Clarkson College Institutional Review Board Application Manual

This manual is intended as a guide to implement Clarkson College Policy OG-8:

Institutional Review of Research Involving Human Subjects Policy

(Revised July 2018)

Clarkson College

Prepare to be the best.

Contents

ACKNOWLEDGEMENTS

Clarkson College gratefully acknowledges College of Saint Mary and the University of Nebraska Medical Center for granting use of their IRB materials to assist in the design of this manual.

SECTION 1: OVERVIEW OF INSTITUTIONAL REVIEW BOARD AT CLARKSON COLLEGE

"Investigators must balance their interest in gathering data and answering research questions with society's mandate to protect the rights and safeguard the welfare of research participants. Society has granted a conditional privilege to perform research on human beings…the condition is that it must be conducted in a way that puts the rights and welfare of human participants first" (Gottesman, 2004, p. i).

Clarkson College created its Institutional Review Board (IRB) during the 2003-2004 academic years. The IRB is composed of at least five members from a variety of disciplines with experience and preparation in research as well as community members. The members determine the viability of proposed research in accordance with institutional standards, professional practice, and applicable law. At least one member's primary concern is scientific, one is non-scientific, and one is not affiliated with Clarkson College. The IRB reserves the right to consult with other experts when a research proposal is beyond the scope of the expertise of the current board members.

IRB Responsibilities

"If there is any element of research in an activity, that activity should undergo review for the protection of human subjects"(Belmont, p.5). In light of that directive, the IRB is responsible for the review of all research performed at Clarkson College in order to ensure that professional, ethical, and legal standards concerning the use of human participants are being followed. The Standards are those in Title 45 Code of Federal Regulations, Part 46: Protection of Human Participants (45 CFR Part 46) and include the ethical principles of The Belmont Report. In order to approve research covered by this policy, the IRB shall determine that risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk. In addition, risks to subjects must be reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result (46.111). Privacy and confidentiality must be protected, and data must be monitored to ensure subject safety. Attention must be paid to subjects' vulnerability to coercion or undue influence in making an informed decision. Additional safeguards must be provided for vulnerable populations including children, veterans of military service, prisoners, and individuals with impaired decision-making ability.

The Clarkson College Institutional Review Board will not approve research that is deemed more than minimal risk to participants and will not approve any research involving animals.

The IRB meets monthly to review applications submitted by the submission deadline. The IRB does not meet in August.

The IRB reviews the application for completeness, accuracy, and coherence. If the application is not approved, the IRB may refer it to the Research Analyst (RA) to consult with the Principal Investigator (PI), who submits the revised application (with all changes highlighted) to the IRB.

SECTION 2: DIRECTIONS FOR CLARKSON COLLEGE IRB APPLICANTS

1. Review the IRB submission deadlines on the Clarkson College IRB webpage.
Choose a target date and allow plenty of time to complete the IRB application-and-approval process (starting two semesters prior to semester of graduation is recommended). The PI may consult with the RA at any time; however, after presenting the proposal to Research Forum (RF), the PI must submit an application draft to the RA for review and recommendations. Researchers continue revising and editing the application until the PI decides it is ready to submit to the IRB. See the IRB link on the College website for all presentation, review, and submission deadlines.

2. Complete CITI ethics training.
See Section 3: Human Participants Protection Education for more information.

3. Determine the site for the data collection, as that will affect which forms you will complete.
Researcher(s) must contact the IRB Committee at the institution where they are collecting data to determine if the healthcare institution requires an alternative IRB application or if the Clarkson College application can serve for their review and approval process.

Investigators are responsible for learning and complying with the procedures required **prior to** data collection at another institution. Final Clarkson College IRB approval cannot be granted without assurance from that institution that the study methodology has been reviewed and that permission is granted for data collection. Other institutions' applications cannot serve as the Clarkson College Application; applications to the Clarkson IRB must be on the Clarkson College IRB application form.

For a Clarkson College student employed at Nebraska Medicine seeking to do a study there, the PI will work with the student to obtain, complete and submit the Employee Request for Electronic Health Data form to clinicalnursingresearch@nebraskamed.com. Faculty and staff seeking to do a study at Nebraska Medicine should contact them directly at that address.

4. Review all three of the Level of Determination checklists.
Start by reviewing all three checklists beginning in Section 4 to determine the level of IRB review that fits your research. Note: *In each Level of Determination, you must check all Categories that apply.* If you are applying for Expedited review, be sure to mark any appropriate Exempt categories as well.

5. A Student Investigator (SI) must work closely with the research advisor.
The Doctoral Committee Chair, PI, or SI presents the study proposal at Research Forum. The Chair or PI reviews the application with the RA, reads the final draft (including the appendices), certifies that it is ready for IRB review, and submits it to the IRB.

6. Complete all sections of the Clarkson College IRB application.

a. Complete each section fully; do not delete sections. Mark sections that do not apply with N/A, followed by a brief explanation.
b. Make sure all components of the research design are organized, clearly, and based on solid research practices.

c. Adhere to all formal writing conventions and format the text in accordance with the most recent edition of the APA Style Manual.
d. Professional and academic writing standards apply, so carefully proofread each section.
e. Include all necessary consent forms; see Consent Form Guidelines in Section 6, and submit consent forms on College letterhead stationery.
f. Prior to IRB submission, submit all surveys the RA for review, and include all data collection tools with the application. Following approval, submit online surveys to the Coordinator of Quality Assurance for formatting.
g. Include all letters of permission from the study site(s) with the application, and state the role of the investigator at the site (e.g., staff or manager).
h. Complete the application fully. Incomplete applications will be returned and may delay your research timeline and progression in your program of study.

7. The PI submits the completed application to the IRB by the submission deadline. The IRB recommends that the PI submit the application a semester before graduation.

8. Remember that fully completed applications are scheduled for review at the next IRB meeting. Within 7-10 business days, the chair notifies the PI of the IRB decision. For approved applications, the chair sends the IRB# and approval and expiration dates in a letter. For applications that are not approved, the chair notifies the PI that approval is pending further information or revisions that may entail consultation with the RA. Depending on the Level of Determination, revised applications are reviewed before or at the next scheduled meeting.

9. After the application is approved, add the IRB# and approval and expiration dates to the consent document and distribute it with the Rights of Research Participants to the potential participants.

10. The PI submits any study extension and change-in-protocol requests to the IRB chair using the Extension/Protocol Change Request Form found in Section 9

11. The PI submits the Closing the Study Form found in Section 10 to the IRB chair within 30 days of study completion.

12. Research already approved by another IRB may be subject to further review and approval or disapproval by the Clarkson College IRB. Any application that the Clarkson College IRB reviews must be submitted on the Clarkson College IRB application form.

