

Clarkson College Institutional Review Board Application Manual

**This manual is intended as a guide to implement Clarkson College Policy OG-8:
Institutional Review of Research Involving Human Subjects Policy**

For any questions, please contact your research project advisor.

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ACKNOWLEDGEMENTS

Clarkson College thanks our colleagues at College of Saint Mary and the University of Nebraska Medical Center for use of their IRB materials to assist in the design of our handbook.

SECTION 1: OVERVIEW OF INSTITUTIONAL REVIEW BOARD AT CLARKSON COLLEGE

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

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

IRB Responsibilities

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

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

Clarkson College IRB meetings will be held monthly. IRB applications must be submitted at least two weeks before regularly scheduled meetings. Meeting dates may be accessed on the Clarkson College IRB webpage and will be planned at the beginning of each academic year. The IRB will meet the following months:

- September, October, and November (Fall Semester)
- January, February, March, and April (Spring Semester)
- June and July (Summer Semester)

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The IRB will review the application for its completeness, accuracy, and coherence and may require an ARC review for additional revisions needed prior to acceptance of the IRB Application. Following needed revisions, the completed application will be forwarded to the IRB for review and approval. Please be aware that further revisions may be required prior to approval.

SECTION 2: DIRECTIONS FOR CLARKSON COLLEGE IRB APPLICANTS**1. Review the IRB submission deadlines on the Clarkson College IRB Webpage**

Choose a target date and allow yourself plenty of time (e.g. one semester prior to your graduation date) to complete the process. Submitting early is a good idea because you cannot conduct your research without prior IRB approval.

2. Complete your ethics training

Provide a copy of the printout of your CITI ethics certificate. The website is:

<http://www.citiprogram.org> . Record your login information, so that you can return to the site, if needed. There is also process to search for your login if it is not available to you. See CITI TRAINING (Section 3) for more information.

3. Determine the site for your data collection, as that will affect which forms you will complete.

- a) If the research is to be conducted at TNMC, the IRB application will have to be approved by the UNMC IRB **after** approval from the Clarkson IRB is granted. Access <http://www.unmc.edu/irb/> for instructions for filling out the UNMC form.
- b) The researcher(s) who plans to collect data at other healthcare institution(s) must contact the IRB Committee at the institution where they are collecting data to determine if the healthcare institution requires an alternative IRB application or if the Clarkson College Application can serve for approval consideration.

The researcher needs to be responsible for learning and complying with the procedures required **prior to** data collection at another institution. Final Clarkson College IRB approval will not 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.

4. Review all three of the following Level of Determination checklists

Start by reviewing all three checklists beginning in Section 4 to determine the level of IRB review that fits your research. If in doubt, always go one level higher. You will need to select the appropriate Level of Determination checklist on your IRB application form.

5. If you are a student, work closely with your research advisor to determine when you are ready to complete your IRB application. Your Research Advisor or Committee Chair, as the principal investigator, must review and sign the Certification of Review section on the IRB application form, and present your research proposal to Research Forum prior to submission.

6. Complete your application using the Clarkson College IRB form.

- a. Include all sections of the application. If a section does not apply, do not delete it; mark it N/A.
- b. Work closely with your research advisor on your research design. Be sure that it is sound before moving forward.
- c. Adhere to all formal writing conventions and format your text in accordance with the most recent edition of the APA Style Manual.
- d. Proofread and edit the text of your application with care.
- e. Include all necessary consent forms—see Consent Form Guidelines in Section 6. Remember to submit consent forms on CLARKSON COLLEGE letterhead
- f. Include all data collection instruments (surveys, interview protocols, etc.). Surveys must be reviewed with The Coordinator of Quality Assurance and Institutional Effectiveness.
- g. A letter of permission from a community site must be submitted before final approval to conduct the research will be granted.
- h. Incomplete applications will be returned and may delay your research timeline and thus progression in your program of study.
- i.

7. The PI's will email your completed Application Packet to the IRB co-chairs by the submission deadline, prior to IRB regularly scheduled meetings at IRB@clarksoncollege.edu. The IRB strongly recommends that your application is submitted one semester prior to your targeted graduation date.

8. Remember that complete, accurate, and coherent applications that are submitted by an IRB submission deadline will normally be reviewed at the next IRB meeting. If approved, the investigators will be issued a letter that includes the research IRB approval number, approval date, and expiration date.

Note: Applications that are incomplete, inaccurate, or incoherent will be returned to the principal investigator via official correspondence from the IRB with 7-10 business days. The principal investigator is then required to join the Application Review Committee (ARC) to address the concerns of the IRB committee. Subsequent revisions must be re-submitted at least two weeks before the next scheduled IRB meeting.

9. Following Approval, duplicate the approved consent form (with assigned IRB Number, approval date and expiration date) and Rights of Research Participants form for distribution to all participants.

10. Note that Extensions and Changes of Protocol may be requested, if the research project extends past one year, using the *Extension/Protocol Change Request Form* found in Section 9

11. When research is complete, submit the one-page *Closing the Study Form* (see Section 10) to IRB@clarksoncollege.edu within 30 days of completing your study.

