

IRB NUMBER: xxxxxxxxxxxxxxxx

LOYOLA UNIVERSITY MEDICAL CENTER
MAYWOOD, ILLINOIS
DEPARTMENT OF (INSERT)

INFORMED CONSENT

Participant's Name: _____

Medical Record Number: _____

PROJECT TITLE:

This project will undergo re-review on or before xx/xx/xxxx.

Patient Information

Principles Concerning Research: You are being asked to take part in a research project. It is important that you read and understand the principles that apply to all individuals who agree to participate in the research project described below:

1. Taking part in the research is entirely voluntary.
2. We do not know if you will personally benefit from taking part in the research but the knowledge obtained may help others.
3. You may withdraw from the study at any time without anyone objecting and without penalty or loss of any benefits to which you are otherwise entitled.
4. If during your participation in the research project, new information becomes available which would affect your being in the research project (such as better treatments or the side effects of the treatments), your doctor will discuss this new information with you and will help you make a decision about your continuing in the research.

The purpose of the research and how it is to be done and what your part in the research will be is described below. Also described are the risks, inconveniences, discomforts and other important information which you need to make a decision about whether or not you wish to participate. You are urged to discuss any questions you have about this research with the staff members.

Document ID#:
Version Date: 10/30/2006

PURPOSE OF STUDY:**DESCRIPTION AND EXPLANATION OF PROCEDURES:****RISKS/DISCOMFORTS:****REPRODUCTIVE AND SEXUAL ACTIVITY INFORMATION:****BENEFITS:****ALTERNATIVE TREATMENTS:****FINANCIAL INFORMATION:****RESEARCH RELATED INJURY:****INFORMATION COLLECTED AND WHAT WILL HAPPEN TO IT:**

In order to meet the goals of the research study (see Purpose of Research section of this consent), we will collect information on you, your test results and how you do. The information will be collected by [INSERT PRINCIPAL INVESTIGATOR'S NAME], the study physician(s), the research nurses, data administrators and secretaries. Information about you will be provided to Loyola University of Chicago, [INSERT SPONSOR NAME] the research sponsor, its data collection and study verification agencies and/or government regulatory agencies such as the Food and Drug Administration. In this way we will learn about [INSERT-THE SAFETY AND

Document ID#:
Version Date: 10/30/2006

EFFECTIVENESS OR BRIEFLY RESTATE THE MAJOR GOAL OF THE STUDY].

The information we will collect and send includes [TELL WHAT INFORMATION, IF ANY, WILL BE SENT TO THE SPONSOR OR HIS/HER DESIGNEE; SUCH AS]:

_____ DEMOGRAPHIC INFORMATION (E.G., NAME, ADDRESS, PHONE NUMBER, SOCIAL SECURITY NUMBER)

_____ BILLING AND PAYMENT INFORMATION

_____ MEDICAL RECORD (INCLUDING BUT NOT LIMITED TO HISTORY AND PHYSICAL EXAM NOTES, PROGRESS NOTES, CONSULTATION REPORTS, LABORATORY TEST RESULTS, OPERATIVE REPORTS.

_____ INFORMATION RELATING TO ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS) OR HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION.

_____ INFORMATION RELATING TO TREATMENT FOR DRUG OR ALCOHOL ABUSE.

_____ INFORMATION RELATING TO MENTAL OR BEHAVIORAL HEALTH OR PSYCHIATRIC CARE EXCLUDING PSYCHOTHERAPY NOTES.

_____ PHOTOGRAPHS, VIDEOTAPES, OR DIGITAL OR OTHER RADIOGRAPHIC IMAGES

_____ TISSUE SAMPLES

_____ BLOOD SAMPLES

We will collect and provide this information about you for as long as you are in the study [INDICATE HOW LONG THE INFORMATION WILL BE COLLECTED AND SENT. –E.G. FOR YOUR LIFETIME OR UNTIL THE SPONSOR TERMINATES THE NATIONAL STUDY.]

Once the information is disclosed outside of LUMC, it may no longer be protected by federal privacy laws.

It is possible that the sponsor [INSERT MONITORING COMPANY NAME OR LEAVE GENERIC IF POSSIBILITY OF NAME CHANGE], research nurses, its data collection and/or study verification agencies, data administrators or staff or Food and Drug Administration [CUSTOMIZE] will come to Loyola University Medical Center (“LUMC”) and view the medical record (see above for description of content) and the research records. They may take notes or copy pages of the medical record. This is done to verify the accuracy of the information LUMC is sending to them.