SECTION 3: HUMAN PARTICIPANTS PROTECTION EDUCATION

Clarkson College requires all investigators, study personnel, and protocol coordinators engaged in human subject research to undergo training in the protection of human subjects. Each IRB applicant must complete the Collaborative Institutional Training Initiative (CITI) and submit an e-copy of the completion certificate with the application.

a) Go to the CITI website: http://www.citiprogram.org

b) Click on Register; this will take you to another page, where you will see the Participating Institutions box. In the box, type in UNMC/UNO and continue to Registration.

c) At the Registration page, type in the appropriate information to create your CITI Program username and password.

d) Record your username and password in a safe place, for you will need them to access the course to complete the modules, which can be done one or more at a time.

e) Continue to the next step, where you will be asked if you want to participate in a survey and if you want to earn Continuing Education Units (CEUs), which are an additional cost to you.

f) In the next step, complete profile information and continue to the next page, where you will select Human Subjects Research. (Do not complete the Good Clinical Practice or HeSC (Human Embryonic Stem Cells) courses unless you have been asked to do so.)

g) In the next page, you will be asked if you have previously taken the Basic Course in the Protection of Human Research Subjects. If you have never completed CITI training before, choose the **Basic Course**.

h) Then you will be asked which Course you need to take based on which Group you are associated with. Select **Group 1: Biomedical Research Course** and continue to Finalize Registration. Note: All Nebraska Medicine affiliates and partners (including Clarkson College faculty, students, and staff) must complete **Bio-Medical and Social/Behavioral (SBE)** training.

i) You will receive an email from www.citiprogram.org to complete registration and (using your username and password) access the website from the link sent in the email.

j) Follow the directions on the screen to complete the training. Most modules are brief, and you may re-take the quizzes if you are not satisfied with your score.

k) Save and print out your Course Completion Record when you have completed the Bio-Medical and SBE courses. CITI sends your Record to UNMC's Office of Regulatory Affairs, which houses but does not send to the College. You are responsible for sending your Record to IRB@clarksoncollege.edu. The IRB office cannot not review your application without proof that you completed the training.

Note: Certification lasts three years.

SECTION 4: LEVEL OF DETERMINATION CHECKLISTS

TITLE OF STUDY_____
PRINCIPAL INVESTIGATOR and Co-INVESTIGATOR(S)_____
DATE_____

***Note**: If you determine that your study qualifies for exempt review, complete this checklist and submit a copy with your IRB Application. (Exempt Review means the study must still be reviewed, but not by the full IRB review process). The applicant must request exemption of the research, including the research protocol, from full Board review by submitting the appropriate application and noting at least one or more of the categories of exemption as described below. The IRB, upon review of the application, can determine that the application is not appropriate for the exemption.*

LEVEL OF DETERMINATION CHECKLIST #1 EXEMPT REVIEWS

A study may qualify for an exempt IRB review if it fits into one of the categories outlined below**.**
Check all those that apply:

____Category 1: 45 CFR 46.101(b)(1)

Research is conducted in established or commonly accepted educational settings, involving normal educational practices, such as

(a) research on regular & special education instructional strategies, or
(b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

____Category 2: 45 CFR 46.101(b)(2)

FOR ADULTS: Research involving the use of educational tests (e.g. cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or the observation of public behavior UNLESS

(a) data obtained are recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects;
(b) any disclosure of the human subjects' responses would place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation; and/or
(c) the research deals with sensitive aspects of the participant's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol.

____Category 3: 45 CFR 46.101(b)(3)

FOR SUBJECTS WHO ARE ELECTED OR APPOINTED PUBLIC OFFICIALS OR CANDIDATES FOR PUBLIC OFFICE: Research involving the use of educational tests (e.g. cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or the observation of public behavior.

____Category 4: 45 CFR 46.101(b)(4)

Research involving the collection or study of existing data, documents, records, or specimens if:

(a) the sources are publicly available; or

(b) the information is recorded by the investigator in such a manner that subjects cannot be identified, either directly or through identifiers or codes linked to the subjects. **Note 1**: "Existing" means the data have already been collected for some other purpose at the time the research is proposed.

"Publicly available" means available to the general public, with or without charge.

Note: Under condition (b) above, investigators with legitimate access may view identified information, but may not record identities, identifiers, or codes that link private information to individual subjects. Even a brief recording of identifiers or codes disqualifies the exemption. This category excludes studies of publicly authored documentation such as newspaper articles, novels, works of art, or a literature review.

____**Category 5: 45 CFR 46.101(b)(5)**

Research and demonstration projects that are conducted by or subject to the approval of supporting agencies, and which are designed to study, evaluate, or otherwise examine:

(a) public benefit or service programs;
(b) procedures for obtaining benefits or services under those programs;
(c) possible changes in or alternatives to those programs or procedures; or
(d) possible changes in methods or levels of payment for benefits or services under those programs.

____**Category 6: 45 CFR 46.101(b)(6)**

Taste and food quality evaluation and consumer acceptance studies,

(a) if wholesome foods without additives are consumed or
(b) if a food is consumed that contains a food ingredient at or below the level, and for a use, found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration and approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Exempt categories do not apply to research involving deception of subjects, sensitive behavioral research, or to research involving children, pregnant women, military service veterans, prisoners, fetuses, individuals who are decisionally impaired including psychiatric patients, and other subject populations determined to be vulnerable

NOTE: Even if your initial determination is "Exempt," review the following checklists for "Expedited" and "Full" reviews. If ANY of those characteristics apply, your study is NOT "Exempt."

LEVEL OF DETERMINATION CHECKLIST #2: EXPEDITED REVIEWS
Note: If you determine that your study qualifies for expedited review, complete this checklist and submit a copy with your IRB Application.

Expedited Review by the IRB is provided for research which involves no more than minimal risk, no vulnerable populations, or review of minor changes in previously approved research or research protocols. For the review covered by the regulations 45 CFR 46.110, the IRB will determine that all of the requirements are satisfied.

Minimal risk as defined by 45CFR 46.102(I) http://www.hhs.gov/ohrp/ 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 the performance of routine physical or psychological examinations or tests. A study may qualify for an expedited IRB review if it fits into one of the categories outlined below.

Check all those that apply:

____**Category 1:**
Studies involving the recording of information so that participants are identifiable (audio or video recordings) require at least an expedited review

____**Category 2:** .
Studies using instruments, questionnaires, or surveys that have been generated or modified by the researchers require an informed consent and at least an expedited review.

____**Category 3:**
Obtaining data from subjects 19 years or older using routine noninvasive procedures

____**Category 4:**
Analysis of video or audio recordings

____**Category 5:**
Moderate exercise by healthy volunteers

____**Category 6:**
Studies involving collection of existing unidentifiable specimens by non-invasive means.

____**Category 7:**
Studies of individual or group behavior, or characteristics of individuals, without manipulating subjects' behavior and in a manner that does not cause stress to subjects

NOTE: Even if your initial determination is “Expedited”, be sure to complete the checklist for “Full” review. If ANY of those characteristics apply, your study is NOT “Expedited”.

LEVEL OF DETERMINATION CHECKLIST #3: FULL REVIEWS
Note: If you determine that your study requires full review, complete this checklist and submit a copy with your IRB Application.