12. Research that has been approved by another IRB may be subject to further appropriate review and approval or disapproval by the Clarkson College IRB. Any application that the

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Clarkson College IRB committee reviews must be submitted on the Clarkson College IRB application form.

SECTION 3: HUMAN PARTICIPANTS PROTECTION EDUCATION

Clarkson College requires all investigators, study personnel, and protocol coordinators engaged in human subjects' research to undergo training in the protection of human subjects. **Each IRB applicant must complete the CITI training and submit an electronic copy of the completion certificate with the IRB application. The training can be accessed through the website listed below.**

- a) Go to the CITI website: <http://www.citiprogram.org>
- b) Click on "Register ": This will take you to another page.
- c) Choose the "Participating Institutions" drop down box.
- d) Select "University of Nebraska Medical Center (UNMC/UNO)" and Click "Continue to Step 2".
- e) You will be taken to a Registration Page. Type in the appropriate information.

Please note that you only need to type in the information in which there is an * next to it!
Click "Continue to Step 3"

- f) Create your own User Name and Password using the instructions given.

Choose a security question in case you forget your login information. Record your User Name and Password in a safe place because you will need them to access the course.
Click "Continue to Step 4".

- g) Now you will be asked questions about gender, ethnicity, and race.
After completion, click "Continue to Step 5."
- h) Complete Step 5 and click "Continue to Step 6."

i) Now you will be asked information requested by the University of Nebraska Medical Center. Please note that you only need to type in the information in which there is an * next to it! After completion, click "Continue to Step 7."

- j) Now you will be asked a series of questions.

Do you conduct research in any of the following settings? Select "Human Subjects Research"

Have you previously completed the basic course before?

- Select "**No, I have not completed the Basic Course...I need to complete the Basic Course**" since you are required to complete the appropriate CITI Course(s) at this time.

Regarding which group you belong to?

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- Select **Group 1** Biomedical Investigators and Key Personnel and Click “Next” and then “Finalize Registration”

An email will be sent to you with a link to complete your registration.

k) Your User Name and Password are what you selected. Therefore, you will be able to access the website from the link sent in the email www.citiprogram.org

Please note the following:

- All UNMC and Nebraska Medical Center faculty/students/affiliates/collaborators must complete the Bio-Medical and Social/Behavioral (SBR) training.

Follow the directions on the screen to complete the training. Most of the modules are brief, and the quizzes can be re-taken if you do not pass.

Please be sure to print out a copy of your Course Completion Record when you have completed the Bio-Medical and SBR courses and save it electronically. Maintain a copy for your records, and send a copy to IRB@clarksoncollege.edu. It is crucial that the Clarkson IRB Office receives a copy of your Course Completion Record with your IRB application. CITI certification lasts for three years.

SECTION 4: LEVEL OF DETERMINATION CHECKLISTS

TITLE OF STUDY _____

PRINCIPAL INVESTIGATOR and Co-INVESTIGATOR(S) _____

DATE _____

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

LEVEL OF DETERMINATION CHECKLIST #1 EXEMPT REVIEWS

A study may qualify for an exempt IRB review if it fits into one of the categories outlined below.

Check all those that apply:

____ **Category 1: 45 CFR 46.101(b)(1)**

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

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

____ **Category 2: 45 CFR 46.101(b)(2)**

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

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

____ **Category 3: 45 CFR 46.101(b)(3)**

FOR SUBJECTS WHO ARE ELECTED OR APPOINTED PUBLIC

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

____ **Category 4: 45 CFR 46.101(b)(4)**

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

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

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

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

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

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

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

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

Taste and food quality evaluation and consumer acceptance studies,

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

NOTE:

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

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

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LEVEL OF DETERMINATION CHECKLIST #2: EXPEDITED REVIEWS

Note: If you determine that your study qualifies for expedited review, complete this checklist and submit a copy with your IRB Application.

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

Minimal risk as defined by 45CFR 46.102(I) <http://www.hhs.gov/ohrp/> means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. A study may qualify for an expedited IRB review if it fits into one of the categories outlined below.

Check all those that apply:**___ Category 1:**

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

___ Category 2: .

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

___ Category 3:

Obtaining data from subjects 19 years or older using routine noninvasive procedures

___ Category 4:

Analysis of video or audio recordings

___ Category 5:

Moderate exercise by healthy volunteers

___ Category 6:

Studies involving collection of existing unidentifiable specimens by non-invasive means.

___ Category 7:

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

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

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LEVEL OF DETERMINATION CHECKLIST #3: FULL REVIEWS

Note: If you determine that your study requires full review, complete this checklist and submit a copy with your IRB Application.

