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| **Instructions for this template**  Gold boxes (like this one) are instructional and must be deleted before submitting your document to the IRB for review. They are single cell tables - please “right click” and choose “delete table” to remove it. For Mac users, click inside the box, click the Layout tab, then click delete.  **The header and footer are for IRB use only; do not modify or delete.**  Text and tables that are not inside gold boxes (other than headings) should be modified to suit your study.  **This document is designed to solicit specific information in each section so the IRB can make the required regulatory determinations. Address only the information required, as described by the template instructions, in each section. Do not repeat information or place information in sections that is not appropriate for the information.**  If a section does not apply to your study, **do not delete the section**. Insert “N/A” to indicate the section does not apply.  DO NOT include supporting documents within this Protocol Document. All such material, including Consent Information/Scripts, Recruitment Materials, and data collection instruments are to be submitted as separate, supporting documents in the submission in eRA.  Your final document must be submitted to the IRB as an **MS Word** document. |

**Title:**

IRB Record/Protocol Number: This number generates when you create the Initial Application submission in eRA.

**Protocol version Date:**

**Version:**

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| We suggest that you add a version number to maintain an accurate and current record throughout the life of the study. Version numbers follow IRB approvals. The initial approved version will always be Version 1, regardless of how many times it is revised before it is approved. If you amend the protocol after approval, the next will be Version 2, and so forth. |

Principal Investigator (PI)

**Name:**

**Telephone:**

**Email:**

Key Personnel

**Name**:

**Role in project**: [Co-investigator, Faculty Advisor, Research Coordinator, Research Assistant, etc.]

**Name**:

**Role in project**: [Co-investigator, Faculty Advisor, Research Coordinator, Research Assistant, etc.]

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| List all Key Personnel in this section. |

General Research Staff

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| General Research Staff are individuals who are engaged in the conduct of the research but are not Key Personnel (e.g., students who rotate every semester in a lab). These individuals do not need to be named, but their specific responsibilities should be described here. These individuals have the same training requirements (CITI) and Conflicts of Interest reporting (DEPA) as Key Personnel; it is the PI’s responsibility to ensure this training is complete.  If you have General Research Staff for your protocol, list how many, state training responsibilities, and describe their activities here.For example:  “Four undergraduate/graduate research assistants will assist with this protocol at a time. The PI will ensure appropriate CITI and protocol specific training is maintained and DEPA reporting is conducted annually. General Research Staff responsibilities will include distributing flyers, administering survey instruments, and data entry.”  IRB staff will make determinations about the appropriateness of General Research Staff responsibilities on a case-by-case basis. |

Exempt Categories:

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| Indicate the Exempt Category(ies) that apply to this research.  **Note:**   * All aspects of the research must meet the requirements for one or more Exempt Categories for the research to qualify for exemption. Research that includes activities not covered in an Exempt Category must be reviewed using Expedited or Convened Board procedures. * There are limitations to including minors as participants in Exempt research. See the Exempt page on the IRB website or contact the IRB for details. * **If your research does not qualify for Exemption, you must use the Non-Exempt Protocol Template – do not continue with this template.** |

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| Exempt Category 1 | Research, conducted in established or commonly accepted educational settings, that specifically involves 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. | |
| Exempt Category 2 | Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if one of the following criteria is met: | |
|  | 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. |
|  | 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. |
|  | 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). |
| Exempt Category 3 | Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written 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: | |
|  | 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. |
|  | 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. |
|  | 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). |
| Exempt 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: | |
|  | The identifiable private information or identifiable biospecimens are publicly available. |
|  | Information, which may include information about biospecimens, 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, the investigator does not contact the subjects, and the investigator will not re-identify subjects. |
| Does this research involve researchers from another institution? |  | Yes – Exempt research is not eligible for IRB Reliance agreements (i.e., Single IRB). Each participating institution will conduct its own Exempt determination. |
|  | No |

