Applied Research Manual

Clarkson College

Clarkson College

Prepare to be the **best.**

Table of Contents

Executive Summary

This document is intended to clarify and emphasize the expectations and process flow of research at Clarkson College for internal and external constituents (including students, faculty, and staff), as well as provide guidance for Institutional Review Board requirements and processes. The Mission of Clarkson College is to prepare students to professionally provide high quality, ethical and compassionate healthcare services. Through the Values of the College: Learning, Caring, Commitment, Integrity and Excellence, the College remains student centered and is focused on the delivery of extraordinary education.

Applied research at Clarkson College is defined in this document and reflects the student success skills, which are the student learning outcomes of communication, critical thinking, technology, diversity, and professional behavior. The applied research process includes students in all undergraduate and graduate academic programs, faculty, staff, and external constituents. The process requires continuous assessment and reporting. The outcomes of this process, coupled with the academic program assessment, are used to make recommendations for improvements annually.

Questions regarding the flow and information in this manual can best be answered through consultation with your program director or research project advisor. Questions regarding the IRB process or overall research compliance should be directed to either the IRB Chair or the Director of Research Compliance.

Applied Research Overview

Clarkson College Applied Research Definition:

The following definition was chosen by the College which reflects both the Mission and the Clarkson College Student Learning Outcomes: Communication, Critical Thinking, Technology, Diversity and Professional Behavior.

Clarkson College Applied Research focuses on the practical scholarship of integration and application. ***Professional*** *practice benefits from the translation of original research to the* ***global society,*** *bringing life theory and reality to research. Scholarship is demonstrated through a research project that reflects the breadth of the student's education and that synthesizes the knowledge gained through their course of study. Students will use* ***critical thinking*** *skills to propose an evidence-based strategy, implement an intervention, and/or evaluate outcomes. The project may take on many forms. However, the common elements are translation of evidence to improve practices, processes and/or outcomes related to the research question, and to* ***communicate*** *their findings using appropriate* ***technology****.*

Leveling of Research at Clarkson College
Research concepts are introduced to our students in all degree levels:

The **Undergraduate Level (Associates and Bachelors programs)** provides a basic knowledge of research elements and design of the research process. Students are introduced to statistics, literature review, and appraisal of published articles. Students are expected to create analytical papers supported and/or substantiated with scholarly sources. A variety of assignments and projects are used to assess a student's learning of research skills throughout the undergraduate programs.

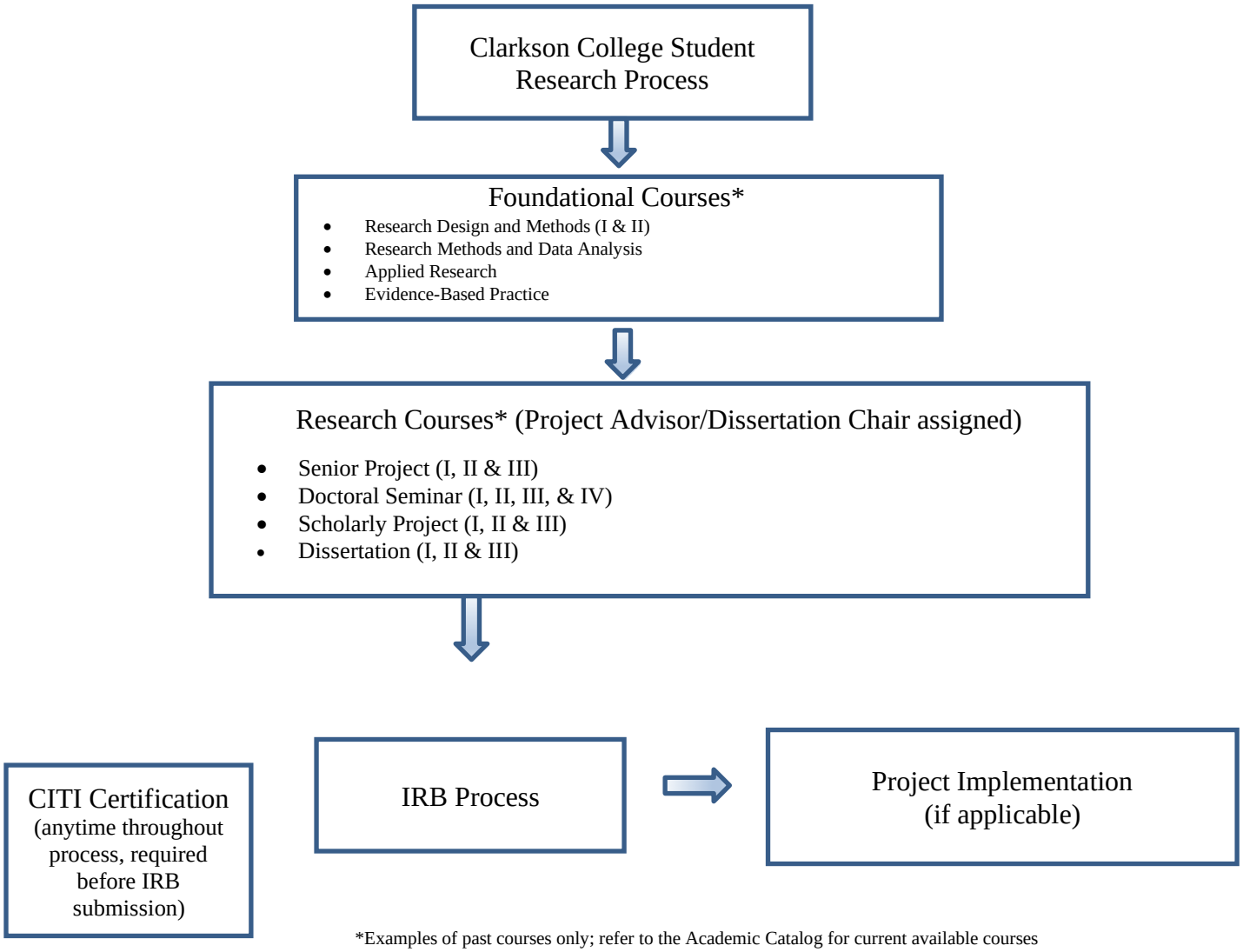
The **Graduate Level** (Master and Doctoral programs)

Masters Programs provide the students an in-depth knowledge of the research process. Various research designs are analyzed in addition to exploring the relationship between research, theory, and practice. The courses will prepare the student to appraise published research studies and apply research findings to guide evidence-based practice. Students are expected to integrate and synthesize knowledge, strategies, theories, and principles learned throughout the course of study, bridging the gap between coursework and professional practice.

Doctoral Programs provide the students an advanced knowledge of the applied research process. The courses will prepare the student to evaluate published research studies and design and implement applied research. Students are expected to integrate and synthesize knowledge, strategies, theories, and principles learned throughout the course of study culminating in a scholarly project or dissertation.

Applied Research Process - Students

All students follow the Research Process appropriate to their status at the College. Students conducting research must work within the guidelines of their academic program procedures and designated project advisor/chair, etc., whose background or interests coincide with the purpose and content of the research. It is recommended that students have taken a foundational research, scientific investigations, or evidence-based practice course(s) or can demonstrate they have had the appropriate research components in their discipline. Students must complete the certification in research ethics education, the Collaborative Institutional Training Initiative (CITI). The research project must be approved by the Clarkson College Institutional Review Board (IRB) prior to implementation, as necessary. The principal investigator is encouraged to contact the Office of Research Compliance prior to submission to the IRB for clarification and guidance in terms of project development and ethical requirements for human subjects research. The student constituents are depicted in the following processes.



*Examples of past courses only; refer to the Academic Catalog for current available courses

Applied Research: Faculty, Staff & External Constituents

The College does not require their faculty to research or publish as part of their contract; however, the Applied Research Process appropriate to their status at the College as a faculty or staff member follows the process below. The faculty, staff and external constituents are depicted in the following processes and the details in each step of the flow are outlined in detail in the table below.

Level	Content
1. **Faculty/Staff Research Project**	**1. Research Project Process –**Notify Director/Supervisor of intent for research • Provide current CITI certification. • Work with Director of Research Compliance as needed during the research process and before IRB submission. • Submit application to IRB to obtain approval. • Submit closing form to IRB.
2. Faculty/Staff as Students at Clarkson College	**2. Research Project** • Faculty and Staff who are Clarkson College students will follow the same Research Process as the Clarkson College Students.
3. Clarkson College Faculty & Staff who are Students at an External Institution using Clarkson College subjects	**3. Clarkson College Faculty, Staff or Students, as subjects** • Seek IRB approval from the external institution. • Complete IRB application to conduct research at Clarkson College and obtain approval letter from director of that program in which you wish to conduct research. • Submit IRB application and approval letter to Clarkson College IRB for approval.
4. Clarkson College Faculty & Staff who are Students at an External Institution using external subjects	**4. External Employees or Patients, as subjects** • Comply with the external institution's research protocol.
5. External Constituents using Clarkson College subjects	**5. Clarkson College Faculty, Staff or Student as subjects** • Request approval from department head who is responsible for the population sample, who will consult with the Clarkson College IRB chair. • Obtain documentation of the department supervisor's decision. • Submit application to the CC IRB for approval (Clarkson College IRB will send letter of final approval to requestor and department head.)