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

___ **Category 1:**

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

___ **Category 2:**

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

___ **Category 3:**

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

___ **Category 4:**

Studies involving deception or if the subjects are not fully informed of the purpose and procedures of the study

___ **Category 5:**

Studies involving support from non-university sources requiring full IRB approval

___ **Category 6:**

Likelihood of risk or substantial stress or discomfort to the subject

___ **Category 7:**

Procedures that may potentially threaten or embarrass subjects

___ **Category 8:**

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

___ **Category 9:**

Healthcare procedures not conducted for the primary benefit of the subject

___ **Category 10:**

Diagnostic or therapeutic assessments, interventions, or measures that are not standard, generally acceptable, or common practice

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_____ Category 11:

Exposure to surgery, drugs, or chemical agents

_____ Category 12:

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

_____ Category 13:

Collection of blood samples or other body fluids in any amount

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

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

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

SECTION 5: IRB GUIDELINES FOR APPLICATION

A. *The IRB Application standard form will be reviewed with specific attention to the components in the applications that address the following:*

1. Purpose of the study.
2. Description of population.
3. Description of subject selection.
4. Description of study sites.
5. Methods and procedures for data collection.
6. Process and procedures of informed consent.
7. Documentation of informed consent.
8. Compensation for participants.

B. Applications will be critiqued attending to Federal Regulations 45, Part 46, section 111 with particular evaluation of the following:

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

SECTION 6: DEFINITION OF TERMS FOR IRB APPLICATION

*Note: Be sure to read Directions for Application and complete your Level of Determination checklist **BEFORE** attempting to complete the IRB application form (which can be found on the IRB webpage)*

Title of the Research Study: consult APA manual for proper wording

Problem Statement (e.g. PICO): what is your problem statement that succinctly states the problem, current remedy or solution, proposed remedy or solution, and the outcomes you hope to accomplish.

Purpose, Background and Rationale of the Study.

Briefly identify the specific aim of the research – why is the research being conducted?

In the Background and Rationale, provide a summary of the background information and reason(s) this research is needed. State the research question(s). State the hypotheses, if applicable. Overview relevant research that provides a foundation for this study:

- a. An exempt review requires at least 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 should include five or more citations 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 this application.

Population and Characteristics:

Indicate the minimum and maximum number of participants. If more than one site is used, please indicate the maximum number of participants per site.

What are the specific inclusion criteria for participation? If there are participation restrictions (e.g., gender, race, religion, age, etc.), provide rationale as to why these restrictions are necessary.

Method of Subject Selection. Describe all techniques used to recruit individual participants and methods used to seek site approval for agencies and locations other than Clarkson College. All recruitment materials (e.g. phone scripts, emails, letters, flyers, etc...) must be attached to this application in the appendix.

Study Site(s): Describe specifically where the study will be conducted. You must attach letters of agreement with agencies or locations in the appendix..

Description of Research Design and Procedures for Recruitment and Collection of Data:

Describe whether you will be using a quantitative, qualitative, or mixed methods approach. Briefly note how you will ensure validity and reliability in your study. (Note: A poorly-designed study may be considered a waste of research participants' time, so could be considered unethical and will not be approved by the IRB).

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Describe the study. Discuss study procedures; sequential description of what subjects will be asked to do; assignment of subjects to various arms of the study, if applicable; how data are to be collected (questionnaire, interview, focus group, audio taping, videotaping or other measures). Include information on who will collect data, who will conduct procedures or measurements. Indicate the number and duration of contacts with each subject, outcome measurements, and follow-up procedures.

Ultimate Disposition of the Data Collected: how will the data be stored and ultimately disposed of?

Risk/Benefit Assessments: review consent forms in the guide book under Section 7

Steps to Protect Confidentiality and Privacy: Address how data will be kept confidential. Will any identifiers be used to specifically link data to an individual participant? If so, provide justification as to why identification of individuals is necessary. If data will be aggregated, mention that. Review section 7.

Informed Consent. (See guidelines in Section 4 and 7 for full information).

The form should include full disclosure of the study. 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). 12

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

SECTION 7: IRB CONSENT FORM GUIDELINES

DEVELOPMENT OF THE INFORMED CONSENT FORM

The following instructions and examples are provided to assist in development of the Informed Consent Form.

General Formatting Directions:

Consent forms must be printed with CLARKSON COLLEGE letterhead (provided in Appendix D)

All forms should be submitted suitable for reproduction (printed single sided) using a 12 point font (Times New Roman or Ariel are recommended) and one-inch margins. Each page of the consent form should be full without inappropriate divisions; sections can be split so that large blank areas do not exist.

Upon final approval, all pages must include (1) the assigned IRB number in the upper left, (2) the page number in the upper right corner, (3) a participant's initial blank in the lower right corner (see example)

The following should be considered when developing the consent form:

1. **Second Person Language:** The informed consent form must be written in the second person. When combined with conditional language, utilization of the second person personalizes the consent form and reflects the existence of voluntary decision-making on the part of the prospective participant.

2. **Readability:** The consent form must be written in simple enough language so that it is readily understood by the least educated of the participants to be utilized. Normally the highest level of language in the consent form should equate to a **6th grade** standard depending on the subjects being recruited for the study. Scientific terms and abbreviations should be avoided. Use brief sentences and one syllable words when possible. Utilize the Microsoft program to obtain the Flesch-Kincaid Grade Level and put that information in your application. See references for more information.