Funding

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| Explain if there are grants, funding or other financial support (e.g., This research is being funded by [insert name of sponsor].) If the research is not funded, enter none. |

Objectives

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| Describe the purpose of the study. Include the research question and state the primary objectives and/or hypotheses. Describe secondary objectives and/or hypotheses if there are any. |

Background and Significance

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| Provide background information to address why the research is being done. Describe/explain the gaps in current knowledge. Explain the significance of the human research in terms of why it is important and how it will add to existing knowledge. |

Research Study Design and Procedures

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| This section details "what" data is being collected (Study Design) and “how” that data will be collected from participants (Study Procedures).  The Study Design discussion should include the following information as applicable:   * The study design and research methods used to meet the study objectives stated above (e.g., surveys, open ended interviews, participant observation, benign behavioral intervention, etc.). * A description of the data collection tools/methods used and what data each collects. Explain whether these are standardized in the field of study or designed for this specific study. * If there are multiple participant groups, explain the groups and the data collected from each. * Describe randomization procedures, if used. * Indicate how many participants will complete the study and provide the sample size calculation/justification and power analyses. * Address how the data will be analyzed in support of your research question, objectives and/or hypotheses (i.e., quantitatively, or qualitatively and what statistical tests are planned), how the interpretation will address the research questions, and how the research will be disseminated. * Provide the expected duration of the study from the start of recruitment through analysis and study closure.   Note: Data collection instruments, surveys, questionnaires, etc. must be uploaded as separate documents with your submission in eRA. The IRB will review the full text of each instrument.  The Procedures discussion describes, in chronological order, all research activities involving participants. It should be a step-by step description of “how” the data is collected from a participant using the data collection tools described above – it is a walkthrough of what a participant will experience. If data collection for participants occurs over multiple time points, break it down by visit and complete the corresponding table.  The Procedures section should include the following information as applicable:   * Where procedures will take place (in person at “X” location, online via “X” platform, phone call, etc.) * Include an estimate of the time each participant will spend completing the activities (in minutes or hours), the number of sessions the participant will engage in, and the total length of participation (in days, weeks, months, or years) from the beginning to the end of the study. * Any plans to conduct audio or video recording of research participants. State whether audio/video recording is optional or mandatory for participation in the research, and whether the recordings are identifiable. * If follow-up with participants is planned, discuss the procedures and under what circumstances follow-up will occur.   The table below is a supplement to the narrative of this section and is used as a quick reference for visits and scheduled tasks. |

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| Visit # | Procedures/Tools | Location | How much time the visit will take |
| EXAMPLE: Visit 1  (REMOVE OR REPLACE THIS ROW) | * Task/test/procedure 1 (time to complete) * Task/test/procedure 2 (time to complete) |  |  |
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About the Participants

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| In this section, describe the participant population.   * How many participants or records are needed for the study? * If there is more than one group of participants, provide the number needed for each group as well as the total needed for the entire project. * List the age range of participants. * Describe the ethnic distribution of participants. * List the inclusion criteria. (These are criteria that must be met for individuals to be enrolled in the study.) * List the exclusion criteria and rationale. (This is not the opposite of inclusion. Exclusion criteria are characteristics that would exclude someone who would otherwise meet inclusion criteria.) * Address whether vulnerable populations will be considered for the study and describe how undue influence and/or coercion will be avoided in this population. Vulnerable populations can include cognitively impaired individuals; educationally or economically disadvantaged individuals; participants with disabilities that may affect their ability to participate in the Consent process or other study activities (sight or hearing impairments); non-English speaking individuals; members of Native American groups or nations, children under the age of 18; etc.   (NOTE: Some vulnerable populations cannot participate in Exempt research. If you are unsure about your subject population, contact the IRB for assistance.)  Describe any third party/secondary participant population(s).   * If the primary participants will be asked to provide information about family members or other social contacts and if the information provided about the family member or other social contact is private, identifiable information, that person becomes a third party participant. |

