**CLARKSON UNIVERSITY**

## INFORMATION REQUIRED FOR APPROVAL OF RESEARCH WITH HUMAN SUBJECTS

# **Instructions**

**Before working on your protocol**, please complete the online CITI Human Subjects Research training modules. The training covers concepts and laws to help you better understand what issues to cover in your protocol. The training instructions on the IRB website are in the right-hand column. Select the module most appropriate to your research.

Most researchers (including faculty, grad students, and staff) will need to take the Biomedical Research, Social & Behavioral, or Data or Specimens Only (data or specimens provided by a third party such as a tissue bank) module. Undergraduate students working on minimal-risk class projects or as supervised research assistants should take the Students Conducting No More Than Minimal Risk Research module.

Undergraduate students working on more than minimal-risk class projects or as supervised research assistants should take the Biomedical Research, Social & Behavioral, or Data or Specimens Only (data or specimens provided by a third party such as a tissue bank) module. If you have questions about which module to take, please email irb@clarkson.edu for advice.

Please submit an electronic version of this form **as a Word .doc file only** by emailing it to the IRB at irb@clarkson.edu. The IRB uses Microsoft Word’s Track Changes and Comment features in our review process, making reviewing documents in other formats difficult.

Please include all attachments, forms, and advertisements within the one proposal file as clearly labeled appendices. **Your full protocol must arrive in Sponsored Research Services by noon, at least two weeks before the meeting at which you would like it to be reviewed**. Meeting dates are posted on our website and announced to the campus each term. During the first week after your protocol is submitted, the IRB will contact you about any major revisions that might need to be made before the full IRB can review the protocol.

When all required revisions have been completed, you will receive an IRB approval number. Once you have this approval number, submit one signed copy of the cover sheet (page 2 of this form) to the IRB email at irb@clarkson.edu. Signed copies should not be sent to the Chair of the IRB).

The Clarkson IRB web page provides guidelines for completing this IRB proposal form. If you have questions about this form or its procedures, contact the IRB at irb@clarkson.edu.

*(Please complete the bottom half of this page when you first submit your proposal.)*

**Name of Investigator:**

**Name of Investigator:**

(Add lines for additional Investigators.)

**Name(s) of Research Assistant(s) (including staff and students):**

(Add lines for additional Investigators.)

**Advisor (for student research):**

For students: Has your advisor read this proposal version and approved it for submission?

[ ]  Yes [ ]  No

### Name of department, campus mailing address, and e-mail address for primary contact and any non-Clarkson Investigators:

**Mailing address (if other than department):**

**Title of Research**:

**Date submitted:**

**Proposed start date:**

**Expected completion date:**

**If proposal is for external funding, list agency**:

**Is this research being conducted in collaboration with another institution that has a review process?**

* **If so, list the other institution(s):**
* **If so, has this project been approved by the review board at that institution?**

 [ ]  Yes [ ]  No

* **If yes, please submit evidence of approval; if the proposal is undergoing review, approval by the Clarkson IRB will be contingent upon evidence of approval at other institutions.**

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## COVER SHEET FOR IRB-APPROVED RESEARCH WITH HUMAN SUBJECTS

Complete the following information after the proposal has been fully approved by Clarkson’s IRB and you have received an approval number. Return the signed, paper copy of this form directly to the IRB email at irb@clarkson.edu

**Title of research**:

**IRB approval number:**

**Proposed start date:**

**Approved until:**

**Expected completion date:**

**The investigators and faculty advisors for this project assume the following responsibilities:**

**PI Responsibilities**: All researchers and research assistants in contact with human subjects or with data obtained from the involvement of human subjects must be trained in human subjects research and must agree to uphold the principles of the Belmont Report and the Common Rule (described in the required training). All Primary Investigators (PI) must provide Sponsored Research Services certification that they have completed the online Human Subjects Research Certification course; PI must maintain documentation that all research assistants have completed this training. PIs for any IRB-approved research proposal (or faculty advisors, when PIs are students), are responsible for ensuring that all students and/or research assistants follow appropriate ethical procedures regarding human subjects research.

