

HUMAN PARTICIPANTS REVIEW SUB-COMMITTEE (HPRC)

Protocol Form

Who should complete this Protocol Form?

All faculty members (including contract, adjuncts, and seconded) who are conducting funded or un-funded, minimal or more than minimal risk* research that involves the use of human participants, must complete this Protocol Form. Students who are conducting funded minimal or more than minimal risk research that involves the use of human participants must also complete this form. This includes all experiments, interviews, and participant observation. If you are a student and your research is non-funded AND minimal risk, please consult with your Department Chair's, Graduate Programme Director's or Faculty Dean's office to discuss the approval process for your research.

How long will the review process take?

The average time to process minimal risk protocols is approximately twenty working days from the date of receipt in the Office of Research Ethics (ORE). **INCOMPLETE OR ILLEGIBLE PROTOCOLS WILL BE RETURNED TO THE RESEARCHER, WHICH WILL DELAY THE PROCESS.**

Online Ethics Review System

If you would like to submit your protocol using the Online Ethics Review System, please click on the following link: <http://www.yorku.ca/research/support/documents/#ethics>. Please note that the system is currently only accessible to faculty members and requires a York Passport Account. A signed hardcopy of your application is **not** required if you are submitting your protocol via the online system.

Who can I contact if I have any questions?

Please contact the Coordinator, Research Ethics Review, Office of Research Ethics at ext.55201 or (wjokhoo@yorku.ca).

*The HPRC uses the definition of minimal risk as outlined in the SSHRC/NSERC/CIHR *Tri-Council Policy Statement "Ethical Conduct for Research Involving Humans"* (December 2010): "If potential subjects can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the subject in those aspects of his or her everyday life that relate to the research then the research can be regarded as within the range of minimal risk" (p. 1.5). An expanded version of this definition is available from ORE upon request.

Please submit a signed HPRC Form, with attachments to:

Secretary, Human Participants Review Sub-Committee

Office of Research Ethics

5th Floor, Kaneff Tower

****A signed hardcopy is not required if you are using the Online Ethics Review System**

Checklist:

- Original HPRC form signed **(6 copies are NO longer required)**
- Consent statement is attached (informed consent form, letter, online consent or verbal statement)
- Interview questions/ questionnaire or survey/ advertisements, flyers, posters
- Additional Documentation (Ethics approval certificates/ letters of permission from other institutions or departments) **

** Please visit our [website](#) for Guidelines on:

- Research in an Online Environment
- Research Conducted by External Researchers
- Research in Hospital Clinical Settings
- Research in Educational Settings
- Research Involving Minor Age Participants
- Research with People who are Homeless
- Data Security Guidelines
- Ethical & Hazard Identification Guideline for Classroom and Research Projects Conducted at York University
- Research Involving Aboriginal Peoples
- Aboriginal Research - Checklist for Researchers
- Invasive Procedures

Note: Protocols involving Invasive Procedures and/ or the collection of human bodily fluids will NOT be accepted for review unless the Health & Safety Checklist is completed and all relevant documentation is attached (e.g. Biosafety Permit, Proof/ Certification of delegation of the controlled act by the relevant registered Health Professional, Radiation Safety Permit).

PART A - GENERAL INFORMATION**A. Name of Principal Investigator(s):****B. Department and Home Faculty (or Research Centre/Institute):****Campus Mailing Address:****Extension:****E-mail:****C. Names of any other persons involved in the data collection:**

	Name	Role	Institution/ Research Centre
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			

D. Status of Principal Investigator:

- York Faculty Member
 Graduate Student
 Undergraduate Student
 Other: Research Associate

If student, please provide course director's or supervisor's name:

E. Title of Research Project: Predictors of students' academic performance in large lecture-style classroom settings: A retrospective analysis**F. Is this research defined:**

- Minimal Risk
 Non-minimal Risk

(Please see (*) footnote on first page for definition of minimal risk.)