A full review is indicated under the following conditions. **Check all those that apply**. If you check even one category, your proposal will require a full IRB review

____**Category 1:**
Surveys or interview questions whose answers, if known outside the research, would create legal liability or adverse financial or employment consequences for the participant

____**Category 2:**
Surveys of interviews involving questions dealing with very personal and sensitive behavior, such as sexual behavior, alcohol or drug use, or if subjects may be placed at risk for criminal or civil penalties or would otherwise suffer embarrassment or humiliation if the subjects' responses were to become known outside the research.

____**Category 3:**
Studies that include members of a *protected population* in the pool of participants, including but not limited to children under the age of majority (18 in Iowa and 19 in Nebraska), veterans of military service, persons who are decisionally impaired, fetuses, pregnant women, prisoners, and anyone else who cannot provide informed consent

____**Category 4:**
Studies involving deception or if the subjects are not fully informed of the purpose and procedures of the study

____**Category 5:**
Studies involving support from non-university sources requiring full IRB approval

____**Category 6:**
Likelihood of risk or substantial stress or discomfort to the subject

____**Category 7:**
Procedures that may potentially threaten or embarrass subjects

____**Category 8:**
Personality tests, inventories or questionnaires of a personal and sensitive nature where subjects' identities will not be anonymous to the researcher

____**Category 9:**
Healthcare procedures not conducted for the primary benefit of the subject

____**Category 10:**
Diagnostic or therapeutic assessments, interventions, or measures that are not standard, generally acceptable, or common practice

____Category 11:
Exposure to surgery, drugs, or chemical agents

____Category 12:
Exposure to electromagnetic radiation (X-rays, microwaves), lasers, high frequency sound waves

____Category 13:
Collection of blood samples or other body fluids in any amount

NOTE: If there is any doubt of the procedures or participant matter of any Exempt study, an Expedited or Full Review Application should be submitted to the IRB.

NOTE: Studies involving more than minimal risk to participants will not be approved for study at Clarkson College.

(Level of Determination information modified from Belmont University Institution Review Board: http://www.belmont.edu/irb/, Retrieved 4/04/2011)

SECTION 5: IRB GUIDELINES FOR APPLICATION

A. The IRB reviews applications with specific attention to the following:

1. The investigator's professional or personal status or role at the study site.
2. Purpose, Background, and Rationale for the study.
3. Descriptions of the study site(s), potential population, and recruitment and subject selection.
4. Quality of research design.
5. Detailed, step-by-step (bulleted) methodology and procedure for data collection.
6. Process, procedures, and documentation for written or implied informed consent and, if applicable, assent and request for waiver of written consent.
7. Assessment of risks and benefits, including protection against risks and compensation, which the informed consent letter or invitation will mirror.
8. Readability statistics on all communications to potential participants.

B. The IRB reviews applications according to the Common Rule (Federal Regulations 45, Part 46, section 111) with particular attention to the following:

1. *Risks, physical and mental harms to subjects are minimized*:
   (a) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
   (b) Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
2. *Risks to subjects are reasonable* in relation to the anticipated benefits (risk/benefit ratio), if any, and the importance of the knowledge that may reasonable be expected to result. Only consider those risks and benefits that may result from the research. Do not consider long- range effects of applying knowledge gained in research (for example, the possible effects of the research on public policy) as among those research risk that fall within the purview of responsibility.
3. *Selection of subjects is equitable*. Take into account the purposes of the research and the setting in which the research will be conducted. Be particularly cognizant of the special problems of research involving vulnerable population, such as children, prisoners, pregnant women, mentally disable persons, or economically or educationally disadvantage persons.
4. *Informed consent will be sought* from each prospective subject or the subject's legally authorize representative, in accordance with, and to the extent required by **§46.116**.
5. *Informed consent will be appropriately documented*, in accordance with, and to the extent required by **§46.117**.
6. When appropriate, the research plan makes adequate provision for *monitoring the data collected to ensure the safety of subjects*.
7. When appropriate, there are *adequate provisions to protect the privacy of subjects* and to maintain the confidentiality of data.
8. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, *additional safeguards* have been included in the study to protect the rights and welfare of these subjects.

SECTION 6: DEFINITION OF TERMS FOR THE IRB APPLICATION

Read the directions for application (p. 4) and complete the levels of determination checklist (p. 7) before completing the IRB application form on the IRB webpage.

Title of Study: Consult the current APA Manual for proper wording and punctuation.

Study Site(s): Describe specifically where the study will be conducted, and describe methods used to seek site approval. Include letters of agreement with agencies or locations in the appendices.and methods used to seek site approval

Co-Investigator's Role or Status at the Study Site: Identify your relationship with potential participants and your professional or personal role at the site.

Problem Statement (e.g., thesis statement, PICO, or PICOT): In one concise sentence, state the problem or issue, the current remedy or solution, your proposed remedy or solution, and the outcome(s) you hope to accomplish.

Purpose of the Study: In a few sentences, describe the purpose of your study. This section serves as the springboard for the following section. The Purpose should flow from the Problem.

Background and Rationale: Provide background for context and support for the Purpose with clear reasons for the study, including why this research is needed. If applicable, state the research question(s) and hypotheses. Finally, note the following guidelines:

a. An exempt review requires a summary in APA style with *at least two* relevant citations and a reference page.
b. An expedited review requires a summary in APA style with *at least four* relevant citations and a reference page.
c. A full review requires a summary in APA style distilled from the investigator's review of the literature. This summary includes *five or more c*itations and a reference page. If a grant application or other type of proposal exists, simply summarize the literature and attach the proposal as an appendix to the application.

To protect human subjects, Federal regulations require that an IRB consist of diverse members from a wide variety of backgrounds, including providers, scientists, non-scientists, and members of the community. Your goal is to communicate clearly, so spell out acronyms, define medical jargon, and use ordinary language. Just as with your subjects, your readers may not be providers or experts in your field.

Population and Characteristics: Describe the characteristics of the potential population.

Age Range: Give the age range of potential participants. For adult participants, use the legal age of consent in the state(s) of the study site(s).

Method of Subject Selection: Describe the specific inclusion and exclusion criteria, including screening methods used to screen subjects. Provide reasons for participation restrictions such as

gender, race, religion, or age. Describe all techniques used to recruit individual participants, and. include all recruitment materials such as phone scripts, emails, and flyers in the appendices. Indicate your projected, hoped for, or expected minimum and maximum number of participants. If you are using more than one site, provide the minimum and maximum number of anticipated participants for each site.

Description of Research Design, Methodology, Recruitment Procedures, and Collection of Data: In complete sentences, use bullets or numerals to describe the research design,if you will use a quantitative, qualitative, or mixed methods approach, and note how you will ensure the validity and reliability of your study.

Detail each step in your Methodology, outlining study and recruitment procedures; a sequential description of what subjects will be asked to do; assignment of subjects to various arms of the study, if applicable; and how and in what form data will be collected. In the active voice, state *who* will recruit and consent subjects, *who* will carry out all procedures or measurements, and *who* will collect the data and keep them secure. Include the number and duration of contacts with each subject, outcome measurements, and follow-up procedures.

