**List of Additional Standard Language Statements for the Consent Form**

1. **If your research may enroll UCCS students and employees.** This language is NOT necessary for students recruited through SONA, etc.:

If you are a UCCS 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 UCCS. You will not be offered or receive any special consideration if you take part in this research.

1. **If you will be recording data?**

In this study we will be recording <list whatever applies>. We will use <state medium of recording—e.g. notebook, computer files, cassette tapes, CD’s, video tapes, etc. >. We will keep this information secure and private. We will store it for <state duration of storage>. At the end of that time, we will destroy it.

1. **If your project is NIH funded and requires a data management sharing plan (DMSP) this language may be helpful.**

*UCCS researchers and their collaborators may use the data collected in this study for future research purposes and may share some of the data with others.*

*Sharing data is part of research and may increase what we can learn from this study. Often, data sharing is required as a condition of funding or for publishing study results.  It also is needed to allow other researchers to validate study findings and to come up with new ideas. Your data may be shared with researchers at UCCS and other institutions, for-profit companies, sponsors, government agencies, and other research partners. Your data may also be put in government or other databases/repositories.*

1. **If you are making a decision for someone else or are a Legally Authorized Representative**

Some people in this study may have a condition or a disability that does not allow them to make important decisions for themselves. If you have been asked to decide for someone else whether he or she should be in this study, please read this consent form carefully.

In this form, we use the words “you” and “your.” If you are reading this form and deciding for someone else, the words ‘you’ and ‘your’ refer to that other person, not to you.

1. **If your research meets the definition of a clinical trial.**

This trial will be registered and may report results on [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov) or some other Federally sponsored site that is publicly available.

1. **If your research involves things that must be reported to the authorities, for research with no Certificate of Confidentiality in place**

We respect your right to privacy. However, we cannot keep some things private. If you give us information about child neglect or child abuse, we have to report that to Social Services. If you give us information about someone hurting someone else, we have to report that to the police. If a court orders us to hand over your study records, we have to hand them over to the court.

1. **If your study is funded by NIH or has a Certificate of Confidentiality**

A Certificate of Confidentiality has been obtained from the federal government for this study to help insure 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.

The researchers may disclose your name or identifiable information, document or biospecimen, under the following circumstances:

* To those connected with the research,
* If required by Federal, State or local laws,
* If necessary for your medical treatment, with your consent,
* For other scientific research conducted in compliance with Federal regulations,
* To comply with mandated reporting, such as a possible threat to harm yourself or others, reports of child abuse, and required communicable disease reporting, or
* Under other circumstances with your consent.

A Certificate of Confidentiality does not protect information you or a member of your family voluntarily release.

1. **If your research involves participants in a detention facility**

You have a choice about being in this study. Being in this study will not change your release date, your parole status, or your living conditions.

In this study, we might ask you some questions about illegal drugs or illegal activities. If other people found out this information, you could get into more trouble. To keep that from happening, we will make sure that the paper with your answers on it does not have your name, only a code. We will also make sure that we keep your answers locked up.

The federal government requires us to keep your information private. However, if you give us information about child abuse, we will have to report that. If you give us information about someone hurting someone else, we will have to report that. If a court orders us to hand over your study records, we will have to hand them over to the court.

1. **If participants are assigned to a randomized group**

This study will have <insert number> different groups of research subjects like you. To decide which group you will be in, we will use a method of chance. This method is like flipping a coin or rolling dice. Each group will get slightly different care.

1. **If your research involves the collection of identifiable private information or identifiable biospecimens,** one of the two statements must be included.

It is possible the identifiers will be removed from the < identifiable private information/biospecimens (select one) > and, after the removal, the < information/biospecimens (select one) > could be used for future research studies or distributed to another investigator for future research studies without your consent.

**OR**

Although < identifiable information/biospecimens (select one) > are collected as part of the research, it will not be used for future research studies.

1. **If the subject’s biospecimens are involved**

It is possible that your biospecimens, even if identifiers are removed) may be used for commercial profit. If used, you will/will not share in this commercial profit.

1. **If biospecimens are involved**

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). This means we will map your entire genetic code. If you have questions about this ask the study staff.

1. **If your research involves banking of samples/data in a central/national repository**

When this study is over, we intend to put any remaining samples [*if applicable*: including genetic samples] into the [*name of the repository*] repository for future studies [*if applicable*: related to *specify the future use*]. They will be stored in the repository indefinitely without your name or any other identifying information on them. As such, once your samples are sent to the repository, you will not be able to have them removed. Researchers for future studies must first get permission from the [*name of the repository*] repository to use samples from the repository.

The following checkbox gives you the choice of allowing us to put any remaining samples in the [*name of the repository*] repository. Even if you decide not to have your remaining samples stored, you can still participate in this study.