G. If your research involves the use of human tissue/ blood/ body fluid and/or invasive procedures, please refer to the Submission and [Ethics Review Guidelines](#) for Research Involving Invasive Procedures and/or Collection of Human Bodily Fluids confirm whether Biosafety approval is in place:

- Yes - Please append a copy of your approval certificate to your application
 No - HPRC protocol cannot be reviewed until the ACOBS approval certificate is in place.

Not applicable

For more information on Biosafety please contact the Occupational Health Coordinator & Biosafety Officer, Phone: x44745

H. If your research involves the use of radioactive materials and/or radiation exposure, please confirm whether Radiation Safety approval is in place:

- Yes - *Please append a copy of your approval certificate to your application*
 No - *HPRC protocol cannot be reviewed until the Radiation approval certificate is in place.*
 Not applicable

For more information on Radiation training please contact the Radiation Safety Officer (RSO), Department of Occupational Health and Safety, x44745

I. Does your research involve Aboriginal/ Indigenous Peoples?

- Yes – *Please complete and append a copy of the '[Checklist for Researchers](#)'. Your protocol will first be reviewed by the Aboriginal Research Ethics Review Advisory Group.*
 No

Additional Comments (Optional):

J. Is this a revised version of a protocol previously reviewed by the HPRC?

- Yes
 No

If yes, please explain:

K. Approximate dates for proposed study:

Start: April 2016 **End:** April 2017

L. Is any anticipated funding for this project from internal (i.e., York University) sources?

- Yes
 No

If yes, what is the funding source?:

M. Is any anticipated funding for this project from any external (i.e., outside York) sources?

- Yes
 No

If yes, what is the funding agency and/or program?:

PART B - RESEARCH INFORMATION

1. In layperson's terms, please provide a general and brief description of the research (e.g., hypotheses, goals and objectives, etc.).

Past research has shown variable results regarding whether attendance is correlated with final grades for university-level courses (1, 2). Meanwhile, other studies have shown that early feedback given to students in the form of quizzes, reports and midterms are highly correlated with students' final grades (3). The objective of the present investigation is to assess whether attendance and early feedback given to students in the form of quizzes can be used to predict their performance on a final cumulative exam in a large lecture-style course. It is hypothesized that both attendance and early feedback will be predictive of students performance on a final cumulative exam. The goal of the study is to identify key factors to students' academic success in a course that can then be explicitly communicated to students at the start of the course. For example, if early feedback is highly correlated with students' performance on a final cumulative exam, the instructor could communicate this finding to the class while highlighting the importance of establishing good academic habits early in the semester and doing well from the beginning of the course.

1. Ramirez, B. U. (2015). Correlation of self-assessment with attendance in an evidence-based medicine course. *Adv Physiol Educ*, 39: 378-382.
2. Gonsalvez, D. G., Ovens, M. & Ivanusic, J. (2015). Does attendance at anatomy practical classes correlate with assessment outcome? A retrospective study of a large cohort of undergraduate anatomy students. *BMC Med Educ*. 15: 231-238.
3. Jensen, P. A. & Barron, J. N. (2014). Midterm and first-exam grades predict final grades in biology courses. *Journal of college Science Teaching*, 44(2): 82-89.

2. State who the participant(s) will be (e.g., experimental subjects, interviewees, community members to be observed, etc.). Please provide details about the research subjects that are relevant to your particular research (number, age, sex, students, children, businesspeople, government employees, etc.). Also discuss the relationship of the researchers to the prospective subjects (e.g., teacher, parent, advisor, stranger, etc.).

The participants will be students in a 3rd year undergraduate Psychology course that the PI taught at York University this past Fall and Summer semesters. Student will retroactively be asked for their consent to have their information from the course (e.g., attendance and marks) used in the study. There were approximately 200 students in the course for each semester. All students who provide consent will be included in the study. All students who provide consent will be asked to provide their age and sex for the purpose of reporting participant demographics in the final write-up of the study. At the time of requesting students' consent to participate in the study, they will be notified that their decision to participate in the study will not have any bearing on their mark in the course, any other course they may be taking or their relationship with the Course Instructor and/or York University.

