**Optional Study**

**PHI that will be Used/Disclosed for Optional Study:**

The PHI that we will use and/or disclose (share) for the optional research study includes:\_\_\_\_

**Purposes for which your PHI will be Used/Disclosed for Optional Study:**

We will use and disclose your PHI for the conduct and oversight of the optional research study, including the administration and payment of any costs relating to subject injury.

**Authorization to Use PHI is Required to Participate in Optional Study, but not in the Main Study:**

You do not have to authorize the use and disclosure of your PHI. If you do not authorize the use and disclosure of your PHI for the optional study, then you may not participate in the optional research study. You can still be in the main research study even if you don’t participate in the optional study.

**People that will Use and/or Disclose Your PHI for Optional Study:**

The following people and groups will use and disclose your PHI in connection with the optional research study:

* The Principal Investigator and the research staff will use your PHI to conduct the study.
* The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
* \_\_\_\_\_\_\_\_\_\_ is the Sponsor of the study. The Sponsor may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
* The research team and the Sponsor may use and disclose your PHI, including disclosure to insurance carriers to administer payment for subject injury.
* [Add any others].
* The following people and groups will use your PHI to make sure the research is done correctly and safely:
	+ Children's offices that are part of the Human Research Participant Protection Program and those that involved in study administration and billing.
	+ Government agencies that regulate the research including: [Office for Human Research Protections; Food and Drug Administration].
	+ Public health agencies.
	+ [Add any others.]

**Opting-In to Participation in Optional Study:**

By initialing below, I am opting to let my PHI be used and disclosed as described for the Optional Study.

\_\_\_\_\_\_\_\_\_\_\_\_Initials