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| **Instructions for this template**  Blue 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 blue 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. 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 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 and Consent Form Language for Studies Using MRI” for additional language requirements.** |

TITLE**:** Include full protocol title as listed in eRA

PROTOCOL VERSION DATE**:** Click here to enter a date.

VERSION**:** Click here to enter text.

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| We suggest that you add a version number in order 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: Enter the PI's name -- this must match the eRA eForm

Telephone: XXX-XXX-XXXX

Email**:** example: firstname.lastname@colorado.edu

# 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)

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| When adding non-CU Boulder personnel to the Protocol, include their institutional affiliation. See the Collaborative Studies section below for additional information regarding required documents for collaborative 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 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. **(NOTE: For biomedical research, these individuals are not allowed to conduct informed consent interviews.)** 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. |

# OBJECTIVES

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| Describe the purpose of the study, including identification of specific primary objectives/hypotheses/research question. 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. |

# PRELIMINARY STUDIES

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| Describe any preliminary studies. |

# RESEARCH STUDY DESIGN

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| In this section, describe "what" data is being collected from each subject population (including pre-screen and long term follow-up). How will the data be analyzed in support of your research question, goals or hypothesis?  Describe the instruments/tools used for data collection and the purpose for each.   * Describe the tools in the narrative. * Complete the included table. * Note: Data collection instruments, surveys, questionnaires, etc. should be included with your submission in eRA. The IRB will need to review the full text of each tool.   Describe any study groups/arms. 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., placebo, no treatment, active drug, dose-response, historical). Discuss known or potential problems associated with the control group chosen in light of the specific endpoints/population/condition being studied.  How many subjects you anticipate will complete the study.  Provide the sample size calculation/justification and power analyses.  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., recruitment trough study closure). |

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| Name of procedure/instrument/tool | Purpose (i.e., what data is being collected?) |
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# 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. |

# ABOUT THE SUBJECTS

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| In this section, provide the total number of subjects you plan to enroll.   * The total number of subjects 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 subject is 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 subjects. The sample size should be large enough to conduct your analysis and allow for possible subject attrition, while not placing any more subjects at risk than necessary (including risk of inconvenience). **This number may not be exceeded without prior IRB approval.**   Complete the included Table.   * Subject Population(s) should state the specific group or population of people from which the research subjects will be drawn (i.e., college students in x class). If subjects from more than one population will be enrolled, include each group separately. Number enrolled in each group should be the total number of subjects from each group or population that will be enrolled.   Describe the subject population (include age range, gender, ethnic distribution, etc.)  Describe any third party/secondary subject population(s).   * If the primary subjects 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 subject.   List the inclusion criteria - characteristics that must be met for individuals to be enrolled in study.   * If these criteria are answered in affirmative, subjects will be allowed on study. For example, if the inclusion criterion is “aged 30-60 years,” subjects can participate only if they are between 30-60 years old.   List the exclusion criteria - characteristics that will exclude otherwise eligible individuals from the study.   * If these criteria are answered in affirmative, subjects will NOT be allowed on study. For example, if the exclusion criterion is “ride a bicycle less than 5 miles per week,” subjects can participate only if they ride a bicycle more than 5 miles per week.   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 subjects in the research.  Provide justification for the exclusion of any population. |

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| Subject Population(s) | Number to be enrolled in each group |
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# 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 * [Subjects who report to or are students of the investigator](https://www.colorado.edu/researchinnovation/node/294/attachment/newest) * Non-English speaking individuals * Members of Native American groups or nations * Children under the age of 18 * Prisoners * Placental/fetus tissue * Pregnant Women (Only if the subject’s pregnancy may be affected by the research) * Neonates (non-viable/uncertain viability) |

# RECRUITMENT 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 subjects will actually be recruited - that is, how potential subjects will be identified, how the study will be described to potential subjects, and their participation in the research solicited.  Submit any 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. Audio and video recruitment materials should be accompanied by a script.   Complete the included Table. List any materials to be seen (e.g., Buff Bulletin script, flyers, email text, etc.) or heard (e.g. radio announcement script). List ONLY materials or methods used in recruitment (do not list Consent Forms or data collection instruments).  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).  Sample Recruitment Text for SONA Pool Subjects (credit site):   * “Subjects will be drawn from the SONA class credit subject pool. SONA subjects are enrolled in the pool via an accredited psychology class. Subjects 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 Subjects. * 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.   Include who will conduct recruiting activities, and the context in which the activities will occur.  How will undue-influence or coercion will be avoided in recruiting subjects?  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. |

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| List recruitment methods/materials and attach a copy of each in eRA |
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# COMPENSATION

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| Describe the payment schedule for participants, including amount, format, and timing. State whether or not payment will be prorated in the event of early withdrawal.  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 subjects to understand. |

# INFORMED CONSENT

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| Describe the setting (where and when) consent will be obtained.  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](https://www.colorado.edu/researchinnovation/node/304/attachment/newest) guidance document. 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](http://colorado.edu/researchinnovation/node/303/attachment/newest). 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.  If the research involves [deception](https://www.colorado.edu/researchinnovation/node/302/attachment/newest) (which requires informed consent to be altered), explain why this is necessary and the means for debriefing the subjects. 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. |