Research Support Services

Department/Program Resources: Investigators are encouraged to reach out to the department/program director, project advisor, and/or other faculty members with the expertise in the area of research being conducted. Refer to any Academic and Program specific handbooks and policies as they may also be helpful to investigators throughout the research process.

Library Resources:
The Library offers all resources to the online students through the Clarkson College Website. The Library's present trend to utilize technologies to support student access to information resources is possible through full-text databases, EBSCO's A to Z tool, electronic books and instructional materials available on the College Online Campus course management system.

Writing Lab:
The Writing Lab offers all students both on campus and online the ability to review and learn scholarly writing. This includes feedback on content, APA formatting, grammar and punctuation.

Applied Research Forum:
The Applied Research Forum has been established by the College and is organized by the Research Compliance Office. The purpose of the Forum is to address contemporary research issues and to assist faculty, students, and staff in exploring and expanding their knowledge of scholarly research and how to actively engage in applied research. The Applied Research Forum is considered a resource to help in the early phases of the research process and will provide educational sessions to the College community. The Forum meets once a month, and sessions will be recorded and archived. Faculty, staff, and students are encouraged to attend at any time.

Principal Investigator Resources:

- **IRB Chair:** leads the IRB committee and is available to any faculty and staff to consult on IRB issues, applications, and process to ensure the protection of human participants in the research process.
- **Director of Institutional Effectiveness:** available to assist researchers and constituents of the College in the formatting and delivery of surveys and dissemination of survey data following IRB approval.
- **Director of Research Compliance**: available to consult on IRB applications and process, general research compliance, and ethical requirements to ensure the protection of human participants in the research process.

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.

Note: The Clarkson College Institutional Review Board will not approve any research involving animals.

The IRB meets 5 times during the academic year monthly to review full-board applications submitted by the submission deadline (see IRB application submission deadlines and meeting schedule posted on the Clarkson College IRB web page).

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

DEFINITION OF TERMS FOR THE IRB APPLICATION

Complete the IRB human subject research determination form on IRB webpage (IRB Determination Form | Clarkson College) and read all directions for application *before* completing the IRB application form located on the IRB webpage/Canvas IRB Companion/Student Success Guide.

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

Principal Investigator: Principal Investigator (PI) – A Principal Investigator is the primary individual responsible for the preparation, conduct, and administration of a research project or grant and is obligated to ensure the project is conducted in compliance with applicable laws and regulations and institutional policy governing the conduct of sponsored research. Identify your professional or personal role at the site, and any relationship with potential participants. For example, doctoral students are the designated principal investigator.

Co-Investigator (Co-I) – Co-Is are key personnel who have responsibilities similar to that of a PI on research projects. While the PI has ultimate responsibility for the conduct of a research project, the Co-I is also obligated to ensure the project is conducted in compliance with applicable laws and regulations and institutional policy governing the conduct of sponsored research. Identify their professional or personal role at the site, and any relationship with potential participants. For example, a doctoral student's scholarly project advisor or dissertation chair is the co-investigator.

Problem Statement (e.g., research question, 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 a brief 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, giving special attention to any vulnerable populations (see definition below).

Vulnerable Population: The World Medical Association (WMA) states some persons require protection because "some groups and individuals are particularly vulnerable and may have an increased likelihood of being wronged or of incurring additional harm. All vulnerable groups and individuals should receive specifically considered protection" (WMA, 2018). Examples of vulnerable populations include prisoners, children, pregnant women, neonates/fetuses, mentally disabled persons, military service veterans, and the economically or educationally disadvantaged.

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). For example, the legal age of consent in Nebraska is 19.

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. You must also include any data collection instruments (e.g., interview or survey questions, pre/post-test tools, or evaluation documents) in your appendices.

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).

EXPLANATION OF REVIEW LEVELS

Data collected for the purpose of institutional administrative use (e.g., accreditation or regulatory requirements) or internal programmatic development and/or evaluation does not require IRB review, unless any of the following apply:

- The data will be disseminated outside of Clarkson College (e.g., conferences, publications).
- Data collection, analysis or dissemination involves an external entity or partner.
- Data collection involves asking participants questions of a sensitive nature or eliciting personal information regarding their perceptions, feelings, or beliefs rather than about a specific institutional policy or program.

All research that involves human subjects or data and does not qualify under institutional or programmatic use (see section 1.2), must submit a IRB Human Subject Determination Form (IRB Determination Form | Clarkson College) for preliminary IRB review.

A project that is considered exempt must still be submitted to the IRB and the IRB will certify exemption from expedited or full-board review.

All student projects must be approved by the IRB prior to any data collection or implementation.

If you are unsure if your research involves human subjects and requires IRB review/approval, please contact the Research Compliance Office for assistance.

Exempt (45 CFR 46.104) – Research may be considered exempt if it falls within one of the below categories:

a. Surveys, interviews, educational tests, and public observations (that do not involve children)
b. Benign behavioral interventions
c. Secondary research uses of identifiable private information or identifiable biospecimens
d. Federal research or demonstration projects
e. Taste and food quality evaluation studies

Research is not exempt if it:
is greater than minimal risk
or;
involves administration or use of drugs or devices

Expedited (45 CFR 46.110) – Research involves no more than minimal risk, and for minor changes in previously approved research. Research may qualify for expedited review if it falls within one of the below categories:

a. Clinical studies of drugs and medical devices only when certain conditions are met
b. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture in certain populations and within certain amounts
c. Prospective collection of biological specimens for research purposes by noninvasive means
d. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.
e. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes
f. Collection of data from voice, video, digital, or image recordings made for research purposes
g. Research on individual or group characteristics or behavior or research employing survey,

interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies

Full Board (45 CFR 46.110) – The probability and magnitude of harm or discomfort anticipated in the research are greater in and of themselves from those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests or are not in a category allowed for Expedited Research. Research that does not qualify for exempt or expedited (presents more than minimal risks to subjects) will require review at a fully convened IRB committee meeting.

Note: Most scholarly journals require proof of IRB exempt certification or expedited or full-board approval for manuscript publication. PIs are encouraged to proceed with exempt certification even if they believe their project does not fall under the definition of research that requires IRB review.

GUIDANCE FOR TYPES OF RESEARCH THAT MAY REQUIRE IRB APPROVAL

When a study does not require *any* IRB review:

- Uses publicly available data/information
- Data collected for the purpose of institutional administrative use (e.g., accreditation or regulatory requirements) or internal programmatic development and/or evaluation, unless any of the following apply:
    - The data will be disseminated outside of Clarkson College (e.g., conferences, publications).
    - Data collection, analysis or dissemination involves an external entity or partner.
    - Data collection involves asking participants questions of a sensitive nature or eliciting personal information regarding their perceptions, feelings, or beliefs rather than about a specific institutional policy or program.

When a study may require *some* IRB review (Exempt):

- Anonymous surveys (that do not include protected populations)
- Quality improvement and quality assurance projects are generally not considered research unless any of the following apply:
    - The data will be disseminated outside of Clarkson College (e.g., conferences, publications).
    - Data collection, analysis or dissemination involves an external entity or partner.
    - Data collection involves asking participants questions of a sensitive nature or eliciting personal information regarding their perceptions, feelings, or beliefs rather than about a specific institutional policy or program.
- Information-gathering interviews where questions focus on things, products, or policies rather than people or their thoughts regarding themselves
- Coded private information or biological specimens that were not collected for the currently proposed projects do not need IRB review as long as the investigator cannot link the coded data/specimens back to individual subjects

Note: A project that is considered exempt must still be submitted to the IRB and the IRB will certify exemption from expedited or full-board review.

When a study requires IRB review/approval (Expedited or Full-Board):

- Information-gathering interviews or focus groups, where questions focus on participants perceptions, feelings, beliefs, or behaviors rather than a policy or product (expedited or full-board)
- Review of minor changes in previously approved research or research protocols (expedited**)**Any secondary data collection where the information is not publicly available *and* where research subjects cannot be deidentified (expedited or full-board)
- Anything that involves protected populations (full-board)
- Research that is considered more than minimal risk (full-board)

*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.

