

**Division of Research & Economic Development**

**Office of Research Compliance |Institutional Review Board**

(phone) 208.426.5401 | MS 1138

humansubjects@boisestate.edu

EXPEDITED/FULL BOARD PROTOCOL APPLICATION

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| **INSTRUCTIONS** |

* The application must be typed. **Handwritten applications will not be accepted.**
* Spellcheck will not work on this application. Proofread before submitting.
* **Submit completed application and ALL SUPPORTING appendices to:** **HumanSubjects@boisestate.edu**
* The second page must be signed by all applicable investigators and must be submitted to the Office of Research Compliance via:
	+ Email—humansubjects@boisestate.edu (as a scanned PDF);

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| **SECTION A: General Information** |
| 1. | This project is: |

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| [ ]  | Social Behavioral | [ ]  | BioMedical |

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| 2. | Project Title:  |  |
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| 3. | Anticipated Start Date: |  | Anticipated End Date: |  |
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| 4. | **PRINCIPAL INVESTIGATOR (PI)** (Refer to the [IRB PI Eligibility](https://www.boisestate.edu/research-compliance/irb/guidance/principal-investigator-eligibility/) requirements. IRB staff will confirm your eligibility. Graduate thesis or dissertation students MUST list eligible faculty as PI – student may be a Co-Principal Investigator. |

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|  | Name: |  |
|  | Title: | [ ]  | Full Professor | [ ]  | Associate Professor | [ ]  | Assistant Professor |
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|  | [ ]  | External Investigator | [ ]  | \*Other: |
|   | \*(This category is allowed under special circumstances only) |
|  | **🡩 *If you DO NOT fall into one of the above titles, you may be a Co-Principal Investigator (Co-I) with a qualified PI.*** |

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|  | Department: |  | Phone:  |  |
|  | E-mail:  |  |
|  | **Roles and responsibilities in this study:** |

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|  | CITI Training Completed: | [ ]  Social & Behavioral Researchers | [ ]  Biomedical Researchers |

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| 5. | **CO-PRINCIPAL INVESTIGATOR/CO-INVESTIGATOR** (IRB staff will confirm your title with the directory.) |
|  | Name: |  |
|  | [ ]  | Full Professor | [ ]  | Associate Professor | [ ]  | Assistant Professor |
|  | [ ]  | Adjunct Faculty | [ ]  | Lecturer | [ ]  | Undergraduate Student |
|  | [ ]  | Staff | **[ ]**  | Graduate Student  | [ ]  | Thesis  | [ ]  Dissertation |
|  | [ ]  | Other: |  |
|  | Department: |       | Phone: |  |
|  | E-mail: |       |
|  | **Roles and responsibilities in this study:** |

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|  | CITI Training Completed: | [ ]  Social & Behavioral Researchers | [ ]  Biomedical Researchers |

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| 6. | Do you have additional research personnel (Co-PI, Co-I, key personnel, student research assistants, etc.)? |
|  | **[ ]  NO** |
|  | **[ ]  YES**  |
|  | To list additional investigators and/or key personnel, complete and attach an [ADDITIONAL PERSONNEL](https://www.boisestate.edu/research-compliance/irb/forms-templates/) form. |

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| 7. | Will/Does this project receive financial support?  |
|  | **[ ]  NO** |
|  | **[ ]  YES:**  |
|  | **[ ]** Local: |  |
|  | **[ ]** Federal: |  |
|  | **[ ]** Non-Profit: |  |
|  | **[ ]** Off-campus  collaborator: |  |
|  | **[ ]** Unknown:  |
|  | OSP Proposal Number (if known): |  |
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| 8. | Has this protocol previously been considered by Boise State University’s IRB? |
|  | **[ ]  NO** |
|  | **[ ]  YES:**  | IRB Number:  |  | Date Approved: |  |

