[Add the following text to your consent form if GDPR applies to your research. To determine whether GDPR is applicable review COMIRB Guidance on GDPR.]

The researchers will collect personal information about you for this study. This includes your name and some demographic information, your responses to study surveys or interviews, and all of the other information about you described above in this consent form.

If you withdraw your permission, your participation in the study will end. No new information will be collected about you. Your withdrawal has no effect on the lawfulness of the data processing that occurred prior to your withdrawal.

Your Personal Information that has already been collected to the time of your withdrawal will be kept and used to guarantee the integrity of the study and/or for any other purposes permitted under applicable data protection and privacy laws.

Your Personal Information will not be used for further research. However, if permitted by applicable law, your Personal Information may be anonymized so that the information cannot identify you personally, and such anonymized information may be used for further research.

Your Personal Information will be treated in compliance with applicable data protection laws.

The researcher is based in the United States. The European Commission has determined that the data protection laws of the United States do not protect personal information to the same extent as those of the European Economic Area. By signing this consent form, you consent to the transfer of your information to the United States and those working with the University will take steps to maintain the confidentiality of your Personal Information.

The University, its IRB, Privacy Officer and Legal Counsel, and other University professional staff are permitted to access and use your Personal Information to conduct and oversee the research and ensure compliance with legal and regulatory requirements, including:

* verify that the study is conducted correctly and that study data are accurate;
* answer questions from IRB, or government or regulatory agencies;
* contact you during and after the study (if necessary); and
* answer your data protection requests (if any).

Your rights related to your Personal Information collected under the study are described below. If you wish to exercise any of these rights, you must contact COMIRB@ucdenver.edu.

* You have the right to see the information being collected about you in the study.
* You have the right to correct or update your Personal Information if it is inaccurate.
* You have the right to limit the collection and use of your Personal Information under certain circumstances (for example, if you think that the information is inaccurate).
* You have the right to receive your Personal Information in a structured, common computer format (for example, in a readable text electronic file or chart) for your own purposes or for giving it to others, as required by applicable data protection laws. You may not have the right to receive your Personal Information that has been used for public interest purposes or in the exercise of official authority vested in The University.
* You have the right to request the deletion of your Personal Information if you are no longer participating in the study. However, there are limits on your ability to request deletion of your Personal Information. The University may keep and use some or all of your Personal Information if deletion would seriously impair the study (for example, if deletion would affect the consistency of study results) or if your Personal Information is needed to comply with legal requirements.
* You have the right to make a complaint to a data protection authority within the EU (http://ec.europa.eu/justice/data-protection/article-29/structure/data-protection-authorities/index\_en.htm).

[Include the following text if data will be transferred to another non-EEA entity. Otherwise delete.]

Your Personal Information needed for the research will be saved, analyzed and, if necessary, transferred outside of the University. Before the researchers transfers your Personal Information, the Study Site will replace your name with a unique code and remove information that directly identifies you. This is called your “Coded Information” in this form, and it is sometimes called “pseudonymised data” by data protection laws.

The University and some of the other people using your Personal Information, including your Coded Information, may be based in countries other than your country, including the United States. Data protection and privacy laws in these countries may not offer the same level of protection as those in your own country. The University, your study site, and those working with The University and your Study Site will take steps to maintain the confidentiality of your Personal Information.

If your Personal Information is transferred by the University to other countries that have not yet been found by European regulators to meet requirements for protection of Personal Information, data transfer agreements will be used to protect your Personal Information. [Note to researcher: If standard contractual clauses are not the mechanism used to legitimize data transfer, this language should be modified accordingly to reflect the mechanism used.]

[If obtaining consent when written documentation is possible, include the following signature block]

Signature Block for Adult subject

Your signature documents below documents that you have freely given your consent to the use of Personal Information as described in this GDPR Addendum.

Signature of Subject

Printed Name of Subject Date

Signature of person Obtaining Consent Date

Printed name of person obtaining consent

[Add the following block if a witness will observe the consent process]

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 Witness to Consent Process

[If obtaining consent online or when written documentation is not possible, include the following signature block]

Your checking this box documents that you have freely given your consent to the use of Personal Information as described in this GDPR Addendum.