3. **Clarifying Consent Form Sections:** The informational content of the elements of informed consent should not be mixed or repeated unless necessary. Information presented under any given element should be reasonably complete and restricted to content appropriate to that element. This helps the prospective participant focus on each individual element of consent thereby increasing the validity of the consent process.

4. **REQUIRED Consent Form Formats are provided on the following pages:** Structure the consent forms just as these are structured. Provide the questions in bold and below the question provide the appropriate statements. Examples of the statements are given in box parentheses. If

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necessary, alter statements to fit your study, but the statements must include all elements of those provided. Your consent form will probably be only two pages in length.

5. Under-aged Participants: Please note that: *adult// participants must be 19-years of age or older in Nebraska*. Each state determines the age of adulthood. If participants are under 19-years of age in Nebraska, different consent forms must be used. See the Adolescent Assent Form and the Parent and Child Consent Forms.

6. Waiver of Written Consent Documentation:

Justification for a waiver of written (i.e., signed) consent. The default is for subjects to sign a written document that contains all the elements of informed consent. Under limited circumstances, the requirement for a signed consent form may be waived by the IRB if either of the following is true:

- a. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality (e.g., study topic is sensitive so that public knowledge of participation 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. Note: This justification cannot be used in FDA-regulated research.
- b. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context (e.g., phone survey). Explain.

Applicants who are seeking a Waiver of Informed Consent **MUST** complete a Request for Waiver of Written Consent Documentation (see p. 33). It should be noted that consent must be obtained orally, by delivering a fact sheet, through an online consent form, or be incorporated into the survey itself. Include a copy of the consent script, fact sheet, online consent form, or incorporated documents.

7. RIGHTS FOR RESEARCH PARTICIPANTS Each participant in your research study needs to receive a hard copy of the following form on p. 19 (or one like it that has been adapted to your population):

THE RIGHTS OF RESEARCH PARTICIPANTS

AS A RESEARCH PARTICIPANT AT Clarkson College YOU HAVE THE RIGHT:

1. TO BE TOLD EVERYTHING YOU NEED TO KNOW ABOUT THE RESEARCH BEFORE YOU ARE ASKED TO DECIDE WHETHER OR NOT TO TAKE PART IN THE RESEARCH STUDY. The research will be explained to you in a way that assures you understand enough to decide whether or not to take part.
2. TO FREELY DECIDE WHETHER OR NOT TO TAKE PART IN THE RESEARCH.
3. TO DECIDE NOT TO BE IN THE RESEARCH, OR TO STOP PARTICIPATING IN THE RESEARCH AT ANY TIME. This will not affect your relationship with the investigator or Clarkson College.
4. TO ASK QUESTIONS ABOUT THE RESEARCH AT ANY TIME. The investigator will answer your questions honestly and completely.
5. TO KNOW THAT YOUR SAFETY AND WELFARE WILL ALWAYS COME FIRST. The investigator 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. TO PRIVACY AND CONFIDENTIALITY. The investigator will treat information about you carefully and will respect your privacy.
7. 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. TO BE TREATED WITH DIGNITY AND RESPECT AT ALL TIMES.

THE INSTITUTIONAL REVIEW BOARD IS RESPONSIBLE FOR ASSURING THAT YOUR RIGHTS AND WELFARE ARE PROTECTED. IF YOU HAVE ANY QUESTIONS ABOUT YOUR RIGHTS, CONTACT THE INSTITUTIONAL REVIEW BOARD at IRB@clarksoncollege.edu or 402.552.3100.

ADAPTED FROM THE UNIVERSITY OF NEBRASKA MEDICAL CENTER, IRB WITH PERMISSION.

CLARKSON COLLEGE CONSENT FORMS**ADULT CONSENT FORM**

IRB#: **Approval Date:** **Expiration Date:**

Title of this Research Study. *List the title in this section exactly as it appears on the IRB Application using all capital letters and bold type.*

Invitation. *Invite the prospective participant to participate in the study using the following standard invitation to participate:*

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.

Why are you being asked to be in this research study? *Explain succinctly and simply why the prospective participant is eligible to participate. As appropriate, major eligibility criteria may be included in this section (e.g. "You are being asked to be in this study because you are either an employee or a supervisor working a night shift").*

What is the reason for doing this research study? *This section should state the scientific purpose of the study. If appropriate, brief background material may be provided to help the potential participant understand why the research is being done (e.g., "People who work at night employ 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 to (1) better understand these strategies and (2) determine whether „supervisor strategies“ could be successfully used by employees.") This information should be provided in simple language without reference to the participant.*

What will be done during this research study?

Describe the procedures chronologically using simplistic language, short sentences (1-3 lines) and short paragraphs (less than 6 sentences). The use of subheadings helps to organize this section and increases readability. The description 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 participants to know prior to consenting that the study involves randomization, explain that they will be assigned by chance to a study group. Explain the study groups. Indicate if there are specific requirements of the research participants, such as follow-up interviews or questionnaires.

