

Study Title: **TISSUE COLLECTION, STORAGE AND DISTRIBUTION**

Principal Investigator: Florence M. Hofman, Ph.D.

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

You have been asked to participate as a subject in a medical experiment. Before you decide whether you want to participate in the experimental procedure, you have a right to the following information:

CALIFORNIA LAW REQUIRES THAT YOU MUST BE INFORMED ABOUT:

1. The nature and purpose of the study.
2. The procedures in the study and any drug or device to be used.
3. Discomforts and risks reasonably to be expected from the study.
4. Benefits reasonably to be expected from the study.
5. Alternative procedures, drugs, or devices that might be helpful and their risks and benefits.
6. Availability of medical treatment should complications occur.
7. The opportunity to ask questions about the study or the procedure.
8. The ability to withdraw from the study at any time and discontinue participation without affecting your future care at this institution.
9. Be given a copy of the signed and dated written consent form for the study.
10. The opportunity to consent freely to the study without the use of coercion.

I have carefully read the information contained above and I understand fully my rights as a potential subject in this study.

Date: _____ Time: _____

Signature: _____
(Research Participant)

Study ID: HS-09-00520 Valid From: 3/30/2010 To: 10/14/2010

INFORMED CONSENT

TITLE: A PROTOCOL FOR COLLECTING BRAIN TUMOR SPECIMENS FOR GLIOMA VACCINE

**PRINCIPAL INVESTIGATOR: FLORENCE M. HOFMAN, PH.D.
THOMAS C. CHEN, M.D., PH.D**

**DEPARTMENT: PATHOLOGY
NEUROLOGICAL SURGERY**

24-HOUR TELEPHONE NUMBER: (323) 865-3000

We invite you to take part in a research study. Please take as much time as you need to read the consent form. You may also decide to discuss it with your family, friends, or your doctor. You may find some of the language difficult to understand. If so, please ask questions. If you decide to participate, you will be asked to sign this form.

WHY IS THIS STUDY BEING DONE?

You are invited as a possible participant because you have been scheduled for surgery to remove tumor(s) in your brain. If the tumor you have is the type of tumor we wish to study, then we will ask to keep the discarded tissue and store it in a bank for future research. By studying the clinical data and characteristics about the specimens, we hope to gain a better understanding of brain tumors.

About 50 participants will take part in this study, and 10 participants will be from USC.

WHAT IS INVOLVED IN THE STUDY?

You have already been scheduled for surgery to remove the tumor(s). In order to diagnose your tumor, a biopsy where a sample of the tumor was removed or an excision where as much of the tumor is removed as possible, will be done. How the tissue is obtained and the risks from getting this tissue will be explained to you separately.

The tissue removed in your diagnostic procedure will undergo testing to find out the type of tumor you have. Any tissue that is removed and left over from the surgery that is not needed to make the diagnosis is usually thrown away. If you have the type of tumor that we wish to study, we would like to keep this unused tissue from your diagnostic procedure or excision. You will not have any additional procedures performed as part of this study once the tumor tissue is obtained.

We would also like to take 30 ml (about 2 tablespoons) of your blood during your surgery. During surgery, a doctor will draw blood from the same needle that is used to provide you with the drug that makes you sleep. You will not need an extra needle stick

to donate your blood sample for this study. Your blood will be tested for HIV and hepatitis B and C. If you are tested positive for HIV or hepatitis, the tumor samples will not be used in this study. If you do not wish to know your HIV and Hepatitis results but your results are positive, the results will be destroyed. However, if the results are positive, by law, we must report the results to the California Health Department.

Please indicate below whether you wish to know the results of the blood testing for HIV and Hepatitis B & C:

YES _____ NO _____ INITIALS _____

In addition, we will review your medical record to collect information related to your disease and treatment. You will not have to return to the clinic for follow up as part of this the study.

Letting us keep your left over tissue and obtain the blood sample are the only procedure associated with this study.

You and your study doctor will not be informed of the research testing results.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

There are no specific risks for allowing the leftover portion of your tissue (after pathology review) to be studied for research purposes.

