HIPAA Authorization to Collect, Use, and Share Your Health Information for Research

Sponsor / Study Title:

Protocol Number:

Principal Investigator:
(Study Doctor)

Telephone:

Address:

Instructions: To use this template, complete all required sections (substituting appropriate language for any ***italicized blue*** text) and any applicable optional sections, then delete all instructions, brackets and omitted optional sections.

PURPOSE OF THIS AUTHORIZATION

You are being asked to allow the use and sharing of your health information for participation in a research study. This document explains what information may be used, who may use and share it, and why.

AUTHORIZATION TO COLLECT, USE, AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide to be in this study, the study doctor and study staff will use and share health information about you to conduct the study. Health information may include:

- Your name, date of birth, address, and contact information
- Your medical history and current health status
- Results from study-related tests and procedures
- Information from your medical records, including diagnoses, lab results, imaging studies, and treatments.
- ***[Please list any other PHI that may be used or disclosed, if applicable]***

For this study, the study staff may share health information about you with authorized users. Authorized users may include:

- Representatives of ***[sponsor name, if applicable]***
- Representatives of ***[CRO name, if applicable]***
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study)
- The Food and Drug Administration (FDA) and other U.S. federal and state agencies
- Government agencies to whom certain diseases must be reported

- Governmental agencies of other countries
- Outside individuals and companies, such as laboratories and information storage companies, who work with researchers and sponsors and need to access your information to conduct this study.
- Other research doctors and medical centers are participating in this study, if applicable
- An information safety monitoring board which oversees this study, if applicable.
- ***[Please list any other authorized users, if applicable.]***

Your health information will be used to conduct and oversee the research, including for instance:

- To conduct and monitor the study.
- To determine the safety and effectiveness of the investigational product
- To meet legal or regulatory reporting requirements.
- ***[Please list any other uses, if applicable.]***

Once your health information has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Your permission to use and share health information about you will not expire unless you revoke (withdraw) it in writing. You may revoke your permission to use and share health information about you at any time by writing to the study doctor at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new health information that identifies you will be gathered after your written request is received. However, health information about you that has already been gathered may still be used and given to others as described in this form.

If you decide not to sign this form, you will not be able to take part in the study.

AUTHORIZATION FOR THE COLLECTION, USE, AND DISCLOSURE OF HEALTH INFORMATION

I have read and understand the information in this authorization document. I have had an opportunity to ask questions, and all of my questions have been answered to my satisfaction. I authorize that my health information, as agreed above, be collected/disclosed in this study until I decide otherwise. I do not give up any of my legal rights by signing this authorization document. I will receive a copy of this signed authorization document.

_____
Subject's Printed Name

_____ _____
Subject's Signature Date

_____
Printed Name of the Person Conducting the Authorization Discussion

_____ _____
Signature of the Person Conducting the Authorization Discussion Date

[If applicable, add:]

_____
Printed Name of Legally Authorized Representative

_____ _____
Signature of Legally Authorized Representative Date

_____
Authority of Legally Authorized Representative to act on behalf of Subject