HIPAA AUTHORIZATION TEMPLATE LANGUAGE

- This HIPAA authorization template language must be used for studies under the oversight of the Allina IRB or an external IRB under contract with Allina (e.g., Advarra, WCG IRB). **The language below has already been included in the Allina combined consent/authorization templates.** When added to a sponsor consent form, the HIPAA authorization language should be incorporated into the consent form before the signature line (note: it is not required to be placed immediately before the signature line). The signature line represents the signature for both consent and authorization in this situation.
- A heading for the template language below can be used, such as "How is my health information used and shared?" or "Authorization for Use and Disclosure of Protected Health Information."
- This template includes instructions in red for creating the form. Prior to uploading this template language into the consent document for IRB review, delete or replace all template instructions (including these introductory instructions), and reformat the document so that the entire template is in black. (To do this, press Ctrl + A at the same time. In the menu bar, select black as the font color.)

HIPAA Authorization:

By signing this form, you are authorizing the use and disclosure (release) of your health information in connection with your participation in the above-named research project. Your information will be used only as stated in this authorization or as required by law. Your participation in this research is voluntary. Refusing to sign will not affect the present or future care you receive at Allina Health but you cannot participate in this study.

We (the investigators and research team OR the study doctor and study staff) are requesting your authorization to review and collect information from your medical records about [include a description of the PHI that will be used and disclosed in a specific and meaningful summary, e.g., your past medical history, the results of past blood tests, etc.]. It may also include information you provide to us through [surveys, etc.]. We will use this information for the purposes of this study as described above. We may send this information to the following people, groups, and organizations who will be authorized to use and receive this information for the purposes of conducting this research, monitoring this study, and/or providing services:

- The investigators/study doctors and research team/study staff of this research project
- All persons and entities from Allina Health engaged in managing, analyzing, storing, transmitting, or overseeing the information
- The U.S. Food and Drug Administration (FDA)
- The Office for Human Research Protections (OHRP) in the U.S. Department of Health and Human Services
- The sponsor and their affiliates [list/name them]
- The National Institutes of Health (NIH)
- The Data Monitoring Committee or Data Safety Monitoring Board
- [list any other entity that may access identifiable information]

We cannot prevent re-disclosure of your health information by anyone who receives the information under this

authorization, and the information may not be covered by state and federal privacy protections after it is released from Allina Health. This authorization will not expire unless or until you cancel it. You may change your mind and cancel your authorization to use or disclose your health information by notifying [insert individual to be contacted to terminate the authorization, e.g., the study doctor] in writing at the address listed on the first page of this form. Your cancellation will be effective after the date it is received. Any health information about you that has already been collected may still be used or disclosed to maintain the integrity or reliability of the research.