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| **Instructions for this template**  Gray boxes (like this one) are instructional and should be deleted before submitting your document to the IRB for review. They are single cell tables - please “right click” and choose “delete table/row” to remove it. For Mac users, click a row or cell, 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 gray boxes (other than headings) should be modified to suit your study.  **This document is designed to solicit specific information in each section in order for the IRB to make the required regulatory determinations. It should be written using clear, non-technical language comprehensible to scientists and the layperson. Address only the information required, as described by the template instructions, in each section.**  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 Forms/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.  **Note: If your study will include MRI scans at Intermountain Neuroimaging Consortium (INC), please see the Guidance Document “**[**Protocol Standards and Language for Studies Involving MRI**](https://www.colorado.edu/researchinnovation/sites/default/files/attached-files/mri_guidance_document_07.31.2017.pdf)**” for additional language requirements.** |

**TITLE:** [Enter full protocol title as listed in eRA]

**PROTOCOL VERSION DATE:**

**PRINCIPAL INVESTIGATOR (PI)**

**Name:** [*PI name here must match the eRA eForm*]

**Telephone:**

**Email:**

**KEY PERSONNEL**

**Name:** [*Enter name of key personnel*]

**Role in project:** [*Enter the role (e.g., co-investigator, faculty advisor, research coordinator)*]

**Name:** [*Enter name of key personnel*]

**Role in project:** [*Enter the role (e.g., co-investigator, faculty advisor, research coordinator)*]

**Institutional Affiliation:** *[If affiliates of other institutions are Key Personnel, include this information*]

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| **Key Personnel** are individuals who have direct contact with participants for research purposes.  When adding non-CU Boulder personnel to the Protocol, include their institutional or community affiliation. See the [Working with Other Instutitions/Single IRB](#_WORKING_WITH_OTHER) section below for additional information regarding collaborative or multi-site studies.  To add additional key personnel, highlight the above text, then copy (CTRL+C or Control +C) and paste (CTRL+V or Control +V). |

**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 study). These individuals do not need to be named, but their specific responsibilities should be described here. These individuals have the same human subjects research training requirements 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 human subjects research and protocol specific training is maintained and DEPA reporting is conducted annually. General Research Staff responsibilities will include distributing flyers, equipment set-up, and data entry/analysis.”  IRB staff will make determinations about the appropriateness of General Research Staff responsibilities on a case-by-case basis. |

# 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, including identification of specific primary objectives/hypotheses/research question(s). Describe secondary objectives/hypotheses if there are any. |

# BACKGROUND AND SIGNIFICANCE

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| Provide the scientific or scholarly background and rationale for the research based on the existing literature.  Describe the relevant prior experience and 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.  This should not be a copy-pasted significance section from a grant. Rather, create a more concise version that highlights the key points and that is accessible to non-scientist reviewers. |

# PRELIMINARY STUDIES

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| Describe any preliminary studies. |

# RESEARCH STUDY DESIGN AND PROCEDURES

**Study Design**

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| Describe what data are being collected from each participant population (including pre-screen and long-term follow-up). Explain how the data be analyzed in support of your research question(s), goals, or hypothesis.   * Describe the instruments/tools/process used for data collection and the purpose for each, first in narrative form and then in the included table. * Note: Data collection instruments, surveys, questionnaires, etc. should be included with your submission in eRA as stand-alone documents. The IRB will need to review the full text of each tool.   Describe any study groups/sub-studies. Include table/diagrams/flow chart, if appropriate, for more complex study designs.  Describe randomization procedures, if used.  If a control group is used, include a rationale for the choice of control (e.g., no treatment).  Explain how many participants you need to meet study objectives.  Provide the sample size calculation/justification and power analyses, if relevant.  Provide the data analysis plan. Include the methods for assessing how the objectives are met (i.e., the study outcome measures).  Provide the expected duration of the study (i.e., from recruitment to study closure).  If your research is in a school district, see: the [Research in K-12 Schools Guidance Document](https://www.colorado.edu/researchinnovation/media/6019) on the IRB webpage. Attach the approval letter from the School District review body or designated individual with this application. [Contact the IRB](mailto:irbadmin@colorado.edu?subject=Question%20about%20Research%20in%20Denver%20Public%20Schools) if research is being conducted in Denver Public Schools. |

