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| **IRB Number:** |
| **Human Subjects Research – Protocol Form**  **Guidelines for completing this research protocol:**   * Please submit typed applications via email. Handwritten forms and hard copy forms will not be accepted. * For items and questions that do not apply to the research, indicate as “not applicable.” * Provide information for all other items clearly and avoid using discipline specific jargon. * Please only include text in the provided boxes. The text boxes will expand as they are typed in to accommodate large amounts of text.   **Before submitting this application, ensure that the following have been completed.**   * Protocol Form is complete. * Relevant CITI modules have been completed for all members of the research team at [www.citiprogram.org](http://www.citiprogram.org). * Informed consent/assent/parental permission document(s) are provided. * Relevant waivers and appendices are provided. * Recruitment materials are provided. * Research materials (e.g. surveys, interview guides, etc.) are provided. * Any relevant letters of support are provided.   Instructions on the non-exempt review process and guidance to submitting applications, can be found on the OPRS [website](https://oprs.research.illinois.edu). You may also contact OPRS by email at [irb@illinois.edu](mailto:irb@illinois.edu) or phone at 217-333-2670.  **Submit completed applications via email to:** irb@illinois.edu. |

**Section 1: PRINCIPAL INVESTIGATOR (PI)**

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| --- | --- | --- | --- | --- |
| **The Illinois** [**Campus Administrative Manual**](http://cam.illinois.edu/policies/eligibility-to-serve-as-principal-investigator/) **allows assistant, associate, and full professors to act as PI. Other individuals may serve as PI after obtaining approval from the necessary party.** | | | | |
| Last Name: | First Name: | | Degree(s): | |
| Dept. or Unit: | Office Address: | | | |
| Street Address: | City: | State: | | Zip Code: |
| Phone: | E-mail: | | | |
| Urbana-Champaign Campus Status:  Non-visiting member of (Mark One)  Faculty  Academic Professional/Staff  (*Student Investigators cannot serve as PI*) | | | | |
| Training  Required CITI Training, Date of Completion (valid within the last 3 years),  Additional training, Date of Completion, | | | | |

**Section 2. RESEARCH TEAM**

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| **2A. Are there other investigators engaged in the research?**  Yes (include a [Research Team Form](https://oprs.research.illinois.edu/forms-templates/forms/research-team-form))  No |
| **2B. If yes, are any of the researchers not affiliated with Illinois?**  Yes  No |

**Section 3. PROTOCOL TITLE**

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**Section 4. FUNDING SOURCE**

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| **4A. Is the research funded?**  Research is **not funded** and is **not pending** a funding decision (Proceed to Section 5).  Research is **funded** (funding decision has been made).  Funding decision is **pending**. Funding proposal submission date: |
| **4B. Indicate the source of the funding.**  University of Illinois Department, College or Campus, *please specify*:  Federal, *please specify*:  Commercial Sponsorship & Industry**[[1]](#footnote-1)**,**[[2]](#footnote-2)**, *please specify*:  State of Illinois Department or Agency, *please specify*:  Other, *please specify*: |
| **4C. Sponsor-assigned grant number, if known:** |
| **4D. A complete copy of the funding proposal or contract is attached.**  Attached, *please specify title*: |
| **4E. Funding Agency Official To Be Notified of IRB Approval (if Applicable)**  **Name:**  **Agency:**  **E-mail:**  **Phone:** |

**Section 5. CONFLICTS OF INTEREST**

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| **Please indicate below whether any investigators or members of their immediate families have any of the following.** If the answer to any of the following items is yes, please submit the University of Illinois approved conflict management plan. If you have any questions about conflicts of interest, contact [coi@illinois.edu](mailto:coi@illinois.edu). |
| **5A.** Financial interest or fiduciary relationship with the research sponsor (e.g. investigator is a consultant for the research sponsor).  Yes  No |
| **5B.** Financial interest or fiduciary relationship that is related to the research (e.g. investigator owns a startup company, and the intellectual property developed in this protocol may be useful to the company).  Yes  No |
| **5C.** Two or more members of the same family are acting as research team members on this protocol.  Yes  No |

