**Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study**

1. **Purpose:** You have been asked to be part of a research study under the direction of, the Principal Investigator, and his or her research team. If you sign this document, you give permission to **[*name or other identification of individuals e.g., specific health care provider(s) or description of classes of persons, e.g., all doctors, all health care providers*]** at **[*name of covered entity or entities*]** to use or disclose (release) your health information that identifies you for the research study described here: **[*Provide a description of the research study, such as the title and include a statement regarding the purpose of the research.*]**
2. Health Information to be used or Disclosed**:** The health information that may be used or disclosed (released) for this research includes: **[*Describe the information to be used or disclosed for the research project. This may include for example information in a medical record, results of physical examinations, medical history, lab tests, or certain health information indicating or relating to a particular condition.*]**
3. Recipient(s) of the Health Information**:** The health information listed above may be used by and/or disclosed (released) to: **[*Name or class of persons involved in the research; i.e., researchers and their staff.*]**

Your health information may be shared with others outside of the research group for purposes directly related to the conduct of this research study or as required by law, including but not limited to: **[*List ALL names or other identification, or ALL classes, of persons who will have access to the protected health information (PHI) for the research study (e.g., research collaborators, sponsors, and others who will have access to data that includes PHI). Examples may include, but are not limited to the following: Data coordinating centers that will receive and process PHI; Sponsors who want access to PHI or who will actually own the research data.*]**

Your information may also be shared with individuals or entities responsible for general administration, oversight and compliance of research activities. Examples include internal oversight staff, Safety Monitoring Boards, an Institutional Review Board, or certain government oversight agencies that have authority over the research. Your information may also be shared with other entities as required by law.

[***Optional*:** No publication or public presentation about the research described above will reveal your identity without another authorization from you. If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.]

1. Potential for Re-disclosure**: [*Name of covered entity*]** is required by law to protect your health information. By signing this document, you authorize **[*Name of covered entity*]** to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.
2. Expiration Date**:** This Authorization does not have an expiration date **[*or as appropriate, insert expiration date or event, such as "end of the research study."*]**
3. Right to Refuse to Sign this Authorization**:** You do not have to sign this authorization, but if you do not, you may not be allowed to participate in this study or receive any research related treatment that is provided through the study. Your decision not to sign this authorization will not affect any other treatment, payment, or enrollment in health plans or eligibility for benefits.
4. Right to Revoke this Authorization**:** Please note that you may change your mind and revoke (take back) this Authorization at any time, except to the extent that **[*name of covered entity/entities*]** has already acted based on this Authorization. To revoke this Authorization, you must write to: **[*name of the covered entity/entities and contact information*].** If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization.

 Signature of participant or participant’s personal representative

Printed name of participant or participant’s personal representative

Description of the personal representative’s authority to sign for the participant,
if applicable.

Date

Note: Participants must be provided with a copy of the signed authorization.

**Checklist for HIPAA Authorization for Research**

A HIPAA Authorization for research must include the following core elements and required statements:

**Authorization Core Elements** (see Privacy Rule, 45 C.F.R. §164.508(c)(1))

* Description of PHI to be used or disclosed (identifying the information in a specific and meaningful manner).
* The name(s) or other specific identification of person(s) or class of persons authorized to make the requested use or disclosure.
* The name(s) or other specific identification of the person(s) or class of persons who may use the PHI or to whom the covered entity may make the requested disclosure.
* Description of each purpose of the requested use or disclosure. Researchers should note that this element must be research study specific, not for future unspecified research.
* Authorization expiration date or event that relates to the individual or to the purpose of the use or disclosure (the terms "end of the research study" or "none" may be used for research).
* Signature of the individual and date. If the Authorization is signed by an individual's personal representative, a description of the representative's authority to act for the individual.

**Authorization Required Statements** (see Privacy Rule, 45 C.F.R. § 164.508(c)(2))

* The individual's right to revoke his/her Authorization in writing and either (1) the exceptions to the right to revoke and a description of how the individual may revoke Authorization or (2) reference to the corresponding section(s) of the covered entity's Notice of Privacy Practices.
* Notice of the covered entity's ability or inability to condition treatment, payment, enrollment, or eligibility for benefits on the Authorization, including research-related treatment, and, if applicable, consequences of refusing to sign the Authorization.
* The potential for the PHI to be re-disclosed by the recipient and no longer protected by the Privacy Rule. This statement may be a general statement that the Privacy Rule may no longer protect health information disclosed to the recipient.

Additional information regarding requirements for HIPAA Authorization and sample language is available at: <http://privacyruleandresearch.nih.gov/authorization.asp>