In the Methodology, describe who will be obtaining consent (or permission) and from whom. Include description, as relevant, of any waiting period between the initial consent discussion and obtaining consent, and steps that will be taken to minimize coercion or undue influence. If children will be enrolled as subjects, describe the provisions for obtaining parental permission and assent of the child if appropriate. If decisionally impaired adults are to be enrolled, describe the provision for obtaining surrogate consent from a legally authorized representative (LAR).

Applicants must include the Informed Consent Form(s) with the application in the appendices.

Note: Flawed or weakly designed studies that are deemed sub-standard will not be approved.

Ultimate Distribution and Disposition of the Data Collected: List the entities (Graduate Symposium, for example) with whom study findings will be shred. Study data must be kept securely for up to 3 years. State how you will store and ultimately dispose of all data collected.

Risk/Benefit Assessment: This section breaks down into several sections in which you evaluate and describe all potential risks and benefits to subjects and society. The evaluation of risks and benefits are critically important in the fully informed consent process (see Section 7) and must also appear in the invitation to participate.

Compensation for Participation: Your assessment of benefits also includes any tangible compensation for subjects who consent to take part in your study. Compensation may include cash, gifts, gift cards, coupons, reimbursements, educational materials, and food or drink.

Steps to Protect Confidentiality and Privacy: Describe how you will ensure that the confidentiality and privacy of your subjects are protected. If you collect data or identifiers that may link data to individual participants, justify why collecting these data is necessary. If data collected will be used and reported in the aggregate, state that here and in the consent form (see Section 7).

SECTION 7: IRB CONSENT FORM GUIDELINES

DEVELOPING THE INFORMED CONSENT FORM

Formatting: Consent forms must be printed with the institution's letterhead, submitted suitable for reproduction (printed single sided), and typed in 12-point typeface (Times New Roman or Arial) with one-inch margins. Include a line for the IRB number (assigned upon IRB approval) in the upper left, the page number in the upper right, and, if applicable, a line for the participant's initials in the lower right.

Composing the Consent Form:

1. **Second-Person Language:** Except where noted below, use direct address (*you*) to personalize the consent form and emphasize the voluntary nature of the potential subject's decision.

2. **Readability:** Make the form easy to understand with ordinary words and simple sentences. Spell out acronyms, and define any medical and scientific jargon. Regardless of the degree level of your audience, write at the 8th-grade level. The Flesch-Kincaid Grade Level available on Microsoft can determine the readability of letters, fliers, and surveys. Report these levels in the Readability Statistics section of the application. See References for more information.

3. **Completing the Sections:** Keep each section focused and free of repetition. The goal is to give full information without cluttering it with redundant or immaterial information. As you write, ask yourself, "Exactly what do potential subjects need to know and understand to make a fully informed decision?"

4. **Consent Form Templates:** The following pages provide several formats to organize written (signed) and implied consent forms for various populations. Rather than copy and paste template language, write the invitation in your own professional writing voice as you make sure to include all essential pieces of information for a fully informed decision.

5. **Under-Aged Participants:** Adult participants must be at least 19 years of age in Nebraska and Alabama and at least 18 years of age in all other states. If your study involves under-age participants, use the Adolescent Assent Form and the Parent and Child Consent Forms.

6. **Waiver of Written (Signed) Consent**: You may request a waiver of written or signed consent but must justify it in a completed Request of Waiver of Written Consent (below) submitted with the application.

7. Rights for Research Participants: Each participant in the study must receive a hard copy or e-copy of the following form. You may adapt the form to suit the needs of your population.

The Rights of Research Participants

As a research participant at Clarkson College, you have the following rights:

1. **You have the right to be told everything you need to know about the research study *before* you are asked to decide whether or not to take part.** The research will be explained to you in a way that assures you understand enough to decide whether or not to take part.

2. **You have the right to freely decide whether or not to take part in the research.**

3. **You have the right to decide not to be in the research or to stop participating at *any* time.** Your decision will not affect your relationship with the investigator(s) or with Clarkson College.

4. **You have the right to ask questions about the research at *any* time.** The investigator(s) will answer your questions honestly and completely.

5. **You have the right to know that your safety and welfare will always come first.** The investigator(s) will display the highest possible degree of skill and care throughout this research. Any risks or discomforts will be minimized as much as possible.

6. **You have the right to privacy and confidentiality.** The investigator(s) will treat information about you carefully and will respect your privacy.

7. **You have the right to keep all the legal rights that you have now.** You are not giving up any of your legal rights by taking part in this research study.

8. **You have the right to be treated with dignity and respect at all times.**

The Clarkson College Institutional Review Board (IRB) is responsible for assuring that your rights and welfare are protected. If you have any questions about your rights, contact the IRB at IRB@clarksoncollege.edu or 402.552.3100.[1]

[1] Adapted from the University of Nebraska Medical Center IRB.

CLARKSON COLLEGE WRITTEN (SIGNED) CONSENT FORMS

TEMPLATE FOR ADULT CONSENT FORM

Date:

Title. Using all capital letters and bold font, state the title just as it appears on the application.

IRB # (assigned upon approval) **Approval Date:** **Expiration Date:**

Salutation. Dear [role that makes them eligible to participate, such as Dear Nursing Educator:]

Introduction. Introduce yourself and your role (e.g., student investigator and program of study) and invite the prospective participant to take part in the study. For example,

> You are invited to take part in this research study. The information in this form is meant to help you decide whether or not to take part. If you have any questions, please ask.

Reasons why they are asked to be in this research study. Explain briefly and simply why the prospective participant is eligible. As appropriate, include major inclusion criteria. For example,

> You are being asked to be in this study because you are either an employee or a supervisor who has been working the night shift for at least one year.

Body paragraphs. State the purpose of the study with a brief background to help the potential subject understand why the research is being done. Use objective, unbiased language without reference to the potential participant. For example,

> People who work at night use different strategies for staying awake during their shifts. These methods are likely to be different between employees and supervisors because of their different levels of responsibility. This research is designed (1) to better understand these strategies and (2) to determine whether supervisor strategies could be successfully used by employees.

Description of what will be done. Describe the steps of the study chronologically using simple language and short sentences. For readability and visual appeal, avoid paragraphs more than 7 lines. Include *when* the research will occur, *where* it will occur, *what* will happen, and *how* much time will be needed.

If it is important for them to know in making an informed decision that the study involves randomization, explain that they will be assigned by chance to a study group and explain the study groups. List any other requirements for subjects, such as follow-up interviews or surveys.

Write from the point of view of potential subjects so they have everything they need to make a fully informed decision.

Potential risks. The most serious and common risks should be addressed first, followed by disclosure of uncommon and less serious risks in a separate paragraph, if warranted. Risks common to social science and behavioral research may include loss of confidentiality and

emotional or psychological distress. Stating that there are no known risks for participating in the research study does not preclude describing possible risks as listed in the application.

Protection against risks. If the research requires collection of sensitive information (social, financial, legal, or other) from participants, include a brief description of the precautions you will use to protect that data. If you will share or distribute information from this study to other entities, including study site management, you must disclose that to potential participants for fully informed consent. The following standard language can be used:

> The only persons who will have access to your research records are the study personnel, the Institutional Review Board (IRB), and any other person or agency required by law. The information from this study will be presented at Graduate Symposium [add any other entities] and may be published in scientific journals or presented at scientific meetings. However, reasonable steps will be taken to protect your privacy and the confidentiality of your study data, and your identity will be kept strictly confidential.