**This is only a guide and is not an exhaustive list. If you have questions regarding the type of review required for your study complete the IRB Human Subjects Determination Form (IRB Determination Form| Clarkson College) located on the IRB webpage/Canvas/Student Success Guide and/or contact your faculty advisor (if applicable), the IRB Chair or the Director of Research Compliance.

HUMAN SUBJECTS REGULATION DECISION CHART

(45 CFR part 46)

Does your activity involve obtaining information about living individuals? [45 CFR 46.102(f)]

→ **NO** → **NO IRB REVIEW REQUIRED**

↓ **YES**

Is the activity a systematic investigation designed to develop or contribute to scientific knowledge? [45 CFR 46.102(d)]

↓ **YES**

IRB APPROVAL IS REQUIRED PRIOR TO BEGINNING DATA COLLECTION

↓ **NO**

Activity is not research; however, IRB review may be required if the focus is on certain protected populations. [45 CFR. 46.111(b)]

Does the activity intentionally focus on or include one or more specific populations:

- Children
- Neonates/ Fetuses
- Prisoners
- Pregnant women
- Mentally disabled persons
- HIV/AIDS patients
- Crime victims
- Students or employees under the supervisory or evaluative authority of the researcher
- Substance abusers
- Non-English speaking
- Terminally ill
- Institutionalized individuals
- Economically or educationally disadvantaged persons
- Military service veterans

↓ **YES**

IRB review may be required before starting beginning data collection. Contact Department of Research Compliance for further guidance.

↓ **UNKNOWN**

IRB review may be required before beginning data collection. Contact Department of Research Compliance for further guidance.

→ **NO**

NO IRB REVIEW REQUIRED

*This chart is intended as a reference only.
All researchers must review IRB materials and are encouraged to contact the Department of Research Compliance for further guidance.

APPLICATION PROCESS

1. **Review the IRB submission deadlines on the Clarkson College IRB webpage.**
   Though exempt and expedited applications can be submitted at any time and will be reviewed on a rolling basis, it is recommended that you allot at least one semester prior to beginning the project to complete the IRB application-and-approval process. If you are planning to submit an application that may require a full-board review, **pay particular attention to full-board IRB submission deadlines**, **as the full-board IRB committee only meets 5 times each academic year and requires applications be submitted prior to the specified deadline.**

2. **Complete CITI ethics training.**
   See Human Participants Protection Education section of this manual for more information.

   ***NOTE: You must obtain both Bio-Medical and Social/Behavioral CITI training certifications*.**

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 that 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 those who wish to conduct research at any Nebraska Medicine facility, it is *strongly encouraged* that you engage the Nursing Research and Innovation Committee for assistance in gaining access to any desired unit or study population. You can contact them at clinicalnursingresearch@nebraskamed.com.

   For a Clarkson College student employed at Nebraska Medicine seeking to do a study there, the PI *must* obtain, complete, and submit the Employee Request for Electronic Health Data form to clinicalnursingresearch@nebraskamed.com.

4. **Complete IRB Human Subjects Determination Form.**
   Start by completing the IRB Human Subjects Determination form (IRB Determination Form | Clarkson College), located on the IRB webpage, to determine the level of IRB review that fits your research. Once you have completed that form, you will be directed to submit the appropriate IRB application form (i.e., Exempt or Expedited/Full-Board).

5. **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. Complete the application fully. Incomplete applications will be returned and may delay IRB approval, your research timeline, and progression in your program of study.
f. Include all applicable and/or required appendices. Incomplete appendices may delay IRB approval, your research timeline, and progression in your program of study.
    - CITI Training Certification for *both* bio-medical and social/behavioral research
    - Data collection instruments (e.g., interview or survey questions, pre/post-test tools, or evaluation documents)
    - 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).
    - Recruitment language (e.g., letter, email, phone call script)
    - Consent forms (see Consent Form Guidelines and submit consent forms on Clarkson College letterhead stationery)
    - Educational materials that will be disseminated to participants (e.g., Powerpoint slides or handouts)

6. **Exempt and expedited applications are reviewed on a rolling basis.** Within 14 days of the submission of an exempt or expedited application, the IRB chair will notify the PI of the IRB decision. For approved applications, the chair will send the IRB# and approval and expiration dates in a letter. For applications that are not approved, the chair will notify the PI that approval is pending further information or revisions. Depending on the level of review, revised applications are reviewed before or at the next scheduled meeting.

7. **Full-board applications are scheduled for review at the next IRB meeting.** Within 14 days of the conclusion of the IRB meeting, the IRB chair will notify the PI of the IRB decision. For approved applications, the chair will send the IRB# and approval and expiration dates in a letter. For applications that are not approved, the chair will notify the PI that approval is pending further information or revisions. Depending on the level of review, revised applications are reviewed before or at the next scheduled meeting.

8. **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.

9. **The PI submits any study extension requests** to the IRB chair using the Request for IRB Renewal form (request-for-renewel.pdf (clarksoncollege.edu).

10. **The PI submits any change-in-protocol requests** to the IRB chair using the Change of Protocol Request Form (CHANGE OF PROTOCOL.08.05.2020.docx (clarksoncollege.edu).

11. **The PI submits the Study Closeout Form** (study-closeout-form.pdf (clarksoncollege.edu) to the IRB chair within 30 days of study completion (*required* for expedited and full-board; *encouraged* for exempt).

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.

IRB GUIDELINES FOR APPLICATION

1. The IRB reviews applications with specific attention to the following:
   a. The investigator's professional or personal status or role at the study site.
   b. Purpose, Background, and Rationale for the study.
   c. Descriptions of the study site(s), potential population, and recruitment and subject selection.
   d. Quality of research design.
   e. Detailed, step-by-step (bulleted) methodology and procedure for data collection.
   f. Process, procedures, and documentation for written or implied informed consent and, if applicable, assent and request for waiver of written consent.
   g. Assessment of risks and benefits, including protection against risks and compensation, which the informed consent letter or invitation will mirror.
   h. Readability statistics on all communications to potential participants.

2. The IRB reviews applications according to the Common Rule (Federal Regulations 45, Part 46, section 111) with particular attention to the following:
   a. *Risks, physical and mental harms to subjects are minimized*:
      i. By using procedures which are consistent with sound research design, and which do not unnecessarily expose subjects to risk, and
      ii. Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
   b. *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.
   c. *Selection of subjects is equitable*. Consider 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, military service veterans, mentally disable persons, or economically or educationally disadvantage persons.
   d. *Informed consent will be sought* from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by **§46.116**.
   e. *Informed consent will be appropriately documented*, in accordance with, and to the extent required by **§46.117**.
   f. When appropriate, the research plan makes adequate provision for *monitoring the data collected to ensure the safety of subjects*.
   g. When appropriate, there are *adequate provisions to protect the privacy of subjects* and to maintain the confidentiality of data.
   h. 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, military service veterans, or economically or educationally disadvantaged persons, *additional safeguards* have been included in the study to protect the rights and welfare of these subjects.

SUBMISSION OF APPLICATION

Exempt and Non-Exempt (Expedited and Full-Board) applications can be found on the IRB web page/Canvas/Student Success Guide. All IRB applications (and required attachments) must be submitted through the submission form located on the Clarkson College IRB webpage (IRB APPLICATION SUBMISSION PORTAL) or mailed to Clarkson College Institutional Review Board, 101 S. 42nd Street, Omaha, NE 68131.

- Applications must be submitted by the Principal Investigator listed on the application.
- A scanned PDF of the executed (signed) signature page(s) can be attached with the submission.
- Incomplete applications will be returned to the Principal Investigator without review.
- Attachments shall be included in the form of appendices.
    - Attachments may include, but are not limited to:
        - ✓ CITI Training Certification for *both* bio-medical and social/behavioral research
        - ✓ Data collection instruments (e.g., interview or survey questions, pre/post-test tools, or evaluation documents)
        - ✓ 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).
        - ✓ Recruitment language (e.g., letter, email, phone call script)
        - ✓ Consent forms (see Consent Form Guidelines and submit consent forms on Clarkson College letterhead stationery)
        - ✓ Educational materials that will be disseminated to participants (e.g., Powerpoint slides or handouts)
    - Applications missing required attachments will be returned to the Principal Investigator without review.
- Refer to the Submission and Review Schedule located on the IRB web page/Canvas/Student Success Guide for full-board submission deadlines and meeting dates. Exempt and Expedited applications can be submitted at any time and will be reviewed on a rolling basis.

IRB APPLICATION REVIEW FLOW CHART

Exempt and Expedited Applications can be submitted at any time and will be reviewed on a rolling basis. Full board applications will be reviewed per the full board review schedule.

