Authorization Fact Sheet for Patients

What is HIPAA?

HIPAA is an acronym for the Health Insurance Portability and Accountability Act. HIPAA contains federal regulations that govern the privacy and confidentiality of medical information maintained by healthcare providers. Participants in clinical trials are protected by HIPAA regulations.

How is Authorization different from Informed Consent?

Informed consent verifies you have received information regarding a research study you and documents your agreement to participate.

Authorization gives the study physician/medical facility permission to release your protected health information in order to conduct research.

Authorization may be included as a component of the informed consent document.

What is protected health information?

Protected health information (PHI) is personal information that can identify you or that can be linked to you. Examples of protected health information include:

?? Personal demographic information
?? Information that characterizes your disease
?? History of your disease and treatment
?? Other relevant medical conditions that may affect your treatment
?? Baseline medical data including laboratory test results and tumor measurements
?? Results from tests performed to identify disease presence including CT scans, MRI’s, X-Rays, pathology results, and other laboratory results
?? Information on treatment
?? Follow-up information including late side effects from treatment, disease status, general health status

Who gives permission for my information to be released?

You, or your legally authorized representative, must give permission in order for your study physician/medical facility to release your protected health information.
Where will this information go when it is released by the study physician/medical facility?

This information may be released to researchers if the information is necessary to prepare the research study. The researchers will make every effort to limit the protected health information to the minimum amount necessary to accomplish the intended purpose.

How will the released information be handled?

The information released will be used within (NAME OF COOP GROUP)/CTSU. Policies and procedures have been developed to ensure the confidentiality of the protected health information released. Our employees are trained in (NAME OF COOP GROUP)/CTSU’s privacy procedures and have designated an individual who is responsible to ensuring the procedures are followed.

What if I do not want to give permission to release my protected health information?

You may refuse to sign the authorization releasing your protected health information. However, if you do not sign the authorization, you will not be able to take part in the study.

Can I revoke my authorization?

Yes. You may revoke your authorization at any time. You must revoke your authorization in writing. Any new protected health information will no longer be used for research. However, protected health information collected before you revoked your authorization may be used for research.

How long is the authorization valid?

The authorization to use your protected health information has no expiration date. Your authorization remains in effect throughout the duration of the study.