**[*Note: Instructions and recommended text for completing this form are in blue enclosed in square brackets. Delete instructional text, unused recommended text, and brackets for finalization of the document. This Authorization is designed to either be a companion to the informed consent form or the text can be embedded in a combination/hybrid informed consent document. NOTE: Authorizations for Psychotherapy notes may not be combined with Informed Consent Documents for Research]***

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

[Insert Study Title]

Who May Use or Release Your Health Information and for What Purpose

If you sign this document, then you give permission to any covered entity, such as, but not limited to a health plan, physician, health care professional, hospital, clinic, laboratory, pharmacy, medical facility, or other health care provider that has provided payment, treatment or services to you or on your behalf to use or disclose (release) your health information that identifies you for the research study described here: [Provide a description of the specific research study, such as the title and purpose of the research.]

[Insert the following section when the study includes the creation of a database or tissue repository that may be used for future research, beyond the life of this study (this information must also be included in the consent form); use of PHI for future, un-specified research must be optional…subjects must be given the option to participate in the main study but turn down the opportunity to participate in secondary or ancillary studies, such as participation in a biobank.]

This study also includes an optional [Insert description of ancillary study and the purpose of the study (e.g., the creation of a database of information and/or a specimen bank that may include blood, tissue, or other bodily fluids,-specify per study. The “opt-in” box (opt IN – not out- is REQUIRED) should appear in the body of the informed consent “portion” of the document, along with the explanation of the purposes, risks, benefits, etc. of the optional research.].

You do not have to participate in this portion of the study. You may still participate in the main study, even if you don’t want to participate in this secondary study. If you have elected to participate in the optional [insert description, i.e. biomarker study] as described in this document and the informed consent document, your health information may be [describe used for/disclosed to… etc. – HIPAA requires you to adequately describe potential future purposes such that it would be reasonable for the individual to expect that his or her protected health information could be used or disclosed to for such future research. Examples may include “Disclosed to appropriately qualified investigators for… future biomedical research,… future biomedical research into my specific disease or condition,…other. If there is a reasonable possibility that future research may include sensitive types of research, such as research involving genetic analyses or mental health research, that may alter an individual’s willingness to participate in the research, this should be included, for example; “Disclosed to appropriately qualified investigators for future biomedical research which could include research on genetic disease, mental health disorders, sexually transmitted diseases”]*.*

What Health Information May be Used or Released

The health information that a covered entity may use or disclose (release) for this research includes [complete as appropriate]:

[Provide a description of information to be used or disclosed for the research project, information that will be *created* and added to the medical record during the research project, AND, if applicable include medical information to be used or disclosed for the secondary or ancillary project (biobank etc.) denoted appropriately. This may include, for example, all information in a medical record, results of physical examinations, medical history, lab tests, or certain health information indicating or relating to a particular condition. Include all direct and indirect identifying information that will be accessed or used during the study (e.g., name, initials, medical record number, date of birth, dates of treatment) and information that will be accessed/used such as “all medical records and information of your treatment for …”, “laboratory test results, radiology reports, pathology reports, surgical reports”, etc. Avoid medical jargon, e.g., “Chem7” if possible.

Example:

* Your identifiable information including your name, medical record number, initials, date of birth, dates of diagnosis, dates of procedures/tests, and dates of treatment.
* Your medical records, including medical history and treatment for your condition.
* Any laboratory results, imaging scans (CT, MRI, ultrasound), surgical reports, pathology reports, etc., relating to your diagnostics, treatment and follow-up care.]

[Insert the following paragraph when subject’s access to portions of the subject’s electronic medical/health record is temporarily suspended during research; otherwise delete it.]

Because of the nature of this study, you will not be able to review or obtain a copy of research related portions of your medical record during your participation in the study. As soon as the research is completed, you will be able to review or obtain a copy of your medical record as allowed by law. If it is necessary for your care, then your health information will be provided to you or your physician.

