

**YALE UNIVERSITY
PROCEDURE**

**INSTRUCTIONS FOR PREPARING THE
RESEARCH AUTHORIZATION FORM**

As explained more fully in the Yale University Statement of Policy on Uses and Disclosures of Protected Health Information for Research Purposes, the Privacy Officer may permit the use and disclosure of Protected Health Information (PHI) pursuant to a completed and signed Research Authorization form. This form will need to be carefully prepared by the Principal Investigator to ensure that the form covers the necessary uses and disclosures of "Protected Health Information." For instructions on determining whether a study will involve "Protected Health Information," please refer to the Yale University Procedure, "Determining Whether Human Subject Research" Involves Use/Disclosure of "Protected Health Information."

1. ***"Who will disclose, receive, and/or use the information?"*** – Please list, class of persons, or organization (including government agencies, companies, etc.) or *each* person who might create, disclose, receive, and/or use the information in connection with the particular study listed on the form. Check the boxes on the form, **or delete them**, as appropriate. ***If you leave boxes unchecked, or*** if a person or organization is not included on this authorization form, that person or organization may not receive PHI or create or use PHI in connection with this Study, and that person or organization may be unable to disclose a subject's PHI to any other party in connection with the Study. Remember to delete the phrase "your child" if the authorization will be signed by the subject and not a parent or guardian.

2. ***"What information will be used or disclosed?"*** – Describe the PHI in a way that allows both the prospective subject, and any person or organization that must use or disclose information pursuant to this authorization, to understand what information may be used or disclosed. For example, acceptable descriptions would be "laboratory results from July 2002," "all laboratory results," or "results of MRI performed in July 2002." The language used should be clear to any reader, including the research subject.

YALE UNIVERSITY

RESEARCH AUTHORIZATION

Subject Name: _____

Medical Record #: _____

Principal Investigator: _____

IRB #: _____

**Principal Investigator's
Contact Information:** _____

To the Subject:

The health-related information that we gather about you and your child in this study is personal. The Yale School of Medicine and the Yale New Haven Hospital researchers are required by law to protect the privacy of the information known as protected health information or PHI. All reasonable efforts will be made to protect the confidentiality of your and your child's PHI, which may be shared with others to support this research, to conduct public health reporting, and to comply with the law as required. Despite these protections, there is a possibility that information about you and your child could be used or disclosed in a way that it will no longer be protected by federal law. For example, some of the individuals listed on page 2 of this form may not be required by law to meet HIPAA standards for privacy of health information. These individuals or companies are nonetheless required through other agreements with Yale to keep your information confidential.

In this form, we describe who will be working with this information and ask for your permission to use the information in the research study.

Please read this form carefully. If you have any questions, please ask the Principal Investigator listed above before signing this form.

By signing this form, you give permission for the researchers to use and/or disclosure the information as described below, for this research study. The reason for the uses and disclosures is to **[insert brief description of study]**.

You have a right to refuse to sign this form. Your (your child's) health care outside the study, the payment for your (your child's) health care, and your (your child's) health care benefits will not be affected if you do not sign this form.

If you do not sign this form, you (your child) will not be able to enter this research study and will not receive treatment as a study participant.

If you sign this form, you may change your mind at any time, but the researchers may still use the information collected before you changed your mind in order to complete the research.

This form will never expire unless and until you change your mind and retract it. To retract the permission to use your information, please tell the study staff or write to **[insert name of responsible person]**.

[**Optional** (only for research that includes treatment as part of the protocol): You will not be allowed to see or copy the part of your medical records that describe a research treatment until the research is completed, but you may see and copy the research treatment information at the end of the research in agreement with institutional medical record policies.]

You have a right to receive a copy of this form after you have signed it. If after you have signed this form you have any questions about your rights, please contact the Yale Privacy Officer at 203/432-5919.

Use and Disclosure Covered by this Authorization

(1) Who will disclose, receive, and/or use the information?

The following person(s), class(es) of persons, and/or organization(s) may share, use, and receive the information listed below in connection with this Study. These persons are authorized to use and disclose the information to the other parties on this list, to you or your personal representative, or as permitted by law.

[Check appropriate boxes and add requested information on names/classes of recipients of PHI. Delete all boxes and categories that do not apply. Note that when the specific individual may change over the course of the project it is preferable to list their class as opposed to specific names. For example reference the “research coordinator” as opposed to the name of the current individual performing that role.]

- The following health care facilities or research site(s) and research staff involved in this study: **[list]**
- Health care providers at **[name the facility]** who provide services to you in connection with this study
- Laboratories and other individuals and organizations that analyze your health information in connection with this study, in accordance with the study’s protocol
- The following research sponsors: **[list]**
- The United States Food and Drug Administration
- The members and staff of the Human Investigation Committee that approved this study
- Those individuals at Yale who are responsible for the financial oversight of research including billings and payments
- Principal Investigator: **[name]**
- Additional members of the Research Team **[these people do not need to be named. This bullet can stay as is]**
- Contract Research Organization **[Name]**
- Data and Safety Monitoring Boards and others authorized to monitor the conduct of the Study:
- Others (as described below)

(2) What personal health information will be used or disclosed?

The following information about you may be used and disclosed:

[Check appropriate box and provide description of PHI, Delete all boxes and categories that do not apply]

- Research study records.
- Medical and laboratory records of only those services provided in connection with this Study.
- The entire research record and any medical records held by [Institution] created from: _____ to:

- The following information:

Signature

I have read this form and all of my questions about this form have been answered. By signing below, I authorize the described uses and disclosures of information.

Signature of Subject or Personal Representative

Print Name of Subject or Personal Representative

Date

Description of Personal Representative's Authority

***THE SUBJECT OR HIS OR HER PERSONAL REPRESENTATIVE MUST BE PROVIDED WITH
A COPY OF THIS FORM AFTER IT HAS BEEN SIGNED***

Reviewed and Acknowledged

Human Investigation Committee
Yale University