**

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

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

VERSION***:*** We suggest that you add a version number in order to maintain an accurate and current record throughout the life of the study

# **PRINCIPAL INVESTIGATOR (PI)**:

Name: Enter the PI's name -- this must match the eRA eForm

Address: Enter the PI's address

Telephone: XXX-XXX-XXXX

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

# KEY PERSONNEL

**Name**: Enter name of key personnel -- must match name in eRA eForm

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

**Name**: Enter name of key personnel -- must match name in eRA eForm

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

* *To add additional key personnel, highlight the above text, then copy (CTRL+C or ⌘ +C) and paste (CTRL+V or ⌘+V). If not, delete this text.*

# OBJECTIVES

*Describe the purpose of the study, including identification of specific primary objectives/hypotheses. Describe secondary objectives/hypotheses, if there are any.*

# BACKGROUND AND SIGNIFICANCE

* *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

* *Describe any preliminary studies.*

# RESEARCH STUDY DESIGN

* *Describe the study design.*
* *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.*
* *Provide the sample size calculation/justification and power analyses.*
* *Clearly state the total number of subjects you plan to enroll (to sign consent form). The number of subjects should be adequate to meet the goals of the study, while avoiding unnecessary exposure to risk.*
* *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.*

# FUNDING

* 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

* *What is 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.***
  + *In the Table below, 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.*

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| *Subject Population(s)* | *Number to be enrolled in each group* |
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* *How many subjects do you anticipate will complete the study?*
* *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 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 “aged 30-60 years”, subjects can participate only if they are less than 30 or older than 60 years.*
* *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.*

# VULNERABLE POPULATIONS

* *What vulnerable populations will be considered for this study?*

*Examples include:*

* + *Cognitively impaired/educationally disadvantaged individuals*
  + *Economically disadvantaged individuals*
  + [*Subjects who report to or are students of the investigator*](http://www.colorado.edu/vcr/node/294/attachment/newest)
  + *Non-English speaking individuals*
  + *Children under the age of 18*
  + *Prisoners*
  + *Placental/fetus tissue*
  + *Pregnant Women (Do no select if subject’s pregnancy will not be affected by the research)*
  + *Neonates (non-viable/uncertain viability)*
* *Describe the additional safeguards that are included to protect their rights and welfare.*
* *How will coercion be avoided in this population?*

# RECRUITMENT METHODS

* [*Recruitment & Advising Guidance*](http://www.colorado.edu/vcr/node/300/attachment/newest)
* *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 Method 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. Refer to the Guidance Document:* [*Pre-Screening of Potential Participants*](http://www.colorado.edu/vcr/node/301/attachment/newest) *for more information.*
* *Where appropriate, include names of hospitals, clinics, etc.*
* *Describe the methods that will be used to identify potential participants. This description should include who will conduct recruiting activities, and the context in which the activities will occur.*
* *How will undue-influence or coercion be avoided in recruiting subjects?*
* *Recruitment materials must be approved by the IRB in their final form, including any graphical elements, before they can be implemented. List any materials to be seen (e.g.Buff Bulletin script) or heard (e.g. radio announcement script) by a potential subject – flyers, letters, email text, website content pertaining to research, etc. Audio and video recruitment materials should be accompanied by the script.*

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

* *Describe the payment schedule for participants, including amount and timing. State whether or not payment will be prorated in the event of early withdrawal. If it will be prorated, explain the mechanism/calculation for prorated payments.*

# CONSENT PROCESS

* *Describe the setting (where and when) consent will be obtained.*
* *If you are requesting IRB approval to alter or waive informed consent, see the* [*Waiver of Informed Consent*](http://www.colorado.edu/vcr/node/304/attachment/newest) *guidance document. This section should include a 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*](http://www.colorado.edu/vcr/node/302/attachment/newest)*, explain why this is necessary and the means for debriefing the subjects. Attach the debriefing form or script to the eRA submission.*
* *For research involving minors, describe how assent will be obtained, whether parental permission will be obtained, whether permission will be obtained from both parents unless one is deceased, unknown, incompetent, etc.*

# PROCESS TO DOCUMENT CONSENT IN WRITING

* *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 for waiver of documentation of consent, see the* [*Verbal Consent*](http://www.colorado.edu/vcr/node/303/attachment/newest) *guidance document. This section should include rationale for the request.*
* *Depending on the populations being studied, multiple versions of the informed consent / assent / permission forms may be needed, e.g., screening, study participation, future use specimens, and assent form for minors of different age groups. If different forms will be used, they should be identified here.*

