**Instructions for this form**

Blue text boxes (like this one) and blue highlighted text in the body of this document are instructional and should be deleted before submitting your document to the IRB for review. Please “select” and “delete” the text box and highlighted text to remove it. A yellow box indicates new or revised instructions.

Text that is not shaded is sample language that can be included in your consent form. This language may need to be modified, deleted, or expanded to adequately represent your study.

***The header and footer are for IRB use only; do not modify or delete.***

Your final document must be submitted to the IRB as a 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/media/1301) for additional language requirements.

## Title of research study: Insert Title of Study

## IRB Protocol Number: XX-XXXX This is the "Record Number" at the top left of the Protocol Window in eRA

## Investigator: Insert name of Principal Investigator

## Sponsor: Insert name of sponsor Delete this line if there is no sponsor

***Key Information***

**\*\*NEW INFORMATION\*\***

Informed Consent Documents must begin with a concise and focused presentation of the key information that is most likely to assist a prospective participant in understanding why one might or might not want to participate in the research. This section cannot exceed three pages or one third of the length of the remaining consent document (exclusive of face page and signature blocks), whichever is shorter.

Examples of this information are:

* + Time commitment (number of visits, amount of time visits may take)
	+ Limitations on daily activities (not driving on the day of a visit)
	+ Restrictions (not taking medications, fasting before a visit, avoiding certain foods);
	+ Performing a certain activity for an extended period of time (eating an M&M every day)
	+ The participant may/may not benefit from the study and some of the potential benefits and risks (if any)
	+ Potential costs
	+ Drug is/is not FDA approved
	+ Exposure to radiation
	+ The participant will also be asked to participate in sub-studies

***Purpose of the Study***

This section should:

1. Explain the purpose of the research using lay language.
2. Explain the background of the research problem.
3. Describe how the research will advance the knowledge of the field/benefit others in the future.
4. If drugs or devices are used, indicate whether they are FDA approved or investigational.
5. Explain how many subjects will participate.
6. Explain how long participation will last.

The purpose of the study is \_\_\_. Continue the paragraph with background, benefits to others, etc.

We expect that you will be in this research study for \_\_\_\_\_\_\_\_. Indicate length of time as hours/days/months/weeks/years, until a certain event, etc.

We expect about \_\_\_ people will be in this research study. Include the following sentence only if the CU Boulder site is part of a national or international multi-site study. We expect about \_\_\_ people in the entire study nationally or internationally.

Note: Indicate how many participants you will enroll (i.e., provide consent); not how many you expect to complete the study.

***Explanation of Procedures***

Tell the subject what to expect using lay language and simple terms. For studies that require multiple visits, provide a brief overview in paragraph form (e.g., “You will have a total of four study visits, each lasting one hour. During these visits you will…” Etc.) then provide a breakdown of what subjects will do at each visit:

Visit 1:

Describe procedures for visit 1.

Visit 2:

Describe procedures for visit 2, indicating how many days/weeks/months after the previous visit it will occur. Etc.

If subjects will be randomized into groups, include the following information before the individual visit breakdown. When describing the study procedures, make sure it is clear what is expected of each group.

The treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment you get. You will have an equal/one in three/etc. chance of being given each treatment. For double-blinded research add the following sentence: Neither you nor the study doctor will know which treatment you are getting. For single blinded research add the following sentence: You will not be told which treatment you are getting; however, your study doctor will know.

If subjects will be deceived, or information about the study's purposes or procedures will be incompletely disclosed to participants, include the following language. NOTE, this language is required for studies involving benign behavioral interventions that also involve incomplete disclosure or deception to receive an Exempt determination. See the IRB's Guidance Document on [Deception and Incomplete Disclosure](https://www.colorado.edu/researchinnovation/node/302/attachment/newest) for more information.

We cannot tell you everything about what we are doing in this study or why. A full explanation of the purpose of the research and procedures will be provided after you complete the study.

For all studies, include the following information as applicable to your study in the Explanation of Procedures section. For studies that have multiple visits, consider including a table or chart to accompany the description.

* Where the research will be done
* When the research will be done
* How often procedures will be performed
* The length and duration of visits and procedures
* With whom the subject interact
* Description of all devices that will be used
* Descriptions of psychological tests and/or questionnaires
* Description of observations or interviews that will occur as part of the research
* Description of any manipulation of the subject's environment and activities that will take place as a part of the research
* Description of all data to be collected about subjects, and the source of that data (such as data from existing records, data from non-research specific sources such as standardized tests, etc.)
* Include all telephone or written follow-ups
* If blood will be drawn, indicate the amount per visit and total for the study (in units and lay terms) and frequency
* Describe any other specimens (e.g., tissue or body fluids) that will be collected as part of the research
* List experimental procedures and therapies and identify them as such

***Voluntary Participation and Withdrawal***

Whether or not you take part in this research is your choice. You can leave the research at any time and it will not be held against you.