**Study Procedures**

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| Discuss, in detail how exactly that data will be collected, especially regarding the experience of the individuals participating in the research. Describe what the participant will encounter throughout the study. For each participant population/data element included in the Study Design discussion, explain exactly where/in what context that an individual’s participation will take place, and what their experience of data collection will involve.  Describe all study procedures, assessments, and participant activities, using lay terminology   * Do NOT include pre-screening or consent activities in this section.   Describe 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.  What is the total time commitment for participants?  If you are using focus groups, please remember to inform participants of the topics to be discussed, the risks and benefits of participation, and how data will be collected and how confidentiality is being maintained.  Describe the procedures first in narrative form and then list in the included table. |

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| Visit # | Procedures/Tools | Data Collected | 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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| Provide the total number of participants you plan to enroll to meet your study objectives.   * The total number of participants includes everyone who signs a consent form and/or begins the study (if no consent form is required), or whose data you obtain for secondary data analysis. A participant counted from the time they enroll, even if they fail screening, withdraw from the study, or otherwise fail to complete the study. Parents who give permission for their child to participate are not counted, unless the parents themselves are also participants. The sample size should be large enough to conduct your analysis and allow for possible participant attrition, while not placing any more participants at risk than necessary (including risk of inconvenience). For more than minimal risk studies this number may not be exceeded without prior IRB approval. * Participant Population(s) should state the specific group or population of people from which the research participants will be drawn (i.e., college students in x class). If participants from more than one population will be enrolled, include each group separately. Number enrolled in each group should be the maximum number of participants from each group or population that will be enrolled.   Describe the participant population (include age range, gender, ethnic distribution, etc.)  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/ secondary participant.   The same criterion should NOT be listed as both inclusion and exclusion criterion. For example, do not state age > 30 years old as an inclusion criterion and < 30 years old as an exclusion criterion.  Inclusion and exclusion criteria should be clearly defined in an objective manner, so that anyone involved in the study or anyone attempting to replicate the study can reproduce the inclusion decisions, i.e., include the same participants in the research.  Provide justification for the specific exclusion of any population (e.g., non-English speaking persons, pregnant persons, genders, etc.) |

# VULNERABLE POPULATIONS

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| Describe any vulnerable or other special populations that will be considered for this study. In general, this section is to be completed if specifically enrolling participants from the following examples. Discuss how undue influence and/or coercion will be avoided in this population.  Describe the additional safeguards that are included to protect their rights and welfare.  Examples include:   * Cognitively impaired individuals * Participants with disabilities that may affect their ability to participate in the Consent process or other study activities (sight or hearing impairments) * Educationally disadvantaged individuals * Economically disadvantaged individuals * [Participants who report to or are students of the investigator](https://www.colorado.edu/researchinnovation/media/1274) * Non-English speaking individuals * Members of Native American groups or nations * Children under the age of 18 * Prisoners * Pregnant Women (Only if the participant’s pregnancy may be affected by the research) |