**Section 6. SUMMARY & PURPOSE OF RESEARCH**

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| **6A. In lay language, briefly summarize the objective and significance of the research.** |
| **6B. Indicate if your research includes any of the following:**  Secondary data (use of data collected for purposes other than the current research project)  Data collected internationally (include [International Research Form](https://oprs.research.illinois.edu/forms-templates/forms/international-research-form))  Translated documents (include [Certificate of Translation Form](https://oprs.research.illinois.edu/forms-templates/forms/certificate-translation-form) and translated documents)  Research activities will take place at Carle (include documentation (email or letter) from Carle stating that the review of your [Research Services Request Form](https://carle.org/For-Providers/research-institute/Research-Support) is complete) |
| **6C. Letters of support from outside institutions or entities that are allowing recruitment, research, or record access at their site(s) are attached.**  Yes  Not Applicable |

**Section 7. PROCEDURES**

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| **7A. Select all research methods and/or data sources that apply.**  Surveys or questionnaires,  *select all that apply*:  Paper  Telephone  Online  Interviews  Focus groups  Field work or ethnography  Standardized written, oral, or visual tests  Taste or smell testing  Intervention or experimental manipulation  Exercise and muscular strength testing  Noninvasive procedures to collect biological specimens (e.g., hair and nail clippings, saliva, etc.)  Noninvasive procedures to collect physiological data (e.g., physical sensors, electrocardiography, etc.)  Procedures involving radiation  Recording audio and/or video and/or taking photographs  Recording other imaging  Materials that have already been collected or already exist, *specify source of data*:  [HIPAA-protected data](https://www.hhs.gov/hipaa/index.html)  [FERPA-protected data](https://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html)  [GDPR-protected data](https://gdpr-info.eu/)  Other, *please specify*: |
| **7B. List all testing instruments, surveys, interview guides, etc. that will be used in this research.**    **Drafts or final copies of all research materials are attached.**  Yes |
| **7C. List approximate study dates.** |
| **7D. What is the duration of participants’ involvement?** |
| **7E. How many times will participants engage in research activities?** |
| **7F. Narratively describe the research procedures in the order in which they will be conducted.** |

**Section 8. PERFORMANCE SITES TO INCLUDE INTERNATIONAL, SCHOOL, AND COLLABORATIVE STUDIES**

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| **8A. List all research sites for the protocol. For non-University of Illinois at Urbana-Champaign sites, describe their status of approval and provide contact information for the site. If the site has an IRB, note whether the IRB has approved the research or plans to defer review to the University of Illinois at Urbana-Champaign.** | |
| **Performances Sites** | |
| **#1** |  |
| **#2** |  |
| **#3** |  |
| If there are additional performance sites, include them on an attachment and check here: | |
| **8B. Is this a multi-center study in which the Illinois investigator is the lead investigator, or the University of Illinois at Urbana-Champaign is the lead site?**  Yes  No  **If yes, answer 8C and 8D. If no, proceed to Section 8E.** | |
| **8C. Who is the prime recipient of funding, if funded?** | |
| **8D. What is the management and communication plan for information that might be relevant to the protection of research subjects (e.g. unanticipated problems involving risks to subjects, interim results, and protocol modifications)?** | |
| **8E. If subjects will be recruited from Illinois public or private elementary or secondary schools, additional deadlines and procedures may apply. Criminal background clearances might be required. Special consideration must be given to the exclusion of protected populations. Please contact the** [**School University Research Relations**](https://education.illinois.edu/associate-dean-for-research/school-research-partnerships) **(**[**researchplacements@education.illinois.edu**](mailto:researchplacements@education.illinois.edu)**) for more information. Select one:**  Illinois schools **will**be used  Illinois schools **will not** be used | |

