**Research Informed Consent**

Title of Study: Analysis of Human Spinal Fluid

Principal Investigator (PI): Jeffrey Loeb, M.D., Ph.D.
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48201
(313) 577-1244

**Purpose**

You are being asked to be in a research study to find out what molecules are present in your spinal fluid because you have or are suspected of having a neurological disorder and a spinal tap has been ordered as part of your regular care. This study is being conducted at Wayne State University and the Detroit Medical Center. The estimated number of study participants to be enrolled is 300, over a three year period. **Please read this form and ask any questions you may have before agreeing to be in the study.**

In this research study, your cerebral spinal fluid (CSF) will be stored in a freezer for future analysis of proteins and other molecules that could help us understand brain disorders and develop new and better ways to diagnosing and treating diseases of the brain and nervous system.

**Study Procedures**

As part of your regular medical care, you will have a spinal tap. A needle will be inserted in the middle of your back and a small amount of fluid, will be taken out of your spinal column for testing. If you take part in this research study, you will allow doctors to collect an additional small amount of fluid, 5 to 10 mls or 1 to 2 teaspoons. The collection of additional fluid will take approximately 1 to 2 minutes to collect. If during the procedure you are unable to tolerate the additional 1 to 2 minutes of time to collect the fluid, the fluid will not be collected.

**Benefits**

As a participant in this research study, there will be no direct benefit to you, however, information from this study may benefit other people in the future.

**Risks**

The risks of having a spinal tap, as part of your regular clinical care, have been explained to you by your doctor. These risks may include headache, bleeding and infection at the site of the needle insertion. By taking part in this study, you will experience no additional risks from removing this small amount of fluid, except for a few extra minutes of procedure time. There may be risks involved in taking part in this study which are not known to researchers at this time.

**Alternatives**
The only alternative is to not participate in the study.

**Study Costs**

You or your insurance company will be charged for the spinal tap which is considered to be the "standard of care". Standard of care means treatments that you would receive even if you were not taking part in this research study such as lab tests, clinic or office visits, etc. There will be no charge for the new test.

**Compensation**

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

**Research Involving the Future Use of Biological Specimens**

Samples of your spinal fluid will be used for our research studies and the remainder will be stored frozen for future studies. As medicine is rapidly advancing, we do not know all of the possible studies that will be done, but we will not link the sample to your name or any information that would allow anyone to identify you. The sample will be permanently housed in a research laboratory at Wayne State University and can be destroyed or returned to you at any time. It is also possible that your sample will be provided to a third-party to conduct specialized testing based on formal arrangements between Wayne State University and the third party. In this event, we would not provide any of your personal information that would enable the third party to reveal your identity.

**Research Related Injuries**

In the event that this research related activity results in an injury, treatment will be made available including first aid, emergency treatment, and follow-up care as needed. Cost for such care will be billed in the ordinary manner to you or your insurance company. No reimbursement, compensation, or free medical care is offered by Wayne State University or the Detroit Medical Center. If you think that you have suffered a research related injury, contact Dr. Loeb right away at 313-577-1244.

**Confidentiality**

All information collected about you during the course of this study will be kept confidential to the extent permitted by law. You will be identified in the research records by a code name or number. Information that identifies you personally will not be released without your written permission. However, the study sponsor, the Human Investigation Committee (HIC) at Wayne State University, or federal agencies with appropriate regulatory oversight [e.g., Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), Office of Civil Rights (OCR), etc.) may review your records.

When the results of this research are published or discussed in conferences, no information will be included that would reveal your identity.

**Voluntary Participation/Withdrawal**

Taking part in this study is voluntary. You have the right to choose not to take part in this study. You are free to only answer questions that you want to answer. You are free to withdraw from participation in this study at any time and request to have any specimens stored disposed. Your decisions will not change any present or future relationship with Wayne State University or its affiliates, or other services you are entitled to receive.

**Questions**

If you have any questions about this study now or in the future, you may contact Jeffrey Loeb, M.D., Ph.D.or one of his research team members at the following phone number 313-577-1244. If you have questions or concerns about your rights as a research participant, the Chair of the Human Investigation Committee can be contacted at (313) 577-1628. If you are unable to contact the research staff, or if you want to talk to someone other than the research staff, you may also call (313) 577-1628 to ask questions or voice concerns or complaints.