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| **SECTION B: Financial Conflict of Interest Disclosure** |
| *Conflicts of interest must be disclosed in accordance with the Boise State Conflict of Interest and Commitment* [*Policy #1110*](https://www.boisestate.edu/policy/governance-legal/conflict-of-interest-and-commitment/)*.*  |
| 1. | Do any investigators (PI, Co-Principal Investigator, Co-Investigator) or research team members (key personnel) have any relationship or equity interest with any institutions or sponsors related to this research that might present or appear to present a conflict of interest with regard to the outcome of the research? |
|  | **[ ]  NO POTENTIAL CONFLICTS EXIST**  |
|  | **[ ]  YES:** |
| 2. | Name of the person(s) with the potential COI:  |  |
|  | [ ]  This potential conflict has been disclosed to the [Boise State Conflict of Interest Office](https://www.boisestate.edu/research-export/). |
|  | **[ ]**  This conflict has not been disclosed to the Boise State COI Office. |

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|  | **Note: If a significant conflict of interest exists, you must also attach the Boise State COI Committee approved management plan.** If you have questions about conflicts of interest, contact the Boise State Conflict of Interest Officer at (208) 426-1252. |

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| **SECTION C: Restricted Data or Privacy Certificate** |
| *Does accessing the data require a Restricted Data Use Agreement or a Privacy Certificate?* |
| 1. | If you will need to complete a Restricted Data Use Agreement or a Privacy Certificate, which will you need: |
|  | **[ ]  Restricted Data Use Agreement**  |
|  | **[ ]  Privacy Certificate** |
| 2. | What agency(ies) or organization(s) will this be done through:  |
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**\*You must attach a copy of the Data Use Agreement with your IRB submission.**

Please note that Data Use Agreements must also be reviewed and approved by the Data Security Committee. Submit your Data Use Agreement [here](https://www.boisestate.edu/research-compliance/data-use-agreements/).

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| **SECTION D: Signatures** |
| **Principal Investigator/Faculty Advisor Assurance and Acknowledgement***I certify that the information provided in this application is complete and accurate. As the principal investigator, I have ultimate responsibility for the conduct of this study, the ethical performance of the project, the protection of the rights and welfare of human participants, and strict adherence to any stipulations designated by the IRB. I accept and will conform to all federal, state, and institutional provisions concerning the protection of human participants in research. I will ensure all personnel involved in the research will be appropriately trained for all procedures used in this project.* *I agree to conduct the research involving human participants as presented in this protocol application as approved by the Boise State Institutional Review Board (IRB), and am qualified to perform the procedures described herein. I will submit any proposed changes/modifications for review and approval before they are implemented. I agree to notify the IRB and Office of Research Compliance of any adverse events that may occur during the study. I also assure that I will follow through with the storage and destruction of data as outlined in the protocol. I understand that Boise State owns the research data. If I choose to transfer to another institution, I will need departmental approval to take the data with me.**If I am the Principal Investigator for a student’s thesis, dissertation or research project, I agree to be available and to personally supervise the student investigator in solving problems as they arise.* ***I understand that data collection (including recruitment) is not permitted until final approval is granted by the IRB.*** |
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| **Principal Investigator (PRINT)** |  | **Signature** |  | **Date** |  |

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| **Co-Principal Investigator Acknowledgement** *I certify I have read this protocol application and that the information is complete and accurate. I ensure that the principal investigator is qualified to perform the procedures described. I understand that I will be included in all email correspondence related to the protocol application including questions from the IRB committee and approval notifications.**I further agree to meet with the principal investigator on a regular basis to monitor the progress of the study. I will arrange for an alternate Co-Investigator to assume responsibility if I become unavailable, as when on sabbatical leave or vacation, and will notify the IRB of this change. I assure that the PI will follow through with the storage and destruction of data as outlined in the protocol.**If I am a graduate student investigator on this research application, I further agree to meet with my faculty adviser on a regular basis to discuss the progress of the study and to solve protocol issues as they arise.*  |
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| **Co-Principal Investigator (PRINT)** |  | **Signature** |  | **Date** |  |