EXEMPT APPLICATION

FILE CREATED BY RESEARCH OFFICE

FILE SENT TO IRB FOR REVIEW

REVIEWED BY IRB CHAIR AND DIRECTOR OF RESEARCH COMPLIANCE FOR EXEMPT DETERMINATION/CERTIFICATION

- APPROVE/CERTIFY
- APPROVAL PENDING REVISIONS
- DENY

- **IRB CHAIR TO DRAFT/SIGN APPROVAL/DENIAL LETTER**
- **DIRECTOR OF RESEARCH OFFICE TO DISSEMINATE LETTER TO PI, ADVISOR, AND IRB**

EXPEDITED/FULL-BOARD APPLICATION

FILE CREATED BY RESEARCH OFFICE

FILE SENT TO IRB FOR REVIEW

EXPEDITED

REVIEWED BY IRB CHAIR AND 2 IRB MEMBERS AS APPPOINTED BY THE CHAIR

- APPROVE
- APPROVAL PENDING REVISIONS
- DENY

FULL-BOARD

REVIEWED BY QUORUM OF IRB MEMBERS ACCORDING TO IRB MEETING SCHEDULE

- APPROVE
- APPROVAL PENDING REVISIONS
- DENY

- **IRB CHAIR TO DRAFT/SIGN APPROVAL/DENIAL LETTER**
- **DIRECTOR OF RESEARCH OFFICE TO DISSEMINATE LETTER TO PI, ADVISOR, AND IRB**

IRB Application Review Check Sheet

Please assess the applicant's proposed project in relation to the following criteria. You are not required to assess the validity of the experiment nor the quality of writing in the application. Note that some items are not relevant to all applications and consent forms. Indicate non-relevant items with "N/A."

Applicant Name: | **Date Reviewed:**

Reviewer Name:

Reviewer Decision:
(Approved / Revisions Required / Rejected)

Researchers, Participants & Funding:

Criterion for Consideration	Decision (*Satisfactory / Unsatisfactory / Not Applicable*)	Rationale for Decision / Notes
Are other institutions involved in the research (school districts, hospitals, other Universities)? If so, are the cooperation & contribution letters by the other institutions involved in the research attached to the application? **These MUST be provided on the institution's letterhead and clearly state their willingness to participate in the research project and their contribution to the project.*		

Is the participant population, # of participants, participant characteristics, and methods of participant selection (inclusion & exclusion) clearly stated?		
Is the funding status of the project explained? If part of a proposal to an external funding agency, is a copy of the funding proposal attached?		

Research Methodology & Benefit / Risk Assessment:

Criterion for Consideration	**Decision** (***Satisfactory / Unsatisfactory / Not Applicable***)	**Rationale for Decision / Notes**
Is there sufficient background information to assess the justification for the study and use of human participants? Does the information adequately justify the research and use of human subjects?		
Are the methods and procedures clearly explained in sufficient detail to assess the potential impact on the human participants? Do the proposed methods and procedures include any procedures that could cause undue discomfort or harm to the participant?		
Are copies of questionnaires, interview guides, surveys, testing instruments, etc. included? Do all questions & procedures protect the safety and privacy of the participants? And, do any questions / procedures have the ability to cause undue discomfort to the participant?		

Are benefits & risks (if any) to the participants described clearly and completely? Are precautions taken to minimize or eliminate each of the risks clearly stated?		

Participant Recruitment & Confidentiality:

Criterion for Consideration	Decision (*Satisfactory / Unsatisfactory / Not Applicable*)	Rationale for Decision / Notes
Are recruiting procedures used to obtain subjects clearly and completely described? Are copies of ads or recruitment letters / scripts included? Do the ads / letters / scripts correctly portray the nature of participation in the research?		
Is compensation (money, academic credit, ect) to be given in exchange for participation? If so, is the compensation clearly described and appropriate for the time commitment from the participants?		
Are the precautions described to protect the privacy of the participants and the confidentiality of any records identifying subjects or their individual data sufficient?		

Informed Consent:

Criterion for Consideration	Decision (*Satisfactory / Unsatisfactory / Not Applicable*)	Rationale for Decision / Notes
Is the informed consent form present?		
Is the purpose of the research clearly stated in the form?		
Is the length of time needed to participate mentioned in the informed consent form?		

Are age guidelines included in the form (under 19 needs parental consent)?		
Are the experimental procedures identified and adequately described in the form? Do all methods reported in the application & the informed consent form demonstrate consistency & coherence?		
Are the risks and discomforts to participants explained in the informed consent form? If no risks, does it state that there are no known risks?		
Are benefits to participants and to others that might be expected from the research explained in the informed consent form?		
Are alternative procedures or courses of treatment that might be advantageous to the participant identified in the informed consent form, if relevant?		
Does the informed consent form adequately explain how confidentiality of records for the participant will be maintained?		
Is compensation offered to the participants? If so, is it adequately explained in the informed consent form?		
Are medical treatments available if injury occurs during or as a result of the experiment? If so, are they clearly described in the form? Is the party who will pay for those treatments (if they are deemed necessary) identified in the informed consent form?		
Are the conditions that would exclude participants from participating included in the informed consent form?		

Does the informed consent state that participants have a right to ask questions and have those questions answered?		
Does the informed consent clearly state that the participants have the right to discontinue the study at any time with no negative consequences for doing so?		
Are the names and phone numbers of the persons to contact for answers to questions about research provided? Is the contact information for healthcare professionals that can be consulted regarding any realization of the risks of the research provided?		

Used/adapted with permission from the Union College HSRB, June 16, 2020

IRB DECISION APPEALS POLICY

IRB decisions are final and cannot be appealed. Modifications to the IRB application can be made and resubmitted based on the IRB's recommendations. However, there is no guarantee that the IRB will approve the revised version.

Human Subject Research Guidelines

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.

1. Go to the CITI website: http://www.CITIprogram.org
2. 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.
3. At the Registration page, type in the appropriate information to create your CITI Program username and password.
4. 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.
5. 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.
6. 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.)
7. 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**.
8. 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.***
9. 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.
10. Follow the directions on the screen to complete the training (bio-medical *and* social/behavioral). Most modules are brief, and you may re-take the quizzes if you are not satisfied with your score.
11. 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 required CITI trainings.**

Note: Certification lasts three years.

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 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

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

UNANTICIPATED PROBLEMS/ADVERSE EVENTS REPORTING POLICY AND PROCESS

This policy describes the reporting requirements for reporting:

- Unanticipated problems involving risks to subjects and others,
- Serious and continuing non-compliance and/or
- Termination or suspension of a study by the IRB.

Required statute:

CFR §46.108 (4) Establish and follow written procedures for ensuring prompt reporting to the IRB; appropriate institutional officials; the department or agency head; and the Office for Human Research Protections, HHS, or any successor office, or the equivalent office within the appropriate Federal department or agency of
(i) Any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and
(ii) Any suspension or termination of IRB approval.

Definitions:

Adverse event:

The term adverse event in general is used very broadly and includes any event meeting the following definition:

- Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research
- Adverse events encompass both physical and psychological harms. They occur most commonly in the context of biomedical research, although on occasion, they can occur in the context of social and behavioral research.

Unanticipated problem:

OHRP considers *unanticipated problems,* in general, to include any incident, experience, or outcome that meets **all** of the following criteria:

1. unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;

2. related or possibly related to participation in the research (in this guidance document, *possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and

3. suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Unanticipated problems place subjects or others at increased risk of harm, but no harm occurs.

Policy:

1. Any unanticipated problems or reportable adverse events that arise in the conduct of research shall be reported immediately to the IRB by the investigator or by subjects. The IRB shall suspend approval of the research until the events are reviewed and a determination made regarding any necessary changes in protocol.
2. One or more of the following will be notified, as appropriate, of any serious and continuing noncompliance, unanticipated problem involving risks to subjects or others, suspension or termination of IRB approval of a study within 15 days.

- Institutional Review Board
- Principal investigator
- Sponsor, if the study is sponsored
- Contract research organization, if study is overseen by one
- Department Chair or supervisor of principal investigator
- Head or appropriate designee of the funding department or agency
- Appropriate designee of the sponsoring company or organization
- FDA, when the research is FDA-regulated
- OHRP, in all cases
- Other federal agencies when the research is overseen by those agencies, and they require reporting separate from that to OHRP.

3. All serious and continuing non-compliance, serious adverse events, suspensions, terminations or unanticipated problems and involving risks to subjects or others will be reported within 15 days to OHRP and/or FDA. The Director of Research Compliance will draft a letter that outlines;

- Nature of the event.
- Name of institution conducting the research.
- Title of the research project and/or grant proposal in which the problem occurred.
- Name of principal investigator.
- Number assigned by the IRB.
- Detailed findings of the IRB.
- Actions taken by the IRB.
- Reasons for the IRB's action.
- Plans for continued investigation or action.
- Plans, if any, to send a follow-up report or final report.