# RECRUITMENT METHODS AND PRE-SCREENING

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| Review the [Advertising and Recruitment Guidance Document](https://www.colorado.edu/researchinnovation/media/6093) for more information about what information should (and should not) be included in recruitment materials.  Discuss how the participants will be recruited - that is, how potential participants will be identified, how researchers have access to participants’ contact information, how the study will be described to potential participants, how they will be invited to participate, who will perform recruitment activities, etc.  Indicate from where the study population will be drawn, including when, where, and how potential participants will be recruited (e.g., Boulder community, student health service, out-patient clinics, SONA). Explain who will conduct recruiting activities, and the context in which the activities will occur. Explain how undue influence or coercion will be avoided. List any materials to be seen (e.g., Buff Bulletin script, flyers, email text, etc.) or heard (e.g. radio announcement script).  Submit materials (such as emails, scripts, letters, or flyers) that will be used in this process. Recruitment materials must be approved by the IRB in their final form, including any graphical elements, before they can be implemented. If you are using audio and/or video recruitment, submit the script.  The [Advertising Components Form](https://www.colorado.edu/researchinnovation/media/6037) can be used to receive approval specific recruitment text elements for some written recruitment documents (i.e., flyers, online advertisements, and newspaper ads). Once the Advertising Components Form has been approved, these written recruitment documents can be created (using only the approved text) and used without additional IRB approval.  Sample Recruitment Text for SONA Pool Participants (credit site), if relevant:   * “Participants will be drawn from the SONA class credit participant 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.”   If **pre**-screening will be done before consent is obtained, the process must be described in the Recruitment Methods section (e.g., where/how are screening procedures performed, by whom, etc.).   * Submit pre-screening materials for IRB review. * Provide the screening questions used for SONA Pool Participants, if relevant. * If the study is FDA regulated, you will need to use the Pre-screening Consent Script (found on the IRB website). If the study is **not** FDA regulated, the Pre-screening Consent Script is not needed. |

# INFORMED CONSENT

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| Describe the setting (where and when) consent will be obtained and who will obtain participants’ consent.  Describe whether and how consent/assent of the participant will be documented in writing.  In accordance with 45 CFR 46.117, a copy of the form used to document consent must be given to the person signing the form.  If you are requesting IRB approval to alter or waive informed consent, see the [Waiver of Informed Consent Guidance Document](https://www.colorado.edu/researchinnovation/media/1463). This section should include a rationale for the request.  If you are requesting IRB approval for waiver of documentation of consent, see the guidance document, [Waiver of Written Documentation of Informed Consent and Verbal Consent](https://www.colorado.edu/researchinnovation/media/1462). This section should include rationale for the request.  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 and attach consent forms and other documents in other languages to the application.  If the research involves [deception or incomplete disclosure](https://www.colorado.edu/researchinnovation/media/1433) (which requires informed consent to be altered), explain why this is necessary and the means for debriefing the participants. Submit the debriefing form or script to the for IRB review.    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.  If focus groups are being used, please remember to inform participants of the topics to be discussed, the risks and benefits of participation, and the manner and form in which data will be collected. |

# COMPENSATION

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| Describe the payment method for participants, including amount, format, and distribution procedure. State whether payment will be prorated in the event of early withdrawal. Include if other non-monetary forms of compensation (raffle, course credit, etc) are being used for compensation.  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.  If you are using course credit as a form of compensation, include this information. If a participant is a student who does not want to participate in the research, they should be offered an alternative activity (write a paper, critique an article on topic, etc.) with equivalent credit opportunity. |

# COST TO PARTICIPANTS

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

# DATA MANAGEMENT

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| The Data Security section of the HRP 211 Initial Application eForm provides data security information when completed. Use that information as a starting point for completing this section. Identify any deviations from the prescribed data security requirements and provide sufficient justification (NOTE: deviations from the data security requirements may not be approved).  For assistance with designing and adhering to data security requirements, contact the Office of Information Technology at [InfoSec@colorado.edu](mailto:InfoSec@colorado.edu).  **NOTE: This section addresses the regulatory requirement that there are adequate provisions to maintain the confidentiality of data. Confidentiality refers to the safeguarding of data about participants in a manner commensurate with the possible risks that that data may pose.** Describe where data will be stored, who will have access to the data, and measures taken to secure the data. Include procedures for maintaining participant confidentiality, any special data security requirements, and record retention per the sponsor’s requirements.  For hardcopy data, 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 coded data (data where a link between the participants' identities and a code number is maintained), describe how the key to the code will be stored and when/how it will be destroyed.  Describe safeguards for devices used to access study data, e.g., password access, automatic log-off.  State whether electronic files will be password-protected, encrypted, on a secure network, etc.  The IRB recommends not storing data on portable devices. Instead, data can be saved to a CU Boulder server and accessed remotely using a VPN. However, if portable devices or media (e.g., laptops, USB drives) must be employed for data collection and/or storage, the 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.  If data are to be generated in one location and transferred to another group, describe the responsibilities of each party.  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. If the 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 the data for future research. (NOTE: Participants must give permission for their data to be used for future research. See the [Consent Form Template](https://www.colorado.edu/researchinnovation/media/6030) for additional information.) |