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| **SECTION E: Review Category** |
| Indicate the applicable review category for your research: |
|  | **[ ]  FULL BOARD Review:**  |
|  | Any research or training project involving the use of human participants which does not fall into an exempt or expedited review category must be submitted for full board IRB review. Research involving more than minimal risk requires full board review. |
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|  | [ ]  **EXPEDITED Review** (Indicate [category(ies)](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html) below): |

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| [ ]  | **1.** | **Clinical studies of drugs and medical devices only when condition (a) or (b) is met.** |
|  | [ ]  **a.** | research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review). |
|  | [ ]  **b.** | research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling. |
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| [ ]  | **2.** | **Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:** |
|  | [ ]  **a.** | from healthy, nonpregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or |
|  | [ ]  **b.** | from other adults and children1 considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week. |
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| [ ]  | **3.** | **Prospective collection of biological specimens for research purposes by noninvasive means.** |
|  |  | Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization. |
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| [ ]  | **4.** | **Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)** |
|  |  | Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject’s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing where appropriate given the age, weight, and health of the individual. |
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| [ ]  | **5.** | **Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).** (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human participants. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.) |
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| **[ ]**  | **6.** | **Collection of data from voice, video, digital, or image recordings made for research purposes.** |
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| [ ]  | **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.**  (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human participants. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.) |
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| **[ ]**  | **8.** | **Continuing review of research previously approved by the convened IRB as follows:** |
|  | [ ]  **a.** | where (i) the research is permanently closed to the enrollment of new participants; (ii) all participants have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up participants; or |
|  | [ ]  **b.** | where no participants have been enrolled and no additional risks have been identified; or |
|  | [ ]  **c.** | where the remaining research activities are limited to data analysis.  |
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| [ ]  | **9.** | **Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.** |

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| **SECTION F: Purpose** |
| 1. | Provide a summary of the purpose of your project. Include information about the background and rationale for the study and goal(s) of the proposed study. Use language understood by a person unfamiliar with this area of research. Specific jargon should be avoided or explicitly explained. |

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|  | What is your research question? State your hypothesis. |

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|  | What will you do with the results of your study (e.g. contributing to generalizable knowledge, publishing, sharing at conference, etc.)? If this project is only for internal evaluation or to complete a class assignment, IRB may not be required. Please contact the ORC for additional information. |

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| 1. | Does the research involve the storage or maintenance of *identifiable private information or bio-specimens*? |
|  | **[ ]  No**  |
|  | **[ ]  Yes** |
|   |  |
| 2. | Will you be keeping the *identifiable private information or bio-specimens* for future use in research? |
|  | **[ ]  No** |
|  | **[ ]  Yes** |
|  | *If yes, provide information on how long the data or specimens will be stored, what kind of future research will occur, and if the data and/or specimens will be used to create a repository:* |
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| **SECTION G: Participant Population** |
| 1. | Provide a description of the participant population you intend to recruit and collect data from. Describe the characteristics of the participant population such as gender, age ranges, ethnic background and health status, as applicable to the research. |

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| 2. | Will your research involve vulnerable populations, such as children or adolescents under the age of 18, pregnant women, prisoners or cognitively, economically, or educationally impaired participants? |
|  | [ ]  NO [ ]  YES (indicate population):  |  |
|  | If yes, describe additional safeguards planned to protect the rights and welfare of this population(s): |

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| 3. | Will you be recruiting students from a class that you teach? (See IRB [guidelines](https://www.boisestate.edu/research-compliance/irb/guidance/using-university-students-in-research/) for using your own students.) |
|  | [ ]  NO [ ]  YES |
|  | If yes, explain why this population is necessary to the study, and how you will ensure participants do not feel coerced to participate. Coercion is a significant concern. |