Who Your Health Information may be Used by or Released to

The health information listed above may be used by and/or disclosed (released) to: [Name or classes/categories of persons involved in the research (e.g., researchers and their staff)\*]

[**\*** Where a covered entity conducts the research study, the Authorization must list ALL names or other identification, or ALL classes, of persons who will have access through the covered entity 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; and/or
* Institutional Review Boards or Data Safety and Monitoring Boards
* OSF Research Administration

If the research study is conducted by an entity other than the covered entity, the Authorization need only list the name or other identification of the outside researcher (or class of researchers) and any other entity to whom the covered entity is expected to make the disclosure.]

[Insert the following if the study has a sponsor; otherwise delete it.]

As part of the study, we will disclose your information to [Insert name of sponsor – coordinate with applicable provisions in Sponsored Research Agreement], the sponsoring company for this research study.

[Retain this statement for all studies.]

As part of this study, we may disclose your information to the Department of Health and Human Services Office for Human Research Protections, Office of Civil Rights, the Food and Drug Administration, the IRB of record (i.e., the IRB reviewing/approving this study for OSF [Insert name of IRB of record]), and other federal, state or international agencies and other programs responsible for the oversight and conduct of research.

Potential for Information Disclosed to no longer be Protected under HIPAA

Covered entities must comply with the requirements of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 and its privacy regulations, and all other applicable laws that protect your privacy. Covered entities are required by law to protect your health information.

Despite these protections, there is a possibility that your information could be used or disclosed in a way that it will no longer be protected. By signing this document, you authorize covered entity/entities 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. Covered entities must provide upon request their Notice of Privacy Practices (a separate document), which provides more information on how covered entities protect your information. You should ask your respective provider(s) for a copy of the Notice. You may also ask your research team for assistance with obtaining a Notice.

Your health information will be used or disclosed when required by law.

Right to Refuse to Sign

You have a right to refuse to sign this HIPAA Authorization.

If you do not sign this form, you will not be allowed to join the research study. Your decision to not sign this Authorization will not affect any other treatment, health care, enrollment in health plans or eligibility for benefits to which you are normally entitled

Right to Revoke

If you decide to sign this Authorization today, you may change your mind and revoke (take back) this Authorization at any time. If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization. No more medical information will be collected after you withdraw your Authorization.

To revoke this Authorization, you must write to: [Name of the Principal Investigator and contact information].

The Principal Investigator (PI) and/or the PI’s delegate will be responsible for communicating your decision to revoke (take back) your authorization to all health care providers (i.e., covered entities) that have used/disclosed your protected health information.

**NOTE: The covered entity allowing use/disclosure of your PHI will continue to do so UNTIL it receives from the PI notification of your revocation.**

Even if you revoke this Authorization, [name or class of persons at OSF involved in the research] may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. The withdrawal of your permission will not affect your right to receive health care at OSF Healthcare System or other provider/covered entities that have disclosed your protected health information.

Expiration of the Authorization

[Choose one of the following options for the duration of Authorization. Delete the others]

This Authorization to use your information will expire [Insert “on specific date” or say “at the end of the research study.

-OR-

If retention for future un-specified use, this statement should read something like,]

If you elected to allow your information to be used for future research, this Authorization has no expiration date. If you did not elect to allow your information to be used for future research then this Authorization will expire at the completion of the research study [or specific date].

Right to Receive a Signed Copy

You will be given a signed copy of this form for your records.

By signing below, you are indicating that you authorize the use and disclosure of your health information as described in this form.

[If applicable, add]

*If* you elected to participate in the secondary study involving [Insert description, i.e. biobank etc.], then signing this form also authorizes that use.

**[NOTE: signature lines should all remain on the same page]**

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Printed name of Subject

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Signature of Subject or /Legally Authorized Representative Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If LAR, LAR’s Relationship to Subject

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Person Who Explained This Form Date

**[OPTIONAL ELEMENTS:**

Examples of optional elements that may be relevant to the recipient of the protected health information:

• Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, and conducting public health surveillance, investigations, or interventions.

• 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.]