Potential benefits to subjects. If direct participant benefits can reasonably be anticipated as a result of participation, describe these possible benefits. Using the conditional "may," add that they may not get any direct benefit from being in the research study. On the other hand, if direct benefits to the participant are not anticipated, you state, "You are not expected to get any direct benefit from being in this research study."

Potential benefits to other people. State the possible benefits of the study to society in terms of the advancement of knowledge and/or ultimate possible benefits to those in the prospective participants' position.

Alternatives to being in this research study. In reasonable detail, describe alternatives the potential subject has to being in the study. For example, "Instead of being in this research study, you can choose not to participate."

Cost of participation. State the commitment in time and any financial obligations the participant will incur as a result of participation. If there are no financial obligations, you can state, "There is no cost to you to be in this research study."

Compensation for participation. If the subject will receive any monetary or tangible compensation or reimbursement for participating, state the amount of compensation and conditions for payment. If no compensation is provided, you can write, "You will not be paid or compensated for being in this research study."

Participant problem during the study. Your estimation of risk determines what additional information you will include. Clarkson College will not approve studies that pose greater than minimal risk to subjects. For studies classified as minimal risk, you can use the following:

> Your welfare is the major concern of every member of the research team. If you have a problem as a direct result of being in this study, you should immediately contact one of the people listed at the end of this consent form.

Rights of research participants. Inform potential subjects of the following:

> You have rights as a research participant. These rights have been explained in this consent form and in "The Rights of Research Participants" that you have been given. If you have any questions concerning your rights, talk to the investigator(s) or contact the Clarkson College Institutional Review Board (IRB) at 402.552.3100.

When a potential subject decides not to participant or when a subject decides to stop participating. You can use the following standard sentences:

> You can decide not to be in this research study, or you can stop being in this research study at any time before, during, or after the research begins. Deciding not to be in this research study or deciding to withdraw will not affect your relationship with the investigator(s), Clarkson College, or [name(s) of any other sites or entities].
>
> You will not lose any benefits to which you are entitled. If the research team gets any new information during this research study that may affect whether you would want to continue being in the study, you will be informed promptly.

Informed consent. Tell potential participants that if they choose to participate, they should [do whatever you are asking them to do] and how long participation will take (refer to your *Description of Methodology*). Remind them of the following:

> Participation is strictly voluntary, and your responses or decision not to respond will not affect your relationship with [*Study Site(s)*], Clarkson College**,** or any other entity. Your completion and submission of the [data tool] indicate your fully informed consent to participate.[2] You may withdraw at any time by not completing and submitting the survey (or ending the interview). This study does not cost you in any way, except the time spent completing the [tool or interview].
>
> Please read *The Rights of Research Participants* below. If you have questions about your rights as a research participant, call the Clarkson College IRB Board at 402-552-3100 or email IRB@clarksoncollege.edu. If you have comments, problems**,** or questions about the study, contact the researcher(s), and thank you for considering our invitation to participate.

Documentation of informed consent. You can use the following standard paragraph:

> You are freely making a decision whether to be in this research study. Signing this form means that (1) you have read and understood this consent form, (2) you have had the consent form explained to you, (3) you have had your questions answered, and (4) you have decided to be in the research study. If you have any questions during the study, contact one of the investigators listed below. You will be given a copy of this consent form and "The Rights of Research Participants" to keep. If you are [add legal age] years of age or older and agree with the above, please sign below.

Signature of Participant: _____ Date and Time: _____

[2] Alter the wording for participation in a scheduled live interview.

Participant's initials. Add a line at the bottom of each page for a participant to initial to show they have read each page.

Then include a statement from the investigator(s):

> My signature certifies that all the elements of informed consent described on this consent form have been explained fully to the participant. In my judgment, the participant possesses the legal capacity to give informed consent to participate in this research and is voluntarily and knowingly giving informed consent to participate.

_____ _____
Signature of Investigator Time and Date

Authorized Study Personnel. Identify all personnel authorized and CITI-certified to document consent as listed in the IRB application. Use the following subheadings: Principal Investigator, Co-Investigator, and Participating Personnel. Include daytime phone numbers and emails for all listed individuals.

Principal Investigator: _____ Phone: _____ Email: _____

Co-Investigator: _____ Phone: _____ Email: _____

Participating Personnel: _____ Phone: _____ Email: _____

.

IMPLIED INFORMED CONSENT FORM[3]

When research is being done using online or handout tests and surveys or when consent is being sought for a scheduled phone interview, an alternative to the standard written (signed) informed consent document can be used. However, investigators must carefully explain the rationale for using this alternative in the IRB application, for it serves as the formal invitation to potential subjects. Use Clarkson letterhead for all paper and e-correspondence to outside entities and carefully proofread to make sure that language, spelling, grammar and punctuation are professional and correct.

The Implied Informed Consent Form contains all the required components of the standard informed consent but entails *implied*, not signed, consent. With survey research, those invited can decline participation by not completing and submitting the test, survey, or questionnaire or by submitting a blank tool. They can also end participation by halting completion of the tool at any time. A statement addressing this option is required in the Implied Informed Consent Form.

With phone interviews, participants can decline to schedule an interview when contacted or can end their participation at any time during the interview. At the beginning and throughout the interview, researchers must acknowledge the participant's right to end it at any time.

The *Rights of Research Participants* must be provided as part of the Implied Informed Consent Form**.** Note that all online surveys must be formatted by and distributed through the Office of Quality Improvement and Institution Effectiveness at Clarkson College. Online data will be stored in that Office also. The following template includes suggested language addressed directly to potential participants, but it should be adjusted (when appropriate).

TEMPLATE[4] FOR INVITATION AND IMPLIED INFORMED CONSENT FORM

Date:

Title of the study in all capital letters and bold font as it appears on the application.

IRB # (tba) **Approval Date:** **Expiration Date:**

Salutation. Dear. . . .

Introduction. You are invited to take part in a research study because you are (see *Population and Characteristics* and/or *Inclusion Criteria*). The purpose of this study is to (see *Purpose of Study*). This research study is being conducted as part of the requirements of my (degree) program at Clarkson College.

Description of what will be done from the point of view of your potential subjects so that they know everything they need to know to make a fully informed decision.

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[3] This version of a fully informed consent derives from the standard written consent form above. To make sure you include all pieces of information for informed implied consent, study the standard form first!

[4] Rather than cut and paste template language, investigators should use their *own* writing voice as they incorporate these elements in their invitation to potential subjects to participate in the study.

In 1-3 lines, describe the step-by-step process using language that your audience will understand (see *Description of Methodology*). Avoid long paragraphs and consider using subheadings to enhance organization and readability. State *when* and *where* the research will occur, *who* will do *what*, *what* will happen and *what* they will do, and *how* much time will be needed.

To make a fully informed decision, if it is important for potential subjects to know that the study involves randomization, explain that they will be assigned by chance to a study group and explain the study groups. Include all requirements for participation, such as follow-up interviews, surveys, or tests.