The greatest risk to you is the release of information from your health records. We will do our best to make sure that your personal information will be kept private. The chance that this information will be given to someone else is very small.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART IN THIS STUDY?

You will not receive any direct benefit from taking part in this study. However, your participation in this study may help us develop treatments for various diseases in the future.

WHAT OTHER OPTIONS ARE THERE?

An alternative would be to not take part in this study and continue with your scheduled surgery

WILL YOUR INFORMATION BE KEPT PRIVATE?

The investigator and the Institutional Review Board (IRB) will keep your records private as far as the law allows. The IRB is a research review board that is made up of professionals and community members who review and monitor research studies to

protect the rights and welfare of research participants. We may publish the information from this study in journals or present it at meetings. If we do, we will not use your name.

Every tissue sample has information about a person's genes. By using genes, a person might be identified, even if there is no name on the samples. We will make every effort to keep your genetic information private as far as the law allows. We will store any genetic testing results from this study at ERC America (tissue bank). We will not put the genetic information in your medical records.

WHAT ARE THE COSTS?

Neither you nor your insurance plan will be billed for your taking part in this study. There is no charge to you for the tests done on the tumor tissue. There is no charge for the banking of tumor tissue.

ARE THERE ANY PAYMENTS TO YOU FOR TAKING PART IN THE STUDY?

No financial compensation will be provided for participation in this study.

POSSIBLE COMMERCIAL PRODUCTS

There is no plan for you to receive payment for any commercial products that are developed.

WHAT HAPPENS IF YOU GET INJURED OR NEED EMERGENCY CARE?

If you get hurt or sick from taking part in the study, we will give you the medical care you need. You and/or your health plan/insurance company/government program must pay for the care. Normally, you will not receive any compensation for being hurt or sick.

WHAT ARE YOUR RIGHTS AS A PARTICIPANT, AND WHAT WILL HAPPEN IF YOU DECIDE NOT TO PARTICIPATE?

Your participation in this study is voluntary. Your decision whether or not to take part will not affect your current or future care at this institution. You are not giving up any legal claims or rights. If you do decide to take part in this study, you are free to change your mind and stop being in the study at any time. If you decide now that your tissue can be kept for future research and change your mind later, contact your doctor and let him know that you no longer want your tissue used for research purposes.

ARE THERE ANY POTENTIAL CONFLICTS OF INTEREST?

The Investigator has a financial interest in the company sponsoring this study (Epitopoietic Research Corporation [ERC]). The Investigator receives speaker fees as a member of ERC's Scientific Advisory Board.

WHOM DO YOU CALL IF YOU HAVE QUESTIONS OR CONCERNS?

You may contact Florence Hofman, PhD at (323) 865-3000 with any questions or concerns about your participation in this study. If you feel you have been hurt by taking part in this study, please contact Florence Hofman, PhD at (323) 865-3000. If you have questions, concerns, or complaints about the research and are unable to contact the research team, or if you want to talk to someone independent of the research team, please contact the Institutional Review Board (IRB) Office at 323-223-2340 between the hours of 8:00 AM and 4:00 PM. (Fax: 323-224-8389 or email at irb@usc.edu). If you have any questions about your rights as a study participant, please also contact the Institutional Review Board Office at the numbers above or write to the Institutional Review Board at the LAC+USC Medical Center, General Hospital, 1200 North State Street, Suite 4700, Los Angeles, CA 90033.

You will get a copy of this consent form.

AGREEMENT:

I have read (or someone has read to me) the information provided above. I have been given a chance to ask questions. All my questions were answered. I have decided to sign this form in order to take part in this study.

Name of Research Participant	Signature	Date Signed
------------------------------	-----------	-------------

Name of Witness	Signature	Date Signed
-----------------	-----------	-------------

I have personally explained the research to the subject and answered all questions. I believe that he/she understands the information described in this informed consent and freely consents to participate.

Name of Investigator/Person Obtaining Informed Consent	Signature	Date Signed
--------------------------------------------------------	-----------	-------------

I have verbally translated this informed consent form to the research participant.

Name of Translator	Signature	Date of Signature
--------------------	-----------	-------------------