

THIRD PARTY PATIENT AUTHORIZATION TO USE AND/OR DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH (HIPAA)

(In Keeping with the Health Insurance Portability and Accountability Protection Act)

What is Confidentiality of records all about?

The Naval Medical Center San Diego makes every effort to maintain the confidentiality of protected health information we obtain about your dependent. However, we cannot absolutely guarantee confidentiality because other people may need to see your dependent's information in the course of this research study. Most people and organizations will protect the privacy of your dependent's information, but may not be required to do so by the law. Also, if the results of this research study are presented at meetings or are published, your dependent's name will not be used.

What is HIPAA all about?

The Health Insurance Portability and Accountability Act (HIPAA) requires that we get your permission to use your dependent's protected health information that is either created by or used in connection with this research study. This permission is called an Authorization. The information we use includes your dependent's entire research record and supporting information from your dependent's medical records, results of laboratory test, X-rays, MRIs, CT scans and observations made by a physician or nurse which are both clinical and research in nature.

What will we do with this information?

Your dependent's protected health information will be collected and used during the course of the research study, to monitor your dependent's health status, to measure the effects of drugs or devices or procedures, to determine research results, and to possibly develop new tests, procedures, and commercial products.

Your dependent's research doctor will use this information to report the results of research to sponsors and federal agencies, like the Food and Drug Administration (FDA). The information may also be reviewed when the research study is audited for compliance. When the study is over, you have the right to see the information collected about your dependent and receive a copy of it for your records.

Who will we share your dependent's information with?

Your dependent's information may be shared with any of the following:

- The sponsor of the study, or its agents, such as data repositories
- Other medical centers, institutions, or research investigators outside of the Naval Medical Center San Diego, participating in this research study
- State and Federal agencies which have authority over the research, the Naval Medical Center San Diego or patients. Good examples are: the Department of Health and Human Services (DHHS), the Food and Drug Administration (FDA), the National Institute of Health (NIH), the Office of Human Research Protections (OHRP), and the Department of Social Services (DSS) or other.
- This hospital or clinic.
- Accrediting agencies, such as JCAHO.
- A data safety monitoring board, if applicable
- Clinical staff who may not be involved directly in the research study, but who may become involved in your dependent's care, if it is possibly related to treatment

Enter Summarized Title;

PI: Last name, First initial;

CIP #S-FY-xxx

For this research study, the study investigator may share this authorization form and records, which identify your dependent, to comply with regulatory requirements or for purposes related to this research with all documented Principal, Associate, and Sub-investigators, and the Medical Monitor (if one is assigned).

What if you want to revoke or cancel away this Authorization for your dependent?

If you decide, on behalf of your dependent, for participation in this research study, your Authorization for this study will not expire unless you revoke or cancel it in writing to the research doctor. If you revoke this Authorization, your dependent will also be removed from the study, but standard medical care and any other benefit to which your dependent is entitled will not be affected in any way.

Revoking your Authorization only affects the use and disclosure (sharing) of your dependent’s information after your written request has been received. Federal law requires sending study information to the FDA for studies it regulates, like studies of drugs and devices. In a case like this, your dependent’s information may need to be reported to them and cannot be removed from the research records once it is collected.

Do you have to sign this form?

You have the right to refuse to sign this Authorization form. If this is the case, your dependent would not be a part of this study. You can also tell your dependent’s study doctor you want to withdraw your dependent from the study at any time without revoking the Authorization to use your dependent’s health information. By signing this research Authorization form, you authorize the use and/or disclosure of your dependent’s protected health information described above.

SIGNATURE AND DATE SIGNED:

PRINTED OR TYPED IDENTIFICATION:

Patient/Subject (Date)

Name/Status/Sponsor’s SSN

Parent/Legal Guardian (Date)

Name/Status/SSN

Witness (Date)

Name/Grade or Rank

Researcher/Investigator (Date)

Name/Grade or Rank