**Section 9. SUBJECT ENROLLMENT GOAL & EQUITABLE SELECTION OF SUBJECTS**

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| **9A. For each performance site, indicate the estimated total number of participants.** | | | | |
| **Performance Site** | | **# Male** | **# Female** | **Total** |
| **#1** |  |  |  |  |
| **#2** |  |  |  |  |
| **#3** |  |  |  |  |
| **TOTALS** | |  |  |  |
| If additional performance sites are included on an attachment, check here: | | | | |
| **9B. Select all participant populations that will be recruited.**  **Age:**  Adults (18+ years old)  Minors (≤17 years old)  Specific age range, *please specify*:  **Gender:**  No targeted gender (both men and women will be recruited/included)  Targeted gender, *please indicate*:  Men/boys  Women/girls  Other, *please specify*:  **Race/Ethnicity:**  No targeted race or ethnicity (all races and ethnicities will be recruited/included)  Targeted race or ethnicity, *please specify*:  **College Students:**  No targeted college population  UIUC general student body  Targeted UIUC student population, *provide the instructor or course information, name of the departmental subject pool, or other specific characteristics*:  Students at institution(s) other than UIUC, *please specify*:  *Any research with students on UIUC’s campus needs to be registered with the* [*Office of the Dean of Students*](https://odos.illinois.edu/assessment/research-approval/)*.*  **Other:**  Inpatients  Outpatients  People who are illiterate or educationally disadvantaged  People who are low-income or economically disadvantaged  People with mental or cognitive disabilities or otherwise impaired decision-making capacities  Adults with legal guardians  People who are non-English speaking  People with physical disabilities  Pregnant or lactating women, human fetuses, and/or neonates  Prisoners or people with otherwise limited civil freedoms  Other, *please specify*: | | | | |
| **9C. Describe additional safeguards included in the protocol to protect the rights and welfare of the populations selected above.** | | | | |

**Section 10. INCLUSION/EXCLUSION**

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| **10A. List specific criteria for inclusion and exclusion of subjects in the study, including treatment and control groups.** |
| **10B. Explain how the inclusion/exclusion criteria will be assessed and by whom. If special expertise is required to evaluate screening responses or data, list who will make this evaluation and describe their training and experience.** |
| **10C. Drafts or final copies of all screening materials are attached.**  Yes  Not Applicable |
| **10D. Describe procedures to assure equitable selection of subjects. Justify the use of the groups marked in Section 9B. Selection criteria that target one sex, race, or ethnic group require a clear scientific rationale.** |

**Section 11. RECRUITMENT**

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| **11A. Select all recruitment procedures that will be used.**  Student subject pool, *please specify*:  Email distribution  MTurk, Qualtrics Panel, or similar online population, *please specify*:  US Mail  Flyers/brochures  Website ad, online announcement (e.g. eWeek), or other online recruitment, *please specify*:  Newspaper ad  Verbal announcement  Other, *please specify*:  Not applicable (secondary data only) |
| **11B. Drafts or final copies of all recruitment materials (including verbal scripts) are attached.**  Yes  Not Applicable |
| **11C. For each group of participants, describe the details of the recruitment process.** |

**Section 12. REMUNERATION AND PLAN FOR DISTRIBUTION**

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| **Refer to the University** [**Business and Financial Policies and Procedures**](https://www.obfs.uillinois.edu/bfpp/section-8-payments-reimbursements/) **for further guidance on the compensation process and reporting requirements.** |
| **12A. Will subjects receive inducements or rewards before, during, or after participation?**  Yes  No  If yes, complete the rest of Section 12. If no, proceed to Section 13. |
| **12B. Select all forms of remuneration that apply.**  Cash*, please specify amount:*  Check, *please specify amount:*  Gift Certificate, *please specify amount:*  Lottery, *please specify amount:*       *and odds:*  Course Credit, *please specify amount:*       *and* *specify equivalent alternative activity:*  Other, *please specify*: |
| **12C. Will payment be prorated before, during, or after participation?**  Yes, *please specify how:*  No |
| **12D. For each group of participants, describe the details of the remuneration plan, including how, when and by whom they will be notified.** |
| **12E. The information listed above is provided on the relevant consent forms.**  Yes |