I give permission to have my \_\_\_\_\_\_ stored: (check one below and initial)

□ Yes, store all samples including the genetic samples          \_\_\_\_\_\_ Initials \_\_\_\_\_\_ Initials

□ Yes, store all sample but ­not the genetic samples               \_\_\_\_\_\_ Initials \_\_\_\_\_\_ Initials

□ No, I do not give permission to have any samples stored    \_\_\_\_\_\_ Initials \_\_\_\_\_\_ Initials

1. 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 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.

**NOTE** – If you have plans to return clinically relevant research results, please see the IRB Standard Operating Procedures, Topic XXXI. Lab Certification related to the Clinical Laboratory Improvement Amendment (CLIA).

1. If clinically relevant research results are expected

Include a statement regarding whether clinically relevant research results, including the individual research results, will be disclosed to subjects, and if so, under what conditions. For example, “We will tell you about any relevant results that may affect your health, welfare, or choice to stay in the research.”

**NOTE** – If you have plans to return clinically relevant research results, please see the IRB Standard Operating Procedures, Topic XXXI. Lab Certification related to the Clinical Laboratory Improvement Amendment (CLIA).

1. **If the research involves the use of DEXA (related to bone densitometry)**

As part of this study we will perform <insert number> DEXA scan[s] of your <insert body area>. DEXA is a way of looking inside the body by using X-rays. X-rays are a type of radiation.

Your natural environment has some radiation in it. This DEXA will give you about the same amount of radiation that you would get from your environment in <multiply the number of scans by two > days.

**NOTE** – If the participant is pregnant or believes they may be pregnant, a warning should be provided to consult with their care provider before participating in the research.

Researchers, please get in touch with the CU radiation safety team to obtain any required approvals for the use of the DEXA/DXA machine on campus via email [radsafety@colorado.edu](mailto:radsafety@colorado.edu) or 303-492-6523.

1. **If your research involves having blood taken**

In this study we will need to get about \_\_\_\_\_ [teaspoons/tablespoons] of blood from you. We will get blood by putting a needle into one of your veins and letting the blood flow into a glass tube. You may feel some pain when the needle goes into your vein. A day or two later, you may have a small bruise where the needle went under the skin.

1. **If your research involves having blood taken by finger stick**

In this study we will need to get a few drops of blood from your finger. To do this, we will make a small prick on your finger and draw the blood into a tiny tube. You will feel a slight pain when the needle pricks your finger. Your fingertip may be sore for a day or two.

1. **If your research involves having blood taken by heel stick**

In this study we will need to get a few drops of blood from your baby’s heel. To do this, we will make a small prick on your baby’s heel and draw the blood into a tiny tube. Your baby may cry when the needle pricks the skin. There may be a bruise on your baby’s heel the next day, and your baby’s heel may be sore for a couple of days. We will take blood from your baby \_\_\_\_ times this way during the study.

1. **If your research involves having an IV inserted in your vein**

In this study we will insert a needle, connected to a plastic tube, into a vein in [*on*] your *<insert body location>.* We will use the tube to take blood samples or give you fluids. You will feel some pain when we first insert the tube into your vein. You may have some redness, swelling, or bruising where the tube goes under your skin. In some cases, this type of tube can cause an infection where it goes under the skin. In rare cases, it can cause a blood clot in the vein. You will have this tube inserted for about *<insert time>*.

1. **If your research involves having a skin biopsy**

In this study we will need to take *<insert number>* small sample[s] of your skin. This procedure is called a “biopsy.” Before we take the sample[s], we will give you some medicine to numb the area. Then we will press a hollow needle into your skin. When we take the needle out, it will remove a small circle of skin called a “plug.”

There are some risks to taking a sample of skin this way. There is a small chance that you could get an infection where the needles goes in. There is also a small chance that you could have an allergic reaction to the numbing medicine. After your skin heals up, you may have a small scar where we take the sample.

1. **If your research involves a muscle biopsy**

In this study we take a small sample of muscle tissue from you. This procedure is called "muscle biopsy." Before we take the tissue samples, we will numb the skin. We will then make a small cut in the skin and insert a hollow needle.

You may feel discomfort when we inject the numbing medicine (the anesthetic) but during the actual muscle removal, the discomfort should be minimal. There is a risk of infection, muscle cramp, bleeding, bruising, and nerve damage. The risk of infection, muscle cramp, bleeding, and bruising can be minimized if you follow the instructions for caring for the incision. A very small and minor scar may remain as a result of the incision. You could also have an allergic reaction to the numbing drug. You will be screened prior to the procedure for history of allergic reactions to the numbing medicine (e.g., lidocaine).

1. **If a researcher on your team is a mandatory reporter AND there is a reasonable possibility that mandatory reporting circumstances may occur (this will most likely be research with children or the elderly)**

There may be instances where the researcher(s) cannot keep information you provide them confidential, including reports of abuse or neglect or a child, dependent adult or elder. If such information is reported to the researcher(s), they may have to report it to the appropriate authorities. [Provide example of information that would be reported pertinent to the study]