Risks. There is no compensation or known risk associated with participation. Potential risks include (see *Potential Risks*) and will be protected by (see *Protection Against Risks*). Please note that your responses will be used for research purposes only and will be strictly confidential. No one at Clarkson College or [(*Study Site(s)*] or any other entity will ever associate your responses with your name or email address. The aggregate information from this study will be shared with (list entities in *Ultimate Distribution of Data)* and may be published in scientific journals and presented at professional meetings.

Benefits. You may receive no direct benefit from participating in this study (if you expect them to receive a direct benefit, state what that is**)**, but the information gained may help to (see *Potential Benefits to the Subject* and *Potential Benefits to Society*). You may receive access to the aggregated results of this study by (explain how).

Consent. If you decide to participate**,** please (do whatever you are asking them to do)**,** which should take approximately (see *Description of Methodology*) to complete. Your participation is strictly voluntary. Furthermore, your responses or decision not to respond will not affect your relationship with [*Study Site(s)*], Clarkson College**,** or any other entity.

Your completion and submission of the (survey, pre-test, post-test, questionnaire) indicate your fully informed consent to participate (alter wording for participation in a scheduled phone interview). You may withdraw at any time by not completing and submitting the survey (or ending the interview). This study does not cost you in any way, except the time spent completing the (survey, pre-test, post-test, questionnaire, interview).

Please read *The Rights of Research Participants* below. If you have questions about your rights as a research participant, call the Clarkson College IRB Board at 402-552-3100 or email IRB@clarksoncollege.edu. If you have comments, problems**,** or questions about the study, contact the researcher(s), and thank you for considering our invitation to participate.

If you are (age of majority in state you are conducting research) years of age or older and agree to the above**,** please proceed to (link to survey) to begin.

Sincerely,

Principal Investigator(s)'s name(s)	Co-Investigator(s)'s name(s)
Principal Investigator(s)'s phone/email	Co-Investigator(s)'s phone/email

REQUEST FOR WAIVER OF WRITTEN INFORMED CONSENT

When using Implied Informed Consent, or under other special circumstances, investigators must request a waiver to obtain standard written (signed) informed consent from research subjects. This type of waiver will be given only when there are compelling reasons to do so.

Those seeking a waiver must complete a Waiver of Written (Signed) Informed Consent Request for fully informed consent obtained orally or as implied by delivering and discussing a fact sheet, through an Implied Informed Consent form, and/or by incorporating implied consent into the survey or test. Include a copy of the fact sheet, invitation to participate, Implied Informed Consent, script of the invitation to participate orally, or other incorporated document.

WAIVER OF WRITTEN (SIGNED0 CONSENT FORM

Justification for a Waiver. The IRB may waive the requirement for written (signed) consent if either of the following is true:

a. The only record linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality (e.g., study topic is sensitive and public knowledge of participation and responses could be damaging). *Participants should be asked whether they want documentation linking them with the research, and the participants' wishes will govern whether they sign the form.* (This justification cannot be used in FDA-regulated research.)

b. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written (signed) informed consent is normally required outside of the research context (e.g., phone survey or interview).

For the IRB to consider your request, **answer in full** each of the following, ensuring that each explanation is detailed and thorough, and provide supporting documents as needed.

1) Title of the study in capital letters and bold font

2) Will waiving the written (signed) informed consent adversely affect subjects, their rights, or their welfare? Explain.

3) Will pertinent information be provided to the subjects later, if appropriate? If so, state when and how. If not, explain why not.

4) Explain the plan to protect identifiers adequately from improper use and disclosure.

Principal Investigator _____ Date _____

Co-Investigator(s) _____ Date _____

CLARKSON COLLEGE INSTITUTIONAL REVIEW BOARD

TEMPLATE FOR PARENT/GUARDIAN AND CHILD PERMISSION FORM

IRB # (assigned upon approval): **Approval Date:** **Expiration Date:**

Title. State the title exactly as it appears on the IRB application in capital letters and bold type.

Salutation. Dear Parent or Guardian,

Introduction and invitation. Introduce yourself and your role (student investigator and program of study), and invite the parent or guardian to decide whether or not to give permission for their child to participate. You can use the following standard language:

> Your child is invited to take part in this research study. The information in this form is meant to assist you in the decision of whether or not to give permission for your child to take part. If you have any questions, please ask.

Why are you being asked to be in this research study? In ordinary language, explain why the child is eligible to participate. As appropriate, include eligibility criteria in this section. For example,

> Your child is being asked to be in this study because she or he participates in aquatic therapy.

What is the reason for doing this research study? This section should state the scientific purpose of the study in *non*-scientific language. Provide brief background material to help the parent/guardian and potential participant understand why the research is being done in clear, simple terms without reference to the participant.

What will be done during this research study? Describe the procedures chronologically using ordinary language, brief sentences, and frequent paragraph breaks. Use subheadings to help organize the procedures and enhance readability.

The description of procedures should include when the research activities will take place, where they will occur, and how much time will be required. If it is important for the parent/guardian and child to know prior to consenting that the study involves randomization, explain that participants will be assigned by chance to a study group. Describe each study group and indicate any specific requirements, such as follow-up interviews, surveys, or tests.

What are the possible risks of being in this research study? In a separate paragraph, describe the most serious and common risks first, followed by full disclosure of the less serious and uncommon risks, if warranted. Risks common to social-behavioral research may include loss of privacy and confidentiality and emotional or psychological distress. If there are no known risks, state the following:

> There are no known risks to your child from being in this research study.

Note: The potential risks described in the Risks and Benefits sections in the application must (in ordinary language) reflect those described to the parent/guardian and child.

What are the possible benefits to you? If direct benefits can be reasonably anticipated as a result of participation, describe these possible benefits and conclude with the following:

> However, your child may not get any direct benefit from being in this research study.

If direct participant benefits are *not* anticipated, use this sentence instead:

> Your child is not expected to get any direct benefit from being in this research study.

What are the possible benefits to other people? State the possible benefits to other (society) in terms of advancement of knowledge and/or ultimate possible benefits to persons in the potential subjects' position.

Note: The potential benefits described the Risks and Benefits sections must reflect (in ordinary language) those described to the parent/guardian and child.

What are the alternatives to being in this research study? In clear detail, describe the alternatives the potential subject may have to being in the study. Alternately, use the following standard clause as applicable:

> Instead of your child being in this research study, you can decide that your child will not participate.

What will being in this research study cost you? State the time commitment and any financial obligations that the child and parent/guardian will incur as a result of participation. If there are no financial obligations, use the following standard line:

> There is no cost to you or your child to be in this research study.

Will you be paid for being in this research study? If the participant will receive compensation or reimbursement for participating in the research, state the amount of compensation and conditions for payment. If no compensation is provided, use the following sentence:

> You or your child will not be paid or compensated for being in this research study.

What should you do if you have a problem during this research study? Your estimation of risk determines what additional information to include in this section. Clarkson College will not approve studies that pose greater than minimal risk to participants. For studies classified as minimal risk, use the following standard sentences:

> Your welfare and your child's welfare are the major concern of every member of the research team. If you or your child has a problem as a direct result of being in this study, you or your child should immediately contact one of the people listed at the end of this consent form.

