**If a clinical protocol includes plans to allow for further data collection after a subject’s withdrawal from the interventional portion of the study, the IRB will require use of an approved consent form and HIPAA authorization to obtain permission from the subject for collection of additional information.**

**Clinical Data Collection after Withdrawal/Release of Information and HIPAA Authorization Addendum**

In this form “we” means the researchers and staff involved in running this study at the University of Minnesota, Fairview or Gillette.

## What is the purpose of this form?

Your participation in the Study: **[insert name of study]** was recently terminated. The purpose of this form is to give us your permission to continue to access, use and share your health information for purposes of the Study, and to give your treating health care providers your permission to release this information to us.

**Title of Research Study: *[insert title of research study here with protocol number, if applicable]***

**Investigator Team Contact Information: *[insert name of principal investigator]***

For questions about research appointments, the research study, research results, or other concerns, call the study team at:

|  |  |
| --- | --- |
| Investigator Name:Investigator Departmental Affiliation:Phone Number:Email Address: | Study Staff (if applicable):Phone Number:Email Address:  |

[Include if the investigator is also the participant’s treating physician. Otherwise delete.] Your doctor, who is also responsible for this research study, [or, If your doctor is also the person responsible for this research study, please note that s/he…] is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

**Supported By:** [List all monetary and/or non-monetary support for this research.] This research is supported by \_\_\_\_\_\_\_\_\_\_.

**Financial Interest Disclosure:** [Include if there is a personal and/or institutional financial interest to disclose. Otherwise delete.] The following disclosure is made to give you an opportunity to decide if this relationship will affect your willingness to participate in this research study:

**What will happen if you agree to participate in this follow up study?**

You will not have any further Study visits as may have been described in the Consent Form you signed previously. But we will continue to access, use and share the information outlined below, and your treating health care provider(s) will make this information available to us:

* your medical records
* your laboratory results
* [other clinical results specified]

If we need any more sensitive information from your medical records, the boxes below will be marked and you will be asked to initial to permit this information to be made available to us:

[ ]  My drug & alcohol abuse, diagnosis & treatment records \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(initial)

[ ]  My HIV/AIDS testing records \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (initial)

[ ]  My genetic testing records \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(initial)

[ ]  My mental health diagnosis/treatment records \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(initial\_

[ ]  My sickle cell anemia records \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(initial)

We will ask you to provide the name and contact information of any health care providers who are taking care of you. We will continue to access, use and share this information so long as the Study continues.

**What are the risks of agreeing to take part in this follow up study?**

The main risk of this follow up study is loss of confidentiality of your health information. There is some risk of a data breach involving the information we have about you. We comply with the University’s security standards to secure your information and minimize risks, but there is always a possibility of a data breach.

**Could you be helped by being in this follow up study?**

This follow up study is NOT a treatment study. You are not expected to receive any direct medical benefits from your participation. The information from this research study may lead to a better understanding of the results of the Study: **[insert name of study]**.

**Will being in this follow up study cost you any money?**

You will not have any costs for being in this follow up study.

**What are your other choices?**

Your alternative is to not be in this follow up study.. Taking part in this follow up study is voluntary. Your choice not to be in this follow up study will not negatively affect your right to any present or future medical care, payment for your care, enrollment in or eligibility for benefits, [Insert as applicable] your academic standing as a student, or your present or future employment. If you join this follow up study, you may decide to leave the follow up study at any time.

## Will you be paid for being in this follow up study?

[indicate if compensation is planned] [ If no compensation is planned, include the following: You will not get any money for being in this follow up study. ]

**How will your information be shared?**

If you agree to participate in this follow-up study by signing this form, your information will be shared with:

* The researchers who conducted the previous Study that you participated in and any institutions or individuals collaborating on the research with us
* Others at the University of Minnesota or M Health who provide support for research or who oversee research to make sure it is conducted correctly
* People who pay for the study [**insert name of sponsor]**
* People who evaluate study results, which can include sponsors that make the drug or device being studied, researchers at other sites conducting the same study, and government agencies that provide oversight such as the Food and Drug Administration (FDA)
* Organizations that process any payments that may be made to you for participating in this follow-up study

When we share your information with others, privacy laws may no longer protect your information and there may be further sharing of your information.

The information collected from you might be published in a medical journal or report, or presented at a conference. Information that makes it easy to identify you (such as your name and contact information, SSN and medical records number) will not be part of any publication or presentation. If you have an extremely unique or rare condition that is not shared by many others, it is possible that some people may be able to determine your identity even without these identifiers.

A description of the main clinical trial is available on *http://* [*www.ClinicalTrials.gov*](http://www.ClinicalTrials.gov)*,* as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

**What if you sign the form but then decide you don't want your information shared?**

You can change your mind at any time. If you take part in this follow up study, and want to leave, you should contact the Principal Investigator listed below. Any information about you that was already used and shared may continue to be used and shared for the Study and this follow up study.

## Please contact the researchers listed below to:

* Obtain more information about the Study, this follow up study, your participation and the information being collected about you
* Report an illness, injury, or other problem (you may also need to tell other health care providers who are treating you)
* Express a concern about the Study or this follow up study

 Principal Investigator:

[**Include Name, address, phone #]**

**What if you have a concern about this follow up study?**

This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants’ Advocate Line at 612-625-1650 or go to <https://research.umn.edu/units/hrpp/research-participants/questions-concerns>. You are encouraged to contact the HRPP if:

* Your questions, concerns, or complaints are not being answered by the research team.
* You cannot reach the research team.
* You want to talk to someone besides the research team.
* You have questions about your rights as a research participant.
* You want to get information or provide input about this research.

**Signatures**

**What does your signature mean?**

If you sign this document, you are agreeing to participate in this follow up study and to allow us to access, use and share your health information as described in this form, and to give your permission to any other of your health care providers to release this information to us.

Before you sign this form, please ask questions about any part of this follow up study that is not clear to you. Your signature below means that you understand the information given to you about the study and in this form.

***[There are three sets of signature options listed below. Use the signature block appropriate for your study. Delete those that do not apply. This form must be signed by the participant or the participant’s legally authorized representative prior to participating in the research.]***

**Signature Block for Capable Adult:**

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Participant Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Participant

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Person Obtaining Consent Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Person Obtaining Consent

 **Signature Block for Witness:**

**WITNESS STATEMENT:**

The participant was unable to read or sign this consent form because of the following reason:

[ ]  The participant is illiterate

[ ]  The participant is visually impaired

[ ]  The participant is physically unable to sign the consent form. Please describe:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  Other *(please specify)*:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**For the Consent of Non-English Speaking Participants when an Interpreter is Used:**

A**s** someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject’s own language, and that the subject was given the opportunity to ask questions.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Interpreter Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Interpreter

**OR:**

**Statement from a Non-Interpreter:**

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject’s own language, and that the subject was given the opportunity to ask questions.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Individual Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Individual

**Signature Block for Adult Unable to Consent:**

Your signature documents your permission for the named participant to take part in this research.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Participant

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Legally Authorized Representative Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Legally Authorized Representative Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Person Obtaining Consent Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Person Obtaining Consent Date

Printed Name of Person Obtaining Consent Date