

INFORMED CONSENT DOCUMENT
-For Investigational Drugs or Treatments- 1/18/07

The Informed Consent Document is only one step in the consent process. The consent document should explain all of the information that a reasonable person would want to know to decide about research participation.

It is required in the Code of Federal Regulations (45 CFR 46.116) and FDA Regulations (21 CFR 312.50) that the informed consent includes the following elements:

- a) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
- b) A description of any reasonably foreseeable risks or discomforts to the subject;
- c) A description of any benefits to the subject or to others which may reasonably be expected from the research;
- d) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- e) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- f) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- g) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
- h) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

When appropriate, one or more of the following elements of information shall also be provided to each subject:

- a) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
- b) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
- c) Any additional costs to the subject that may result from participation in the research;
- d) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

- e) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
- f) The approximate number of subjects involved in the study.

The following is an example of a consent format. All language is sample language. *Letters in Italic are instructions for the Investigator, please do not insert them in the Informed Consent Document.*

SAMPLE-INFORMED CONSENT

TITLE: _____

Comment [ORA1]: The study title must match on all the submitted documents (IRB Wise application, protocol, consent documents).

PROTOCOL NO.: _____

Comment [ORA2]: If applicable, add the study identification number assigned by the sponsor.

SPONSOR: _____

Comment [ORA3]: Provide the name(s) of the sponsor(s) of the study. If the study is not sponsored, state or otherwise explain that there is no sponsor.

INVESTIGATOR: _____

Comment [ORA4]: List the names and degrees of the PI and Co-PI in their respective affiliations (department and institution).

SITE(S): _____

Comment [ORA5]: Identify the site(s) where the study will be conducted. Include if there is a collaborating site.

STUDY-RELATED PHONE NUMBER(S): _____

This consent form may contain words that you do not understand. Please ask the study investigator or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

Comment [ORA6]: Standard required paragraph.

I-INTRODUCTION

You have been invited to participate in a research study. However, before you agree to take part in this study, please read this consent form carefully and ask as many questions as you need in order to be sure you understand the study procedures, including risks and benefits.

Comment [ORA7]: For studies that use the same informed consent document for both adult and pediatric subjects, the following text may be substituted for the first paragraph:

You, or your child, have been invited to participate in a research study. However, before you or your child agree to take part in this study...

II- PURPOSE OF THE STUDY

Briefly explain in lay terms the reason for doing this study.

Comment [ORA8]: For example: Disease Z is known to be caused by increased levels of a particular protein, called Y, in the bloodstream. Research in animals has shown that a new drug, called X, can lower the levels of the Y protein. This research study is being done to learn what effect 3 months of treatment with drug X will have on the levels of protein Y in the bloodstream of patients with Disease X.

Briefly identify the criteria to participate in the study.

An investigational drug is one that is not approved by the U.S. Food and Drug Administration (FDA).

Comment [ORA9]: If the study involves an investigational drug, include this statement.

III- STUDY PARTICIPANTS

Taking part in this study is completely voluntary. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

Who can take part in this study?

Comment [ORA10]: List important eligibility criteria in lay terms. Also include a discussion of important exclusion criteria, if applicable.

How many people (subjects) are expected to take part in this study?

Comment [ORA11]: Insert the total number of subjects you expect to enroll. If this is a multi-site study, include the total number over all sites as well as the number at the MSC. For example "300 subjects are expected to participate, 25 at the UPR Medical Sciences Campus and 275 at other sites around the United States". If the study includes different subject pools, note that also. For example: "100 total subjects (25 subjects with Alzheimer's disease and 75 healthy subjects)"

IV-PROCEDURES

What exactly will be done to me in this study? What kinds of research procedures will I receive if I agree to take part in this study?

How much of my time will be needed to take part in this study? When will my participation be over?

Comment [ORA12]: Describe in lay terms the experimental/investigational procedures. Standard medical procedures must be clearly distinguished from the experimental procedures.

V- RISKS AND DISCOMFORTS

Include information regarding risks of study drug, devices or procedures.

Include the possible known side effects and if applicable include that there may be side effects which are unknown at this time.

Drawing blood from your arm may cause pain, bruising, lightheadedness, and, on rare occasions, infection.

