INFORMED CONSENT DOCUMENT

- For Investigational Drugs or Treatments –

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 knows to decide about research participation.
It is required in the Code of Federal Regulations (45 CFR46.116) and FDA Regulations (21CFR 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.*

MEDICAL SCIENCES CAMPUS
UNIVERSITY OF PUERTO RICO

INFORMED CONSENT DOCUMENT

TITLE:

PROTOCOL NO.:

SPONSOR:

INVESTIGATOR:

SITE(S):

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.

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.

II- PURPOSE OF THE STUDY

Briefly explain in lay terms the reason for doing this study.
Briefly identify the criteria to participate in the study.

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

Comment [MSOffice1]: Includes the title of the study (may be abbreviated) or # protocol officer and the page number format (Page # of #) on the header (header).

Comment [MSOffice2]: The study title must match on all the submitted documents (IRBWise application, protocol, consent documents) and should be in the same language as the rest of the content.

Comment [MSOffice3]: If applicable, add the study identification number assigned by the sponsor. If there no sponsor, you could include the official number of the Protocol (do not use the number beginning with "H").

Comment [MSOffice4]: 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.

Comment [MSOffice5]: List the names and degrees of the PI and Co-PI in their respective affiliations (department and institution).

Comment [MSOffice6]: Identify the site(s) where the study will be conducted. Include if there is a collaborating site.

Comment [MSOffice7]: Include the contact phone numbers and name.

Comment [MSOffice8]: Standard required paragraph.

Comment [MSOffice9]: For studies that use the same informed consent document for both adult and pediatric subjects, the following text may e substituted for the first paragraph:

Comment [MSOffice10]: 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…

Comment [MSOffice11]: 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 ... [1]

Comment [MSOffice12]: If the study involves an investigational drug, include this statement.

III- STUDY PARTICIPANTS

Who can take part in this study?
Include general criteria for eligibility and exclusion of participants.

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

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?

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.
Include the risks of other procedures if needed, especially any invasive procedure.
Your [disease, condition, symptoms] may not get better or may become worse while you are in this study.
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.

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 [MSOffice13]: List important eligibility criteria in lay terms. Also include a discussion of important exclusion criteria, if applicable.

Comment [MSOffice14]: 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)"

Comment [MSOffice15]: Describe in lay terms the experimental/investigational procedures. Standard medical procedures must be clearly distinguished from the experimental procedures.

Comment [MSOffice16]: Describe time in hours, number of visits, amount of time each visit will entail. Include expectations for long term follow up, if applicable.

Comment [MSOffice17]: 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.

Comment [MSOffice18]: For studies collecting blood samples, include this paragraph.

Comment [MSOffice19]: If a treatment study, include this paragraph:

Comment [MSOffice20]: If the study drug is taken home, include this paragraph.

Comment [MSOffice21]: This is a required MSC pregnancy language for drugs studies. Other pregnancy language supplied by the sponsor might be used subject to IRB approval.

VI- BENEFITS

You may not receive any personal benefits from being in this study.
Your [disease, condition or symptoms] may improve as a result of your participation in this study. However, there is no guarantee of this.

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

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.

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

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]*.

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:

[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

PLEASE LEAVE 2 INCHES AT THE BOTTOM MARGIN (STAMP IRB)

Comment [MSOffice22]: This should always be the first sentence.

Comment [MSOffice23]: Specify

Comment [MSOffice24]: Specify

Comment [MSOffice25]: If there are no charges include this sentence.

Comment [MSOffice26]: 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.

Comment [MSOffice27]: If you are paying include this sentence.

Comment [MSOffice28]: If you are not paying include this sentence.

Comment [MSOffice29]: 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.

Comment [MSOffice30]: Specify

Comment [MSOffice31]: 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.

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

[If necessary, add any institutional names above UPR-MSC 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

Comment [MSOffice32]: If applicable

Comment [MSOffice33]: Indicate where the information is going to be located (how, who).

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]

Comment [MSOffice34]: Insert the name of the PI, institutional addresses, and phone numbers. *In the case of studies for Master's or Doctoral degrees must include the name and contact information of the Preceptor.*

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.

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 change 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 [MSOffice35]: If the Medical Sciences Campus is responsible for compensation in case of injury, include this paragraph.

----------0----------

Comment [i36]: Determine which paragraph is applicable and do not include both

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

Comment [MSOffice37]: 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.

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.

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: 787-758-2525 Exts. 2510 to 2515
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).

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.

Page 3: [1] Comment [MSOffice11] **2/13/2012 1:37:00 PM**

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.