3. (a.) How will participants be recruited (e.g., snowball technique, random sampling, previously known to interviewer, telephone solicitation, etc.)?

A message will be sent out to the class about the study through the course moodle site. A second follow-up message will be sent after about 1-2 weeks to remind any interested students about the study.

Please see Appendix B for a draft of both of these messages.

(b.) Will you be using any advertisements, flyers, posters etc.?

- Yes - *If yes, please attach a copy with your application.*
 No

4. Will you be offering inducements to participate (e.g., money, gift certificates, academic credit, etc.)?

- Yes
 No

If yes, please elaborate:

5. What exactly will be required of the participant(s) (e.g., answer a formal questionnaire, respond to interview questions, engage in a free-ranging discussion, undergo any medical procedures, etc.)? If applicable, please attach any research instruments (e.g., sample interview questions, questionnaires, etc.).

Participants will not have to engage in any activities. The current investigations consists of a retrospective analysis of whether their attendance and quiz marks from a course that they have already completed correlate with their performance on the final cumulative exam.

6. What, if any, are the risks to the participants?

Or, No risks:

7. What, if any, are the benefits to the participants?

Or, No benefits

Participants will be notified of the results of the study through the moodle course website, which may help them in their academic performance in any course they are currently taking or will be taking in the future.

8. Is there a possibility of an apparent, actual or potential conflict of interest on the part of researchers, the University or sponsors? (E.g. commercialization of research findings; self-funded research)

- Yes
 No

If yes, please elaborate and outline how the potential or real conflict of interest will be addressed:

9. This section pertains to issues around informed consent. Before completing, please read "Important Statement Regarding Informed Consent" attached to the end of this form.

(a) Will you provide to the participants a full explanation of the research prior to their

participation?

- Yes
 No

If no, please elaborate and provide a copy of the debriefing statement:

(b) Is substitute consent involved (e.g., children, youths under 16, incompetent adults, etc.)?

- Yes
 No

If yes, please elaborate and provide a separate assent form:

(c) Is deception involved?

- Yes
 No

If yes, please elaborate and provide a copy of the debriefing statement (including issues around debriefing, if applicable):

(d) Will individuals remain anonymous?

Please note that it is expected that participants remain anonymous unless participants explicitly have given their permission otherwise.

- Yes
 No

If no, please elaborate:

(e) Will the data be kept confidential?

Please note that it is expected that the data be kept confidential unless the participants explicitly have given their permission otherwise.

- Yes
 No

If no, please elaborate:

(f) How will data security and management be addressed?

Please provide details regarding proposed measures for safeguarding information – in particular personally identifiable data - for the full life cycle of information: its collection, use, dissemination, retention and/or disposal. At a minimum, researchers should **consider the full implications of the data collection, use, retention and destruction/archiving when developing data security and management plans.** (Researchers are encouraged to review the [Data Security Guidelines](#) for reference re their responsibilities for data management).

Each participant will be identified by a unique participant identification number, designated upon

commencement of the study, and all data will be stripped of identifiable information. All data will be stored by experiment and participant identification number. Experimental data will be maintained separately from consent forms. When the process of collecting consent is completed, the online site that we made to collect consent will be deleted and only a hard copy of the lists of students who consented to participate in the study will be retained. This list will be stored in a locked cabinet, in a locked room at York University. Once the study is completed, this list will be shredded.

(g) How will informed consent be obtained? (Please check all that are applicable):

- Informed Consent Form (please attach draft version)
- Letter* (please attach draft version)
- Verbally* (please attach draft approximation of what participants will be verbally told)
- Online Consent Form** (please attach draft version)

**If informed consent is being obtained by letter or verbally, please provide a rationale regarding why an informed consent form is not being used:*

**If online consent is being obtained, please indicate the website where the questionnaire/ survey will be hosted:*

website identified here

10. Is there any additional information that you would like to add that may assist the HPRC in reviewing your protocol?

I have examined the guidelines and principles detailed above, and *the Senate Policy for the Ethics Review Process for Research Involving Human Participants*, and affirm that, to the best of my knowledge, this research conforms thereto. I hereby undertake to notify the Human Participants Review Committee if I make any major procedural changes involving the use of human participants on this project. I will also notify the Human Participants Review Committee if any unforeseen risks not specified in the research proposal appear. In such a case, the study will be suspended pending clarification.

