## **COLORADO MESA UNIVERSITY**

## **INFORMED CONSENT TEMPLATE**

**\*\* NOTICE \*\***

**UPDATED INFORMED CONSENT REQUIREMENTS**

**Key Information**

As of January 21, 2019, Federal regulations require that the informed consent contain a concise and focused presentation of the ‘Key Information’ that is most likely to help potential subjects understand why they might or might not want to participate in the study.

The key information must be presented first and should include the following:

* Identification of the project as a research study;
* Statement that participation is voluntary;
* Purpose of the research, duration of participation, and a description of research procedures;
* Foreseeable risks or discomforts, if any;
* Expected benefits to subjects or others, if any;
* Alternative procedures or treatments that might benefit the subject (Note: applies primarily to clinical research).

**Private Identifiable Information**

An ‘Informed Consent’ must also include one of two statements about the collection of private identifiable information or identifiable bio-specimens for future research.

* The data collected may be used for future research or distribute to other researchers without further consent after identifiers have been removed (if this is a possibility in the research).
* The information or bio-specimens will NOT be used for future research even if identifiers are removed.

**General Consent Requirements**

The ‘Informed Consent,’ as a whole, MUST present information in sufficient detail relating to the research, and MUST be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the potential participant, or legally authorized representative, an understanding of the reasons why one may or may not want to participate in the research.

Electronic Signatures are allowed AND a written copy of the ‘Informed Consent’ MUST be given to the person signing the consent form.

If potential participants, or legally authorized representative, are members of a distinct cultural group or community in which signing forms is not the norm, and the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

‘Broad Consent’ may be obtained in lieu of a full ‘Informed Consent’ ONLY with respect to storage, maintenance, and secondary research uses of private identifiable information and identifiable bio-specimens.

Clinical Trial consent forms MUST be posted on a publicly available federal website.

(**Note**: A publicly available federal website established as a repository for consent forms does not yet exist. Until a website is established, or further guidance is available, an option is posting the consent form to ClinicalTrials.gov.)

**\*\* END OF NOTICE \*\***

**CONSENT FORM INSTRUCTIONS**

[You are encouraged to model your consent form after this consent form. If you choose not to use this format, your consent form must at a minimum include the same elements as this model and the required texts. Before using this model, remove all text in brackets and the notice above. In addition, your consent form should be printed on university letterhead.]

## **COLORADO MESA UNIVERSITY**

## **INFORMED CONSENT SUMMARY**

This summary is an overview. Please read the entire consent form before you make a decision. If you have questions later, the contact information for the primary research investigator in charge of the study is below.

**TITLE OF PROJECT**

**[Insert title here]**

**STUDY SUMMARY**

You are invited to participate in a research study. Taking part in this research is voluntary and you can withdraw at any time.

**Purpose**

The purpose of this study is to [insert a brief non-technical description of the study’s purpose here].

**Procedures**

If you choose to participate in this study, you will be asked to [identify the research activities the subjects will be asked to complete; give details of each activity (i.e., what, when, where and how)]. This will require approximately [identify how much time your study will take a subject to complete].

**[Alternative Procedures**

Include this section only if alternative procedures or courses of treatment exist that might be advantageous to the participant. Include the alternate research activities available to the subject; give details of each activity (i.e., what, when, where and how) and identify how much time your study will take a subject to complete].

**Potential Risks, Discomforts and Inconveniences**

**Potential risks, discomforts and inconveniences may** include [insert a brief description of the study’s risks, discomforts and inconveniences].

**Potential Benefits**

Potential benefits of this study may include [insert brief description of potential direct benefits to subjects, or identify if there are no direct benefits to the subjects].

**STUDY CONTACT**

**If you have any questions or concerns about the research, please feel free to contact:**

**[Identify the primary investigator by name and include credentials, institutional affiliation and appropriate contact information (e.g., physical address, e-mail address, phone number, etc.)]**

## **COLORADO MESA UNIVERSITY**

## **INFORMED CONSENT TO PARTICIPATE IN A RESEARCH PROJECT**

**TITLE OF PROJECT**

**[Insert title here]**

**PURPOSE OF THE STUDY**

[State what the study is designed to assess or establish using simple language.]