**Section 13. RISKS & BENEFITS**

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| **13A. Describe all known risks to the participants for the activities proposed, such as risks to the participants’ physical well-being, privacy, dignity, self-respect, psyche, emotions, reputation, employability, and criminal and legal status. Risks must be described on consent forms.** |
| **13B. Describe the steps that will be taken to minimize the risks listed above.** |
| **13C. Indicate the risk level.**  **No more than minimal risk**  (The probability and magnitude of harm or discomfort anticipated for participation in the proposed 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).  **More than minimal risk** (answer 13D) |
| **13D. If you checked that the research is more than minimal risk, describe the provisions for monitoring the data to ensure the safety of subjects, such as who will monitor data and how often, what criteria will be used to stop the research, etc.** |
| **13E. Describe the expected benefits of the research to the subjects and/or to society.** |
| **13F. Weigh the risks with regard to the benefits. Provide evidence that benefits outweigh risks.** |

**Section 14. INFORMED CONSENT PROCESS TO INCLUDE: WAIVERS, ASSENTS, ALTERATIONS, ETC.**

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| **14A. Indicate all that apply for the consent/assent/parental permission process.**  Written informed consent (assent) with a document signed by  adult subjects  parent(s) or guardian(s)  adolescents aged 8–17 years  Waiver of Documentation (signature) of Informed Consent *(include the relevant* [*Waiver*](https://oprs.research.illinois.edu/forms-templates/forms/waiver-documentation-informed-consent-form) *Form)*  adult subjects  parent(s) or guardian(s)  adolescents aged 8–17 years  Waiver of Informed Consent *(include the relevant* [*Waiver Form*](https://oprs.research.illinois.edu/forms-templates/forms/waiver-informed-consent-form)*)*  adult subjects  parent(s) or guardian(s)  adolescents aged 8–17 years  Alteration of Informed Consent *(include the relevant* [*Alteration Form*](https://oprs.research.illinois.edu/forms-templates/forms/alteration-informed-consent-form)*)*  adult subjects  parent(s) or guardian(s)  adolescents aged 8–17 years |
| **14B. List all researchers who will obtain consent/assent/parental permission from participants.** |
| **14C. Describe the method for obtaining consent/assent/parental permission.** |
| **14D. Describe when consent/assent/parental permission will be obtained.** |
| **14E. Will participants receive a copy of the consent form for their records?**  Yes No, *if no, explain*: |
| **14F. Indicate factors that may interfere or influence the collection of voluntary informed consent/assent/parental permission.**  No known factors  Research will involve students enrolled in a course or program taught by a member of the research team  Research will involve employees whose supervisor(s) is/are recruiting participants  Participants have a close relationship to the research team  Other, *specify any relationship that exists between the research team and participants*:  **If applicable, describe the procedures to mitigate the above factors.** |
| **14G. Copies of the consent form(s) are attached.** Yes Not applicable |
| **14H. Will this project be registered as a clinical trial?** Yes No  If yes, effective January 21, 2019, an informed consent form must be posted on the Federal Web site after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit. |

