|  |
| --- |
| 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:[[1]](#footnote-1)       |
| 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:** |

|  |
| --- |
| **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 sA 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: 1. 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;
2. 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
3. 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: 1. 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;
2. 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
3. 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,[[2]](#footnote-2) 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.[[3]](#footnote-3) *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:1. The identifiable private information or identifiable bio-specimens are publicly available;
2. 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. 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
4. 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,**1. If wholesome foods without additives are consumed, or
2. 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:1. 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;
2. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with 46.117;
3. 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
4. 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): |
| 1. Potential Psychological, Social, Economic, or Legal Risks:
 |
| 1. Risk Classification:
 |
| 1. Potential Risks:
 |
| 1. 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):       |
| 1. Readability Statistics (e.g., Flesch-Kincaid) of cover letters, fliers, surveys, questionnaires, tests):[[4]](#footnote-4)
 |
| 1. Documentation of Consent:
 |
| 1. 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 REVIEWAs 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 |
| **Signature of Co-Investigator**  |
| Submit the Application and Appendices through the submission form located on the Clarkson College IRB webpage ([IRB APPLICATION SUBMISSION PORTAL](https://app.smartsheet.com/b/form/f6eedbe8565c47f69a1026e9003583c7)) 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 CALENDARExempt 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. |

Rev. July 2020

1. Investigators outside the College should provide the email address issued by their institution. [↑](#footnote-ref-1)
2. Physical and invasive procedures include FitBits and saliva collection. [↑](#footnote-ref-2)
3. Subject debriefing is strongly encouraged. [↑](#footnote-ref-3)
4. Regardless of subject pool’s educational background, readability of documents should be at or around 8th-grade reading comprehension levels. [↑](#footnote-ref-4)