**PARTICIPATION**

**You can choose whether to participate in this study or not. If you volunteer to be in this study, you may withdraw at any time without consequences of any kind. [Use the following sentence with modifications as appropriate: Participation or non-participation will not affect your grade, treatment, care, employment status, or any other personal consideration or right you usually expect.] You may also refuse to answer any questions you do not want to answer and remain in the study. The investigator may withdraw you from this research if circumstances arise which warrant doing so. [If appropriate, describe the anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subjects consent.]**

**Participation Requirements**

To participate in this study you must [identify the eligibility criteria (e.g., age, gender, language, health condition, etc.) in simple, non-technical language. Also, include information regarding any important exclusion criteria, if applicable.].

**Payment for Participation**

**[State whether the subject will receive payment for participating in the study. If not, so state. If subject will receive payment, describe remuneration amount, payment schedule, and prorated schedule of payments should the subject decide to withdraw from the study or is withdrawn by the investigator.]**

**Cost of Participation**

**[State whether the subject will have to incur any type of costs for participating in the study (e.g., parking). If not, so state.]**

**PROCEDURES**

**If you volunteer to participate in this study, we would ask you to do the following things:**

**[Describe the procedures chronologically using simple language, short sentences and short paragraphs. The use of subheadings helps to organize this section and increases readability. Medical and scientific terms should be defined and explained. Identify any procedures which are experimental. If applicable, sample questions or question descriptions should be included.]**

**[Specify the subjects assignment to study groups, length of time for participation in each procedure, the expected duration of the subjects participation, frequency of procedures, location of research study (address, building, room number), etc.]**

**[Alternative Procedures]**

[Include this section only if alternative procedures or courses of treatment exist that might be advantageous to the participant.

**Describe the procedures chronologically using simple language, short sentences and short paragraphs. The use of subheadings helps to organize this section and increases readability. Medical and scientific terms should be defined and explained. Identify any procedures which are experimental. If applicable, sample questions or question descriptions should be included.]**

**[Specify the subjects assignment to study groups, length of time for participation in each procedure, the expected duration of the subjects participation, frequency of procedures, location of research study (address, building, room number), etc.]**

**POTENTIAL RISKS, DISCOMFORTS AND INCONVENIENCES**

**The potential risks, discomforts and inconveniences associated with this study include:**

**[Describe any reasonable foreseeable risks, discomforts, inconveniences, and how these will be managed.]**

**[If there are any significant physical, psychological, or social risks to participation that might cause the researcher to terminate the study, please describe them.]**

**The researchers will try to minimize these risks by [insert how you minimize each of the risks, discomforts and inconveniences identified above. For example, psychological risks may be mitigate by providing subjects with counseling resources.]**

**POTENTIAL BENEFITS TO SUBJECTS AND / OR TO SOCIETY**

**[Describe benefits to subjects expected from the research. If the subject will not benefit from participation, clearly state this fact.]**

**[State the potential benefits, if any, to science or society expected from the research.]**

**CONFIDENTIALITY**

**Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. The only people who will know that you are a research subject and may have access to the records of this research study are members of the research team and representatives of Colorado Mesa University’s IRB which approves and monitors research studies.**

**[If this study is being funded by an external agency/individual, you will to need add the following statement: In addition, representatives of XXX, the study’s sponsor, will also have access to this information.]**

**[If information will be released to any other party for any reason, state the person/agency to whom the information will be furnished, the nature of the information, and the purpose of the disclosure.]**

These authorized representatives may see your name, but they are bound by rules of confidentiality not to reveal your identity to others.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity. If photographs, videos, or audiotape recordings of you will be used for educational purposes, your identity will be protected or disguised.