# PROCEDURES

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| As a whole, this section should describe what the participant will encounter throughout the study so it is clear to an independent reader. While the Study Design section of your Protocol Document discusses "what" data will be collected in support of this research, the Procedures section should discuss, in detail "how" exactly that data will be collected, especially with regard to the experience of the subjects participating in the research. For each subject population/data element included in the Study Design section, please discuss here exactly where/in what context that subject's participation will take place, and what their experience of data collection will involve.   * For biomedical research, this section should be organized by visit. The section should provide a detailed description of what a subject will experience as they progress through the study.   Describe all study procedures, assessments, and subject 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 subjects who participate?  Complete the included Table. Note the table is a SUPPLEMENT to the required narrative description described above. |

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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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# SPECIMEN MANAGEMENT

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| For biological specimens (blood, saliva, tissue, etc.) obtained using procedures from this study, describe:   * How and where specimens will be stored * Whether the specimens are directly identifiable, coded, or de-identified * The plans for the disposal or de-identification * Any plans to use the specimens for future research. (NOTE: subjects must give permission for their identifiable specimens to be used for future research. See the Consent Form Template for additional information.) * Whether the specimens (even if identifiers will be removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit. * Whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).   For biological specimens **not** obtained using procedures from this study, describe:   * The nature of the specimens being sent or received * What information will be associated with the specimens * How specimens will be transported and stored |

# DATA MANAGEMENT

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| Indicate the Data Security Risk Level as determined in the HRP-211 Initial Application form and include the appropriate data security plan. It is not necessary to copy the security requirements from the HRP-211 Initial Application Form. The remainder of this section should address *how* those requirements are actually being met in your study.  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 subjects 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, 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 coded data (data where a link between the subjects' 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.  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.  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: Subjects must give permission for their data to be used for future research. See the Consent Form Template 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.  **Information regarding storage, use or management of information about subjects 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 subjects withdraw from the research, including:   * The type and timing of the data to be collected for withdrawal of subjects. * Whether and how subjects are to be replaced. * Any follow-up for withdrawn subjects. |

# 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.  Describe the procedure for pregnancy screening and birth control counseling. Be sure to also include this into your informed consent document.  If applicable, indicate which procedures may have risks to an embryo or fetus should the participant be or become pregnant. |

# 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, or coding of data to protect confidentiality. |

# POTENTIAL BENEFITS

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| Describe the possible benefits the subject may experience.   * Do not overstate benefits * Compensation is not a benefit   If there is no direct benefit to the subject, 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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| Describe any plans to periodically evaluate the data collected to ensure the safety of subjects.   * 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. |

# MEDICAL CARE AND COMPENSATION FOR INJURY

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| If the research involves more than minimal risk, describe the provisions for medical care and available compensation in the event of research-related injury. |

# COST TO PARTICIPANTS

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

# DRUG ADMINISTRATION

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| Drugs are articles that are:   * recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia in the Unites States or official National Formulary; * intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease; * intended to affect the structure of any function of the body (other than food).   If the study involves drug administration, each drug product should be listed separately.  Recommended subsections for each drug product are:   * Formulation, Packaging, and Labeling: Include the name of the manufacturer of the agent. Information in this section can usually be obtained from the Investigator’s Brochure (IB) or the package insert. IB or package insert should be attached to your submission in eRA. * Preparation, Administration, Storage, and Dosage of Study Agent(s)/Intervention(s): Include thawing, diluting, mixing, reconstitution/preparation instructions, as appropriate. Describe agent’s storage needs; include storage requirements and stability (temperature, humidity, security, container of the agent. List study agent(s) route, doses, duration, and frequency of administration. Include any specific instructions or safety precautions for administration of study products or masking (blinding) of the product for the administrator. Include maximum hold time and conditions of product once thawed, mixed, diluted, reconstituted, etc. * Study Agent Accountability Procedures: Provide plans for how the Study Agent(s)/Intervention(s) will be distributed including participation of a drug repository, frequency of product distribution, amount of product shipped, and plans for return of unused product.   If placebo is used, describe the formulation, manufacturing, preparation, administration, storage, and accountability of the product, as appropriate. |

# INVESTIGATIONAL DEVICES

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| A medical device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:   * recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them * intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or * intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.   An Investigational Device is a medical device that is the subject of a clinical study designed to evaluate the effectiveness and/or safety of the device. The FDA defines a clinical trial/study as “any experiment that involves a test article [drug or device] and one or more human subjects.”  For studies involving Investigational Devices, provide a description of each important component, element, property, and principle of operation of the investigational device.  Describe, if applicable, any anticipated change(s) in the investigational device during the course of the clinical study. If no changes to the device are anticipated, state this.  See the [Investigational Device Studies](https://www.colorado.edu/researchinnovation/node/2763/attachment/newest) guidance document to determine which, if any, FDA regulations apply to your study.  If your study uses an FDA-approved device in accordance with the labeled indications, this section does not apply. |

# WORKING WITH OTHER INSTITUTIONS

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| If there are multiple institutions engaged in the research, the protocol will need to address each institution’s engagement. See the [IRB’s website](https://www.colorado.edu/researchinnovation/research-administration/compliance/human-research-irb/templates-guidance-other-resources/working) for more information on types of collaborative research and the requirements for each.  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. |

# SHARING OF RESULTS WITH PARTICIPANTS

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| Describe any plans to share the results of the research (group or individual results) with participants.  If applicable, add a statement regarding whether clinically relevant research results will be disclosed to subjects, and if so, under what conditions. |

# REFERENCES

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