4. The letter is sent to the Institutional Review Board Chair for review, approval, and signature.

DATA COLLECTION WITHOUT INSTITUTIONAL REVIEW BOARD APPROVAL POLICY AND PROCESS

1. The IRB is responsible for the review of all research performed at Clarkson College to ensure that professional, ethical, and legal standards concerning the use of human participants are being followed (45 CFR Part 46 Regulations).
2. Data collected for the purpose of institutional administrative use (e.g., accreditation or regulatory requirements) or internal programmatic development and/or evaluation does not require IRB review, unless any of the following apply:
   - The data will be disseminated outside of Clarkson College (e.g., conferences, publications).
   - Data collection, analysis or dissemination involves an external entity or partner.
   - Data collection involves asking participants questions of a sensitive nature or eliciting personal information regarding their perceptions, feelings, or beliefs rather than about a specific institutional policy or program.
3. All research that involves human subjects or data and does not qualify under institutional or programmatic use (see section 1.2), must submit a Human Subject Determination Form (IRB Determination Form | Clarkson College) for preliminary IRB review.
4. A project that is considered exempt must still be submitted to the IRB and the IRB will certify exemption from expedited or full-board review.
5. All student projects must be approved by the IRB prior to any data collection or implementation.
6. If you are unsure if your research involves human subjects and requires IRB review/approval, please contact the Research Compliance Office for assistance.

Purpose

Data collected for research purposes without prior IRB review and approval may be subject to review and discussion by the IRB at a convened meeting. This document describes the circumstances and processes for which data are considered to have been obtained without prospective IRB review.

Policy and Procedure

1. Data obtained for human subjects research activities in which Clarkson College considers to have been collected without IRB approval fall under the following circumstances:
   - With no prior IRB approval
   - With no prior letter of determination confirming IRB oversight is not required
   - With no informed consent from the subjects or their legally authorized representatives (and when the IRB has not approved a waiver of consent or documentation)
   - Using procedures that were not previously described and approved in the IRB- approved consent document (unless it has been determined to be in the best interest of the subjects enrolled in the study to continue in the research in consultation with the IRB Chair or Director of Research Compliance)
   - After expiration of the IRB approval
   - After suspension or termination of IRB approval
2. The IRB cannot grant retroactive approval for use of data that was previously collected without IRB approval. Federal regulations allow for IRB approval only when it is prior to the initiation of the research activities.

3. The IRB cannot require the investigator to destroy data or prevent the investigator from analyzing or publishing the data collected without prior IRB approval. Federal regulations do not state how data collected without IRB approval may be used.
4. **Actions Following Data Collected without IRB Approval**
   a. Any investigator who discovers they have conducted research involving human subjects without prior IRB review and approval or exemption determination, must report their project promptly to the IRB. Investigators should also contact their faculty advisor if they are a student researcher or notify their department chair if they are a faculty member.
   b. The investigator must immediately cease all activities involving human subjects.
   c. The investigator must submit in writing to the IRB (IRB@clarksoncollege.edu) a summary of the project. The Summary must include the following information:
      i. A description of the project (including the dates and location of activities, the human subjects participant population, examples or copies of the survey materials, interview guides, instruments, etc., that were used to collect data);
      ii. A description of the consent process;
      iii. A discussion of how the rights and welfare of the participants were not adversely affected (including whether there were any complaints, concerns, complications, unanticipated outcomes or adverse events associated with the research);
      iv. If identifiable data were collected, the disposition of these materials;
      v. Why the appropriate IRB approvals were not initially sought; and
      vi. How the research team will avoid future occurrences.
5. **Corrective and Preventative Actions**
   a. Depending on the circumstances leading to the lack of approval, the IRB may require any of the following corrective actions, or any other action as appropriate:
      - Warning letter: Issue a letter of warning to the investigator.
      - Publications and presentations: If the data are intended for publication, the investigator must disclose to the publication editor that the data was previously collected without prior IRB approval.
      - Publications and presentations: Data cannot be described as being a part of a Clarkson College IRB-approved study.
      - Halt ongoing activities: If the study is on-going, interactions with the human subjects must cease until the IRB has reviewed and approved all the study procedures.
      - Modification: If data was collected under an existing study for which the appropriate procedures were not described, some or all part of the protocol may require modification.
      - Recollection of data: Data are collected again, but with IRB approval.
      - Notification to participants: In some instances, the IRB may require the investigators to notify all participants of the investigator's lack of compliance with the IRB procedures.
      - Reconsent: The participants are provided the opportunity to consent to the use of their data for research purposes, using IRB approved documents.
      - Retraining: Require retraining of the investigator and researchers conducting the project.
      - Notification to OHRP: If there was any risk of harm to the participants, the IRB will report the incident to OHRP and appropriate officials as required by the Federal Wide Assurance.
      - Funding agency notification: If the study is federally funded, then the IRB staff must notify the Institutional Official to report that the research was conducted without prior IRB approval to determine applicable reporting requirements.
      - Suspension and termination: If, after the IRB has intervened to take corrective action and the investigator initiates a second study without IRB approval, the IRB may recommend to the

Institutional Official that further sanctions (e.g., suspension or termination) be considered for violation of institutional policy.

- Recommendation of sanctions on data use: Although the IRB cannot impose sanctions on the use of the data, the IRB may recommend that the Institutional Official, or other appropriate officials (e.g., Program Director) consider the following actions:
    - Require that data not be published or presented Require data not be used for a thesis or dissertation Require that data be destroyed.
    - Other actions as appropriate.

b. The IRB staff, after review by the IRB, will send a letter of determination to the investigator detailing any corrective actions.

Scope

These policies and procedures apply to all research submitted to the IRB or under the jurisdiction of the institution.

Responsibility

a. The investigator is responsible for ensuring they obtain IRB approval prior to initiating activities involving human subjects. The investigator is also responsible for notifying the IRB of when a violation occurs and ceasing all activities until the IRB has reviewed a summary of the incident.
b. The IRB staff, IRB Chair, and/or Director of Research Compliance are responsible for receiving and reviewing reports of investigators collecting data without prior IRB approval. The IRB staff will facilitate the initial review of the report and will notify investigators of the IRB decision and any corrective action(s) in writing. The IRB staff, IRB Chair and/or Director of Research Compliance are responsible for notifying the Institutional Official, as appropriate.
c. The IRB is responsible for reviewing reports of noncompliance with this policy and federal regulations.

Process Overview

a. The IRB staff, IRB Chair, and/or Director of Research Compliance will initially receive the reported data collection without IRB approval. The IRB staff will determine whether an approved protocol was in place during the time period in question. If an approved protocol does not/did not exist, then the IRB will review the summary of information provided to the IRB staff.
b. The IRB will make a formal determination as to whether the data collected required IRB approval. The IRB will assess:
    - Whether the activity constituted research involving human subjects, as defined by federal regulations;
    - Whether the project was eligible for an exempt determination, expedited review procedures, or full board review. This determination will also include the category of exemption or expedited review, if applicable;
    - A risk/benefit analysis of the research to the participants and whether the project posed any risks of harm to the subjects and how those risks (if any) were mitigated by the researcher;
    - Whether there was any coercion or undue influence on the participants.

c. Following review and assessment, the IRB may require corrective actions (as described in 2. 5 above) and issue a letter of determination to the investigator.
d. The IRB staff will coordinate with the IRB Chair and/or Director of Research Compliance to follow-up on any corrective actions required by the IRB.

References:
45 CFR 46 Regulations
OHRP Investigator Responsibilities FAQs

ADAPTED FROM THE UNIVERSITY OF CALIFORNIA, SANTA BARBARA WITH PERMISSION, JUNE 2021

CLARKSON COLLEGE Institutional Review Board (IRB) Exempt Application	
Instructions: Be sure to consult the IRB Applied Research Manual as you complete each section as directed and in full.	
SECTION I	
Title of Study:	
Principal Investigator:	
Address:	
Clarkson College Student ID# (if applicable):	
Phone Numbers: (work)	(cell/home)
Email:[2]	
Principal Investigator's Status: ☐ Student ☐ Faculty ☐ Staff ☐ Other (please identify)	
Co-Investigator:	
Address:	
Clarkson College Student ID# (if applicable):	
Phone Numbers: (work)	(cell/home)
Email:	
Co-Investigator's Status: ☐ Faculty ☐ Student ☐ Staff ☐ Other	
Type of Study (Check all that apply): ☐ Research ☐ Demonstration ☐ Class Project ☐ Independent Study ☐ Evidence-Based Practice (EBP) ☐ Quality Improvement/Assurance ☐ Dissertation ☐ Other (please identify)	
Present or Proposed Source of Funding (*if applicable*):	
(Office Use Only) **IRB #:** **Date Received:**	

[2] Investigators outside the College should provide the email address issued by their institution.

SECTION II

Exempt Review means the study must still be reviewed, but not by the Full Board. After reading the Categories below, check all the Categories that apply. Upon review of the application, the IRB office will determine if the application is eligible for Exempt Review.

