# HIPAA Authorization Language to be Included in the Informed Consent Addendum

For research that accessing, using, and/or sharing protected health information from a covered entity, the following content is **required to be included in the informed consent form**. Add the following content to the informed consent form. Remove the content red font instructions and yellow high incorporate the appropriate content where the language is highlighted in yellow.

---

**Authorization to Disclose/Use Protected Health Information (PHI)**

*[Include for studies obtaining protected health information (PHI) (HIPAA-regulated data) and will have a HIPAA authorization. Otherwise delete this section.]*

The Health Insurance Portability and Accountability Act (HIPAA) is a federal law that protects the security and privacy of a person's health information (called "protected health information (PHI)").

*What information is being collected, used, and/or shared?*

**To do this research, we will need to collect, use, and share your protected health information (PHI).** By signing this authorization as part of this informed consent form, you agree that health care providers may release your PHI to the research team, and that the research team may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as PHI from your medical record (which may include information such as medical conditions, medical tests and lab results, HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

- PHI that is collected, used, and/or shared in this research includes **list out PHI obtained for research** (e.g., name, email address, phone numbers, medical record number (MRN), date of birth or age over 89 years old, etc.) or if complete health records will be received
- The research team may receive, use, and disclose your PHI from **list out entities.**

*Who will see, use, or share the information?*

The people who may request, receive, use, or share your PHI include the research team. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this authorization, you are giving permission to the research team to use and share your information with others outside of

Vanderbilt University. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it. Your covered entity provider may also use and share your PHI consistent with that covered entity's (the location where your medical record is coming from) Notice of Privacy Practices.

*Do you have to sign this Authorization?*

You do not have to sign this Authorization, but if you do not, you may not participate in the study.

*How long will your information be used or shared?*

Unless revoked, your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

*What if you change your mind?*

You may change your mind and cancel this Authorization at any time. To cancel this authorization, you must inform the Principal Investigator (PI) in writing at the address included below insert PI name and mailing address. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization. Your cancellation will be effective when the provider authorized to make the disclosure is informed of the cancellation by the PI.

[*Optional. If applicable, include. Otherwise delete.]*: You have the right to see and copy the PHI we gather on you for as long as the study doctor or research site holds this data. To ensure the scientific quality of the research study, you will not be able to review some of your research data until after the research study is finished.]

If you decide not to take part in this research study, it will not affect your treatment, payment, enrollment, or eligibility in any health plans or affect your ability to get benefits. You confirm that you have read and understand this Authorization, your questions have been answered, and you understand that, by signing this form, you are authorizing the use and sharing of PHI. You will get a copy of this form after it is signed.