How will information about you be protected? Begin with the following standard line:

> Reasonable steps will be taken to protect your privacy, your child's privacy, and the confidentiality of all study data.

Next, if the research requires collection of sensitive information (social, financial, legal, or otherwise) from the prospective participant, add to the previous standard line a brief description of the precautions you will use to protect that data and conclude with the following:

> The only persons who will have access to your research records are the study personnel, the Institutional Review Board (IRB), and any other person or agency required by law. The information from this study will be presented at Graduate Symposium and may be published in scientific journals or presented at scientific meetings. However, your identity will be kept strictly confidential.

Note: If you will share or distribute information from this study to other entities, including study site management, you must disclose that to the parent/guardian and child for fully informed consent.

What are your child's rights? You can use the following sentences:

> Your child has rights as a research participant. These rights have been explained in this consent form and in "The Rights of Research Participants" that you have been given. If you have any questions concerning your rights or your child's rights, talk to the investigator(s) or contact the Clarkson College Institutional Review Board (IRB) at 402.552.3100.

What will happen if you or your child decides not to participate in this research study or decide to stop participating once it starts? You can use the following clause:

> You or your child can decide not to be in this research study or can stop being in this research study at any time before, during, or after it begins. Deciding not to be in this research study or deciding to withdraw will not affect your relationship with the investigator(s), Clarkson College, or [name(s) of any other sites or entities].
>
> Your child will not lose any benefits to which she or he is entitled. If the research team gets any new information during this research study that may affect whether you would want your child to continue being in the study, you will be informed promptly.

Documentation of informed (signed) consent. Use the following clause:

> You are freely making a decision whether to allow your child to be in this research study. Signing this form means that (1) you have read and understood this consent form, (2) you have had the consent form explained to you, (3) you have had your questions answered, and (4) you have decided to give permission for your child to be in the research study. If you or your child has any questions during the study, talk to one of the investigators listed below. You will be given a copy of this consent form to keep.

Signature of Parent/Guardian: _____ Date and Time: _____

Signature of Child: _____ Date and Time: _____

Participant's initials. Add a line at the bottom of each page for a parent/guardian to initial to show they have read each page.

Then include a statement from the investigator(s):

My signature certifies that all the elements of informed consent described on this consent form have been explained fully to the participant and parent/guardian. In my judgment, the parent/guardian possesses the legal capacity to give informed consent to participate in this research and is voluntarily and knowingly giving informed consent to participate.

Signature of Investigator(s): _____ Date and Time: _____

Authorized Study Personnel. Identify all personnel authorized and CITI-certified to document consent as listed in the IRB application. Use the following subheadings: Principal Investigator, Co-Investigator, and Participating Personnel. Include daytime phone numbers and emails for all listed individuals.

Principal Investigator: _____ Phone: _____ Email: _____

Co-Investigator: _____ Phone: _____ Email: _____

Participating Personnel: _____ Phone: _____ Email: _____

CLARKSON COLLEGE INSTITUTIONAL REVIEW BOARD

TEMPLATE FOR ADOLESCENT ASSENT FORM FOR PARTICIPANTS AGED 12 TO 18

Note: Use both the Adolescent Assent Form and the Parent/Guardian Consent Form for participants aged 12 to 18.

IRB # (assigned upon approval) **Approval Date:** **Expiration Date:**

Title. State the title exactly as it appears on the IRB application in capital letters and bold type.

Salutation. Dear. . . .

Introduction and invitation. Introduce yourself and your role (e.g., student investigator and program of study), and invite the potential subject to participate in the study while being sensitive to the reading comprehension (grade) level for this subject pool. For example,

> We're asking you to be in a research study. As you know, research is a way to learn new things. You will be in the study only if you decide that you want to be. We'll tell you about the study, and then you should take time the time you need to decide. You should also talk to your parents or guardian before you decide.

Why are you being asked to be in this research study? Explain simply why the prospective subject is eligible to participate. As appropriate, include major eligibility criteria, e.g., "You are being asked to be in this study because you are a girl between the ages of 12 and 18."

What is the reason for doing this research study? State the scientific purpose of the study in ordinary language, define any technical or medical terms, and provide a brief background to help the potential participant understand why the research is being done. For example,

> This study will look at what girls your age think about leadership.

What will be done during this research study? Describe the procedures chronologically using simple language, short sentences (1-3 lines), and short paragraphs (no more than 7 lines). Consider using subheadings to organize this section and increase readability. Describe *when* the research activities will take place, *where* they will occur, *what* will happen, and *how much time* it will take. For example,

> First you will be given a survey with 40 statements. Then you will be asked to read each one and give it a score from 1-5, depending on how much you agree or disagree with it.

What will being in this research study cost you? State the financial obligations the participant will incur as a result of participating in the study. If there are no financial obligations, write

> There is no cost to you to be in this research study.

Will you be paid to be in this research study? Describe any financial arrangements made to compensate the subject for participating in the study. If there is none, state,

> You will not be paid to be in this research study.

What are the possible good things about being in this study? Explain the benefits. If direct participant benefits can reasonably be anticipated as a result of participation, describe these possible benefits, and conclude with the following caveat:

> However, there might not be any good things in particular about being in this study.

What are the possible bad things about being in this study? The most serious and common risks should be addressed first, followed by disclosure of uncommon and less serious risks in a separate paragraph, if warranted. Risks common to social science and behavioral research may include loss of confidentiality and emotional or psychological distress. Alternately, if there are no known risks, state the following:

> We don't think there are any bad things about being in this research study.

How long will this take? Explain the time commitment. For example,

> Most students need 30-45 minutes to finish this survey.

Will people know that I am in the study? Define confidentiality, but avoid using the word "secret." For example,

> The other girls in your Girl Scout Troop will know that you are in the study. The researchers will also know that you are in the study, but they won't use your name if they talk or write about it.

Is it O.K. to say, "No, I don't want to be in this study"? Assure the potential subject in the following or similar language:

> Of course! Instead of being in this research study, you can decide not to take part. If you decide to be in the study and then change your mind, you can stop any time you feel like it. No one will be angry or upset with you.

Is there anything else I should know about the study? If there is additional information that needs to be disclosed, be sure to state that.

What are your rights as a research participant? Use the following standard clause:

> You have rights as a research participant. These rights have been explained in this form and in *The Rights of Research Participants* that you have been given. If you have any questions about your rights, talk to the investigator or call the Institutional Review Board (IRB) at Clarkson College, 402-552-3100 or email IRB@clarksoncollege.edu.

Do you understand what you are being asked to do? Add the following:

> I understand. All my questions were answered. Here is my decision:

___I want to be in the study

___I don't want to be in the study

Your signature: _____ _____ Today's date: _____

Signature of person explaining the study: _____ Today's date: _____

Participant's initials. Add a line at the bottom of each page for the participant to initial to show they have read each page.

