Official Title: Prospective Study Using Nipple Discharge Molecular Testing to Differentiate Benign and Malignant Lesions

Institution: Breast Center, Hubei Cancer Hospital

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Ethics Approval: This study has been reviewed and approved by the Ethics Committee of Hubei Cancer Hospital.

Prospective Study Using Nipple Discharge Molecular Testing to Differentiate Benign and Malignant Lesions

Informed Consent Form

Introduction and Background

You are invited to take part in a clinical research study titled "Prospective Study Using Nipple Discharge Molecular Testing to Differentiate Benign and Malignant Lesions," conducted by the Breast Center of Hubei Cancer Hospital. This is a prospective diagnostic study designed to explore whether molecular markers in nipple discharge can help distinguish benign from malignant lesions before surgery. This consent form provides information to help you decide whether to participate. Your participation is entirely voluntary. Your routine diagnosis and treatment will not be affected by your decision.

Purpose of the Study

By collecting your nipple discharge and blood samples and performing low-coverage whole-genome sequencing (lcWGS), methylation testing, and related analyses, we aim to build a new, minimally invasive molecular diagnostic model that, in the future, may help reduce unnecessary surgery for patients.

What Will Happen if You Join

If you agree to participate, in addition to the routine tests needed for your clinical care, we will:

1. Collect one nipple discharge sample (approximately 0.5–1 mL) before surgery by a doctor or nurse.
2. Collect one blood sample (approximately 5 mL) by venipuncture before surgery.

3. Obtain your postoperative pathology report, which will serve as the “gold standard” reference for this research.
4. Be authorized to review de-identified medical records related to this visit (for example, imaging reports) for research analysis.

Your samples will be assigned a code and de-identified. All testing will be used only for this research. This study will not affect your treatment plan or surgical decisions.

Potential Benefits

This study will not directly change your treatment. However, the samples and information you provide will contribute to the development of more precise and minimally invasive diagnostic methods, which may help future patients avoid unnecessary surgery and associated costs.

Potential Risks and Discomforts

1. Nipple discharge collection is noninvasive and may cause mild discomfort.
2. Blood draw may cause brief pain, local bruising, or, very rarely, infection or fainting. All procedures will be performed by trained medical staff using standard sterile techniques to minimize risk.

Alternatives

There are no study-specific treatments or interventions. You may choose not to participate and continue with all standard diagnostic and treatment procedures as recommended by your care team.

Privacy and Confidentiality

Your privacy will be strictly protected. Your name, national ID number, and other personal identifiers will not be disclosed. All research data will be labeled with a study code; only the study team can access the link between the code and your identity, and only under confidentiality safeguards. Your samples and information

will be used solely for this project. Research results will never include any information that can identify you personally.

Costs and Payments

You will not be charged any additional fees for participating. The costs of sample collection and research analyses will be covered by the study. There is no financial payment for participation.

Voluntary Participation and Right to Withdraw

Your participation is voluntary. You may withdraw from the study at any time for any reason. Your medical care and legal rights will not be affected, and your relationship with your healthcare providers will not be impacted. If you withdraw, your samples and data will be destroyed or no longer used upon your request.

Contacts

If you have questions about this study or experience any discomfort, please contact the study doctor:

Study Doctor: _____ Phone: _____

For questions about your rights as a research participant, please contact the Ethics Committee of Hubei Cancer Hospital: +86-27-87671663.

Consent and Signatures

By signing below, I confirm that I have read this informed consent form. The study doctor has explained the purpose, procedures, potential risks and benefits, and privacy protections of this study, and has answered all my questions. I understand the information provided and voluntarily agree to participate.

Participant's Name: _____ Participant's Signature: _____ Date: //_____

Witness’s Name (if needed): _____ Witness’s Signature: _____ Date: //_____

Researcher’s Name: _____ Researcher’s Signature: _____ Date: //_____

Notes:

- If the participant cannot read or fully understand this form, a witness should sign.
- If the participant lacks decision-making capacity, the legally authorized representative must consent and sign.

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