A study may qualify for **exempt review** if it fits into one of the Categories under 45 CFR 46.104. The IRB office will determine if the protocol is exempt. Check all those that apply:

_**Category 1:** **Research conducted in established or commonly accepted educational settings** involving normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

_**Category 2:** **Research that only includes interactions involving educational tests** (cognitive, diagnostic, aptitude, achievement), surveys, interviews, **or observations of public behavior** (including visual or auditory recording) if at least one of the following criteria is met:

a) data obtained are recorded in such a way that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
b) any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, educational advancement, or reputation; or
c) the information obtained is recorded by the investigator in such a way that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 46.111(a)(7), which relates to having adequate provisions for protecting privacy and maintain confidentiality.

Note: This exemption does not apply to surveys that include collection of biospecimens or interventions. It further does not apply to surveys, interviews, or subject observation with children. (Public behavior observation without intervention is permitted.)

__**Category 3:** **Research involving benign behavioral interventions in conjunction with the collection of information from adult subjects** through written or verbal responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

a) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
b) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
c) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 46.111(a)(7).

Benign behavioral interventions are defined as brief, harmless, painless, not physically invasive,[3] and not likely to have a significant adverse lasting impact on the subjects; and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Examples include subjects' playing online games, solving puzzles under various noise conditions, or deciding how to allocate a nominal amount of received cash between themselves and someone else.

A benign behavioral intervention may include authorized deception IF the subject is told that they will be unaware or misled about the nature or purposes of the research and IF the subject prospectively agrees to the intervention and information collection.[4]

Note: This exemption is only for benign behavioral research with adults and is not to research involving any subject population, including (but not limited to) children, military service veterans, prisoners, fetuses, or individuals with impaired decision-making ability (including psychiatric patients) determined to be vulnerable.

__**Category 4:** **Secondary research for which consent is not required**: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(a) The identifiable private information or identifiable bio-specimens are publicly available;
(b) Information, which may include information about biospecimens, is recorded by the investigator in such a way that the identity of the subjects cannot readily be ascertained directly or through identifiers or codes linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

[3] Physical and invasive procedures include FitBits and saliva collection.
[4] Subject debriefing is strongly encouraged.

(c) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated by HIPAA for purposes of health care operations, research, or for public health activities and purposes as those terms are defined in HIPAA; or
(d) The research is conducted on behalf of a Federal department or agency--as opposed to an investigator-initiated analysis of federally supplied date—if the requirements of certain laws are met.

Note: This category applies only to the re-use of data and specimens that were or will be collected for non-research purposes or from research studies other than the one proposed. Data need not be extant at the time of the study. Data collected may include publicly available materials and medical records.

_**Category 5: Research and demonstration projects that are conducted or supported by a Federal department or agency**, or otherwise subject to the approval of department or agency heads and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods o or levels of payment for benefits or services under those programs.

Note: Projects eligible for this exemption must be published on a publicly accessible Federal website before research can begin.

_**Category 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 FDA and approved by the EPA or the Food Safety and Inspection Service of the USDA.

_**Category 7: Storage or maintenance for secondary research for which broad consent is required**: Storage or maintenance of identifiable private information or identifiable bio-specimens prior to secondary research IF an IRB conducts a limited IRB review to determine that there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data and IF broad consent is obtained.

Note: Under broad consent, data may be collected from de-identified data, data with informed consent, data from research approved without informed consent, or data from secondary analysis when informed consent was secured by the original data collector. Broad consent must include at least seven elements of consent.

_**Category 8: Secondary research for which broad consent is required**: Research involving the use of identifiable private information or identifiable bio-specimens for secondary research use, if the following criteria are met:
(a) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable bio-specimens was obtained in accordance with regulations;
(b) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with 46.117;
(c) An IRB conducts a limited IRB review and makes the determination that that the research to be conducted is within the scope of broad consent; and
(d) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from any legal requirements to return individual research results.

Note: Exempt Categories do not apply to research involving any subject population, including (but not limited to) children, military service veterans, prisoners, fetuses, or individuals with impaired decision-making ability (including psychiatric patients) determined to be vulnerable.

Note: Exempt Categories do not apply to research involving deception of subjects, sensitive behavioral research, or 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: 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.

Reference: Belmont University Institution Review Board: http://www.belmont.edu/irb/ (2011).

SECTION III
Title of Study:
Study Site(s) & Address(es) (Include letter(s) of approval for data collection from study site(s) in the Appendices:
Principal Investigator's Role or Status at Study Site:
Problem Statement, Thesis Statement, PICO, or PICOT (1-2 focused sentences):
Purpose of the Study:
Background of and Rationale for the Study:
Population and Characteristics:
Age Range:
Method of Subject Selection, Inclusion and Exclusion Criteria, and Number Anticipated:
Description of Research Design, Methodology, Recruitment Procedure, and Data Collection (enumerated or bulleted):
Ultimate Distribution and Disposal of Data Collected:
Interventions:
Risk/Benefit Assessment (Describe fully):
a. Potential Psychological, Social, Economic, or Legal Risks:
b. Risk Classification:
c. Potential Risks:
d. Protection Against Risks:
Potential Benefits to the Subjects:
Potential Benefits to Society:
Compensation for Participation:
Steps to Protect Confidentiality and Privacy:
Information Purposely Withheld:

Written or Implied Informed Consent Documentation (Include waivers, consent forms, and cover letters in the Appendices):
a. Readability Statistics (e.g., Flesch-Kincaid) of cover letters, fliers, surveys, questionnaires, tests):[5]
b. Documentation of Consent:
c. Consent:
List of Appendices (Include recruitment materials, permission and consent letters and emails, tests, surveys, and data collection tools):

SECTION IV

Applications that are incomplete, inaccurate, or incoherent will be returned to the PI and may be re-submitted to the IRB for review.

CERTIFICATION OF REVIEW

As Principal Investigator, I certify that all sections are completed as directed and in full and agree with the following:
__ CITI certification forms (bio-medical *and* social/behavioral are attached).
__ The research design conforms to discipline standards.
__ The type of review requested is appropriate.
__ The format of the Clarkson College IRB Application conforms to the Clarkson College Applied Research Manual.
__ The Application--including the Appendices--is complete, accurate, and coherent.
__ The Nebraska Medicine Employee Request for Electronic Heath Data to be used in Education-Related Projects is approved and attached (if applicable).
__ In all communications, writing errors (punctuation and grammar) do not impair the integrity of the study or undermine the credibility of Investigators or the College.
__ I have thoroughly reviewed this research study, and it has my full support.

As Investigator(s), we assert that this Application is ready for IRB review:

Printed Name of Principal Investigator Date

Signature of Principal Investigator

Printed Name of Co-Investigator Date

[5] Regardless of subject pool's educational background, readability of documents should be at or around 8th-grade reading comprehension levels.

Signature of Co-Investigator or Student Investigator

Submit the Application and Appendices through the submission form located on the Clarkson College IRB webpage (IRB APPLICATION SUBMISSION PORTAL) or mail them to the address listed below. A scanned PDF of the executed (signed) signature page(s) can be attached with the submission.

Note: The study must not begin prior to IRB approval.

Clarkson College Institutional Review Board
101 S. 42nd Street
Omaha, NE 68131
Phone: 402.552.3100; Fax: 402.552.6019

SECTION V

IRB SUBMISSION AND REVIEW CALENDAR

Exempt and expedited applications are accepted and reviewed on a rolling basis. See blackout dates schedule (located on IRB web page/Canvas IRB Companion/Student Success Guide).

All full-board applications must be received by the IRB submission deadline for the next IRB Review. The Clarkson College IRB meets 5 times per academic year (see current schedule on IRB web page/Canvas IRB Companion/Student Success Guide).

Applications that are incomplete, inaccurate, or incoherent will be returned to the PI and may be re-submitted to the IRB for review.

IRB NON-EXEMPT APPLICATION

CLARKSON COLLEGE – Institutional Review Board (IRB) NON-EXEMPT APPLICATION	
Instructions: Be sure to consult the IRB Applied Research Manual as you complete each section as directed and in full.	
SECTION I	
Title of Study:	
Principal Investigator:	
Address:	
Clarkson College Student ID# (if applicable):	
Phone Numbers: (work)	(cell/home)
Email:[6]	
Principal Investigator's Status: ☐ Student ☐ Faculty ☐ Staff ☐ Other (please identify)	
Co-Investigator:	
Address:	
Clarkson College Student ID# (if applicable):	
Phone Numbers: (work)	(cell/home)
Email:	
Co-Investigator's Status: ☐ Faculty ☐ Student ☐ Staff ☐ Other	
Type of Study (Check all that apply): ☐ Research ☐ Demonstration ☐ Class Project ☐ Independent Study ☐ Evidence-Based Practice (EBP) ☐ Quality Improvement/Assurance ☐ Dissertation ☐ Other (please identify)	
Present or Proposed Source of Funding (*if applicable*):	
Type of Review Requested: ☐ Expedited ☐ Full Board	
(Office Use Only) **IRB #:** **Date Received:**	

[6] Investigators outside the College should provide the email address issued by their institution.