Recruitment and Screening Methods

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| Guidance for Recruitment can be found here: [Advertising and Recruitment](https://www.colorado.edu/researchinnovation/node/300/attachment/newest)  This section should discuss how the participants will be recruited and screened for inclusion/exclusion criteria.  The Recruitment discussion should explain how potential participants will be identified, how the study will be described to potential participants, and their participation in the research solicited. This discussion should also address how you have access to potential participants.  Indicate from where the study population will be drawn, including when, where, and how potential participants will be recruited (e.g., SONA, Boulder community, student health service, out-patient clinics). Include who will conduct recruiting activities, and the context in which the activities will occur.  Sample Recruitment Text for SONA Pool Participants (credit site):   * “Participants will be drawn from the SONA class credit subject pool. SONA participants are enrolled in the pool via an accredited psychology class. Participants voluntarily participate in the pool based on class requirements to obtain research points. Other options for obtaining these points are available for students who choose not to participate in the pool. The SONA system displays available studies and allows interested students to schedule their participation with the researcher at the student's convenience.”   Submit any materials (such as emails, scripts, letters, or flyers) that will be used in this process. These materials must be submitted as separate documents; **do not** include the text of these materials in this document.   * Recruitment materials must be approved by the IRB in their final form, including any graphical elements, before they can be implemented. Audio and video recruitment materials should be accompanied by a script.   The Screening discussion should explain how and when you will assess for inclusion/exclusion criteria (where/how are screening procedures performed, by whom, etc.)   * Submit pre-screening materials for IRB review.   For research using only specimens or tissue samples, describe the source of the materials (e.g., certified specimen banks, prospectively collected samples). Describe whether any individually identifiable information will be associated with the samples. |

Compensation

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| If participants will be compensated, explain the following or state no compensation will be offered:   * The amount and format (e.g., cash, gift card, etc.) * How and when it will be provided (given to participants at the end of each visit, emailed one week after their participation is complete, etc.) * Whether compensation will be prorated for individuals who do not complete the study and the details of proration * Explain how/why the method and amount of compensation is appropriate for the participant population and study activities.   Payment can be calculated on an hourly basis or an amount can be allotted per visit, assessment, etc. Use the calculation that is easiest for you to use and participants to understand. |

Consent

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| Describe the setting (where and when) consent will be obtained (e.g., will it occur in person, via phone call, included in an email text with a link to a survey, or included at the beginning of a survey instrument, etc.).   * Regardless of the setting, use the Exempt Consent document (In Person Consent or Remote Consent) to create the language and upload in your submission as a separate document.   Describe the steps that will be taken to minimize the possibility of coercion or undue influence.  If applicable, describe the process for obtaining informed consent for participants who do not speak English. Discuss the qualifications of the consent form translator.  If the research involves [deception,](https://www.colorado.edu/researchinnovation/node/302/attachment/newest) participants must consent to the deception. Explain why the deception is necessary and how you will debrief participants. Your debriefing must include confirming the participant continues to consent to the research. Submit the debriefing form or script to the for IRB review. The consent language must explain that the purpose of the research or an aspect of the research is being withheld from participants.    For research involving minors, describe how Assent will be obtained, whether Parent Permission will be obtained, whether permission will be obtained from both parents unless one is deceased, unknown, incompetent, etc.  Depending on the populations being studied, multiple versions of the informed consent/assent/permission forms may be needed (e.g., screening, study participation, multiple phases, multiple study groups, assent form for minors of different age groups). If different forms will be used, they should be identified here. |

