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

If you sign this document, you give permission to the Medical University of South Carolina (MUSC) to use or disclose (release) your health information that identifies you for the research study described here:

***[Provide the study title and a sentence explaining the purpose of the study. (For an example of the purpose: This study will examine the safety and effectiveness of an investigational new drug called X4Y4)]***

The health information MUSC may use or disclose (release) for this research study includes information in your medical record, results of physical exams, medical history, lab tests or certain health information indicating or relating to your condition.

The health information listed above may be used by and/or disclosed (released) to the following, as applicable:

* The sponsor of the study including its agents such as data repositories or contract research organizations monitoring the study;
* Other institutions and investigators participating in the study;
* Data Safety Monitoring Boards;
* Accrediting agencies;
* Clinical staff not involved in the study whom may become involved if it is relevant;
* Health insurer or payer in order to secure payment for covered treatment;
* Parents of minor children if less than 16 years old. Parents of children 16 years old or older require authorization from the child; or
* Federal and state agencies and MUSC committees having authority over the study such as:
* The Institutional Review Board (IRB) overseeing this study;
* Committees with quality improvement responsibilities;
* Office of Human Research Protections;
* Food and Drug Administration;
* National Institutes of Health; or
* Other governmental offices, such as a public health agency or as required by law.

MUSC is required by law to protect your health information. By signing this document, you authorize MUSC 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.

You do not have to sign this authorization. If you choose not to sign, it will not affect your treatment, payment or enrollment in any health plan or affect your eligibility for benefits. However, you will not be allowed to be a participant in this research study.

You may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, MUSC may still use or disclose (release) health information already obtained about you as necessary to maintain the integrity or reliability of the research study. If you revoke this Authorization, you may no longer be allowed to participate in this research study. To revoke this Authorization, you must write to:

***(Provide the PI’s name and address here)***

You will not be allowed to see or copy the information described on this Authorization as long as the research study is in progress. When the study is complete, you have a right to see and obtain a copy of the information.

Your health information will be used or disclosed when required by law. 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 for conducting public health surveillance, investigations or interventions. No publication or public presentation about the research study will reveal your identity without another signed authorization from you.

You will be given a copy of this Authorization. This Authorization will expire at the end of the research study. If you have questions or concerns about this Authorization or your privacy rights, please contact MUSC’s Privacy Officer at 843-792-8740.

Regulations require that you be given a copy of the MUSC Notice of Privacy Practices (NPP) describing the practices of MUSC regarding your health information. One can be found at the end of this form.

**[SIGNATURE PAGE TO FOLLOW]**

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

Signature of Research Participant ages 16 & above\* Date

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

Signature of Research Participant’s Legally Authorized Representative Date

(if applicable)

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

Printed Name of Research Participant

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

Printed Name of Research Participant’s Legally Authorized Representative (if applicable)

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

Representative’s Relationship to Research Subject

\*If the research participant is 16 to 18 years of age, signatures of both the research participant and the Legally Authorized Representative are required.

## co9-28logo