**Section 15. DEVICES & DRUGS**

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| **Indicate if your research includes any of the following.**  Equipment [Researchers collecting physiological data, not testing the device]  (*include Appendix A, the* [*Research Equipment Form*](https://oprs.research.illinois.edu/forms-templates/forms/research-equipment-form)*)*  Devices [Researchers planning to test devices on human subjects]  (*include Appendix B, the* [*Device Form*](https://oprs.research.illinois.edu/forms-templates/forms/device-form))  Materials of Human Origin  (*include Appendix C, the* [*Biological Materials Form*](https://oprs.research.illinois.edu/forms-templates/forms/biological-materials-form))  Drugs and Biologics  (*include Appendix D, the* [*Drug and Chemical Usage Form*](https://oprs.research.illinois.edu/forms-templates/forms/drug-chemical-usage-form)) |
| MRI AT BIC To use the [Beckman Institute Biomedical Imaging Center](http://bic.beckman.illinois.edu/) (BIC) in human subject’s research, you must obtain prior approval from the BIC (217.244.0446; [ryambert@illinois.edu](mailto:ryambert@illinois.edu)) and use BIC-approved screening and consent forms. Attach:  BIC approval  BIC screening form  BIC consent form |

**Section 16. CONFIDENTIALITY OF DATA & PRIVACY OF PARTICIPATION**

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| **16A. How is participant data, records, or specimens identified when received or collected by researchers? Identifiers include, but are not limited to, name, date of birth, email address, street address, phone number, audio or video recordings, and SSN.**  No identifiers are collected  Direct identifiers are collected  Indirect identifiers (e.g. a code or pseudonym used to track participants);  Does the research team have access to the identity key?Yes No |
| **16B. Select all methods used to safeguard research records during storage:**  Written consent, assent, or parental permission forms are stored separately from the data  Data is collected or given to research team without identifiers  Data is recorded by research team without identifiers  Direct identifiers are removed from collected data as soon as possible  Direct identifiers are deleted and no identity key exists as soon as possible  Participant codes or pseudonyms are used on all data and the existing identity key is stored separately from the data  Electronic data is stored in a secure, [UIUC-approved location](https://answers.uillinois.edu/illinois/page.php?id=54880), *please specify*  Hard-copy data is stored in a secure location on UIUC’s campus, *please specify*  Other, *please specify*: |
| **16C. How long will identifiable data be kept?** |
| **16D. Describe provisions to protect the privacy interests of subjects.** |
| **16E. Describe the training and experience of all persons who will collect or have access to the data.** |

**Section 17. DISSEMINATION OF RESULTS**

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| **17A. List proposed forms of dissemination (e.g. journal articles, thesis, academic paper, conference presentation, sharing within industry, etc.).** |
| **17B. Will any identifiers be published, shared, or otherwise disseminated?** Yes No  **If yes, does the consent form explicitly ask consent for such dissemination, or otherwise inform participants that it is required in order to participate in the study?** Yes |
| **17C. Do you intend to put de-identified data in a data repository?** Yes No  **If yes, explain how data will be de-identified.** |

**Section 18. INVESTIGATOR & DEPARTMENTAL ASSURANCES**

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| * I certify that the information provided in this application is complete and correct. * I certify that I will follow my IRB Approved Protocol. * I accept ultimate responsibility for the conduct of this study, the ethical performance of the project, and the protection of the rights and welfare of the human subjects who are directly or indirectly involved in this project. * I will comply with all applicable federal, state and local laws regarding the protection of human subjects in research. * I will ensure that the personnel performing this study are qualified and adhere to the provisions of this IRB-certified protocol. |
| **The original signature of the PI is required before this application may be processed (electronic signatures are acceptable).**    Principal Investigator Date |
| **If the PI is not eligible to serve as PI under the** [**Campus Administrative Manual**](http://cam.illinois.edu/policies/eligibility-to-serve-as-principal-investigator/)**, the applicable academic dean, institute director, or campus administrative officer indicates their approval of the researcher to act as Principal Investigator. Please note that departmental assurance only needs to be provided in the initial application.**    Name of Authorizing Individual    Signature of Authorizing Individual Date |

1. Clarify whether or not sponsor requires specific language in the contractual agreement that impacts human subjects research [↑](#footnote-ref-1)
2. Clarify whether or not the sponsor requires the protocol adhere to ICH GCP (E6) standards [↑](#footnote-ref-2)