Data management

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| **NOTE: This section addresses the regulatory requirement for Limited IRB Review of certain Exempt categories.**  **Confidentiality refers to the safeguarding of data about participants in a manner commensurate with the possible risks the data may pose.** Describe where data will be stored, who will have access to the data, and measures taken to secure the data.  For hardcopy data, CDs, tapes, etc., describe any physical safeguards that will be in place. For example: locked cabinet/office, data de-identified by research team, data coded by research team.  For electronic data, state that files will be password protected, encrypted, on a secure network, etc.  For coded data (data where a link between the participants' identities and a code number is maintained – i.e., Identifiable Data), describe how the key to the code will be stored. (Deidentification is discussed later in this section.)  Describe safeguards for devices used to access study data, e.g., password access, automatic log-off.  We suggest not storing data on portable devices. Instead, data can be saved to a CUB server and accessed remotely using VPN.  If portable devices or media (e.g., laptops, USB drives) must be employed for data collection and/or storage, following provisions must be made:   * Describe how any confidential information on portable media will be encrypted. * Loss or theft should be included above as a risk. * Loss or theft of a device containing identifiable or sensitive information – even if temporary – must be reported to the IRB (via eRA as a Reportable Event).   NOTE: For data that is originally captured as hardcopy (e.g., questionnaires) and then transcribed to electronic files, procedures for both the original hardcopy and electronic data must be described.  Describe the plans for the disposal or de-identification of data that are identifiable in any way (directly or indirectly via codes) once the study has ended. **Destroying the key to the code for coded data will de-identify a coded dataset**. If the de-identified data will be kept indefinitely describe the format of the data and purpose of retention. If data will be destroyed, describe the timeline and method.  Describe any plans to use identifiable (including coded) data for future research. **NOTE:** Participants must give permission for their identifiable data to be used for future research. Contact the IRB for more information about storage of data for future research. |

Provisions to Protect the Privacy Interests of Participants

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| **NOTE: This section addresses the regulatory requirement for Limited IRB Review of certain Exempt categories.**  Describe any applicable impact that the study or study procedures may have on participants’ privacy interests.   * **“Privacy interest”** refers to a person’s desire to control access of others to themselves. Privacy involves an individual’s ability to decide not only what information people share, but how much, when, with whom, and the conditions around sharing it. It involves consideration of whether the participants will be comfortable with the research situation. For example, data collection should be conducted in a manner or context that provides the participant and the investigator the ability to control who else may see or hear study information. Observation of participants should occur only in contexts where there is no expectation of privacy, or where consent for the observations has been given.   Describe the steps that will be taken to protect participants’ privacy interests, when applicable.  **Information regarding storage, use, or management of information about participants and confidentiality procedures should be placed in the above Data Management section - not here.** |

Withdrawal of Participants

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| Describe anticipated circumstances under which participants will be withdrawn without their consent (e.g., inability to follow study procedures, possible severe adverse reactions, etc.).  Describe procedures that will be followed when participants withdraw from the research, including:   * The type and timing of the data to be collected for withdrawal of participants. * Whether and how participants are to be replaced. |

Risks to Participants

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| List the risks, discomforts, hazards, or inconveniences to the participants. Consider physical, psychological, social, legal, and economic impacts.  For each risk/discomfort, indicate the probability, magnitude, and expected duration.  Whenever possible, cite relevant published research or data.  If applicable, indicate which procedures may have risks to the participants that are currently unforeseeable. |

Management of Risks

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| Describe how each risk listed in the previous section will be minimized. Examples include: Frequent monitoring, or coding of data to protect confidentiality. |

Potential Benefits

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| If there is no direct benefit to the subject, that should be stated.  Describe the possible benefits the subject may experience.   * Do not overstate benefits * Compensation is not a benefit   Discuss benefits to society.  Justify the importance of the knowledge gained. |

Cost to Participants

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| Describe any costs to the subject for their participation in the study like gas, parking, etc. |

Working with Other Institutions

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| Explain here what the other institutions are doing and how/if data will be shared between them.  **Note:** The Single IRB process does not apply to Exempt research. Each institution engaged in the research will need to make its own Exempt determination. |

Sharing Results with Participants

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| Describe any plans to share the results of the research (group or individual results) with participants. Sharing results is not required. |

References

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| While references are not required, if you have cited outside sources in this document, list them here. |