[Describe the methods you intend to take in order to protect your subjects’ confidentiality or anonymity, how personal identities will be shielded, or explain that subjects’ names may be used in the final research document. If you conduct an experiment where the subjects will be audio, video, or tape-recorded, you must explain what the disposition of the tapes will be at the conclusion of the study.]

[If federally funded, include the following statement: This study is being funded by a federal agency which requires that data be collected in a format that may be analyzed for differences between men and women and races or ethnic groups.]

[If the study has received a Certificate of Confidentiality, include the following statement: This study has received a Certificate of Confidentiality from the government which will help protect the privacy of research subjects. The certificate protects against the involuntary release of information about subjects collected during the course of this research. In addition, the researchers involved in this study cannot be forced to disclose any information collected in this study in any legal proceedings.]

**DATA STORAGE AND USE**

**The data collected as part of this study will [be de-identified or remain identifiable] and [will not be retained for future research or will be retained after the study for future research]. [If you are collecting *de-identified data or biospecimen* include the following sentence: De-Identified means that the information collected will not contain your name or other information that can be used to directly identify you. If you are collecting *identifiable data or biospecimen* include the following sentence: Identifiable means that the information collected may contain your name or other information that can be used to directly identify you.] Institutional policy requires research related information be kept in a secure location and retained a minimum of 3 years. [If you plan to maintain the data for longer than 3 years, identify how long you will keep the data and why.]**

**[Future Use of Data]**

**[If you plan to retain the collected *de-identified data or biospecimen* and use it for future research, you will need to include the following paragraph: The researchers may use or share your de-identified data (or biospecimen) for future research studies. This research may be similar to this study or it may be different. The researchers will not ask you for any additional consent for these studies. The researchers *may or may not* inform you of the details of any future research. The researchers may also share your de-identified data (or biospecimen) with other researchers at Colorado Mesa University or other institutions in the United States or the world.]**

**[If you plan to retain the collected *identifiable data or biospecimen* and use it for future research, you will need to include the following paragraph: The researchers may use or share your identifiable data (or biospecimen) for future research studies. This research may be similar to this study or it may be different. The researchers will not ask you for any additional consent for these studies. The researchers *may or may not* inform you of the details of any future research. The researchers may also share your identifiable data (or biospecimen) with other researchers at Colorado Mesa University or other institutions in the United States or the world.]**

**[If you are collecting biospecimen, you will need to identify if subjects biospecimen (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in the profit.]**

**[If you plan to retain the collected *data or biospecimen* and use it for future research, you must include a statement that the Investigator will not return individual research results to subjects as part of the study plan.]**

**STUDY CONTACTS**

**If you have any questions or concerns about the research, please feel free to contact:**

**Primary Investigator**

**[Identify the primary investigator by name and include credentials, institutional affiliation and appropriate contact information (e.g., physical address, e-mail address, phone number, etc.)]**

**Co-Investigator(s)**

**[Identify the co-investigator by name and include credentials, institutional affiliation and appropriate contact information (e.g., physical address, e-mail address, phone number, etc.). This should be done of each co-investigator.]**

**RIGHTS OF THE RESEARCH SUBJECTS**

**Your participation in this research is voluntary. If you decide to participate, you may withdraw your consent at any time and discontinue participation without penalty or loss of benefits to which you are otherwise entitled. If you have questions regarding your rights as a research subject, contact the Office of Sponsored Programs, Colorado Mesa University, 1100 North Ave., Grand Junction, CO 81501-3122; Telephone: (970) 248-1424.**

**SIGNATURE OF RESEARCH SUBJECT OR LEGAL REPRESENTATIVE**

**I understand my participation is voluntary. I understand the procedures and conditions of my participation described above. My questions have been answered to my satisfaction, and I agree to participate in this study. I have been given a copy of this form.**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Printed Name of Subject**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Printed Name of Legal Representative (if applicable)**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of Subject or Legal Representative Date**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Printed Name of Witness**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of Witness Date**