Comment [ORA13]: Describe time in hours, number of visits, amount of time each visit will entail. Include expectations for long term follow up, if applicable.

Include the risks of other procedures if needed, especially any invasive procedure.

Comment [OAI 14]: Please note that "none" or "not applicable" are not considered appropriate for this section, since even studies involving minimal risks do have foreseeable risks, such as discomfort or inconvenience.

Your [disease, condition, symptoms] may not get better or may become worse while you are in this study.

Comment [ORA15]: For studies collecting blood samples, include this paragraph.

Only you can take the study drug. It must be kept out of the reach of children and persons who may not be able to read or understand the label.

Comment [ORA16]: If a treatment study, include this paragraph:

If you become pregnant during this study there may be other risks to you and your unborn child that are not known. If you are female, and able to become pregnant, must use two (2) contraceptive methods, one should be an acceptable barrier method (diaphragm with spermicidal jelly, condoms, etc) through the study and for at least 4 weeks after you stop taking the study medication. No sexual intercourse is an acceptable method of birth control if you become pregnant during the course of the study, you must stop taking your study medication immediately, and contact your study doctor.

Comment [ORA17]: If the study drug is taken home, include this paragraph.

VI- BENEFITS

You may not receive any personal benefits from being in this study.

Comment [ORA18]: This is a required MSC pregnancy language for drugs studies. Other pregnancy language supplied by the sponsor might be used subject to IRB approval.

Comment [OAI 19]: This should always be the first sentence.

Your [disease, condition or symptoms] may improve as a result of your participation in this study. However, there is no guarantee of this.

Comment [OAI 20]: Specify

The information from this research study may lead to a better treatment in the future for people with [disease, condition, symptoms].

Comment [OAI 21]: Specify

VII- COSTS

*Specify if study drug will be provided by the sponsor.
Please specify if the participant or the insurance will be billed for anything.
Specify who will be responsible if the insurance doesn't pay.*

There are no charges for the study visits.

Comment [OAI 22]: If there are no charges include this sentence

VIII- COMPENSATION FOR PARTICIPATION

You will be paid \$_____ for each completed study visit to cover the transportation and meals expenses. If you do not complete the study, you will be paid for the visits you have completed.

Comment [OAI 23]: Include the amounts and conditions of payment. Investigators are advised that payments to subjects should be prorated, and the amount earned to date should be paid even when subjects withdraw from the study prematurely.

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

Comment [OAI 24]: If you are paying include this sentence.

IX-ALTERNATIVE TO PARTICIPATE

If you decide not to enter this study, there are other treatments available. These include [List of major drugs and/or therapies]. The study doctor will discuss these with you. You do not have to be in this study to be treated for [disease, condition, symptoms].

Comment [OAI 25]: If you are not paying include this sentence.

Comment [OAI 26]: Describe alternatives to participation (e.g. what is usually done to treat the condition or disease. If appropriate, consider informing subjects of alternative studies or by reference to a central source.

X- PRIVACY AND CONFIDENTIALITY

If you choose to be in this study, the investigator will get personal information about you. This may include information that might identify you. The investigator may also get information about your health including:

Comment [OAI 27]: Specify

[Select the ones that apply to your study]

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research about
 - HIV / AIDS
 - Hepatitis infection
 - Sexually transmitted diseases
 - Other reportable infectious diseases
 - Physical exams
 - Laboratory, x-ray, and other test results
 - Diaries and questionnaires

The diagnosis and treatment of a mental health condition

- Records about any study drug you received
- Records about the study device

Complete name and address of PI

The PI might give information about you and your health which might identify you to:

- The U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- The UPR Medical Sciences Campus Institutional Review Board (UPR MSC IRB)

[If necessary, add any institutional names above UPR-MS C IRB]

Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose. The records will be safeguarded as HIPAA regulations.

The information may be given to the FDA. It may also be given to governmental agencies in other countries. This is done so the sponsor can receive marketing approval for new products resulting from this research. The information may also be used to meet the reporting requirements of governmental agencies.

The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

The information may be reviewed by The UPR Medical Sciences Campus Institutional Review Board (UPR MSC IRB). UPR MSC IRB is a group of people who perform independent review of research as required by regulations.

