*Note: As the IRB of record allows, the consent form should appear on the appropriate letterhead for easy identification as a research consent form. The logos included will be one of the following (placed in the upper left-hand corner of the header):*



A black and red logo

Description automatically generated with low confidenceLogo, company name

Description automatically generated

A red and white sign

Description automatically generated with low confidence

*The UNMC IRB number should appear in the header of the consent. When using combined consent documents, pronouns may be modified as appropriate (e.g., “you” may be modified to “your child”).*

**Who can see information about you?**

We also will get medical information about you (like medical record number, medical history, or the results of physical exams, blood tests, x-rays or other medical or research procedures). We call this "protected health information" or PHI. PHI is protected by a law called the HIPAA Privacy Rule. We will collect the smallest amount of PHI that we can. We will keep your PHI as confidential as possible.

By signing this consent form, you are letting us (the researchers listed on this consent form and other people involved in this research at the Organization) have access to your PHI. Your PHI will be used only for the purposes described in the section "What is the reason for doing this research study?"

You can change your mind and tell us to stop collecting your PHI for use in this research at any time by writing to the principal investigator. We can still use the PHI we have already collected. If you tell us to stop collecting your PHI, you will have to stop being in this research.

We may share your PHI with other groups listed below:

* The UNMC Institutional Review Board (IRB)
* Institutional officials designated by the UNMC IRB
* The HHS Office for Human Research Protections (OHRP)

We may share your PHI with other groups listed below. The HIPAA Privacy Rule requires these groups to protect your PHI.

* The Food and Drug Administration (FDA) *[if study involves FDA regulated drug, device, or biologic]*
* National Institutes of Health (NIH) *[if study is funded by the NIH]*
* Researchers at *[insert the name of the institution(s) involved in the study if this is a multi-institution study where PHI will be shared with other researchers]*
* Your health insurance company *[if the Institution expects third party payers to pay for clinical procedures performed during the course of the research]*
* The Fred & Pamela Buffett Cancer Center Scientific Review Committee (SRC) *[if the research involves patients with cancer]*

We may share your PHI with other groups listed below. These groups are NOT required by HIPAA to protect your PHI. If we share your PHI with these other groups they may share it with others who also do not have to protect it under HIPAA.

* *[insert name of sponsor]*, which sponsors this research and may pay the Organization to do this research
* *[insert name of CRO]* which has been hired by the sponsor to help run the research
* The Data and Safety Monitoring Committee (DSMC)
* *[insert name of NCI National Cooperative Group, if applicable]*
* The National Cancer Institute's (NCI) Clinical Trial Reporting Program

*In addition, choose one of the statements that appropriately represents your study:*

You are letting us use and share your PHI for as long as the research is going on.

Or:

You are letting us use and share your PHI for as long as the sponsor needs so it can get approval from the FDA.

Or:

There is currently no plan to end this study. You are letting us use and share your PHI for as long as we want.