

**UNIVERSITY OF CALIFORNIA, SAN FRANCISCO  
CONSENT TO PARTICIPATE IN A RESEARCH STUDY**

**Study Title:** Registry of Patients diagnosed with Alpha Thalassemia Major and other Alpha Thalassemia Mutations.

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This is a research study about alpha thalassemia major and other alpha thalassemia mutations. The study researchers, Tippi MacKenzie, M.D., from the UCSF Department of Surgery will explain this study to you.

Research studies include only people who choose to take part. Please take your time to make your decision about participating, and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the researchers.

You are being asked to take part in this study because you have alpha thalassemia major or another alpha thalassemia mutations.

**Why is this study being done?**

The purpose of this study is to collect data so the researchers can learn more about alpha thalassemia major and other alpha thalassemia mutations.

**How many people will take part in this study?**

About 100 people will take part in this study.

**What will happen if I take part in this research study?**

If you agree to be in this study, the following will happen:

- Health Information:* In the course of this study, researchers will gather information about you either directly or by reviewing your medical records. Information recorded for study purposes will be stored in databases for future research. Information gathered will include person health information (PHI), your social security number, results of physical examinations, diagnostic tests, medical questionnaires, diagnosis, treatments, lab reports, and pathology reports.
- Patient Contact:* You may be contacted to update your current treating physician when you are no longer being followed at UCSF. Your current physician may also be contacted to update your information for treatment and disease outcomes.

## **How long will I be in the study?**

Participation in the study will take a total of about 15-30 minutes

## **Can I stop being in the study?**

Yes. You can decide to stop at any time. Just tell the study researcher or staff person right away if you wish to stop being in the study.

Also, the study researcher may stop you from taking part in this study at any time if he or she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

## **What side effects or risks can I expect from being in the study?**

The only risk is a possible loss of privacy. The research team will take all measures to protect your confidentiality. The University of California complies with the requirements of HIPPA and its privacy regulations. Information which identifies you will be kept secure and restricted. However, your personal information may be given out if required by law. If information from this research is published or presented at scientific meetings, your name and other identifiers will not be used. Information which identifies you will be destroyed when this research is complete. The following organization may look at information about you in your medical and research records: *UCSF's Institutional Review Board*.

For more information about risks and side effects, ask one of the researchers.

## **Are there benefits to taking part in the study?**

There will be no direct benefit to you from participating in this study. However, the information that you provide may help health professionals better understand/learn more about alpha thalassemia major and other alpha thalassemia mutations.

## **What other choices do I have if I do not take part in this study?**

You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

## **Will information about me be kept private?**

We will do our best to make sure that the personal information gathered for this study is kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

- Representatives of the University of California

## **Will I be paid for taking part in this study?**

You will not be paid for taking part in this study.

## **What are my rights if I take part in this study?**

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

## **Who can answer my questions about the study?**

You can talk to the researcher(s) about any questions, concerns, or complaints you have about this study. Contact the researcher(s) Tippi MacKenzie, MD at (415) 476-0445.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Institutional Review Board at 415-476-1814.

## **CONSENT**

You have been given a copy of this consent form to keep.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

**PARTICIPATION IN RESEARCH IS VOLUNTARY.** You have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Participant's Signature for Consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Person Obtaining Consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Witness – Only required if the participant is a non-English speaker

AND/OR:

\_\_\_\_\_  
Date

\_\_\_\_\_  
Legally Authorized Representative

\_\_\_\_\_  
Date

\_\_\_\_\_  
Person Obtaining Consent

OR:

*The person being considered for this study is unable to consent for himself/herself because he/she is a minor. By signing below, you are giving your permission for your child to be included in this study.*

\_\_\_\_\_  
Date

\_\_\_\_\_  
Parent or Legal Guardian