Your personal health information will be kept as confidential as possible under the law. However, your personal health information may no longer be protected by the privacy rule once it is disclosed to our associates, and may be shared with others.

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel this authorization at any time by sending a written notice to the principal investigator at the following address:

[Principal Investigator's name]

[Mailing Address]

If you cancel this authorization, the principal investigator will no longer use or disclose your personal health information under the authorization for this study, unless he/she needs to use or disclose some of your personal health information to preserve the scientific integrity of the study. Information submitted before you cancel this authorization can still be used by the associates.

Comment [OAI 28]: If the study does not involve protected health information, and is not subject to HIPAA, and this statement does not otherwise apply, investigators may choose to edit or delete this sentence accordingly. Information in the bulleted section should be added or deleted as applicable to this study.

Comment [OAI 29]: If applicable

Comment [OAI 30]: Insert the name of the PI, addresses, and phone numbers.

The Authorization for Use and Disclosure of Protected Health Information for research purposes is completely voluntary. However, if you do not sign this document you will not be able to participate in this study. If in the future you cancel this authorization, you will not be able to continue participating in this study.

XI- COMPENSATION FOR INJURY

In the event of physical and/or mental injury resulting from this research study, you will receive medical treatment free of charge at the University Hospital or any other hospital designated by the Chancellor or the Medical Sciences Campus of the University of Puerto Rico. The University of Puerto Rico has no plans to provide any form of compensation directly to you. However, by signing this consent form you do not give up any legal rights.

Comment [OAI 31]: If the Medical Sciences Campus is responsible for compensation in case of injury, include this paragraph.

If you suffer a physical or mental injury as a result of receiving the study drug or any medical procedures required by the study, you will be reimbursed by the sponsor for reasonable and customary fees and medical expenses actually incurred to treat such injury, but only to the extent such fees and expenses are not paid by your health insurance or governmental coverage. You will not be offered any financial compensation from the University of Puerto Rico Medical Sciences Campus. Your health insurance may not pay costs of treating a research related injury. No other provision has been made for payments of any other forms of compensation for a research related injury, such as for lost wages, lost time, or discomfort. By signing this consent form you do not give up any legal rights.

Comment [OAI 32]: If the UPR MSC and the sponsor are responsible for the research participant and the sponsor will compensate the research participant in case of injury.

XII- VOLUNTARY PARTICIPATION AND WITHDRAWAL

FOR EXAMPLE:

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

If it is necessary your participation in this study may be stopped at any time by the investigator or the sponsor without your consent.

XIII- SOURCE OF FUNDING FOR THE STUDY

The study doctor is being paid by *[the sponsor] [or other wording, as appropriate]* to conduct this research.

XIV- QUESTIONS

FOR EXAMPLE:

If you have any questions about this study or your participation in this study, or if at any time you feel you have experienced a research-related injury or a reaction to the study medication, contact:

Investigator ____ at *[Phone]*

If you have questions about your rights as a research subject, you may contact:

Human Research Subjects Protection Office
University of Puerto Rico
Medical Sciences Campus
Telephone: 787-282-0018 or 787-282-0010
E-mail: opphi@rcm.upr.edu

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to be in this study, you will receive a signed and dated copy of this consent form with the stamp of IRB approval for your records.

XV- CONSENT

I have read the information in this consent form (or it has been read to me). All my questions about the study and my participation in it have been answered. I freely consent to be in this research study.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not given up any of my legal rights.

Subject Name

Signature of Subject

Date

Signature of Person Conducting Informed
Consent Discussion

Date

If applicable

Name of Father of Mother

Date

Signature of Father or Mother

Date

Signature of Legally Authorized Representative

Date

Authority of Subject's legally Authorized Representative or Relationship to Subject
(When applicable)

----- Use the following only if applicable -----

If this consent form (addendum) is read to the subject because the subject (or legally authorized representative) is unable to read the form, an impartial witness not affiliated with the research or investigator must be present for the consent and sign the following statement:

I confirm that the information in the consent form (addendum) and any other written information was accurately explained to, and apparently understood by, the subject (or the subject's legally authorized representative). The subject (or the subject's legally authorized representative) freely consented to be in the research study.

Signature of Impartial Witness

Date

Note: This signature block cannot be used for translations into another language. A translated consent form is necessary for enrolling subjects who do not speak English.