any concerns arise at a later date |
| | | ----- | Have you described the methods by which confidentiality and anonymity will be attained and maintained? |
| | | ----- | Have you included statements of the following (as applicable)?:<br>i. Participants have the right not to answer questions<br>ii. Participants have the right to withdraw at any time<br>iii. Should a participant withdraw from the study, all data generated as a consequence of their participation shall be destroyed<br>iv. Participants shall address any ethical concerns regarding the research to the Manager of Research Ethics<br>v. How the research will be presented or reported |
| | | ----- | Have you described the storage method, length of retention and disposal method of all data gathered during the study? |
| | | ----- | Have you included a statement indicating that the research has been reviewed and approved for compliance to research ethics protocols by the Human Participants Review Subcommittee (HPRC) of York University? |
| | | ----- | Have you provided contact information for participants should they have questions (a contact phone number for *your Graduate Program Office* and contact information for the *Manager of Research Ethics for the University at the Office of Research Services, 214 York Lanes, phone 416-736-5055*) |
| | | ----- | Have you provided contact information for yourself as the Principal Investigator (your name, your campus address, your status--i.e., Graduate Student) |
| | | | If the study involves the use of a minor, have you included:<br>i. A separate information letter to the parents of the minor<br>ii. A separate parental permission letter which is to be attached to the minor's letter of "assent"<br>iii. A line for the Parent or Guardian to indicate their relationship to the minor<br>iv. A signature line for the parent/guardian of the minor. |
| | | ----- | Have you included a signature line and a date line for participants? |
| | | ----- | Have you included a signature and a date line for yourself as Principal Investigator? |

**APPENDIX C**
**GRADUATE PROGRAM REPORTING FORM**
**FOR COURSES INVOLVING HUMAN PARTICIPANT RESEARCH (From June 1st to May 31st)**

***GRADUATE PROGRAM:*** _____

***Please check one of the following two items:***

_____ ***There were no courses in my graduate program in which students conducted research involving human participants.***

_____ ***The following is a listing of the courses in my graduate program in which students conducted research involving human participants and whose research proposals were reviewed by the Program Committee.***

| ***Course Number*** | ***Course Title*** |
|---|---|
| _____ | _____ |
| _____ | _____ |
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_____ _____
***Graduate Program Director Signature*** ***Date***

**APPENDIX D**
**GRADUATE PROGRAM DIRECTORS' REPORTING FORM**
**FOR MRP'S INVOLVING HUMAN PARTICIPANT RESEARCH (From June 1st to May 31st)**

***GRADUATE PROGRAM:*** _____

***Please check one of the following two items:***

_____ ***There were no Major Research Papers (or equivalent) in my graduate program in which students conducted research involving human participants.***

_____ ***The following is a listing of the Major Research Papers (or equivalent) in my graduate program in which students conducted research involving human participants and whose research proposals were reviewed by the Program Committee.***

| ***Student Name*** | ***MRP (or equivalent) Title*** |
|---|---|
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***Graduate Program Director Signature*** ***Date***

**Appendix E: Table Outlining FGS Procedures for Review of Proposals of Different Types in Cases Where the Research Involves Human Participants**

| **Type of Proposal** | **Documents Required** | **Submit Documents to** | **Proposal Reviewed by** | **N** |
|---|---|---|---|---|
| Coursework research or MRP research that is minimum risk | • 2 copies of proposal<br>• 2 copies of a completed FGS TD2 form | • Graduate Program Office | • Graduate Program Committee **or** Graduate Program Director (or designate) and arm's length faculty member | • |
| Coursework research or MRP research that is funded **or** is not minimum risk | • 1 copy of proposal<br>• 1 copy of a completed FGS TD2 form<br>• Contact HPRC in ORS, 214 York Lanes for further instructions | • Submit one copy of proposal and completed TD2 form to Graduate Program Office<br>• Submit to HPRC *via* ORS the documents they require | • HPRC | • |
| Thesis and dissertation research that is minimum risk | • 1 copy of the thesis or dissertation proposal<br>• 1 TD1 form<br>• 2 copies of the Written Informed Consent Document **or** the Script for Verbal Informed Consent<br>• 2 copies of a completed TD2 form | • Submit all items to the Faculty of Graduate Studies, who will then forward relevant materials to HPRC | • FGS and HPRC | • |
| Thesis and dissertation research that is funded **o**r is not minimum risk | • 1 copy of proposal<br>• 1 copy of completed TD1 form<br>• Contact HPRC *via* ORs in 214 York Lanes for further instructions | • Submit one copy of proposal and completed TD1 form to the Faculty of Graduate Studies<br>• Submit 6 copies of HPRC materials to the Faculty of Graduate Studies, who will then forward relevant materials to HPRC | • FGS and HPRC | • |

*Revised September 2005*

**TD4 Form**
Statement of Relationship between Proposal
and Existing Approved Research/Facilities

***Student:*** _____
(please print)

Program: _____

Proposal Title: _____

_____

_____

Please check appropriate box:

☐ **Research Involving Human Participants**

The above proposal is a subset of a larger project (see title below) for which I am a principal Investigator. The full project has existing approval (**attached**) from the York University Human Participants Review Committee (HPRC). All the procedures, the methods for participant recruitment and methods for obtaining informed consent within this proposal were included in the *HPRC* application of the full project and have not changed. The informed consent form has not changed.

☐ **Research Involving Animals**

The above proposal is a subset of a larger project (see title below) for which I am a principal Investigator. The full project has existing approval (**attached**) from the York University Animal Care Committee (ACC). All the procedures for animal care and use within this proposal were included in the *Animal Use and Care Protocol* application of the full project and have not changed.

☐ **Research Involving Biohazards**

The above proposal is a subset of a larger project (see title below) for which I am a principal Investigator. The full project has existing approval (**attached**) from the York University Advisory Committee on Biological Safety (ACBS). All the procedures relating to the use of biological hazards within this proposal were included in the *Biosafety Certificate (Research)* application of the full project and have not changed.

Project Title: _____

_____

Supervisor's Name: _____

Supervisor's Signature: _____

Date: _____ *Form effective March 2005*