SECTION II

An Expedited Review is indicated for research involving no more than minimal risk, no vulnerable populations, or a 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.

A study may qualify for **expedited IRB review** if it fits into one of the *Federal Register* (1998) Categories under 45 CFR 46.110(a). The IRB office will determine if the protocol qualifies for expedited review. Check all those that apply:

____ **Category 1**. Research on drugs for which an investigational new drug application is not required; or research on medical devices for which (i) an investigational device exemption application is not required or (ii) the device is both approved for marketing and is being used in accordance with its approved labeling.

____ **Category 2**. Collections of blood samples by finger stick, heel stick, ear stick, or venipuncture.

____ **Category 3**. Prospective collection of biological specimens (e.g., hair and nail clippings, teeth, sweat, saliva, mucus) for research purposes by non-invasive means

____ **Category 4**. Collection of data through non-invasive procedures (not involving sedation, x-rays, or microwaves) routinely employed in clinical practice. Where medical devices are used, they must be approved for marketing. Examples include (but are not limited to) physical sensors, weighing or testing sensory acuity, imaging, doppler blood flow, moderate exercise, muscular strength or flexibility testing, and body composition assessment.

____ **Category 5.** Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes such as medical treatment or diagnosis. Some research in this category may be exempt; this listing refers to research that is not exempt. See 45 CFR 46.101(b)(4).

____ **Category 6.** Collection of data from voice, video, digital, or image recordings made for research purposes.

____ **Category 7.** Research on individual or group characteristics or behavior, including (but not limited to) research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior; or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. Some research in this category may be exempt; this listing refers to research that is not exempt. See 45 CFR 46.101(b)(2) and (b)(3).

____ **Category 8**. Continuing review of previously approved research as follows:

(a) Where (i) the research is permanently closed to the enrollment of new subject; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
(b) Where no subjects have been enrolled and no additional risks have been identified; or
(c) Where the remaining research activities are limited to data analysis.

____ **Category 9**. Continuing review of previously approved research in which modifications do not result in significant changes to the risk-benefit analysis or in the informed consent documents.

Note: Even if your initial determination is Expedited Review, complete the checklist for Full Review. If any of those categories apply, your study is not Expedited.

A study may qualify for **full-board IRB review** if it poses greater than minimal risk and fits into one of these Categories**.** Check all those that apply:

____ **Category 1**. Surveys or interview questions which 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 population vulnerable to coercion or undue influence, including children, prisoners, persons with impaired decision-making ability, or economically or educationally disadvantaged persons. Other potentially vulnerable populations include the frail elderly, victims, persons receiving HIV testing or have been diagnosed with AIDS, pregnant women, fetuses, and neonates.

____ **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

Note: Minimal risk as defined by 45 CFR 46.102(j) https://www.ecfr.gov "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."

References:

https://about.CITIprogram.org/wp-content/uploads/2018/07/Final-Rule-Material-Changes-to-Exempt-Determination-Process.pdf
https://about.CITIprogram.org/wp-content/uploads/2018/07/Final-Rule-Material-Updates-to-Expedited-Review-Procedures.pdf
http://www.belmont.edu/irb/ (2011/2019)
https://cphs.berkeley.edu/policies_procedures/2019/rr402.pdf
https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML (2020)
http://www.kumc.edu/human-research-protection-program/institutional-review-board.html (2019)

SECTION III

Title of Study:

Study Site(s) & Address(es) (Include letter(s) of approval for data collection from study site(s) in the Appendices:

Principal Investigator's Role or Status at Study Site:

Problem Statement, Thesis Statement, PICO, or PICOT (1-2 focused sentences):

Purpose of the Study:

Background of and Rationale for the Study:

Population and Characteristics:

Age Range:

Method of Subject Selection, Inclusion and Exclusion Criteria, and Number Anticipated:

Description of Research Design, Methodology, Recruitment Procedure, and Data Collection (enumerated or bulleted):

Ultimate Distribution and Disposal of Data Collected:

Primary Investigator's Consultation, including (if applicable), Review of Survey with Research Analyst: Y / N

Date Study Proposal Presented to Applied Research Forum:

Interventions:

Risk/Benefit Assessment (Describe fully):

e. Potential Psychological, Social, Economic, or Legal Risks:

f. Risk Classification:

g. Potential Risks:

h. Protection Against Risks:

Potential Benefits to the Subjects:

Potential Benefits to Society:

Compensation for Participation:

Steps to Protect Confidentiality and Privacy:
Information Purposely Withheld:
Written or Implied Informed Consent Documentation (Include waivers, consent forms, and cover letters in the Appendices):
d. Readability Statistics (e.g., Flesch-Kincaid) of cover letters, fliers, surveys, questionnaires, tests):[7]
e. Documentation of Consent:
f. Consent:
List of Appendices (Include recruitment materials, permission and consent letters and emails, tests, surveys, and data collection tools):

SECTION IV

CERTIFICATION OF REVIEW

As Principal Investigator, I certify that all sections are completed as directed and in full and agree with the following:
__ CITI certification forms (bio-medical *and* social/behavioral) are attached.
__ The research design conforms to discipline standards.
__ The type of review requested is appropriate.
__ The format of the Clarkson College IRB Application conforms to the Clarkson College Applied Research Manual.
__ The Application--including the Appendices--is complete, accurate, and coherent.
__ The Nebraska Medicine Employee Request for Electronic Heath Data to be used in Education-Related Projects is approved and attached (if applicable).
__ In all communications, writing errors (punctuation and grammar) do not impair the integrity of the study or undermine the credibility of Investigators or the College.
__ I have thoroughly reviewed this research study, and it has my full support.

As Investigator(s), we assert that this Application is ready for IRB review:

Printed Name of Principal Investigator	Date
Signature of Principal Investigator	
Printed Name of Co-Investigator	Date

[7] Regardless of subject pool's educational background, readability of documents should be at or around 8th-grade reading comprehension levels.

Signature of Co-Investigator or Student Investigator

Submit the Application and Appendices through the submission form located on the Clarkson College IRB webpage (IRB APPLICATION SUBMISSION PORTAL) or mail them to the address listed below. A scanned PDF of the executed (signed) signature page(s) can be attached with the submission.

Note: The study must not begin prior to IRB approval.

Clarkson College Institutional Review Board
101 S. 42nd Street
Omaha, NE 68131
Phone: 402.552.3100; Fax: 402.552.6019

SECTION V

IRB SUBMISSION AND REVIEW CALENDAR

Exempt and expedited applications are accepted and reviewed on a rolling basis. See blackout dates schedule (located on IRB web page/Canvas IRB Companion/Student Success Guide).

All full-board applications must be received by the IRB submission deadline for the next IRB Review. The Clarkson College IRB meets 5 times per academic year (see current schedule on IRB web page/Canvas IRB Companion/Student Success Guide).

Applications that are incomplete, inaccurate, or incoherent will be returned to the PI and may be re-submitted to the IRB for review.

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 <u>not</u> 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.[8] 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: _____

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

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

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[9]

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).

[9] 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!

TEMPLATE[10] 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.

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

[10] 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.

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)
Principal Investigator(s)'s phone/email

Co-Investigator(s)'s name(s)
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 (SIGNED CONSENT FORM)

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

1. 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.)

2. 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 _____

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: _____

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.

REQUEST FOR IRB RENEWEL

If a researcher is unable to collect the data in the one calendar year time frame, a researcher may request to the IRB an extension of time to collect data.

Note: This form is for renewal of IRB approval of Human Subjects Research without revision. ***If the research has been revised since its most recent approval, or you intend to revise the research, submit a Change of Protocol Form to the IRB, in addition to the Continuing Review.***

- **It is the PI's responsibility to file a renewal request at least 15 days prior to expiration date (for Exempt and Expedited applications).**
- **If you are requesting renewal for Full-Board approval of an application, you must submit the request form by the deadline stipulated on the Full-Board Submission Deadline Schedule (located on the IRB webpage/Canvas Companion/Student Success Guide).**
- **Approval of a renewal request is not guaranteed.**
- **Automatic termination of IRB approval will occur on the expiration date. We will close this file and all research related to this project must cease.**
- **If you do not need to renew your IRB approval, you must submit a Study Closeout Form (located on the IRB webpage/Canvas IRB Companion/Student Success Guide).**

CLARKSON COLLEGE - Institutional Review Board (IRB) REQUEST FOR RENEWAL	
Instructions: This application must be completed and submitted *prior* to the IRB approval expiration date. If the study requires full-board approval, the application for renewal must be submitted *prior* the submission deadline for full-board review (see full-board meeting schedule located on the IRB web page/Canvas IRB Companion/Student Success Guide). Approval of application for renewal is not guaranteed.	
SECTION I	
IRB#:	
Title of Study:	
Principal Investigator:	
Address:	
Clarkson College ID# (if applicable):	
Phone Numbers: (work)	(cell/home)
Email:[11]	
Co-Investigator:	
Address:	

[11] Investigators outside the College should provide the email address issued by their institution.