**Consent to Participate in a Research Study**

To voluntarily agree to take part in this study, you must sign on the line below. If you choose to take part in this study you may withdraw at any time. You are not giving up any of your legal rights by signing this form. Your signature below indicates that you have read, or had read to you, this entire consent form, including the risks and benefits, and have had all of your questions answered. You will be given a copy of this consent form.

| | |
|---|---|
| Signature of participant / Legally authorized representative | Date |
| Printed name of participant / Legally authorized representative | Time |
| Signature of witness* | Date |
| Printed of witness* | Time |
| Signature of person obtaining consent | Date |
| Printed name of person obtaining consent | Time |

*Use when participant has had this consent form read to them (i.e., illiterate, legally blind, translated into foreign language).

APPROVAL PERIOD
DEC 0 2 '10 DEC 0 1 '11
HUMAN INVESTIGATION COMMITTEE

| | |
|---|---|
| Signature of translator | Date |
| Printed name of translator | Time |

**HIPAA Authorization**

A federal regulation, known as the "Health Insurance Portability and Accountability Act (HIPAA)" gives you certain rights concerning the use and disclosure (sharing with others) of your Protected Health Information (PHI). This regulation provides safeguards for the privacy and security of your information. Your permission (authorization) is required for the use and sharing of any protected health information collected as part of this research study. If you are not willing to sign this authorization to use and/or disclose your PHI by the research team, you will not be eligible to take part in this research study.

The principal investigator (PI) and his research team will use your medical records and information created or collected as part of this research study. Your PHI is important for the PI and his research team in order to collect information about you during the study, to be able to contact you if needed, and to provide treatments to you during the study, if required. The PI may send out your study related health information to the sponsor or other entities involved in this study.

Your medical records, which may contain information that directly identifies you, may be reviewed by representatives from groups identified below. The purpose of these reviews is to assure the study is being conducted properly, that data is being obtained correctly or for other uses authorized by law. These reviews occur at the study site or in the PI's research office and can take place anytime during the study or after the study has ended.

**The PHI that will be "USED"** for this research includes the following: name, elements of dates, medical record number, and any unique identifying numbers or characteristics or code.

**The PHI that will be "DISCLOSED"** or shared with others for this research includes the following: any unique identifying numbers or characteristics or code.

Your study information may be **used** or **shared** with the following people or groups:

- The PI, co-investigators, and key personnel of WSU associated with the research project.
- WSU's HIC and the Institutional Review Boards (IRB)
- Authorized members of WSU's and DMC workforce who may need to access your information in the performance of their duties. [*For example, to provide treatment and services, ensure integrity of the research, or for accounting and/or billing matters.*]
- Federal agencies with appropriate regulatory oversight (e.g., FDA, OHRP, OCR, etc.) may review your records

Once your information has been released according to this Authorization, it could be released again and may no longer be protected by the HIPAA regulations.

This Authorization does not expire. The research team may need to correct it or provide missing information about you even after the study has ended, and your medical records may be needed to assist in this process.

- During your participation in this study you will have access to your medical record and any study information that is part of that record. The PI is not required to release research information that is not part of your medical record.

You may withdraw (take back) your permission for the **use** and **disclosure** of your PHI for this research at anytime, by **writing** to the PI at the address on the first page of this form. Even if you withdraw your permission, the PI for the research project may still use your PHI that was collected prior to your written request if that information is necessary to the study. If you withdraw your permission for use of your PHI, you will also be withdrawn from the research project. Withdrawing your authorization **will not** affect the health care that will be provided by the Detroit Medical Center and/or the WSU School of Medicine Practice Plans.

**Authorization to use and disclose PHI**

- By signing this document, you are authorizing the PI to **use** and **disclose** PHI collected about you for the research purposes as described above.

_____ _____
Signature of participant Date

_____
Printed name of participant

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- For participants unable to give Authorization, the following individual is acting on behalf of the research participant (e.g., children, mentally impaired, etc.).

_____ _____
Signature of authorized representative Date

_____ _____
Printed name of authorized representative Relationship to the participant

_____ _____
Signature of person obtaining Authorization Date

_____ _____
Printed name of person obtaining Authorization Time