

University of Kansas Medical Center
Stroke/TIA Database Project
Informed Consent

INTRODUCTION

As a person who has experienced a stroke or "mini-stroke" (a transient ischemic attack or TIA), I am being invited to participate in the University of Kansas Medical Center (KUMC) Stroke/TIA Database Project. If I consent, information related to my stroke or TIA will be obtained from my medical records, and entered into a database. This information will not be anonymous: the database will include my name and show that this information is about me. I also may be asked to give further information or answer questions in addition to the information from my medical records.

PURPOSE

The purpose of this project is to collect information on people with stroke or TIA into a database, and to use this information for future studies about stroke and stroke rehabilitation. Dr. Wen Liu and the KUMC Stroke Research Interest Group will be conducting studies related to stroke; the database will be used to recruit participants for those particular research studies.

PROCEDURE

Should I decide to participate in this database project, information collected during my medical record will be entered into a database that includes similar information collected from other patients recruited from KUMC clinics and hospital, and other community organizations.

Participating in this database project will not add to the length of my hospitalization or normal follow-up clinic visits because most of this information is already collected as part of the clinical and hospital procedure. I may be called on the phone or mailed forms to gather additional information and this information may also be entered in the database.

The information gathered about me will be used to determine if I am qualified to participate in future stroke studies, such as stroke prevention studies or stroke recovery

studies. If qualified, I understand that I may be contacted by telephone about a specific stroke study. I can decide at that time if I am interested in participating, and am under no obligation to enter a clinical trial or other studies unless I choose to do so.

RISKS

I am taking no foreseeable risks by participating in this study. Efforts will be made to keep the information about me confidential.

BENEFITS

I will not directly benefit from participating in this study. However, the information collected in this database may be useful in doing research to learn about future ways to treat patients who have a stroke or TIA.

PAYMENT TO THE SUBJECT

I will receive no payment for participating in the Stroke/TIA Database Project.

COSTS

There is no additional cost to me for participating in the Database Project.

ALTERNATIVES

My alternative is to not participate in the Stroke/TIA Database Project. Refusing to provide information into the database will have no effect upon my medical care or treatment.

INSTITUTIONAL DISCLAIMER

If I think I have been harmed as a result of participating in research at the University of Kansas Medical Center (KUMC), I should contact the Director, Human Research Protection Program, Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160. Under certain conditions, Kansas state law or the Kansas Tort Claims Act may allow for payment to persons who are injured in research at KUMC.

CONFIDENTIALITY AND PRIVACY AUTHORIZATION

Efforts will be made to keep my personal information confidential. Researchers cannot guarantee absolute confidentiality. Records of my participation in this database will be kept secret to the extent permitted by law. Dr. Wen Liu and KU researchers will have access to the information available in the database. If the results of this database are to be presented in public, information that identifies me will be removed.

The privacy of my health information is protected by a federal law known as the Health Insurance Portability and Accountability Act (HIPAA). If I choose to participate in this database, I will be asked to give permission for uses and disclosures of my health information.

To perform this study, researchers will collect health information about me from my medical record and from my clinic visits. My study-related health information will be used by Dr. Wen Liu and authorized KU affiliated researchers, KU Hospital Medical Record Department, KUMC Research Institute and government or KUMC committees and officials that oversee research.

All study information that is sent outside KU Medical Center will have my name and other identifying characteristics removed, so that my identity will not be known. Because identifiers will be removed, my health information will not be re-disclosed by outside persons or groups and will not lose its federal privacy protection.

Permission granted on this date to use and disclose my health information remains in effect indefinitely. By signing this form I give permission for the use and disclosure of my information for purposes of the study at any time in the future.

SUBJECT RIGHTS AND RIGHT TO WITHDRAW

I understand that I may withdraw from a study at any time. All of the data collected on me will be removed from the database if I request it. I understand that my participation in this database is voluntary and that the choice not to participate or to quit at any time can be made without penalty or loss of benefits. I understand that not participating or quitting will have no effect upon the medical care or treatment I receive now or in the future.

If I want to cancel permission to use my health information, I should send a written request to Dr. Wen Liu. The mailing address is Wen Liu, PhD, Landon Center on Aging, Room Mail Stop 1005, University of Kansas Medical Center, 3901 Rainbow Boulevard, Kansas City, KS 66160. If I cancel permission to use my health information, the research team will stop collecting any additional information about me. I am aware that the research team may use information that was gathered before they received my cancellation.

QUESTIONS

I have read the information in this form. The investigators have answered my questions to my satisfaction. I know if I have any more questions after signing this form, I may contact Dr. Wen Liu at (913) 588-1458. If I have any questions about my rights as a research subject, I may call (913) 588-1240 or write the Human Research Protection Program, Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160.

KUMC STROKE/TIA DATABASE CONSENT

The investigators gave me information about what will be done with my medical documentation for the Stroke/TIA database project. I agree to take part in the collection of my current and future medical records for the Stroke/TIA database. I am aware that I may withdraw my name from the database at any time. I understand that quitting or refusing to provide information into the database will have no effect upon my medical care or treatment I receive in the future.

By signing this form, I give my permission for my health information to be used and disclosed for the purposes of this research study. As part of this project, I give my permission to release a copy of my medical records pertaining to my stroke and subsequent rehabilitation to Dr. Liu and the KUMC Stroke Research Interest Group. If I choose not to sign this form, I will not be able to participate in the study.

I understand that the investigators will give me a signed copy of this form to keep for my records.

Subject Printed Name

Subject Signature

Date

Registry Director Signature

Date

Stroke/TIA Database Information Form

PERSONAL INFORMATION

Name: _____

Date of birth: _____

Current Address: _____

Telephone number: _____

STROKE

Have you experienced multiple strokes? Yes No

Date (or approximate date) of first stroke: _____

Date (or approximate date) of most recent stroke: _____

HOSPITAL (and city if outside of Kansas City metro area) where you received treatment for your TIA(s) or stroke(s):

HEALTH

What side of your body was affected?

Right Left Both None

HEALTH

Do you have any current problems or disabilities related to your stroke or TIA?
Please explain.

Authorization for Release of Protected Health Information

I, _____, born on → _____

Address

Phone

hereby authorize and request that **(name of hospital or medical center where stroke treatment was received)** → _____

provide a copy of my medical records to Dr. Joan McDowd at the University of Kansas Medical Center for use related to my participation in the study entitled "Stroke/TIA Database."

My health information is protected under the Health Information Portability and Accountability Act (HIPAA) I understand that some persons or groups who receive information about me may not be required to comply with federal privacy laws. The health information will lose its federal protection if those persons or groups disclose it. KUMC will protect my information as required by federal privacy laws.

I have the right to cancel this authorization at any time in writing, except to the extent that it has already acted upon. I may cancel my authorization by submitting the cancellation, in writing, to my healthcare provider.

Unless I cancel it, my authorization for the initial disclosure remains in effect for one year.

I will receive a signed copy of this authorization.

I, _____, have read the above information and authorize **(name of hospital or medical center where stroke treatment was received)** → _____

to use and disclose my identifying information for the above-stated purposes.

Signature of Patient or Patient's Personal Representative

Date