浙大二院
THE SECOND AFFILIATED HOSPITAL
ZHEJIANG UNIVERSITY SCHOOL OF MEDICINE

Informed Consent Form for Human Research

Second Affiliated Hospital of Zhejiang University School of Medicine

Dear Patient,

We invite you to participate in a clinical study titled "Large-Scale Multi-Omics Analysis of Human Cerebrospinal Fluid." Before deciding whether to participate in this study, please read the following information carefully. It will help you understand the purpose of the study, the procedures and duration, as well as the potential benefits, risks, and inconveniences of participating.

Below is an introduction to the study:

1. Research Background and Objectives

This study aims to explore the role of cerebrospinal fluid (CSF) biomarkers in aging and neurodegenerative diseases. The main objectives are:

1. To analyze CSF samples from different age groups to identify biomarkers that undergo significant changes during aging, such as amyloid-beta, tau protein, and other proteins related to neuroinflammation and blood-brain barrier function.
2. To develop a predictive model based on the protein content and classification of CSF across different age stages for the early diagnosis of neurodegenerative diseases (e.g., Alzheimer's disease). This may help detect diseases before clinical symptoms appear and provide the possibility for early intervention and treatment.
3. To study the dynamic changes of CSF biomarkers at different stages of disease to understand their roles in disease progression, including early, middle, and late stages, in order to better comprehend the pathological process and identify potential therapeutic windows.
4. To create a database of CSF biomarkers that includes different age groups, disease states, and treatment responses. This will provide valuable data resources for

future research and enhance the scientific community's understanding of neurodegenerative diseases and the development of new therapies.

By achieving these objectives, the study aims to advance the development of CSF biomarkers in neuroscience research and clinical applications, improving the diagnosis, management, and treatment of aging and neurodegenerative diseases.

2. Specific Procedures and Processes

1. During the spinal anesthesia procedure before your surgery, the anesthesiologist will perform a lumbar puncture. After the puncture needle is correctly positioned, the standard procedure involves withdrawing some cerebrospinal fluid (CSF) to ensure that the tip of the needle is located in the subarachnoid space before administering the anesthetic. We will collect approximately 1-2 mL of the CSF that remains in the syringe during this withdrawal for use in our research.

2. If you are a patient with tethered cord syndrome, we will collect 1-2 mL of CSF from within the dura mater during the normal course of your surgery.

3. What You Will Need to Do if You Decide to Participate

If you decide to participate in this study, you will be asked to sign this informed consent form before any research-related activities are conducted. By signing, you agree to allow the researchers to use your cerebrospinal fluid sample for subsequent scientific research.

4. Potential Benefits of Participating in This Study

Participation in this study may not directly improve your health, and you will not receive any direct benefits from being part of this research. However, the information obtained from this study will contribute valuable insights into aging-related diseases. Your participation may ultimately benefit future patients who suffer from neurodegenerative conditions.

5. Potential Adverse Reactions, Risks, and Risk Mitigation

This study involves collecting 1-2 mL of cerebrospinal fluid (CSF) during spinal anesthesia. A very small number of patients may experience headaches or discomfort after

the procedure. If this occurs, we will provide additional fluids to alleviate the symptoms. The CSF collected for this study is the residual fluid from your normal spinal anesthesia procedure, and no additional procedures will be performed. The risks associated with this study are the same as those inherent in the standard spinal anesthesia process and will not introduce any additional risks.

6. Cost Information

Participation in this study will not incur any additional costs compared to standard clinical procedures. No extra tests or procedures will be required, so there will be no additional expenses.

7. Compensation for Participation and Injury Compensation

This study is a non-interventional research and will not incur additional costs for participants. Therefore, there is no compensation or related compensation for participation or any potential injury.

8. Alternatives

If you choose not to participate in this study, there are no alternative options related to this specific research. Your decision will not affect your standard clinical treatment.

9. Confidentiality of Your Personal Information

Your medical records (including research case records and physical examination reports) will be stored in the hospital as required. Only authorized individuals, such as researchers, the ethics committee, monitors, auditors, and regulatory authorities, will have access to your medical records. Others not involved in the research are not permitted to view your records without authorization. The results of this study will be reported publicly without disclosing your personal identity. We will make every effort to protect the privacy of your personal medical information within the permissible scope.

10. Termination of Participation

Participation in this study is entirely voluntary. You may choose not to participate in this research or withdraw from the study at any time without providing a reason. This decision will not affect your relationship with your doctor or result in any loss of medical

care or other benefits.

11. Ethics Committee

This study has been reported to the Human Research Ethics Committee of the Second Affiliated Hospital of Zhejiang University School of Medicine. The committee has conducted a thorough review and risk assessment for participants and has granted approval for the study. For any concerns related to ethics or rights during the study, you can contact the Human Research Ethics Committee at the Second Affiliated Hospital of Zhejiang University School of Medicine. The contact details are as follows:

- **Daytime Phone:** 0571-87783759
- **Nighttime (On-call):** 13757118366
- **Email Address:** HREC2013@126.com

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I confirm that I have read and understood the informed consent form for this study, voluntarily agree to the treatment methods in this research, and consent to the use of my medical data for publication related to this study.

Participant Signature: _____

Contact Information: _____

Date: _____

If applicable:

Representative Signature: _____

Relationship to Participant: _____

Contact Information: _____

Date: _____

Witness (if applicable): _____

Contact Information: _____

Date: _____

I confirm that I have explained the details of the study to the participant, including their rights, and the potential benefits and risks, and have provided them with a signed copy

of the informed consent form.

Researcher Signature: _____

Contact Information (Phone): _____

Date: _____