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| 4.  | Will you be recruiting employees who report to you?  |
|  | [ ]  NO [ ]  YES  |
|  | If yes, explain why this population is necessary to the study, and how you will ensure participants do not feel coerced to participate. Coercion is a significant concern. |

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| 5. | Indicate any exclusion criteria for participants. |

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| 6. | How many participants do you anticipate are needed for this research? |

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| **SECTION H: Recruitment and Informed Consent** |
| 1.  | Attach copies of all applicable **recruitment** materials: |
|  | [ ] Recruitment Scripts (what will be said to participants during recruitment) |
|  | [ ] Recruitment Emails |
|  | [ ] Cover Letters |
|  | [ ] Flyers |
|  | [ ] Advertisements |
|  | [ ] Other:  |

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| 2. | Who will recruit potential participants? |

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| 3. | Describe how, when, and where individuals will be first contacted about their interest in participating in the study (e.g., face-to-face, email, flyers, advertisements, phone call, etc.). |

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| 4. | Are you are directly emailing or mailing participants? |
|  | **[ ]  NO** |
|  | **[ ]  YES** |
|  | If yes, how are you obtaining emails and/or mailing addresses? |

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| **RECRUITING BOISE STATE STUDENTS** |
| Recruiting Boise State students may require additional internal and departmental permissions, in addition to IRB approval. It is the PI’s responsibility to obtain these permissions before moving forward with recruitment. The Boise State Office of the Vice President for Student Affairs (VPSA) provides guidelines for sending mass emails to students. It is the PI’s responsibility to be familiar with these guidelines and any additional departmental, college or unit processes. [Institutional Research](https://www.boisestate.edu/saem/communicating-to-students/emails/) manages requests to use email to contact students for research. |
| 5. | Are you recruiting Boise State students? |
|  | **[ ]  NO, skip to #6** |
|  | **[ ]  YES:** |
|  | Indicate which students or employees you are targeting: |
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|  | [ ]  Approval(s) obtained and attached, if applicable. |

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| *6.*  | *Attach copies of all applicable informed* ***consent*** *materials:* |
|  | [ ] Informed Consent Form |
|  | [ ] Cover Letter |
|  | [ ] Web-based Cover Letter |
|  | [ ] Assent Form |
|  | [ ] Parent/Guardian Informed Consent Form |
|  | [ ] Verbal Consent Script |
|  | [ ] Debriefing Statement |

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| 7. | Are you requesting an alteration or waiver to any informed consent requirements, including documentation of informed consent (signed consent)? |
|  | **[ ]** NO **[ ]** YES |
|  | If YES, complete the section below. If NO, skip to question 4. |

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| **indicate the type of waiver you are requesting:** |
| **[ ]**  | I am requesting to waive the required documentation of informed consent (i.e. waive obtaining the signature for anonymous internet-based survey, telephone survey, mailed survey, etc.). 🡺**COMPLETE SECTION A** |
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| **[ ]**  | I am requesting to waive or alter the required elements of the informed consent process.🡺**COMPLETE SECTION B** |
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|  | **SECTION A** |  |
|  | Check the box next to the condition that best fits your research study and justify how your research study meets that condition. If waiving the signature, you must still submit a verbal script or cover letter for participants that addresses the eight required elements of consent as stated in 45 CFR 46.116 (a)(1-8). |  |
|  | **[ ]  CONDITION 1** |  |
|  |  | The only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant’s wishes will govern. |  |
|  |  | *Justify why your study meets this condition:* |  |
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|  | **[ ]  CONDITION 2** |  |
|  |  | The research presents no more than minimal risk to the participant and involves no procedures for which written consent is normally required outside the research context (i.e. no questions are being asked that could result in potential embarrassment, personally or professionally.) |  |
|  |  | *Justify why your study meets this condition:* |  |
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|  | **SECTION B** |  |
|  | [ ]  I am requesting to **waive the informed consent process.** |  |
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|  | [ ]  I am requesting **alteration** of the informed consent process.*Describe which elements of consent will be altered and/or omitted:* |
|  | You must justify your request to waive or alter the informed consent process in accordance with each of the following four criteria established under 45 CFR 46.116 (d) (1-4). Provide supporting information for **ALL FOUR** criterion: |
|  | 1. | The research involves no more than minimal risk to the participants. |
|  | *Justify:*  |
|  | 2. | The waiver or alteration will not adversely affect the rights and welfare of the participants. |
|  | *Justify:*  |
|  | 3. | The research could not practicably be carried out without the waiver or alteration. |
|  | *Justify:*  |
|  | 4. | Whenever appropriate, the participants will be provided with additional pertinent information after participation. *(If a debriefing statement is used, submit a copy with this application.)* |
|  | *Explain:*  |

