Yale University Form and Instructions
Research Authorization

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."

"Who will disclose, receive, and/or use the information?" – Please list, class of persons, or organization (including government agencies, companies, etc.) or 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, as appropriate. 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.

"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 Form

Subject Name: _____ **Medical Record #:** _____

Principal Investigator: _____ **IRB #:** _____

Principal Investigator's Contact Information: _____

_____

To the Subject:

We understand that information about you obtained in connection with your health is personal, - and we are committed to protecting the privacy of that information. Because of this commitment, we wish to obtain your special authorization before we use or disclose your identifiable health information for the research purposes described below. This form helps us make sure that you are properly informed of how your health information will be used or disclosed. Please read the information below carefully before signing this form. If you have any questions about this authorization, please ask the person listed above before signing this form.

Specific Understandings

By signing this research authorization form, you authorize the use and/or disclosure of the information described below, for this research study. The purpose for the uses and disclosures you are authorizing is to **[insert brief description of study]** and to ensure that the information relating to that research is available to all parties who may need it for research purposes..

All health care providers subject to HIPAA (Health Insurance Portability and Accountability Act) are required to protect the privacy of your information. The research staff at the Yale School of Medicine and Yale New Haven Hospital are required to comply with HIPAA and to ensure the confidentiality of your information. Some of the individuals listed on page 2 of this form may not be subject to HIPAA and are therefore may not be required to provide the same type of confidentiality protection. They could use or disclose your information in ways not mentioned in this authorization. . However to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

You have a right to refuse to sign this authorization. Your health care outside the study, the payment for your health care, and your health care benefits will not be affected if you do not sign this form, but you will not be able to enroll in the research study described in this authorization and will not receive treatment as a study participant if you do not sign this form.

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

This authorization will never expire unless and until you change your mind and revoke it. To revoke this authorization, please 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 portion 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 accordance 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 relating to your rights, please contact the Yale Privacy Officer at 203/436-3650.

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