What are the possible risks of being in this research 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*

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include loss of confidentiality and emotional or psychological distress. Alternately, if there are no known risks use this standard clause:

[There are no known risks to you from being in this research study.]

What are the possible benefits to you? *If direct participant benefits can reasonably be anticipated as a result of participating in the protocol, then describe these possible benefits. Conclude with the following standard clause:*

[However, you may not get any direct benefit from being in this research study.]

If direct participant benefits are NOT anticipated, then use the following standard clause:

[You are 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 society in terms of advancement of knowledge and/or ultimate possible benefits to persons in the prospective participants' position.*

What are the alternatives to being in this research study? *Describe, in reasonable detail, alternatives the prospective participant may have available. Alternately, use the following standard clause if applicable:*

[Instead of being in this research study you can choose not to participate.]

What will being in this research study cost you?

This section should state the financial obligations the participant will incur as a result of participating in the study. If there are no financial obligations to the participant then use the following standard clause:

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

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

[You 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 you will include in this section.*

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For studies classified as minimal risk, use the following standard clause:

[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.]

Note: Clarkson College will not approve studies that have greater than minimal risk to participants

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

[Reasonable steps will be taken to protect your privacy and the confidentiality of your study data.]

Next, if the research requires collection of sensitive information (socially, financially, legally or otherwise) from the prospective participant, follow the introductory standard clause (above) with a brief description of the precautions which will be utilized to protect that data. Finally, for all protocols, conclude with the following standard clause:

[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 may be published in scientific journals or presented at scientific meetings but your identity will be kept strictly confidential.]

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 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 or contact the Clarkson College Institutional Review Board (IRB), at (402)-552-3100.]

What will happen if you decide not to be in this research study or decide to stop participating once you start? Use the following standard clauses:

[You can decide not to be in this research study, or you can stop being in this research study (—withdraw||) 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, or with Clarkson College (also add any other sites to this statement, if needed.

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.]

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Documentation of informed consent. *Use the following standard clause:*

[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, you should talk to one of the investigators listed below. You will be given a copy of this consent form to keep. If you are 19 years of age or older and agree with the above, please sign below.]

Signature of Participant:

Date: Time:

Participant Initials _____ (*Put place for participant initials on each page.*)

For all studies include the following investigator certification clause: [

[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 Investigators:

Date:

Authorized Study Personnel. Identify all personnel authorized to document consent as listed in the IRB Application. Use the following subheadings: Principal Investigator, Secondary Investigator(s), and Participating Personnel. Include day phone numbers and e-mails for all listed individuals.

Principal Investigator: _____ Phone: _____

Co-Investigator: _____ Phone: _____

Participant Initials _____ **should be at bottom of each page** to signify they have read each page.

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PARENT AND CHILD PERMISSION FORM

IRB#: **Approval Date:** **Expiration Date:**

Title of this Research Study. *List the title in this section exactly as it appears on the IRB Application using all capital letters and bold type.*

Invitation. *Invite the parent or guardian to decide whether or not to give permission for their child to participate in the study using the following standard invitation to participate:*

[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 them to take part. If you have any questions, please ask.]

Why are you being asked to be in this research study? *Explain succinctly and simplistically why the prospective participant is eligible to participate. As appropriate, major eligibility criteria may be included in this section (e.g. "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. If appropriate, brief background material may be provided to help the potential participant understand why the research is being done (e.g., ") This information should be provided in simplistic language without reference to the participant.*

What will be done during this research study? *Describe the procedures chronologically using simplistic language, short sentences (1-3 lines) and short paragraphs (less than 6 sentences). The use of subheadings helps to organize this section and increases readability.*

The description 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 participants to know prior to consenting that the study involves randomization, explain that they will be assigned by chance to a study group. Explain the study groups. Indicate if there are specific requirements of the research participants, such as follow-up interviews or questionnaires.

What are the possible risks of being in this research 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 use this standard clause:*

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

What are the possible benefits to you? *If direct participant benefits can reasonably be anticipated as a result of participating in the protocol, then describe these possible benefits. Conclude with the following standard clause:*

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

If direct participant benefits are NOT anticipated, then use the following standard clause:

[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 society in terms of advancement of knowledge and/or ultimate possible benefits to persons in the prospective participants' position.*

What are the alternatives to being in this research study? *Describe, in reasonable detail, alternatives the prospective participant may have available. Alternately, use the following standard clause if applicable:*

[Instead of being in this research study you can choose for your child not to participate.]

What will being in this research study cost you? *This section should state the financial obligations the participant will incur as a result of participating in the study. If there are no financial obligations to the participant then use the following standard clause:*

[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 for participating in the research, state the amount of compensation and conditions for payment. If no compensation is provided, then use the following standard clause:*

[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 you will include in this section. For studies classified as minimal risk, use the following standard clause:

[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.]

Note: Clarkson College will not approve research that is greater than minimal risk.

How will information about you be protected?