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| 8. | Describe the consent **process**. Do not answer, “see attached consent form,” as this does not describe the **process** of obtaining informed consent. **Describe how, when and where the informed consent process will take place and who will obtain informed consent.** |

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| 9. | If the participants are not able to give legal consent (e.g., minors), explain how assent will be secured.  |

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| 10. | Into what languages will the consent be translated? *(NOTE: Translated consent documents must be reviewed and approved by the IRB prior to use.)* |

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| 11. | If your research involves collecting a **combination** of demographic data (e.g., a combination of gender, age, race, and ethnicity) that may make a participant identifiable, you must inform the participants the following: *“For this research project, the researchers are requesting demographic information. Due to the make-up of Idaho’s population, the combined answers to these questions may make an individual person identifiable. The researchers will make every effort to protect your confidentiality. However, if you are uncomfortable answering any of these questions, you may leave them blank.”* If applicable, indicate where and how participants will be informed of this. |

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| **SECTION I: Data Collection** |
| 1. | Attach copies of all data collection tools and methods to be used. Check all that apply.  |
|  | [ ] Questionnaire/Survey *(attach questions)* | [ ] Videotaping  |
|  | [ ] Observation | [ ] Photographing |
|  | [ ] Interviews *(attach questions and scripts)* | [ ] Audiotaping  |
|  | [ ] Focus Groups *(attach questions and scripts)* | [ ] Using direct quotes |
|  | [ ] Reviewing Medical/Education Records | [ ] Deception |
|  | [ ] Other: |

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| 2. | Indicate all biomedical procedures that apply to your research:  |
|  | [ ] Physical Activity | [ ] Body Mass Index |
|  | [ ] Venipuncture | [ ] X-rays |
|  | [ ] Magnetic resonance imaging (MRI) | [ ] Anthropomorphic evaluations |
|  | [ ] Electrocardiograms (EKGs) | [ ] Intravenous catheter insertion |
|  | [ ] Collection of blood samples by finger stick, heel stick, ear stick or venipuncture |
|  | [ ] Other: |

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| 3. | If applicable, describe the procedures being performed already for diagnostic or treatment purpose.  |

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| 4. | What are you going to ask participants to do? Provide a step-by-step description of each procedure, including the frequency and duration of each procedure. **This question is mandatory and may not be skipped. Applications missing this section will not be accepted.** |

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| 5. | Where will the data collection and data analysis procedures take place? (i.e., explain where you are distributing surveys, conducting interviews, etc.)  |

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| 6. | Does your study include plans to conduct research at an external site? (i.e., off Boise State campus. For example, an elementary school, hospital, prison, etc.) |
|  | [ ] YES [ ] NO |
|  | If YES, indicate the external site(s) and you must attach an acknowledgement (letter or email) indicating you have permission to use their facility and personnel.  |

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|  | If YES, does your study include plans to conduct research at external sites that are engaged in the research? If so, will that site’s IRB approve this research or will it rely upon the BSU IRB? |