SECTION 8: RECRUITMENT MATERIALS GUIDELINES

General Recruitment

Advertisements and recruitment material are an extension of the informed consent and participant selection process. As such, *recruitment of participants into a study may not begin prior to IRB approval*. Further, the IRB must approve all recruitment methods and material (e.g., fliers, letters, brochures, email advertisements, radio announcements) prior to use. Materials must also be submitted for review and re-approval at the time of continuing review.

The content of recruitment materials and the method for communicating it must not create undue influence or contain misleading or exculpatory language. The following are examples of common recruitment methods for human research studies. All recruitment methods must be described in the IRB application.

- Use advertisements, notices, and/or emails to recruit subjects. Examples include fliers posted in public settings, newspapers, and radio and television advertisements.
- Recruit participants who do not have personal relationships with the investigators.
- In the professional or educational setting, give potential subjects the IRB-approved invitation letter describing the study. This letter explains the purpose and procedures of the study and informs subjects how to contact the research team. Researchers are prohibited from having access to participant/patient names, addresses, or phone numbers; interested individuals must initiate contact.
- Send an IRB-approved letter to certain individuals asking for referrals of eligible participants interested in the study. The researchers may provide the referring individual with IRB-approved recruitment material for the study to give to potential participants but should not expect them to explain or answer questions unless they are have CITI certification and are part of the research. If interested, the participant contacts the researchers for additional information.
- Avoid recruiting your own students or employees. This method raises ethical concerns because individuals may feel coerced or pressured to participate.

Advertisements

Advertisements should contain information that provides enough detail to allow potential participants to gauge their own eligibility and interest. Visual effects that may create undue influence cannot be used. The following, for example, would not be acceptable in a flier:

"GET PAID $100!!!"

while the rest of the ad appears in lower case

or in a smaller font.

In addition, advertisements cannot incorporate elements that state or imply a certainty of favorable outcome or other benefit beyond what is in the informed consent form or use coercive or catchy language such as “win prizes and drawings," “get a free t-shirt,” or "electrifying research study."

Generally, the elements of any advertisement should be limited to the following:

- The name of the Principal Investigator and Co-Investigator(s) and Clarkson College affiliation;
- An accurate description of the condition(s) under study and/or the research purpose, e.g., "low fat vs. low carb diets for weight loss" or "acculturation of Cuban immigrants";
- Provide the key eligibility criteria that will be used to include or exclude participants, e.g., an acceptable age range or unacceptable physical limitations; and give straightforward, truthful descriptions of the benefits, if any, to participants, such as a free health screening;
- If applicable, state how much compensation may be available. For example, "Participants may receive up to $100." Also include the amount and length of time or other commitment that will be required, as well as the location of the study and the investigators' names and contact information for any questions or concerns.
- Display the IRB approval number unless an exception has been granted by the IRB. If it is not feasible to make copies of the IRB-approved advertisement, it is acceptable to use the exact wording of validation: Clarkson College IRB #, approval date, and approval expiration date.

Tips

- Understand the target population. What media do your potential participants use? Where do they go for information?
- Make concerted efforts to recruit participants from minority and under-represented groups, and describe those efforts in the IRB application.
- Spend the time to make the recruitment advertisements easy to read and understand. Proofread carefully (and then proofread it again, because the quality of your work reflects directly on you and your institution. Advertisements must be written using ordinary language and at the 8th-grade reading level, the same level used in popular magazines and newspapers). Finally, select a font and typeface that are easy to read..

(Modified from University of Connecticut IRB Guidance for Advertising and Recruitment, http://irb.uconn.edu/adv_guidance.html

SECTION 9: APPLICATION FOR EXTENSION OR CHANGE OF PROTOCOL

Applicants may request approval to make changes (amendments) in various aspects of a project. All changes must be approved by the IRB prior to implementation.

Amendments include the following:

- change in study duration
- changes in experimental design
- insertion of new information or correction of errors
- change in principal investigator
- change in number of subjects
- changes in population and/or inclusion/exclusion criteria
- change in study site(s)

A written request must be submitted. If the changes requested will require modifications in the description of procedures in the application, recruitment process or materials, or informed consent, attach the revised documents to the Extension or COP Form with changes highlighted.

Upon completion of review of the application, the IRB chair will notify the researcher(s) of either a request for additional information or an approval notification within 10 business days.

CLARKSON COLLEGE INSTITIUTIONAL REVIEW BOARD

EXTENSION OF STUDY FORM

If a researcher is unable to collect the data in the one calendar year time frame or needs to change the protocol for data collection, a researcher may request to the IRB an extension of time to collect data.

Date:

IRB #:

Principal Investigator:

Phone number:

Email:

Co-Investigator:

Phone number:

Clarkson email address:

Degree being pursued (if applicable):

Advisor's name (if applicable):

Department:

Title of Research Proposal:

Expected time needed to complete the project:

Rationale for Extension:

Signature of Principal Investigator:

Signature of Co-Investigator:

Researchers may request approval to make modification or amendments in various aspects of a study. All changes must be approved by the IRB prior to implementation.

Amendments include the following:

- changes in experimental design
- insertion of new information or correction of errors
- change in principal investigator
- change in number of subjects
- changes in population and/or inclusion/exclusion criteria
- change in study site(s).

Date:

IRB #:

Principal Investigator:

Phone number:

Email address:

Co-Investigator:

Phone number:

Clarkson email address:

Department: Degree being pursued (if applicable):

Title of research proposal:

Proposed changes:

Rationale for proposed changes: Do these changes affect either the risks or the benefits of this study? Explain.

If the proposed changes require a change to the consent form, submit the new consent form with all changes highlighted.

SECTION 10: CLOSING THE RESEARCH STUDY

This form must be completed for all studies approved, including those the IRB office deemed "Exempt" from full-board review. The form must be submitted within 30 days of the conclusion of research activities. The Closing the Study form below should be completed and sent to the IRB chair through the online platform or (for outside constituencies) to: IRB@ClarksonCollege.edu.

CLOSING THE STUDY FORM

Date:

Title*:*

Final outcome *(Submitted as a class project, completed as: an undergraduate capstone project, master's thesis, doctoral dissertation, conference presentation, academic article for submission to professional journal—please specify):*

IRB protocol #:

Initial IRB approval date:

IRB Re-approval date(s) (if applicable):

Briefly describe the purpose of your research:

Briefly describe your findings (or include a copy of your abstract):

Describe any unanticipated problems encountered during your research process and explain how they were addressed:

What advice do you have for future Clarkson College investigators?

Do you have any comments concerning the IRB process?

Principal Investigator:

Phone:

Clarkson College email:

Co-Investigator:

Phone:

Clarkson College email:

Alternate email

SECTION 11: REFERENCES

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Mission

Preparing students to professionally provide high quality, ethical and compassionate health care services.

Values

LEARNING

The lifelong process of education through both structured and unstructured experiences.

CARING

An empowering relationship through an attitude of empathy, compassion and respect for those with whom we interact, serve and lead.

COMMITMENT

Dedication to the shared mission of Clarkson College.

INTEGRITY

Adherence to moral and ethical standards in personal, professional and organizational actions.

EXCELLENCE

A level of performance in which all individuals strive for extraordinary quality.