Begin with the following standard clause:

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

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Next, if the research requires collection of sensitive information (socially, financially, legally or otherwise) from the prospective participant, follow the introductory standard clause (above) with a brief description of the precautions which will be utilized to protect that data. Finally, for all protocols, conclude with the following standard clause:

[The only persons who will have access to your or your child's 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 may be published in scientific journals or presented at scientific meetings but your identity and your child's identity will be kept strictly confidential.]

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

[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 or call the Institutional Review Board (IRB), telephone (402)-399-2400.]

What will happen if you decide not to be in this research study or decide to stop participating once you start? *Use the following standard clause:*

[You can decide for your child not to be in this research study, or you and/or your child can decide to stop being in this research study (—withdraw||) 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 or your child's relationship with the investigator, or with Clarkson College (also add any other sites to this statement, if needed).

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 want your child to continue being in the study, you will be informed promptly.]

Documentation of informed consent. *Use the following standard clause for the remainder for this page:*

[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, you should talk to one of the investigators listed below. You will be given a copy of this consent form to keep.

Signature of Parent: _____

Date: Time: _____

Signature of Participant: _____

Date: Time: _____

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For all studies include the following investigator certification clause:

(My signature certifies that all the elements of informed consent described on this consent form have been explained fully to the participant and parent. In my judgment, the parent 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 Investigators: _____ Date: _____

Authorized Study Personnel

Identify all personnel authorized to document consent as listed in the IRB Application. Use the following subheadings: Principal Investigator, Secondary Investigator(s), and Participating Personnel. Include day phone numbers for all listed individuals.

Principal Investigator _____ Phone _____

Co-Investigator _____ Phone _____

Participating Personnel _____ Phone _____

_____ **Parent Initials** _____ **Child Initials** _____ **(initials of both should be at bottom of each page to signify they have read each page)**

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ADOLESCENT ASSENT FORM FOR PARTICIPANTS AGED 12 to 18 years

(use both Adolescent Assent form and Parent Consent form for 12 to 18 year olds.)

IRB#: **Approval Date:** **Expiration Date:**

Title of this Research Study. *List the title in this section exactly as it appears on the IRB Application using all capital letters and bold type.*

Invitation. *Invite the prospective participant to participate in the study using the following standard invitation to participate. Be sensitive to readability levels:*

{ We're asking you to be in a research study. As you know, research is a way to learn new things. You will only be in the study if you decide that you want to be. We'll tell you about the study and then you should take time to make your decision. You should 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 participant is eligible to participate. As appropriate, major eligibility criteria may be included in this section (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? *This section should state the scientific purpose of the study. If appropriate, brief background material may be provided 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 simplistic language, short sentences (1-3 lines) and short paragraphs (less than 6 sentences). The use of subheadings helps to organize this section and increases readability. The description should include when the research activities will take place, where they will occur and how much time will be required. For example: "First you will be given a questionnaire with 40 statements. Then you will be asked to read each item and give it a score from 1-5, depending on how much you agree or disagree with it."*

What will be in this research study cost you?

This section should state the financial obligations the participant will incur as a result of participating in the study. If there are no financial obligations to the participant then use the following standard clause:

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

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Will you be paid to be in this research study?

This section should state any financial arrangements made to remunerate the participant as a result of participating in the study. If there is no remuneration, then use the following standard clause:

[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 participating in the protocol, then describe these possible benefits. Conclude with the following standard clause:*

[However, there might not be any particular good things about being in this research 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 use this standard clause:*

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

How long will this take? *Explain the time commitment. Example: "Most students need 30-45 minutes to finish this questionnaire. Will people know that I am in the study? Describe confidentiality. Avoid using the word "secret". 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"?

[Yes. Instead of being in this research study you can choose not to participate. If you decide to be in the study and then change your mind, you can stop being in the study at any time. No one will be mad or upset.]

Is there anything else I should know about the study? *If there is additional information that needs to be disclosed, use this section.*

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 concerning 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 and do you want to be in the study?

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I understand. All my questions were answered. Please check one:

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 Initials _____ (must be at bottom of each page of consent form to signify they have read each page.)

ELECTRONIC CONSENT FORMS

In limited instances where research is being conducted utilizing an online survey or when consent is being sought for a scheduled phone interview, an alternative to the standard Informed Consent Form format can be used. The applicant must carefully explain the rationale for use of this alternative form in the IRB application form.

This format contains all of the required components of the standard format, but uses an assumed consent. Consent is assumed when participants choose to complete an online survey or when they agree to participate in a scheduled phone interview when contacted.

With survey research, participants can choose not to participate through not completing the survey or to end their participation and not complete the survey instrument at any time. A statement addressing this option is required in the Online Consent Form format.

With phone interviews, participants can choose not to schedule a phone interview when contacted or can end their participation at any time during the interview. At the beginning of the interview and periodically throughout the interview, it is important that researchers acknowledge the participant's right to end the interview at any time.

The template for Media Consent Forms is provided. It includes the required elements and gives IRB applicants the opportunity to put in information relevant to their study's purposes and procedures.