# PROVISIONS TO PROTECT THE PRIVACY INTERESTS OF PARTICIPANTS

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| 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 (e.g., choosing private spaces for interviews, informing participants of shared lab spaces where others not associated with the research may be present, how to maintain privacy for an interviewee when conducting an interview on Zoom, etc.).  **Information regarding storage, use or management of information about participants and confidentiality procedures should be placed in the above Data Management section, not in this section.** |

# WITHDRAWAL OF PARTICIPANTS

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| Describe anticipated circumstances under which participants may be withdrawn without their consent (e.g., inability to follow study procedures, severe adverse reactions, etc.).  Describe procedures that will be followed when participants withdraw from the research, including:   * Whether and how participants are to be replaced. * Any follow-up for withdrawn participants. * Whether data from withdrawn participants will be retained or deleted. |

# 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 (include references in the References section).  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, the presence of trained personnel who can respond to emergencies, counseling resources, or coding of data to protect confidentiality. Include local and/or national resources when appropriate (hotlines or counseling services). |

# POTENTIAL BENEFITS

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

# PROVISIONS TO MONITOR THE DATA FOR THE SAFETY OF PARTICIPANTS

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| If applicable, describe any plans to periodically evaluate the data collected to ensure the safety of participants.   * This is required for studies conducted at the Clinical Translational Research Center; treatment studies, including behavioral treatment; and high-risk studies. Some funding agencies may also require a data and safety monitoring plan.   Describe the types of statistical interim analyses and stopping guidelines (if any) that are proposed.  Name those who will identify, document, and report adverse events.  Describe the frequency for review of summarized safety information and who will perform the review. |

# DRUGS

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| If you are using a drug during the conduct of this research, or if you are unsure if you are using a drug, contact the IRB at [irbadmin@colorado.edu](mailto:irbadmin@colorado.edu) before completing this document. |

# DEVICES

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| If you are using an investigational device during the conduct of this research, or if you are unsure if the device being used is investigational, contact the IRB at [irbadmin@colorado.edu](mailto:irbadmin@colorado.edu) before completing this document. |

# WORKING WITH OTHER INSTITUTIONS/SINGLE IRB

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| If the research is federally funded or supported and there are multiple institutions engaged in the research, the protocol will need to address each institution’s engagement. See the [Single IRB](https://www.colorado.edu/researchinnovation/research-administration/office-research-integrity-compliance/human-research-irb/single-irb) page on the IRB website for more information.  Use this section to provide an administrative overview of the collaboration. List each engaged institution and principal investigator. Indicate whether each institution will rely on CU Boulder for IRB oversight of the research.  The research activities performed by non-CU Boulder personnel should be clearly described in the appropriate section of this document. For example:   * For collaborative studies where identifiable data will be analyzed at another institution, but no other research activities will take place at that location, the Data Management section should describe how the identifiable data will be transferred to the other institution, etc. * For multi-site studies where the same research procedures will take place at multiple study sites, the recruitment, informed consent, and procedural activities for each location should be addressed as well as how the data will be managed among study sites. If site-specific materials will be used at each institution, those documents should be included in the Initial Application submission, otherwise the same materials will be used across all sites.   For Community Based Participatory Research (CBPR) projects that include engaged individuals who are not affiliated with an institution covered by an IRB:   * Provide name and affiliation of each CBPR affiliate * List what engagement activities will be performed (assisting with developing procedures, recruitment, obtaining informed consent, data collection etc.) * Include a signed [Individual Investigator Agreement](https://www.colorado.edu/researchinnovation/media/6041) for each CBPR affiliate in your submission |

# SHARING OF RESULTS WITH PARTICIPANTS

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| Describe any plans to share the results of the research with participants. |

# REFERENCES

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