



ChildrensHospitalLosAngeles

International Leader in Pediatrics

AUTHORIZATION FORM

PERMISSION FOR USE OR DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES

Patient/Subject Name: _____

Medical Record Number: _____ Date of Birth: _____

BACKGROUND and DEFINITIONS

HIPAA stands 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 research studies are protected by HIPAA regulations. Information used in research studies may include data that identifies you¹. When you consider taking part in a research study, you must give permission for your protected health information to be released from the research team at Childrens Hospital Los Angeles and your doctors to the outside researchers involved in conducting the research study.

Protected health information is personal information that can identify you or that can be linked to you. Examples of protected health information include personal information such as your date of birth or where you live and information about your medical condition. Only you or your legal representative can give permission for your protected health information to be released.

By agreeing to sign this authorization form, you are allowing researchers at Childrens Hospital Los Angeles to collect your protected health information and share it with others involved in doing this research study as detailed below, consistent with California and Federal laws concerning the privacy of this information.

RESEARCH STUDY INFORMATION

¹ This form will also serve as the authorization form for parents to read and sign when their child is the subject in a research study. In that case, “you” refers to “your child”.

Your protected health information will be used for the following research study:

CCI# 06-00198 PRINCIPAL INVESTIGATOR: Shahab Asgharzadeh, MD
(Individual in charge of the research team at CHLA)

TITLE: Neural Tumor Registry

The protected health information that is needed for this research study includes: *(Please describe below, examples are provided)*

- *Personal demographic information;*
- *History and diagnosis of your medical condition;*
- *Specific information about the treatments you have gotten, including treatment(s) you may have had in the past;*
- *Information about other medical conditions that may affect your treatment;*
- *Medical data including laboratory test results, results of tests measuring organ function (e.g., kidney, heart, lung), results from radiology scans, pathology or other test results;*
- *Information on treatment and the side-effects you may experience during this research study and how they were treated; and*
- *Long-term information about your general health status and the status of your medical condition.*

California law prohibits the disclosure of any protected health information not listed in this authorization unless another authorization form is obtained from you or unless such disclosure is specifically required or permitted by law.

In addition, your medical records may need to be reviewed and the researchers may need to discuss your health information with your healthcare providers. This research may also create new information about you as a result of research procedures, tests, questionnaires, interviews, and visits.

The research team at Childrens Hospital Los Angeles receives does not receive payment for your participation in this research study and subsequent use of your protected health information.

DISCLOSURE OF PROTECTED HEALTH INFORMATION

You give permission for the following persons, groups or organizations to use or disclose (release) your protected health information for the research study described in this authorization form.

1. Shahab Asgharzadeh and his/her research staff
2. Physicians and other healthcare providers
3. The Committee on Clinical Investigations for oversight and compliance purposes
4. The Research Subject Advocate and his/her staff

RECEIPT OF PROTECTED HEALTH INFORMATION

You give permission for the following persons, groups or organizations to receive your protected health information for the research study described in this authorization form.

1. The sponsor of the study, Shahab Asgharzadeh or its representatives
2. The following institutions/investigators that are participating in this research:
 - a. Childrens Hospital Los Angeles
3. Federal and State agencies that have authority over the research when required by law.
4. Hospital or other accrediting agencies
5. A data safety board that may be formed to monitor the safety of the research
6. Your health insurer or payer, if necessary, to secure their payment for any covered treatment not paid for by the research.
7. Information that may affect clinical care will be placed in your medical record to be used by hospital and medical staff who are not involved in the study.

CONFIDENTIALITY and PRIVACY

Efforts will be made to ensure that your protected health information will not be shared with other persons, groups or organizations outside of the research study. However, your protected health information may be disclosed to others as required by law and/or to individuals that may not be held to the same legal privacy standards as are doctors and hospitals. The research team cannot guarantee absolute confidentiality and privacy.

EXPIRATION

This authorization will expire on December 31, 2099. This is because information that is collected for research purposes continues to be analyzed for many years and it is not possible to determine when it will be complete.

YOUR RIGHTS

You may decide not to sign this authorization form. If you do not sign this authorization form, you will not be able to take part in this research study. Your regular healthcare including treatment, payment or enrollment in any health plans or your eligibility for benefits will not be affected if you decide not to sign.

You may cancel your permission at any time for Childrens Hospital Los Angeles to use or share your protected health information collected for this research study. However, even if you cancel this authorization, the hospital and the research team may still use information about you that was collected as part of the research project (ie: side-effects related to the research) between the date you signed the current form, and the date you cancelled the authorization. This is to protect the quality of the research results. Once you cancel your authorization, no further protected health information will be disclosed.

Your must cancel your authorization in writing. You may request a form for this purpose from the Committee on Clinical Investigations, (323) 361-2265. This document must be signed by you or on your behalf and delivered to the following address: Shahab Asgharzadeh, Childrens Hospital Los Angeles, 4650 Sunset Boulevard Mail stop #57, Los Angeles, California 90027.

Your cancellation will be effective upon receipt, but will not be effective to the extent that the Childrens Hospital Los Angeles research team or others have acted in reliance upon this Authorization.

You will receive a copy of this Authorization Form.

You have the right to review and/or copy your medical records containing your protected health information kept by Childrens Hospital Los Angeles. You have a right to receive a copy of the blank data forms used for this study. You will not have the right to review and/or copy your research specific records.

Under no circumstances are you required to authorize the disclosure of psychotherapy notes.

SIGNATURES

Your signature below indicates: that you give permission for the use and disclosure of your protected health information as described in this document. This authorization form may not be valid if it has not been filled out completely.

Printed Name _____

Signature _____ Date ___/___/___ Time _____AM/PM

Please indicate the relationship:

patient/research subject legal representative _____
(indicate relationship)

Printed Name of Person Obtaining Permission:

Signature of Person Obtaining Permission:

_____ Date ___/___/___ Time _____AM/PM

Routing: Investigator's file, Subject, Health Information Management (Medical Records)



ChildrensHospitalLosAngeles

International Leader in Pediatrics

Study Title: **Neural Tumor Registry**

Principal Investigator: **Shahab Asgharzadeh**

EXPERIMENTAL SUBJECT’S BILL OF RIGHTS

You have been asked to participate as a subject in a medical experiment. Before you decide whether you want to participate in the experimental procedure, you have a right to the following information:

CALIFORNIA LAW REQUIRES THAT YOU MUST BE INFORMED ABOUT:

1. The nature and purpose of the study.
2. The procedures in the study and any drug or device to be used.
3. Discomforts and risks reasonably to be expected from the study.
4. Benefits reasonably to be expected from the study.
5. Alternative procedures, drugs or devices that might be helpful and their risks and benefits.
6. Availability of medical treatment should complications occur.
7. The opportunity to ask questions about the study or the procedure.
8. The ability to withdraw from the study at any time and discontinue participation without affecting your future care at this institution.
9. Be given a copy of the signed and dated written consent form for the study.
10. The opportunity to consent freely to the study without the use of coercion.

I have carefully read the information contained above and I understand fully my rights as a potential subject in this study.

Date: _____ Time: _____

Signature: _____
(subject)

Signature: _____
(parent or legally authorized representative, if applicable)

If signed by other than the subject, indicate relationship: _____