The *Rights of Research Participants* document must be provided as part of the Online Consent Form. **All online surveys must be distributed through the Office of Assessment and Evaluation at Clarkson College.** Online data will be stored in that office also. (See below for instructions and required format).

Template for Electronic Consent

Date: **(TITLE OF STUDY) – ALL CAPITALIZED LETTERS AND BOLD TYPE IRB #** (enter IRB number assigned) Dear _____, (Address according to the role or connection that makes them eligible for invitation to participate. For example, —Dear Nursing Educator||).

You are invited to take part in a research study because you are (note characteristic that make the person eligible). The purpose of this study is to (describe the general purpose or intention of the study). This research study is being conducted as part of the requirements of my (state type of degree program) program at Clarkson College. You may receive no direct benefit from participating in this study (use the previous statement unless you expect the participant to receive a direct benefit), but the information gained will be helpful to (describe what the expected benefits of knowledge or understanding gained to either the research community or public at large).

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Should you decide to participate you are being asked to complete the following on-line survey which should take approximately (identify specific amount of time) to complete. Your participation is strictly voluntary. Furthermore, your response or decision not to respond will not affect your relationship with Clarkson College or any other entity. Please note that your responses will be used for research purposes only and will be strictly confidential. No one at Clarkson College will ever associate your individual responses with your name or email address. The aggregate information from this study may be published in journals and presented at professional meetings.

Your completion and submission of the questionnaire indicate your consent to participate in the study. You may withdraw at any time by exiting the survey. This study does not cost the participant in any way, except the time spent completing the survey. There is no compensation or known risk associated with participation. Please read *The Rights of Research Participants* below. If you have questions about your rights as a research participant, you may contact the Clarkson College IRB Board at 402-552-3100 or email IRB@clarksoncollege.edu. Thank you sincerely for participating in this important research study. If you have comments, problems or questions about the survey, please contact the researcher(s).

If you are 19 years of age or older and agree to the above please proceed to (put in link to survey) and begin the survey.

Sincerely,

Principal Investigator(s)'s name(s)

Principal Investigator(s)'s Contact Information

Co-Investigator(s)'s name(s)

Co-Investigator(s)'s Contact Information

Request for Waiver of Written Consent Documentation

Under special circumstances, investigators may request a waiver to obtain written informed consent from research subjects. This type of waiver will be given only when there are compelling reasons to do so.

Applicants who are seeking a Waiver of Informed Consent **MUST** complete a Request for Waiver of Informed Consent. It should be noted that consent must be obtained orally, by delivering a fact sheet, through an online consent form, or be incorporated into the survey itself. Include a copy of the consent script, fact sheet, online consent form, or incorporated document.

Clarkson College Waiver of Written Consent Documentation:

Justification for a waiver of written (i.e. signed) consent. The requirement for written consent may be waived by the IRB if either of the following is true:

- a. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality (e.g., study topic is sensitive so that public knowledge of participation 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.* Note: This justification cannot be used in FDA-regulated research.
- b. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context (e.g., phone survey).

In order for your request to be considered, please answer fully each of the following questions. Make sure that each response includes thorough explanation and description. Please provide supporting documentation, as appropriate.

1) **Title of Study: (All caps, bold face)**

2) Will waiving the written informed consent adversely affect subjects, their rights, or their welfare? Please explain.

3) Will pertinent information be provided to the subjects later, if appropriate? If yes, when?

4) Is there an adequate plan to protect the identifiers from improper use and disclosure? Briefly, explain the plan.

Principal Investigator _____ Date _____

Co-Investigator _____ Date _____

SECTION 8: RECRUITMENT MATERIALS GUIDELINES

General Recruitment

Advertisements and recruitment material are considered 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. The IRB must approve all recruitment methods and material (flyers, letters, brochures, e-mail advertisements, radio announcements, etc.) 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 cannot 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 media to recruit subjects. Examples include flyers posted in public settings, newspaper ads, and radio and television advertisements.
- Direct recruitment of participants who are unknown to the researchers. Examples include random digit dialing, approaching people in public settings, snowball sampling (chain sampling), and use of social networks.
- Provide colleagues with an IRB-approved Introduction letter describing the study. This letter would explain the purpose and procedures of the study and inform individuals 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. If interested, the participant contacts the researchers for additional information.
- Avoid approaching your own students or employees. This method raises ethical concerns because individuals may have difficulty saying "no" to an authority figure.

Advertisements

Advertisements should contain information that provides enough detail to allow the prospective participant to determine his/her eligibility and interest. Visual effects that may create undue influence cannot be used, for example, placing the phrase "GET PAID \$100!!!" in all capital letters or an extra-large font while the rest of the ad is in lower case or a smaller font is not acceptable.

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Generally, the elements of any advertisement to recruit participants 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";
- In summary form, the key eligibility criteria that will be used to admit (or exclude) participants into the study, e.g., an acceptable age range or unacceptable physical limitations; straightforward and truthful descriptions of the benefits, if any, to the participant from participating in the study, e.g., "free health screening";
- If applicable, a statement that compensation is available or a statement of how much compensation is available, e.g., "Participants may receive up to \$100"; the amount/length of time or other commitment required of the participants; the location of the research and contact information for obtaining additional information.