For research that is **not** FDA-regulated, describe what will happen to data collected to the point of withdrawal. Describe whether subjects will be asked to explain the extent of their withdrawal and whether they will be asked for permission to collect data through interaction or collection of private identifiable information. For example, a subject may wish to withdraw from the experimental procedure because of unacceptable side effects, but may agree to undergo follow-up procedures and data collection.

Include the following information only for research where this is a possibility:

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include describe reasons why the subject may be withdrawn.

Include the following only if there are potential adverse consequences to withdrawing from the research:

If you decide to leave the research, describe the adverse consequences. If you decide to leave the research, contact the investigator so that the investigator can describe the procedures for orderly termination by the subject, if any.

Include the following only for FDA-regulated research:

If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care. If you agree, this data will be handled the same as research data. If routine medical care is not relevant to your protocol, delete the previous two sentences.

Include the following **only** for studies that may enroll CU Boulder students and employees. This language is **NOT necessary** for students recruited through SONA, etc.:

If you are a CU Boulder student or employee, taking part in this research is not part of your class work or duties. You can refuse to enroll, or withdraw after enrolling at any time, with no effect on your class standing, grades, or job at CU Boulder. You will not be offered or receive any special consideration if you take part in this research.

Include the following only for research where this is a possibility:

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

***Incidental Findings***

This section is only required for studies that involve research-related imaging. Please see Guidance Document “Protocol and Consent Form Language for Studies Using MRI” for specific language requirements.

## Risks and Discomforts

Delete this section if there are no risks or discomforts (minimal risk research only).

The risks of procedures may be presented in a table or narrative form.

Describe each of the following risks, as applicable to your study. If known, describe the probability and magnitude of the risk.

1. Physical risks
2. Psychological risks
3. Privacy risks
4. Legal risks
5. Social risks
6. Economic risks

Include the following only for research that involves procedures whose risk profile is not well known, including all research involving an investigational product:

In addition to these risks, this research may hurt you in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

It is important that you tell the Principal Investigator, include full name if you think you have been injured as a result of taking part in this study. You can call him/her at include phone number.

Include the following sub-section only for research that involves pregnant women or women of child-bearing potential and procedures that involve risks to an embryo or fetus or whose risk profile in pregnancy is not well known.

For women of childbearing potential

The procedures in this research are known to hurt a pregnancy or fetus in the following ways: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. Omit the previous sentence if there are no known risks. The research may also hurt a pregnancy or fetus in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death. Omit the previous two sentences for research whose risk profile in pregnancy is well known. You should not be or become pregnant while on this research study.

Include the following only for research that takes place entirely at the CTRC. For research that includes partial procedures at the CTRC or has designated research-specific physician oversight, contact the CTRC for additional information regarding medical oversight procedures.

If you have a medical emergency, call 911. If you have medical complaints, contact the Clinical and Translational Research Center (CTRC) at (303) 735-2304. After hours, call (303) 206-6339 (physician pager).

***Payment for Research Related Injury***

Include this section only for research involving more than minimal risk.

If you need medical care because of taking part in this research study, seek medical attention immediately (if it is a medical emergency, first call 911). Generally, this care will be billed to you, your insurance, or other third party. Insert the name of the institution has no program to pay for medical care for research-related injury.Describe any compensation available for research related injury. Please contact the investigator as soon as possible to report the event.

***Potential Benefits***

Delete this section if there are no benefits.

Include the following if there are benefits to participation.

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. Describe the potential benefits of participation. First describe any direct benefits to the subject, then any benefits to others. If benefits from participation may not continue after the research has ended, describe them here. Monetary reimbursement for participation is not a benefit.

Include the following only for research involving prisoners:

Taking part in this research study will not improve your housing or correctional program assignments. Your taking part in this research study will not improve your chance of parole or release.

***Alternatives***

Include the following if there are alternatives to participation (this information is required for FDA regulated research):

Instead of being in this research, you choices may include:

* List the major approved alternative options (procedures, devices, etc.).
* For student subject pools describe alternatives for course credit.

Include the following if there are no alternatives to participation for *Biomedical Studies*. If there are no alternatives in Social/Behavioral/Education studies, delete this section entirely:

This research is not designed to diagnose, treat, or prevent any disease. Your alternative is to not take part in the research.

***Confidentiality***

Information obtained about you for this study will be kept confidential to the extent allowed by law. Research information that identifies you may be shared with the University of Colorado Boulder Institutional Review Board (IRB) and others who are responsible for ensuring compliance with laws and regulations related to research, including people on behalf of the Office for Human Research Protections. The information from this research may be published for scientific purposes; however, your identity will not be given out.