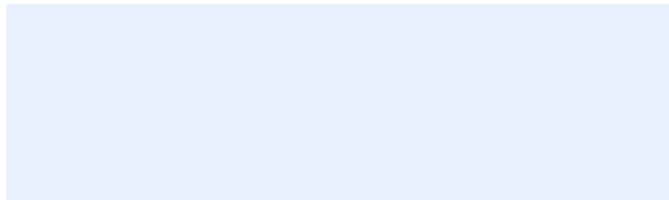
Signature of Principal Investigator (PI)

Date

Signature of Faculty Advisor (if PI is a student)

Date

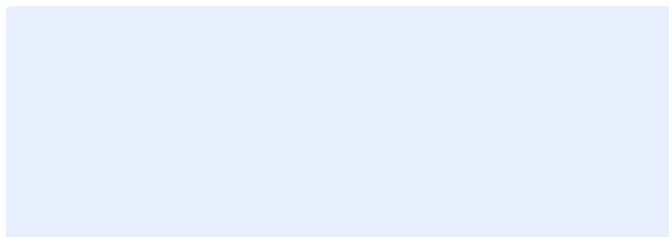
Section to insert Digital Signatures (if applicable):



[Click here to enter a date.](#)

Electronic Signature of Principal Investigator (PI)

Date



[Click here to enter a date.](#)

Electronic Signature of Faculty Advisor (if PI is a student)

Date

Item 9 - Important Statement Regarding Informed Consent

- A. The HPRC has adopted the position that all human participants (e.g., interviewees, research subjects, community members, etc) have the right to be informed of:
- the nature of the research (hypotheses, goals and objectives, etc.);
 - the research methodology to be used (e.g., medical procedures, questionnaires, participant observation, etc.);
 - any risks or benefits;
 - their right not to participate, not to answer any questions, and/or to terminate participation at anytime without prejudice (e.g., without academic penalty, withdrawal of remuneration, etc.)
 - their right to anonymity and confidentiality;
 - any other issues of which the participants should be aware that are relevant to specific protocols and research projects.
- B. The HPRC recognizes that the manner the researcher uses to obtain the informed consent varies according to the nature of the research, status of the participants, and culturally-specific norms. Although the HPRC requires that the principles of informed consent (outlined in A. above) be met, it is very flexible in how this consent is obtained. The HPRC will accept any of the three methods outlined below:
1. **Informed consent form:** The traditional informed consent form is the standard for research involving human participants. This would detail the principles outlined in A. above, and require the participants' signatures.
 2. **Letter:** Where the traditional informed consent form is not appropriate (e.g., interviews with artists or government officials, mass mailed questionnaires, etc.), the researcher may wish to seek permission through a letter inviting them to participate. This letter must nonetheless incorporate the principles of informed consent outlined in A. above.
 3. **Verbal statement:** In some instances, where written communication is not feasible (children, illiterate adults, certain communities), researchers can relay the principles outlined in A. above verbally.
 4. **Online Consent form:** Researchers conducting surveys on-line must obtain consent from the participants. Recognizing that obtaining a signature is not feasible; researchers are advised that consent must be obtained in an alternate manner. Most commonly this can be achieved by including a "checkbox" function whereby participants can click on the box indicating they agree to participate or the box which indicates that they do not agree to participate.

Although it is impossible to come up with *one* generic model that will suffice for every research endeavour, an Informed Consent Form Template is available for your review and assistance on the [York Research website](#).

- C. The HPRC recognizes that researchers completing this protocol may not be at the stage of their research where they are able to provide this information. Nonetheless, the HPRC requires that a "best effort" draft be attached to this protocol. **PROTOCOLS THAT DO NOT ATTACH THIS INFORMATION (CONSENT DOCUMENT) WILL BE RETURNED TO THE RESEARCHER.**