The results of this research study may be published in a journal for the purpose of advancing medical knowledge. You will not be identified by name or by any other identifying information in any publication or report about this research.

Consent for LUMC to use and disclose your medical information is required in order for you to

Document ID#:
Version Date: 10/30/2006

participate in the study.

Withdrawal of Consent: Your consent to use and disclose your medical information for the purpose of this research study is completely voluntary. You can withdraw your consent for LUMC to use and disclose your information and your consent to participate in this study at any time without affecting your ability to receive care and treatment at LUMC unrelated to the research study. Withdrawal means that all study procedures and follow-up will stop and we will not send any more information about you to the sponsor of this research or its designees. However, information already used and disclosed to the research sponsor prior to the time of your withdrawal from this study may continue to be used and disclosed by LUMC and the sponsor [CUSTOMIZE IF IT IS NECESSARY FOR PATIENT TO CONTINUE SEEING DOCTOR].

For your safety we may ask that you return to clinic one more time for [INSERT FOR WHAT]. We will also ask that you return any unused study medication. If you withdraw from the study, you will need to contact your physician(s) to discuss what other options may be available. [CUSTOMIZE IF IT IS NECESSARY FOR PATIENT TO CONTINUE SEEING DOCTOR].

If you withdraw from the study we will ask that you sign the form attached to this consent and send it to [INSERT PRINCIPAL INVESTIGATOR'S NAME] or give it to the study staff. Your withdrawal from the study will not have any affect on any actions by LUMC taken before the attached form is received by LUMC.

Your study doctor, the Institutional Review Board, the regulatory authorities, or [INSERT SPONSOR NAME] may terminate the study at any time with or without your consent. Your study doctor may choose to take you out of the study because of unexpected or serious side effects, treatment non-compliance or because you are not taking the medication as you were instructed. You may also be removed from the study if your study doctor feels that you are not benefiting from the study treatment [MODIFY AS NEEDED].

CONSENT

I have fully explained to _____ the nature and purpose of the above described procedure and the risks that are involved in its performance. I have answered and will answer all questions to the best of my ability. I may be reached at 708-216-[INSERT PRINCIPAL INVESTIGATOR'S NUMBER].

(Signature)

Date

_____, who is the principal investigators for this study, or [his/her] associates will be available to answer any questions you may have. _____ can be

Document ID#:
Version Date: 10/30/2006

reached at: 708-216-[INSERT PRINCIPAL INVESTIGATOR'S NUMBER].

If you ever feel that you have been injured by participating in this study or if you have any questions concerning your rights as a research participant, you may contact Dr. Kenneth Micetich, Chairman, Institutional Review Board for the Protection of Human Subjects-Medical Center (708-216-4608).

Although you have the right to revoke this authorization except that such revocation will not apply to any uses and disclosures of your information that are described in the Loyola University Health System Notice of Privacy Practices or otherwise allowable under any Federal or State laws.

You will receive a signed copy of this informed consent document.

You have been fully informed of the above-described research program with its possible benefits and risks. Your signature below indicates that you are willing to participate in this research study and agree to the use and disclosure of information about you as described above. You do not give up any of your legal rights by signing this consent document.

Date: _____
(Signature: Patient/Legal Representative)

Date: _____
(Signature: Witness)

[INSERT TITLE OF PROJECT]

**REVOCAION OF AUTHORIZATION TO RELEASE
PROTECTED HEALTH INFORMATION (PHI)**

I, _____, hereby revoke my consent to participate in the [INSERT STUDY NAME] at Loyola University Medical Center (“LUMC”). I also revoke my consent to release information I provided to LUMC that allowed LUMC to use and disclose my medical information to [INSERT SPONSOR, ETC.] as outlined on the consent form, which I signed on [INSERT DATE]. I understand that this revocation does not apply to any action LUMC has taken in reliance on the consent I signed earlier.

Patient Name or Personal Representative

Date

Please return this form to:

[INSERT PRINCIPAL INVESTIGATOR’S NAME]
Loyola University Medical Center
2160 South First Avenue
Maywood, Illinois 60153

Document ID#:
Version Date: 10/30/2006