Add the following to the list of organizations that may have access to the subject’s records as applicable:

* The Food and Drug Administration, if the research involves a drug, device, or biologic subject to FDA oversight
* The Department of Health and Human Services, when the research is conducted or funded by DHHS
* the sponsor
* contract research organization
* sponsor’s agent
* other collaborating institutions.

If your study includes identifiable audio or video recordings or photographs, include information regarding how they will be stored, how long they will be kept, and how they will be destroyed.

Include the following only for a FDA regulated study:

The sponsor, monitors, auditors, the IRB, and the US Food and Drug Administration will be granted direct access to your research and/or medical records to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

Include the following for FDA-regulated controlled drug and device trials (except Phase I drug trials) and FDA-regulated pediatric post-market surveillance trials of devices. OR for any other research that will be listed on ClinicalTrials.gov.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Include the following only for research where the sponsor may pay for medical expenses of the subject:

If the sponsor pays any of your medical expenses, we may be required to give the sponsor your name, date of birth, and Medicare ID or social security number.

Describe any limitations on confidentiality based on possible legal issues. For example, if the research team is likely to uncover abuse, neglect, or reportable diseases, explain that this information may be disclosed to appropriate authorities.

There are some things that you might tell us that we CANNOT promise to keep confidential, as we are required to report information like:

* Child abuse or neglect
* A crime you or others plan to commit
* Harm that may come to you or others

Include the following only if the study is funded by the National Institutes of Health or you have obtained a Certificate of Confidentiality specifically for this study:

This study has been issued a Certificate of Confidentiality from the federal government help protect your privacy. This certification means that the researchers cannot be forced to tell people who are not connected with the study, such as the court system, about your participation in this study. But, if you request that we do so, we will release information that is unique to you.

There are three exceptions to this promise of confidentiality:

1. If we see or are told information that makes us reasonably suspect that a child or at-risk adult is being or has been abused, mistreated, or neglected, we will immediately report that information to the county department of social services or a local law enforcement agency.
2. If we learn of a serious threat of imminent physical violence against a person, we will report that information to the appropriate legal authorities and make reasonable and timely efforts to notify the potential victim.
3. This promise of confidentiality does not include information we may learn about future criminal conduct.

Include the following only if the research involves genetic testing:

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

* Health insurance companies and group health plans may not request your genetic information that we get from this research.
* Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
* Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this new federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance, nor does it protect you against genetic discrimination by all employers.

Include one of the following, as appropriate, for federally funded studies:

After the study is completed, we will deidentify the data and/or biospecimens by removing the identifiers that link it to you. The deidentified data and/or biospecimens may be used for future research purposes by the Principal Investigator of this study. The deidentified data and/or biospecimens may also be shared with other investigators for future research. Include the last sentence only if sharing data/biospecimens with others is a possibility.

The data and/or biospecimens collected from you during the course of this research will not be used for future research by the Principal Investigator or shared with other investigators for future research.

If funding or other requirements dictate inclusion of data in a repository or for data sets to be published, address this requirement. Specify where data will be stored or published. Describe whether this information will be individually identifiable. As appropriate address, for how long data will be stored, and how it may be used in future research.

Address the following three items, as appropriate for your study:

Add a statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.

For research involving biospecimens, add a statement that the subject’s biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.

For research involving biospecimens, address whether research will (if known) or might include whole genome sequencing.

***Cost of Participation***

Include this section only for research that may result in additional costs to the subjects.

Taking part in this research study may lead to added costs to you. Describe what these costs are.

***Payment for Participation***

Include the following if subjects will be paid for their participation. In your description you need to not only tell subjects how much they will be paid, but in what format (gift card, cash, check, etc.), how (will payment be mailed or given in person), how often (at each or certain visits or at the end of the study), and what they will be paid if they leave the study early.

If you agree to take part in this research study, we will pay you indicate amount for your time and effort. Payments will be made continue with the description of how much, in what format, how, how often, and amount paid if subjects leave the study early.

It is important to know that payment for participation is taxable income.

Include the following if subjects **will not** be paid for their participation.

You will not be paid to be in this study.

***Contact for Future Studies***

Include this section if you want to request permission for participants to be contacted for future related studies. This section is to be used **only** by investigators developing a study participant database for future research activities. *If using this section, specific procedures for data collection and management must be included in the Protocol Document, Data Management Section.*

We would like to keep your contact information on file so we can notify you if we have future research studies we think you may be interested in. This information will be used by only the principal investigator of this study and only for this purpose.

Please initial your choice below:

\_\_\_ Yes, you may contact me for future research studies. The best way to contact me is: (enter preferred telephone number and/or email address) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_ No, you may not contact me for future research studies.