**Adverse Events**: You are required to immediately inform the IRB of any adverse events, including risk exposure, involving human subjects or their data. Use the Adverse Events form.

**Data and Consent Forms:** You should secure all identifiable data or consent documentation considered confidential. This usually means keeping it in a locked cabinet or drawer and password-protected computers.

**Protocol Modifications**: You are required to submit procedural changes or amendments to this approved proposal to the IRB using the Project Modification Request; you may not make changes without IRB approval except to eliminate immediate hazards to subjects.

**Continuing Review**: If the research is to continue after the “Approved Until” date noted above, you will need to request an extension using the Continuation Request form.

**Audit**: The IRB audits selected research proposals to ensure ethical procedures and the approved protocol are followed. If your proposal is audited, you are required to comply with audit requests.

By signing below, investigators and advisors (for student research) agree that you have read and understand the university's Policy on Research with Human Subjects. You agree to the conditions stated above. You agree to protect the rights and welfare of the human participants ("subjects") through your implementation or supervision.

**PI Name**   **Sign**

**PI Name**   **Sign**

(add lines for additional Investigators)

For student research: **Advisor:**   **Sign**

For faculty research: By signing below as Department Chair, you acknowledge that you have read the Research Summary for this project. This signature is only an acknowledgment that you have read the Research Summary and not a promise to support or fund this research.

**Department Chair:** **Sign:**

 **CLARKSON UNIVERSITY**

## HUMAN SUBJECTS RESEARCH INSTITUTIONAL REVIEW BOARD PROPOSAL

1. Research Summary (400 words or less)

2. Introduction

3. Objectives and Hypotheses

Human Subjects Protection Information

4. Participants

a. Number: Age range: Gender:

b. Recruitment population, including inclusion/exclusion criteria:

c. Recruitment procedures (Attach advertisements or recruitment notices as labeled appendices. Do not begin recruiting until you have an approved protocol.):

d. Incentives and compensation

e. Group assignment method

5. Informed Consent

a. What is the procedure for obtaining informed consent from all participants (or their parent[s] or guardian[s])? Describe who will obtain consent. (Attach Informed Consent form.)

b. If minors or other participants unable to provide legal informed consent are involved, outline procedures to be used in obtaining their agreement (assent) to participate, in addition to the consent of the parent(s) or guardian(s). (Attach assent form or statement.)

6. Study Design and Methods

a. Procedure for data collection and intervention, including duration of subject involvement:

b. Measurement tools. (Attach questionnaires and surveys as labeled appendices.)

c. Equipment interfacing with subjects:

d. If deception is necessary, justify and describe debriefing procedures. (Attached is the debriefing statement, as labeled in the appendix.)

e. Analysis of outcomes:

7. Risks and Benefits

a. Risks: detail stress, physical, psychological, social, or economic harm that may be incurred by participation in this research. Describe risks (including risks associated with the release of personal information) and methods for minimizing these risks.

b. Address how subjects will be monitored for adverse effects and what remediation is offered.

c. Does the data to be collected relate to illegal activities? If so, explain.

d. Rate risk level. Check the most appropriate risk level below. (Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during routine physical or psychological examinations or tests.)

[ ]  The research involves no more than minimal risk to subjects.

[ ]  The research involves more than minimal risk to subjects, but the risk(s) represents a minor increase over minimal risk, **or**

[ ]  The research involves more than minimal risk to subjects, and the risk(s) represents more than a minor increase over minimal risk.

e. Methods for providing anonymity or confidentiality. For research involving patients, describe how HIPAA requirements will be met.

f. Plan for destroying private, identifiable data at the end of the research project. (You must request approval for continuation annually until all private, identifiable data has been destroyed.)

g. Benefits to participants:

h. Benefits to society from the research:

i. Rate benefit level. A research benefit is considered health-related, psychosocial, or other value to an individual research subject or something that will contribute to the acquisition of generalizable knowledge. Money or other compensation for research participation is not considered a benefit but rather compensation for research-related inconveniences. Check the most appropriate benefit level below:

[ ]  No prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about a population group to which the subject belongs;

[ ]  No prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge that may benefit a population group to which the subject belongs or

[ ]  The research involves the prospect of direct benefit to participating subjects.