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| 7. | Will monetary or other compensations be offered to the participants (e.g., gift certificates, raffle, cash payment or class extra credit?)  |
|  | [ ] YES [ ] NO |
|  | If YES, identify the amount of compensation and method of payment. Explain how participants would earn compensation if their participation is anonymous. If students are offered extra credit, you must provide other options to fulfill the research component if they do not wish to participate. |

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| **SECTION J: PARTICIPANT PRIVACY** |
| ***Privacy*** *refers to persons during data collection. It is the control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others (e.g., surveys are completed in the privacy of their own home; interviews will be done in a location of their choosing where it is unlikely they will be overheard).* |
| 1. | Describe the provisions to protect the privacy of the participants **during the data collection procedures**.  |

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| **SECTION K: CONFIDENTIALITY OF DATA** |
| ***CONFIDENTIALITY****: Confidentiality refers to how DATA is handled after collection. It is the treatment of information already revealed and states that there is an expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without permission (e.g., data is secured on a password-protected computer or locked file cabinet, data is de-identified or coded, only the researchers have access to the data).* |
| 1. | Provide details as to how you plan to protect the data while on site and during travel (e.g. from data collection site back to the office). When traveling (especially overseas) or just with portable devices, data security is vital, especially if the device or data is lost or stolen. Address the storage and security of electronic data as well as any physical data, such as paper consent forms or surveys, during travel. |

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| 2. | Describe how you will maintain confidentiality of the data after it has been collected, including measures to protect the identity of the participants and their responses (coding procedures, encryption, etc.).  |

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| 3. | Where will you store the data? A copy of the data must be kept within the campus departmental area, not stored at home. OIT offers virtual servers and storage for BSU researchers, [click](https://www.boisestate.edu/rcs/data-management-storage-sharing-and-publishing/) for more details. Describe procedures for both electronic and hard copy data. |

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| 4. | Who will have access to the data?  |

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| 5. | In what format will the data be stored (e.g., paper or electronic copy)? |

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| **SECTION L: Risks and Benefits** |
| 1. | What are the risks and inconveniences to the participants? Describe all known anticipated psychological, physical, sociological, financial, economic risk to participants: |
|  | Examples include, but are not limited to: |
|  | [ ] Loss of confidentiality  |
|  | [ ] Identifiable links to individual participants |
|  | [ ] Feeling guilty for lying in study requiring deception |
|  | [ ] Emotional stress or discomfort *(describe below)*  |

|  |  |
| --- | --- |
|  | [ ] Physical injury or discomfort *(describe below)*  |

|  |  |
| --- | --- |
|  | [ ] Other: |

|  |  |
| --- | --- |
| 2. | How will you minimize these risks and their impact to the participants? |

|  |  |
| --- | --- |
| 3. | Describe how you are able to identify and handle the risks above. Provide a brief description of all relevant training, experience, education, and credentials.  |

|  |  |
| --- | --- |
| 4. | Describe your plan for an emergency situation. Even if you feel this situation is unlikely, please have a plan in case of emergency (e.g., the researcher will carry a cell phone, etc.).  |

|  |  |
| --- | --- |
| 5. | What are the potential direct benefits to the research participants? (This may not be applicable to your research.) |

|  |  |
| --- | --- |
| 6. | What are the potential broader benefits of the study? |

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| --- |
| **SECTION M: Unanticipated Problems/Adverse Events** |
| **Unanticipated** **Problem**: includes any information that is unexpected, related or possibly related to the research, or indicates that participants or other individuals may be placed at greater risk of harm than initially anticipated by the IRB.**Adverse** **Event**: Any untoward or unfavorable medical occurrence in a human participant, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject’s participation in the research, whether or not considered related to the subject’s participation in the research.**If an unanticipated problem or adverse event should occur, you must immediately complete and submit the IRB Incident Report Form to HumanSubjects@boisestate.edu, and contact the Office of Research Compliance at 208.426.5401.** |