***Storage of Specimens for Future Research***

If specimen storage is **required for participation** in the study, include this information in the “Explanation of Procedures” section and do not create a separate “Storage of Specimens for Future Research” section.

Include this section **only** if you would like to keep leftover identifiable specimens (e.g., blood, tissue) from this study for future research **~OR~** if your study includes an optional component that involves identifiable specimen collection that may be stored for future research. Address the following in your explanation:

* What specimens you will keep
* What type of research will be done with the specimens
* Whether the specimens will be shared with other researchers
* Whether the specimens will be coded or anonymized
* Whether the participant may be contacted for additional consent
* How long the specimens will be stored
* What will be done with the specimens if the subject refuses permission
* How subjects can withdraw consent for future use

Initial your choice below:

\_\_\_ I agree to allow my samples to be kept and used for future research on insert type of research.

\_\_\_ I do not agree to allow my samples to be kept and used for future research.

If you would like to keep identifiable data from this study for future research, IRB approval is required. Please contact the IRB Office for additional information.

***Questions***

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at insert contact information for the research team

This research has been reviewed and approved by an IRB. You may talk to them at (303) 735-3702 or irbadmin@colorado.edu if:

1. Your questions, concerns, or complaints are not being answered by the research team.
2. You cannot reach the research team.
3. You want to talk to someone besides the research team.
4. You have questions about your rights as a research subject.
5. You want to get information or provide input about this research.

***Signatures***

Choose the signature block(s) appropriate for your research. Make appropriate spacing adjustments to ensure signature blocks do not break across more than one page.

Omit the signature page if you received a Waiver of Documentation of Informed Consent.

**Signature for capable adult:** use this signature section when enrolling normal, healthy adults.

Your signature documents your permission to take part in this research.

Signature of subject Date

Printed name of subject

Signature of person obtaining consent Date

Printed name of person obtaining consent

Add the following **only** if a witness will observe the consent process. E.g., short form of consent documentation or illiterate subjects. *Please note, the UCB IRB does not require a witness to the consent process under normal circumstances.*

My signature below documents that the information in the consent document and any other written information was accurately explained to and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of witness to consent process Date

Printed name of person witnessing consent process

***Signatures***

**Signature for adult unable to consent:**  use this section when enrolling adults who are temporarily or permanently cognitively impaired or otherwise unable to consent for themselves.

Your signature documents your permission for the named subject to take part in this research.

Printed name of subject

Signature of legally authorized representative Date

Printed name of legally authorized representative

Signature of person obtaining consent Date

Printed name of person obtaining consent

Add the following if you will document assent of the subject.

Assent of subject:

 Obtained

 Not obtained because the capability of the subject is so limited that the subject cannot reasonably be consulted.

Add the following only if a witness will observe the consent process. E.g., short form of consent documentation or illiterate subjects. *Please note, the UCB IRB does not require a witness to the consent process under normal circumstances.*

My signature below documents that the information in the consent document and any other written information was accurately explained to and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of witness to consent process Date

Printed name of person witnessing consent process

***Signatures***

**Signature block for Parent Permission:** use this section when enrolling subjects under 18 years of age.

|  |
| --- |
| Your signature documents your permission for the named child to take part in this research. |
|  |  |
| Printed name of child |
|  |  |  |
| Signature of parent or individual legally authorized to consent to the child’s general medical care |  | Date |
|  | * Parent
* Individual legally authorized to consent to the child’s general medical care (See note below)
 |
| Printed name of parent or individual legally authorized to consent to the child’s general medical care |
| **Note:** Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child’s general medical care. Contact legal counsel if any questions arise. |
|  |  |  |
| Signature of parent |  | Date |
|  |  |
| Printed name of parent |
| If signature of second parent not obtained, indicate why: (select one) |
| * The IRB determined that the permission of one parent is sufficient. The IRB will make this determination and alter the form accordingly.
* Second parent is deceased
* Second parent is unknown
 | * Second parent is incompetent
* Second parent is not reasonably available
* Only one parent has legal responsibility for the care and custody of the child
 |
|  |  |  |
| Signature of person obtaining consent and assent |  | Date |
|  |  |  |
| Printed name of person obtaining consent |  |  |

Add the following block if you will document assent of children on this form, rather than on a separate Assent Form (note, this is most commonly used for children who are not yet literate or have a limited capacity to read and understand an Assent Form:

|  |  |
| --- | --- |
| Assent | * Obtained
* Not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.
 |

Add the following block if a witness will observe the consent process. E.g., short form of consent documentation or illiterate subjects. *Please note, the UCB IRB does not require a witness to the consent process under normal circumstances.*

|  |
| --- |
| My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject. |
|  |  |  |
| Signature of witness to consent process |  | Date |
|  |  |
| Printed name of person witnessing consent process |