Note: Please be sure to make all relevant modifications to sections in square brackets, convert the text to black and delete all information that is not relevant

By signing this document you are permitting The Children’s Hospital of Philadelphia (CHOP) and the doctors, nurses and other staff involved in this research to use your personal health information collected about you for research purposes within our institution. You are also allowing CHOP staff to disclose your personal health information to outside organizations or people involved with the processing of this study as described in this document.

If you sign this document, you give CHOP permission to collect, 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 purpose of the research.]

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| What information will be used and disclosed as part of this research? |

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

* Information from your medical records at CHOP including [insert description of data to be collected from patient’s existing medical record].
* Results of laboratory tests performed for this study.
* [Provide a description of information to be collected, used or disclosed for the research project. 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.]

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| Who may use or disclose your health information during the research? |

Researchers and others need to inspect and/or copy your research records to conduct this research, assure the quality of the data and to analyze the data: The health information listed above may be used by and/or disclosed (released) to:

* Members of the research team and other authorized staff at CHOP;
* People from agencies and organizations that perform independent accreditation and oversight of research.

Include the following organizations applicable (only if they will receive or have access to PHI)

* The Food and Drug Administration (only if applicable) for purposes of [insert purpose];
* Representatives of SPONSOR NAME who is the study sponsor funding this research for purposes of [insert purpose]
* The Data Coordinating Center at \_\_\_\_\_\_\_ (multi-center research studies) for purposes of coordinating data collected from multiple sites conducting this study
* Groups monitoring the safety of this study (e.g. study monitoring group, DSMB)
* Federal agencies sponsoring this research (list relevant NIH agencies) for purposes of [insert purpose]
* Public health authorities that are required by law to receive information for the prevention or control of disease, injury or disability. (if applicable: sexually transmitted diseases, HIV, AIDS, child abuse, etc. )
* Investigators at [name of entity] who are performing [tests] as part of this study

By law, CHOP is required to protect your health information. The research staff will only allow access to your health information collected for this study to the groups listed above for the purposes stated. By signing this document, you are authorizing CHOP to use and/or release your health information for this research. Some of the organizations listed above may not be required to protect your information under Federal privacy laws. If permitted by law, they may be allowed to share it with others without your permission.

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| **Do you have to sign this Authorization?** |

* You do not have to sign this Authorization. If you do not sign this form, you cannot participate in this research.

[Note: When the research involves research-related treatment by the covered entity or when the covered entity is not providing health care solely for the purpose of creating protected health information to disclose to a researcher also include this statement]

* Your health care provider at The Children’s Hospital of Philadelphia will continue to provide you with health care services even if you refuse to sign this authorization form.

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| **Can you change your mind?**  |

* You may change your mind after signing this form and revoke (take back) this Authorization at any time.
* If you revoke this Authorization, you may no longer participate in the research described in this Authorization.
* Even if you revoke this Authorization, CHOP and [name or class of persons at other covered entity(ies) 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. To revoke this Authorization, you must contact the investigator. We prefer that you do this in writing by sending a letter to:

Dr. Name of Principal Investigator
The Children’s Hospital of Philadelphia
34th and Civic Center Blvd
Philadelphia, PA 19104

This Authorization does not have an expiration date [or as appropriate, insert expiration date or event, such as “end of the research study.”].

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Participant Name |  | Date |
| Signature of subject or subject’s personal representative |  | Date |
| Printed name of personal representative (if applicable)  |  | Relationship to subject |

## Optional Elements (include these when relevant to research activity)

## Examples of optional elements that may be relevant to the recipient of the protected health 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 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.

## Will you be able to access your records? [Include this statement if the subject cannot access their medical records during the study]

You will be able to request access to the information we collect from you for the study when the study is completed. During your participation in this study, you will not be able to access the results of the tests, surveys, and evaluations we do for the research study. This will be done to prevent the knowledge of study results from affecting the reliability of the study. Your information will be available should an emergency arise that would require your treating physician to know this information to best treat you. You will have access to your medical record and any study information that is part of that record when the study is over or earlier, if possible. The investigator is not required to release to you research information that is not part of your medical record.