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| CLARKSON COLLEGE – Institutional Review Board (IRB)NON-EXEMPT APPLICATION | |
| Instructions: Be sure to consult the IRB Applied Research Manual as you complete each section as directed and in full. | |
| **SECTION I** | |
| Title of Study: | |
| Principal Investigator: | |
| Address: | |
| Clarkson College Student ID# (if applicable): | |
| Phone Numbers:       (work) | (cell/home) |
| Email:[[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*): | |
| Type of Review Requested:  Expedited  Full Board | |
| **(**Office Use Only)  **IRB #:       Date Received:** | |

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| **SECTION II**  *An Expedited Review is indicated for research involving no more than minimal risk, no vulnerable populations, or a review of minor changes in previously approved research or research protocols. For the review covered by the Regulations 45 CFR 46.110, the IRB will determine that all of the requirements are satisfied.*  A study may qualify for **expedited** **IRB** **review** if it fits into one of the *Federal Register* (1998) Categories under 45 CFR 46.110(a). The IRB office will determine if the protocol qualifies for expedited review. Check all those that apply:  \_\_\_\_ **Category 1**. Research on drugs for which an investigational new drug application is not required; or research on medical devices for which (i) an investigational device exemption application is not required or (ii) the device is both approved for marketing and is being used in accordance with its approved labeling.  \_\_\_\_ **Category 2**. Collections of blood samples by finger stick, heel stick, ear stick, or venipuncture.  \_\_\_\_ **Category 3**. Prospective collection of biological specimens (e.g., hair and nail clippings, teeth, sweat, saliva, mucus) for research purposes by non-invasive means  \_\_\_\_ **Category 4**. Collection of data through non-invasive procedures (not involving sedation, x-rays, or microwaves) routinely employed in clinical practice. Where medical devices are used, they must be approved for marketing. Examples include (but are not limited to) physical sensors, weighing or testing sensory acuity, imaging, doppler blood flow, moderate exercise, muscular strength or flexibility testing, and body composition assessment.  \_\_\_\_ **Category 5.** Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes such as medical treatment or diagnosis. Some research in this category may be exempt; this listing refers to research that is not exempt. See 45 CFR 46.101(b)(4).  \_\_\_\_ **Category 6.** Collection of data from voice, video, digital, or image recordings made for research purposes.  \_\_\_\_ **Category 7.** Research on individual or group characteristics or behavior, including(but not limited to) research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior; or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. Some research in this category may be exempt; this listing refers to research that is not exempt. See 45 CFR 46.101(b)(2) and (b)(3).  \_\_\_\_ **Category 8**. Continuing review of previously approved research as follows:   1. Where (i) the research is permanently closed to the enrollment of new subject; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or 2. Where no subjects have been enrolled and no additional risks have been identified; or 3. Where the remaining research activities are limited to data analysis.   \_\_\_\_ **Category 9**. Continuing review of previously approved research in which modifications do not result in significant changes to the risk-benefit analysis or in the informed consent documents.  *Note: Even if your initial determination is Expedited Review, complete the checklist for Full Review. If any of those categories apply, your study is not Expedited.*  A study may qualify for **full-board IRB review** if it poses greater than minimal risk and fits into one of these Categories**.** Check all those that apply:  \_\_\_\_ **Category 1**. Surveys or interview questions which answers, if known outside the research, would create legal liability or adverse financial or employment consequences for the participant  \_\_\_\_ **Category 2**. Surveys of interviews involving questions dealing with very personal and sensitive behavior, such as sexual behavior, alcohol or drug use, or if subjects may be placed at risk for criminal or civil penalties or would otherwise suffer embarrassment or humiliation if the subjects' responses were to become known outside the research.  \_\_\_\_ **Category 3**. Studies that include members of a population vulnerable to coercion or undue influence, including children, prisoners, persons with impaired decision-making ability, or economically or educationally disadvantaged persons. Other potentially vulnerable populations include the frail elderly, victims, persons receiving HIV testing or have been diagnosed with AIDS, pregnant women, fetuses, and neonates.  \_\_\_\_ **Category 4**. Studies involving deception or if the subjects are not fully informed of the purpose and procedures of the study  \_\_\_\_ **Category 5**. Studies involving support from non-university sources requiring full IRB approval  \_\_\_\_ **Category 6**. Likelihood of risk or substantial stress or discomfort to the subject  \_\_\_\_ **Category 7**. Procedures that may potentially threaten or embarrass subjects  \_\_\_\_ **Category 8**. Personality tests, inventories or questionnaires of a personal and sensitive nature where subjects' identities will not be anonymous to the researcher  \_\_\_\_ **Category 9**. Healthcare procedures not conducted for the primary benefit of the subject  \_\_\_\_ **Category 10**. Diagnostic or therapeutic assessments, interventions, or measures that are not standard, generally acceptable, or common practice  \_\_\_\_ **Category 11**. Exposure to surgery, drugs, or chemical agents    *Note: Minimal risk as defined by 45 CFR 46.102(j) https://www.ecfr.gov “means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”*  References:  https://about.citiprogram.org/wp-content/uploads/2018/07/Final-Rule-Material-Changes-to-Exempt-Determination-Process.pdf  <https://about.citiprogram.org/wp-content/uploads/2018/07/Final-Rule-Material-Updates-to-Expedited-Review-Procedures.pdf>  <http://www.belmont.edu/irb/> (2011/2019)  https://cphs.berkeley.edu/policies\_procedures/2019/rr402.pdf  <https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML> (2020)  <http://www.kumc.edu/human-research-protection-program/institutional-review-board.html> (2019) |

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| SECTION III |
| Title of Study: |
| Study Site(s) & Address(es) (Include letter(s) of approval for data collection from study site(s) in the Appendices: |
| Principal Investigator’s Role or Status at Study Site: |
| Problem Statement, Thesis Statement, PICO, or PICOT (1-2 focused sentences): |
| Purpose of the Study: |
| Background of and Rationale for the Study: |
| Population and Characteristics: |
| Age Range: |
| Method of Subject Selection, Inclusion and Exclusion Criteria, and Number Anticipated: |
| Description of Research Design, Methodology, Recruitment Procedure, and Data Collection (enumerated or bulleted): |
| Ultimate Distribution and Disposal of Data Collected: |
| Primary Investigator’s Consultation, including (if applicable), Review of Survey with Research Analyst:  Y / N |
| Date Study Proposal Presented to Applied Research Forum: |
| Interventions: |
| Risk/Benefit Assessment (Describe fully): |
| 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):[[2]](#footnote-2) |
| 1. Documentation of Consent: |
| 1. Consent: |
| List of Appendices (Include recruitment materials, permission and consent letters and emails, tests, surveys, and data collection tools): |

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

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| **SECTION V** |
| IRB SUBMISSION AND REVIEW CALENDAR  Exempt and expedited applications are accepted and reviewed on a rolling basis. See blackout dates schedule (located on IRB web page/Canvas IRB Companion/Student Success Guide).  All full-board applications must be received by the IRB submission deadline for the next IRB Review. The Clarkson College IRB meets 5 times per academic year (see current schedule on IRB web page/Canvas IRB Companion/Student Success Guide).  Applications that are incomplete, inaccurate, or incoherent will be returned to the PI and may be re-submitted to the IRB for review. |

Rev. June 2017

1. Investigators outside the College should provide the email address issued by their institution. [↑](#footnote-ref-1)
2. Regardless of subject pool’s educational background, readability of documents should be at or around 8th-grade reading comprehension levels. [↑](#footnote-ref-2)