

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. Joan McDowd 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 STATEMENT

If I believe you have been injured as a result of participating in research at Kansas University 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. Compensation to persons who are injured as a result of participating in research at KUMC may be available, under certain conditions, as determined by state law or the Kansas Tort Claims Act.

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. Joan McDowd 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. Joan McDowd 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.

