**DELETE PRIOR TO SUBMITTING: *This consent form has been updated to reflect changes necessary for in person research during the COVID-19 outbreak. Consent forms must be given to participants and signed before showing up for research procedures so that they can adequately assess their risk and participation before putting themselves at any risk of exposure. Please read all sections carefully and add the appropriate information.*** *The informed consent language and its documentation (especially explanation of the study’s purpose, duration, experimental procedures, alternatives, risks, and benefits) must be written in “lay language”. DO NOT use language copied from the protocol. Avoid technical jargon. All italicized sections need to be addressed prior to submission.* ***Please note there is a separate file available on the IRB website with sample standard language for circumstances including, but not limited to, biospecimens/PII, audio recording of data, funding by NIH, genetic testing, etc.***

**University of Colorado**

**Colorado Springs (UCCS)**

**Consent to be a Research Subject**

**Title**:

**Principal Investigator**:

**Funding Source**:

## Key Information « As part of the revised Common Rule, there is the requirement that the document begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not participate in the research study. It must be organized and presented in a way that facilitates comprehension. Include a BRIEF summary of the protocol, including the following: 1. Consent is being requested and participation is voluntary; 2. The purpose of the research, expected time commitment, and procedures to be followed; 3. reasonably foreseeable risks or discomforts Must mention COVID-19 risks here; 4. Benefits to the participant and others; and 5. Appropriate alternative procedures, if any. »

## Introduction

You are being asked to be in a research study. This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study. A member of the research team will describe this study to you and answer any questions. **It is entirely your choice. If you decide to take part, you can change your mind at any time and withdraw from the research study.**

Before making your decision:

* Please carefully read this form or have it read to you.
* Please ask questions about anything that is not clear.

Feel free to take your time thinking about whether you would like to participate. By signing this form, you will not give up any legal rights.

## Study Overview This study plans to learn more about… « Describe why you are conducting the study. Make sure to provide potential participants with a clear and accurate description of the purpose and objectives of the research. ». Ultimately, this research may be… « published in a journal, as part of a book, presented at a conference, etc. »

## Procedures You are being asked to be in this research study because… « Include information the location of and what will happen during the study and information regarding the approximate amount of time required to participate in the study. If participants will be screened, describe screening procedures and major inclusion/exclusion criteria. All experimental procedures must be identified as such. Be sure to include all COVID-19 mitigation procedures, including procedures participants need to follow (i.e. wear masks, social distancing, waiting in car until notified to enter, etc.), procedures research personnel will follow, disinfecting procedures, etc. »

**Other people in this study**: Up to « *indicate* *number* » people will participate in this study.

## Risks and Discomforts « Provide possible examples of the risks and discomforts that may be associated in the research. Even if the study is of minimal risk, a risk must be specified. If there are no known risks, then use the following suggested statement in this section: "We believe there are no known risks associated with this research study; however, a possible inconvenience may be the time it takes to complete the study. Also, consider a breach of confidentiality." Describe how you will minimize the risks that the subject might face and how you will deal with the risks if they occur during the study. You must include a description of the risks associated with participating during the COVID-19 outbreak, as well as efforts being taken to mitigate these risks»

## Benefits This study is designed for the researcher to learn more about…. « Discuss benefits of the study. First describe any direct benefits to the subject, then any benefits to others. There may not be any benefits for the subjects participating in the study, and if so this needs to be stated clearly. Even if the participant will not profit, there must be a benefit stated such as the greater good for society or knowledge development. »

##### Compensation « Provide the exact amount of compensation here (i.e. $10, 1 point of extra credit, or clearly state if no compensation is provided). Also indicate how they will receive payment and if they will receive payment if they do not complete the study. »

###### Confidentiality

«*Provide how you as the researcher/PI will protect the confidentiality of the research study and research subjects( i.e. data is deidentified, secured, etc*.). »

Your confidentiality will be maintained to the degree permitted by the technology used. Specifically, no guarantees can be made regarding the interception of data sent via the Internet by any third parties.

Certain offices and people other than the researchers may have access to study records. Government agencies and UCCS employees overseeing proper study conduct may look at your study records. These offices include the UCCS Institutional Review Board, and the UCCS Office of Sponsored Programs and Research Integrity. UCCS will keep any research records confidential to the extent allowed by law. A study number rather than your name will be used on study records wherever possible. Study records may be subject to disclosure pursuant to a court order, subpoena, law or regulation.

«Use the most appropriate statement and delete the other»

Your de-identified data collected during this study could be used for future research studies without additional consent.

Your de-identified data collected during this study will not be used for future research studies.

## Voluntary Participation and Withdrawal from the Study

Taking part in this study is voluntary. You have the right *to* leave a study at any time without penalty. Withdrawal will not interfere with your future care or services at UCCS. You may refuse to do any procedures you do not feel comfortable with, or answer any questions that you do not wish to answer. If you withdraw from the study, you may request that your research information not be used by contacting the Principal Investigator listed above and below.

*« Studies involving students should provide information on what alternative activity they could do in lieu of participation. A study that requires testing a novel therapy to improve a particular health aspect of the subject should provide information on an alternative therapy in case the person decides not to participate. The alternative therapy would be a standard therapy, which would have to be specified as well as where the person can obtain the standard therapy. »*

## Contact Information

Contact (PI’s info): *« Your UCCS email address is preferred. »*

* if you have any questions about this study or your part in it,
* if you have questions, concerns or complaints about the research, or
* if you would like information about the survey results when they are prepared.

Contact the Research Compliance Program Director at 719-255-3903 or via email at irb@uccs.edu:

* if you have questions about your rights as a research participant, or
* if you have questions, concerns or complaints about the research.

## Consent

A copy of this consent form will be provided to you.

« If you have any inclination about wanting to contact study participants in the future, you should include the following statement. "Are you interested in being contacted about future research I may conduct? [ ]  Yes or [ ]  No." »

I understand the above information and voluntarily consent to participate in the research. By signing this consent, I am confirming that I am 18 years of age or older.

Signature of Participant Date