Clarkson College ID# (if applicable):	
Phone Numbers: (work)	(cell/home)
Clarkson College Email:	
Present or Proposed Source of Funding (*if applicable*):	
(Office Use Only) **IRB #:** **Date Received:**	

SECTION 1A (for studies in progress)

1. Provide a summary of your progress to date.

2. Describe any additional risks or benefits observed during the course of the study.

3. When do you expect the research to be completed?

SECTION 1B (for studies that have **never** been initiated)

1. Provide an explanation of why the research was **never** initiated.

2. List any additional risks that have been identified since the most recent approval.

(Office Use Only)

IRB #: **Level of Review:** ___ Exempt ___ Expedited ___Full-Board
Approved: Y or N **Date Approved:**
IRB Signature:

SECTION II

Printed Name of Principal Investigator Date:

Signature of Principal Investigator

Submit the Request for Renewal form via email at IRB@clarksoncollege.edu or mail them to Clarkson College at the address listed below. A scanned PDF of the executed (signed) signature page(s) can be attached with the submission.

Note: Changes in protocol must not be implemented prior to IRB approval.

Clarkson College Institutional Review Board **101 S. 42nd Street** **Omaha, NE 68131** **Phone: 402.552.3100; Fax: 402.552.6019**

CHANGE OF PROTOCOL (COP)

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).

CLARKSON COLLEGE - Institutional Review Board (IRB) CHANGE OF PROTOCOL REQUEST	
Instructions: 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.** Approval of amendment request is not guaranteed.	
SECTION I	
IRB#:	
Title of Study:	
Principal Investigator:	
Address:	
Clarkson College ID# (if applicable):	
Phone Numbers: (work)	(cell/home)
Email:[12]	
Co-Investigator:	
Address:	
Clarkson College ID# (if applicable):	
Phone Numbers: (work)	(cell/home)
Email:	

[12] Investigators outside the College should provide the email address issued by their institution.

1. Amendment Description (**Check all as appropriate**):

   ☐ Amendment to currently approved procedures on the application (for example; changes to General information section, data collection methods section, confidentiality section, subject recruitment section, risk and benefits section etc.,)

   ☐ Amendment to Recruitment materials

   ☐ Amendment to currently approved consent/Assent/Permission forms

   ☐ Amendment to Debriefing forms

   ☐ Amendment to Data collection tools

   ☐ Other: ☐

2. List and describe the proposed changes to each document or sections on the application:
   ☐

3. State the reasons for the proposed changes:
   ☐

4. List and describe potential risks that may occur as a result of the proposed amendment(s):

5. **<u>Did you attach amended material,</u>** as applicable (Note: **<u>highlight/Bold/Underline all changes</u>**)?

   ☐ Yes

(Office Use Only)

IRB #: **Level of Review:** ___ Exempt ___ Expedited ___Full-Board
Approved: Y or N **Date Approved:**
IRB Signature:

SECTION IV
Printed Name of Principal Investigator Date:
Signature of Principal Investigator

Submit the Change of Protocol form (and any required attachments) via email at IRB@clarksoncollege.edu or mail it to Clarkson College at the address listed below. A scanned PDF of the executed (signed) signature page(s) can be attached with the submission.

Note: Changes in protocol must not be implemented prior to IRB approval.

Clarkson College Institutional Review Board
101 S. 42nd Street
Omaha, NE 68131
Phone: 402.552.3100; Fax: 402.552.6019

CLOSING THE RESEARCH STUDY

This form must be completed for all approved Expedited and Full-Board studies. The form must be submitted within 30 days of the conclusion of research activities. While Exempt studies are not required to complete and submit a Study Close Out form, we strongly encourage it. The Study Closeout form below should be completed and sent to IRB@ClarksonCollege.edu.

CLARKSON COLLEGE - Institutional Review Board (IRB) STUDY CLOSEOUT FORM	
Instructions: This form must be completed for all approved Expedited and Full-Board studies. The form must be submitted within 30 days of the conclusion of research activities. While Exempt studies are not required to submit a Study Closeout form, we strongly encourage it. The Study Closeout form below should be completed and sent to IRB@ClarksonCollege.edu.	
SECTION I	
IRB#:	
Title of Study:	
Principal Investigator:	
Address:	
Clarkson College ID# (if applicable):	
Phone Numbers: (work)	(cell/home)
Email:[13]	
Co-Investigator:	
Address:	
Clarkson College ID# (if applicable):	
Phone Numbers: (work)	(cell/home)
Email:	
(Office Use Only) **IRB #:** **Date Received:**	

[13] Investigators outside the College should provide the email address issued by their institution.

1. Initial IRB approval date:

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

3. Briefly describe the purpose of your research:

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

5. 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):

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

7. What advice do you have for future Clarkson College investigators?

8. Do you have any comments concerning the IRB process?

Printed Name of Principal Investigator **Date:**

Signature of Principal Investigator

Submit the Study Closeout form via email at IRB@clarksoncollege.edu or mail it to Clarkson College at the address listed below. A scanned PDF of the executed (signed) signature page(s) can be attached with the submission.

Clarkson College Institutional Review Board
101 S. 42nd Street
Omaha, NE 68131
Phone: 402.552.3100; Fax: 402.552.6019

UNANTICIPATED PROBLEM/ADVERSE EVENT REPORTING FORM

CLARKSON COLLEGE Institutional Review Board (IRB) – Unanticipated Problem/Adverse Event Reporting Form	
SECTION I	
Title of Study:	
Principal Investigator:	
Address:	
Clarkson CollegeID# (if applicable):	
Phone Numbers: (work)	(cell/home)
Email:[14]	
Principal Investigator's Status: ☐ Student ☐ Faculty ☐ Staff ☐ Other (please identify)	
Co-Investigator:	
Address:	
Clarkson College ID# (if applicable):	
Phone Numbers: (work)	(cell/home)
Email:	
Co-Investigator's Status: ☐ Faculty ☐ Student ☐ Staff ☐ Other	
(Office Use Only) **IRB #:** **Date Received:**	

[14] Investigators outside the College should provide the email address issued by their institution.

SECTION II

1. ate of Occurrence:
2. Location of event:
3. Brief description of the nature of the unanticipated problem (attach description if more space needed):
4. Are any of the following true regarding the event?

☐ death – date

☐ life-threatening

☐ hospitalization - initial or prolonged

☐ disability / incapacity

☐ congenital anomaly / birth defect

☐ required intervention to prevent permanent impairment

5. Relationship of event to study:

☐ Unrelated

☐ Possible

☐ Definite

6. Was this an unexpected adverse event?

☐ Yes ☐ No

7. What (if any) steps were taken to handle the event?

_____ _____

Printed Name of Principal Investigator **Date:**

_____

Signature of Principal Investigator

Submit this form via email at IRB@clarksoncollege.edu or mail it to Clarkson College at the address listed below. A scanned PDF of the executed (signed) signature page(s) can be attached with the submission.

Clarkson College Institutional Review Board
101 S. 42nd Street
Omaha, NE 68131
Phone: 402.552.3100; Fax: 402.552.6019

REFERENCES

Belmont University Institutional Review Board. Retrieved (2011. April 4) From Http://www.Belmont.Edu/Irb/Directions.Html. *Code of Federal Regulations*. Retrieved (2012, July 15) from http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html.

College Of St. Mary IRB (2010). Application Guidebook. Retrieved (2012, July 15) from https://my.csm.edu/communities/IRB/default.aspx.

United States Office of Health and Human Services Office for Human Research Protection, Retrieved (2012, July 15) from http://www.hhs.gov/ohrp.

University Of Connecticut IRB Guidance For Advertising And Recruitment. Retrieved (2012, July 15) from http://irb.uconn.edu/adv_guidance.html.

University Of Nebraska Medical Center IRB. Retrieved (2012, July 15) from http://www.unmc.edu/irb/.

World Medical Association. (2001). World Medical Association Declaration of Helsinki. Ethical principles for medical research involving human subjects. Bulletin of the World Health Organization, 79(4), 373-374.

ACKNOWLEDGEMENTS

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

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.

Clarkson College

Prepare to be the **best.**