COLORADO MESA UNIVERSITY

**INFORMED CONSENT TO PARTICIPATE IN A MINIMAL RISK, NON-INTERVENTIONAL HIPAA RELATED RESEARCH PROJECT**

[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. In addition, your consent form should be printed on university letterhead.]

TITLE OF PROJECT: [insert title here]

You are asked to participate in a research study conducted by [insert names and degrees of all investigators], from the [insert department] at Colorado Mesa University (CMU).

WHY SIGN THIS DOCUMENT?

To be in this study and let your health care providers from [insert name of institution or organization] share your health information with the researchers in this study from CMU, sign this document.

WHY ARE YOU DOING THIS RESEARCH STUDY?

We want to learn more about how to help people who have [insert condition]. This study will help us learn more about [insert specifics]. We are asking people like you who have [insert condition] to help us.

WHAT HAPPENS IF I SAY YES, I WANT TO BE IN THE STUDY?

If you say yes, we will:

* Ask about [describe survey items, e.g., your health, what you eat, and if you exercise, smoke, or drink alcohol, and what medicines you take].
* Give you a form with questions for you to answer.
* Read the questions out loud and fill out the form with you, if you want.

There are no right or wrong answers to these questions. You can skip any question you do not want to answer.

HOW LONG WILL THE STUDY TAKE?

The study will take about [insert time] of your time.

WHAT INFORMATION WILL YOU GET FROM MY HEALTH CARE PROVIDERS?

If you say yes, we will:

* Send this permission form to your health care providers at [insert name of institution or organization].
* Get [describe in detail the information to be used, e.g., entire medical record, information from your record, such as how often you visited the doctor and the reason for your visits, what medicines you take, the results of lab tests, and your medical record number, sex, and date of birth].

The information we are asking to get is called "Protected Health Information." It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, your health care provider cannot share your health information for research without your permission.

If you want, we can give you more information about the Privacy Rule.

We will do our best to make sure your information stays private. But, once your information has been shared with us, it will no longer be protected by the Privacy Rule. Let us know if you have any questions about this.

WHAT HAPPENS IF I SAY NO?

If you say no:

* We will not get your information for this study.
* No one will treat you differently. You will not be penalized.
* The care you get from your doctor will not change.
* [For studies with prospect of benefit, add: While you will not get the benefit of being in this study, you will not lose any other benefits.] [For studies with no prospect of benefit, add: You will not lose any benefits.]

WHAT HAPPENS IF I SAY YES, BUT CHANGE MY MIND LATER?

You can stop being in the study at any time. You will not be penalized. [For studies with prospect of benefit, add: While you will not get the benefit of being in this study, you will not lose any other benefits.]

You can stop letting your health care providers share information with us. But you have to tell your health care provider in writing. If you want us to tell your health care provider for you, let us know and we will do that. Write or e-mail [insert name and address and e-mail]. If you have any questions, contact [insert name and phone # and e-mail].

If you stop, the care you get from your doctor will not change.

WHO WILL SEE MY ANSWERS?

The only people allowed to see your answers will be the people who work on the study and people who make sure we run our study the right way. [If there is a study sponsor that will have access to the data, name sponsor here.]

Your survey answers, health information, and a copy of this document will be locked in our files. We will not put your answers into your medical record.

When we share the results of the study [insert details here, e.g., in medical journals] we will not include your name. We will do our best to make sure no one outside the study will know you are a part of the study.

WILL IT COST ME ANYTHING TO BE IN THE STUDY?

No.

WILL BEING IN THIS STUDY HELP ME IN ANY WAY?

Being in the study will not help you, but may help people with [insert condition] in the future.

WILL I BE PAID FOR MY TIME?

Yes. We will give you [insert amount]. This is to pay you for your time. You will get this money [insert detail, e.g., at the end of the survey today] even if you decide to skip some of the questions.

IS THERE ANY WAY BEING IN THIS STUDY COULD BE BAD FOR ME?

Yes. There is a chance that:

* The questions could make you sad or upset.
* Someone could find out that you were in the study and learn something about you that you did not want others to know.
* You could have a legal problem if you told us about a crime such as child abuse [list other mandatory reporting required in your state] that we have to report.

We will do our best to protect your privacy.

[*Note to researcher*: Insert details on additional risks if relevant to the study, such as: You could have a legal problem if someone outside the study found out that you did something illegal.]

[Provide details regarding or referrals (e.g., for counseling) if relevant to the study.]

HOW LONG WILL MY HEALTH CARE PROVIDER BE ALLOWED TO SHARE MY INFORMATION?

We expect our study to take [insert number] years. After the study is done, your health care provider at [insert name of institution or organization] will no longer share your information with us. [Edit this statement if authorization ends at an earlier time.]

WHAT IF I HAVE QUESTIONS?

If you have any questions about the study, call the head of the study, [insert name and phone #]. Please call if you have:

* Any questions about the study.
* Questions about your rights.
* Concerns that you have been injured in any way by being in this study.
* Questions about how we will use this information.

You can also call the office in charge of research at [insert phone#] to ask questions about this study.

DO I HAVE TO SIGN THIS DOCUMENT?

No. You only sign this document if you want to be in the study.

WHAT SHOULD I DO IF I WANT TO BE IN THE STUDY?

You sign this document. We will give you a copy.

By signing the document, you are saying:

* You agree to be in the study.
* You are letting your health care provider share your health information with us.
* [Add other uses and disclosures referenced above. For example: By signing the document, you are giving permission to contact you about being in other research studies.]
* We talked with you about the information in this document and answered all your questions.

You know that:

* You can skip questions you do not want to answer.
* You can stop answering our questions at any time and nothing will happen to you.
* You can call the office in charge of research at [insert phone#] if you have any questions about the study or about your rights.

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Your name (Print)

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Your signature Date

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If an interpreter was used

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Signature of interpreter Date

If someone is signing this form for the subject, explain why:

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Name of legally responsible person (Print) Date

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Signature of person signing for the subject

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Relationship to the Subject Date

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Name of person conducting the consent discussion (Print)

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Signature of person conducting the consent discussion Date