Advertisements must display the IRB approval number, unless an exception has been granted by the IRB. If it is not feasible to make copies of the validated version, it is acceptable to use the exact wording of the validation stamp: "Clarkson College IRB, Approval On (date), Approved until (date), Approved by (initials)."

Advertisements **cannot** incorporate elements that:

- Do not state or imply a certainty of favorable outcome or other benefit beyond what is in the informed consent form;
- Do Not Use catchy words like "free" or "exciting."

Recruitment/Advertising Tips and Suggestions

- Understand the target population. What media does the population read or view? Where do they go for information?
- Make concerted efforts to recruit participants from minority and under-represented groups. Describe those efforts in the IRB application.
- Spend the time to make the recruitment flyers easy to read and understand. Triple-check for typos, as your work will reflect directly on Clarkson College. Advertisements must be written using lay language, at an 8th grade reading level (similar to the level used by popular magazines and newspapers) that is appropriate for the participant population. You should select a font style and size that is easy to read such as Times New Roman..

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

SECTION 9: APPLICATION FOR EXTENSION OR CHANGE OF PROTOCOL

Procedures for Requesting Extension or Change of Protocol Applicants may request approval to make changes (amendments) in various aspects of a project. All changes must be approved by the IRB prior to implementation.

Amendments include:

- changes in experimental design
- insertion of new information
- correction of errors in text
- change in primary investigator
- change in study duration
- change in numbers of subjects
- changes in inclusion or exclusion criteria
- number of locations (site).

A written request must be submitted. If the changes of protocol requested will require changes in the description of procedures in the application, recruitment materials, or in the Informed Consent, attach the revised documents to the Extension or Change of Protocol Form with changes tracked or highlighted as well as a clean copy. Upon completion of review of the application, the investigator(s) will be notified of either a request for additional information or an approval notification within 7-10 business days.

CLARKSON COLLEGE INSTITUTIONAL REVIEW BOARD**EXTENSION OF STUDY FORM:**

In the event that a researcher is unable to collect the data in the one calendar year time frame or needs to change the protocol for data collection, a researcher may request to the IRB an extension of time to collect data or a change of protocol. The IRB will consider the request and determine whether further approval will be granted.

Date Extension Request is being submitted:

IRB Number:

Principal Investigator:

Principal investigator's phone number:

Principal investigator's Clarkson email address:

Co-Investigator:

Co-investigator's phone number:

Co-investigator's Clarkson email address:

Degree being pursued (if applicable):

Advisor's name (if applicable): Department:

Title of Research Proposal:

Expected time needed to complete the project:

Rationale for the request:

Signature of Co-Investigator _____

Signature of Primary Investigator _____

CHANGE OF PROTOCOL:

Investigators may request approval to make changes (amendments) in various aspects of a project.

All changes must be approved by the IRB prior to implementation. Amendments include: changes in experimental design, insertion of new information, correction of errors in text, change in primary investigator, change in study duration, change in numbers of subjects, or number of locations (site), slight changes in population sample composition. A written request must be submitted. Upon completion of review (generally within 1 week of the submission), an approval notification will be sent to the primary investigator.

Date Change of Protocol Request Form is being submitted:

IRB Number:

Principal Investigator:

Principal Investigator's phone number:

Principal Investigator's Clarkson email address:

Co-Investigator:

Co-investigator's phone number:

Co-investigator's Clarkson email address:

Department: Degree being pursued (if applicable):

Title of Research Proposal:

Proposed Changes:

Rationale for Proposed Changes: Do these changes affect either the risks or the benefits of this study? Yes No

If yes, please explain:

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

SECTION 10: CLOSING THE RESEARCH PROJECT

This form is to be completed for all studies approved via expedited or full review procedures. The form must be submitted within 30 days of the conclusion of research activities. The Closing the Study form below should be completed and sent directly to: IRB@ClarksonCollege.edu.

Appendix C: Closing the Study Form

This form is to be completed for all studies approved via expedited or full IRB review procedures. It must be submitted within 30 days of the submission of your article, project, thesis, or dissertation for formal review by faculty or a professional journal publication review board or presentation at a conference. Submit it electronically to: delfs@clarksoncollege.edu

Date:

Project Title:

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

IRB Protocol #:

Initial IRB Approval Date:

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

Please briefly describe the purpose of your research:

Please briefly describe your findings (*or include a copy of your abstract*):

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

What advice do you have for future Clarkson College researchers?

Do you have any comments concerning the IRB process?

Co-Investigator's Name(s):

U.S. Mailing Address:

Phone:

CLARKSON COLLEGE Email:

Alternate Email

SECTION 11: REFERENCES

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

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Mission

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

Values

LEARNING

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

CARING

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

COMMITMENT

Dedication to the shared mission of Clarkson College.

INTEGRITY

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

EXCELLENCE

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