8. Investigational Device Exemption (IDE): Does this research involve any device that has not been FDA approved or that is being used for a purpose for which it has not been approved? If so, please review Clarkson’s guidelines regarding IDE. What are the safety testing results for this device?

9. Conflict of interest statement:

10. Citations

Appendices (Please label appendices with a letter and reference them directly in the body of the protocol above.)

**Instructions for Researchers Completing the Informed Consent Document**

Please complete all sections above the signature block**,** using language understandable to typical 8th graders or appropriate to your subject pool. Any sections below the signature may be added if relevant to the study; if so, move those sections above the signature line.

Text in italics contains instructions for you and should be deleted from the final Informed Consent document.

**Clarkson University**

**Documentation of Informed Consent to Participate in Research**

**Project Title**:

**Researcher(s)**:

**Institutional Review Board (IRB) approval number**: **Approval valid until:**

You have been asked to be a part of the research described here. Participation is voluntary.

**Summary of the study:** *Provide a 200-word summary of the research in plain English, written with the potential volunteer in mind. Begin with a one-sentence summary of the study's goals. Follow this with a very short description of what subjects will experience in the study (including rough time commitments). Conclude with a summary of the risks (physical, psychological, or social).*

Please read the material below if you want to participate in this study.

**What to expect**:*Provide brief specifics about the subject's participation requirements.*

In cases where the research involves deception, include the following statement: “Not all information about this study can be revealed at this time.”

If you have any questions about this research, please contact [*insert contact info for Investigator*].

**Risks and discomforts to you if you take part in this study**:

**The benefits to you if you take part in this study**:

**What will you receive for taking part in this study**?[*Note if subjects are not to be compensated for participation*]

**What will happen to the information collected in this study**?*Describe how study records are kept, with special attention to how private information will be kept confidential.*

The information collected will be kept confidential as much as law permits.

**What rights do you have when you take part in this study?** Participation in this research is voluntary. Deciding not to take part or stop participating in this research will result in no penalty, fine, or loss of benefits that you otherwise have a right to. If you have questions about your rights as a research subject or if you wish to report any harm, injury, risk, or other concern, please get in touch with the Clarkson University Institutional Review Board (IRB) for human subjects research at irb@clarkson.edu or (315) 268-6475

*Describe what will happen if subjects withdraw partway through the study, including using their data and/or plans for compensation.*

**Conflict of Interest**:The researchers have no financial interest in performing this study. [*or otherwise.*]

**COVID-19:** The study team has taken all CDC-suggested safety measures to minimize exposure to SARS-CoV-2 (the cause of COVID-19).

**Informed Consent**:Please sign below to show you have had the purpose of this research explained and you have been informed of what to expect and your rights. You should have all your questions answered to your satisfaction. Your signature shows that you agree to take part in this research. By signing below, you also attest that you are at least 18 years old. You will be given a copy of this consent form for your records**.**

If you are recruiting subjects under 18 or not legally allowed to consent to research, don't hesitate to get in touch with the IRB for alternate informed consent/assent documents.

**Signature of volunteer: Date:**

**Signature of researcher**

**obtaining informed consent: Date:**

***Optional Items:*** *If you need any elements below, copy and paste the section heads above the signature line and complete them. Delete all of the sections below you're not using.*

**In addition to the Primary Investigator listed above, the following person has been authorized to obtain Informed Consent:**

**Alternate treatment options:**

**Concerns about pregnancy and fertility:**

**Times when the researchers may stop allowing you to be part of this study:**

**What happens if you withdraw from this study:**

**Costs to you if you decide you want to withdraw from this study:**

**The researchers will tell you about new information that affects you in this study:**

**The number of subjects who will take part in this study**

[*For research involving patients, include additional HIPAA authorization elements*]

**What protected health information (PHI) will be used:**

**Your PHI may be shared with:**

**If you choose to take back authorization to use your PHI**, information already collected may still be used.