# PROCEDURES

* *As a whole, this section should describe what the participant will encounter throughout the study so it is clear to an independent reader.*
* *Describe all study procedures, assessments, and subject activities.*
* *What data will be collected, including pre-screening and long-term follow up.*
* *List instruments/tools used for data collection and the purpose for each.*
  + *Note: Data collection instruments, surveys, questionnaires, etc. should be attached to your submission in eRA. The IRB will need to review the full text of each tool.*

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| *Name of instrument/tool/procedure* | *Purpose (i.e. what data is being collected?* | *Time to Complete* |
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* *Investigators using SONA (psychology subject pool), provide all questions being asked.*
* *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.*
* *State the time for each visit and the total time for all research procedures.*
* *What is the total time commitment for subjects who participate?*

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| --- | --- | --- | --- |
| *Visit #* | *Procedures/Tools* | *Location* | *How much time the visit will take* |
| *Example: Visit 1* | * *Task/test/procedure 1* * *Task/test/procedure 2* |  |  |
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# SPECIMEN MANAGEMENT

* *Describe the specimens being sent or received.*
* *List what information will be associated with specimens.*
* *Describe how specimens will be transported.*

# DATA MANAGEMENT

* *Indicate the Data Security Risk Level as determined in the HRP-211 Initial Application form and include the appropriate data security plan.*
  + *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, please contact Desiree Robinson, Information Risk Manager in the Office of Information Technology* [*desiree.robinson@colorado.edu*](mailto:desiree.robinson@colorado.edu) *or 303-735-6749*
* *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, specimens, 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, 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 final disposition 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.*
* *Note: An investigator may not de-identify data and/or specimens under his or her control (e.g., data collected by the investigator for another study) for future research uses without IRB review.*

# WITHDRAWAL OF PARTICIPANTS

* *Describe anticipated circumstances under which participants will be withdrawn without their consent, e.g., inability to follow study procedures, possible severe adverse reactions.*
* *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

* *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 pregnant 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

* *Describe how each risk above 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

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

# PROVISIONS TO MONITOR THE DATA FOR THE SAFETY OF PARTICIPANTS

* *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.*

# PROVISIONS TO PROTECT THE PRIVACY INTERESTS OF PARTICIPANTS

* *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. It involves consideration of whether the participants will be comfortable with the research situation. For example, persons may not want to be seen entering a place that might stigmatize them, such as a pregnancy counseling center that is clearly identified as such by signs on the front of the building.*
* *Describe the steps that will be taken to protect participants’ privacy interests, when applicable.*

# MEDICAL CARE AND COMPENSATION FOR INJURY

* *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

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

# DRUG ADMINISTRATION

* *If the study involves drug administration, each drug product should be listed.*
* *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

* *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. A medical device is any healthcare product that does not achieve its primary intended purpose by chemical action or by being metabolized.*
* *For studies involving Investigational Devices, provide a description of each important component, ingredient or 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.*
* *If your study uses an FDA-approved device in accordance with the labeled indications, this section can be deleted.*

# MULTI-SITE STUDIES

* *If the study will be performed at more than one institution, describe the administrative organization, including laboratories, data management center, and coordinating center as applicable. See the IRB website section titled* [*non-CU Entity Research*](http://www.colorado.edu/vcr/node/72) *(at the bottom of the Forms and Templates Page) for more information on requirements if involving outside institutions*
* *If enrollment will take place at more than one institution, describe how enrollment procedures will be coordinated among the participating sites. A lead site and study coordinator should be identified.*
* *Indicate if an IRB Authorization Agreement (IAA) will be in place – i.e., which sites/IRBs will cede review to CU-Boulder. See the* [*IAA guidance*](http://www.colorado.edu/vcr/sites/default/files/attached-files/IRB%20Authorization%20Agreement%20Guidance.pdf) *document.*
* *If CU-Boulder is the lead site, appropriate forms (e.g., Eligibility Screening Worksheet, Registration Forms) should be developed and included with the submission. These forms must be used by all participating institutions.*

# SHARING OF RESULTS WITH PARTICIPANTS

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