

RUSH UNIVERSITY MEDICAL CENTER

SUBJECT INFORMATION SHEET AND CONSENT DOCUMENT

INSTRUCTIONS FOR USING THIS TEMPLATE

A consent form is only one part of the informed consent process. This process involves providing the subject with all the information needed to make an informed decision regarding possible participation in a study.

Please remember the following important points:

- This consent form is a model and contains information and language required by the Rush Institutional Review Board (IRB).
- It is extremely important to use the simplest language possible.
- The current requirement for writing the consent document is for 6th to 8th grade reading comprehension.
- Medical or scientific terms must be explained in simple language.
- Do not use medical or technical jargon.
- Whenever possible, avoid the use of parentheses and complex sentences. It is better to use several short, simple sentences than one long complex one.
- Include page numbers and a version date on your final document.
- The use of Times New Roman font of at least 12 point size is strongly encouraged.

Please be sure to remove the instructions from the final version of the consent document. The instructions are **bolded** and bulleted for your convenience. If you need clarification, contact the Office of Research Affairs at 312-942-5498.

RUSH UNIVERSITY MEDICAL CENTER

Subject Information Sheet and Consent Document

Name of Principal Investigator:

Telephone number:

Addresses where the research will take place:

Title of Research Study:

INTRODUCTION

You are being invited to take part in a research study at Rush University Medical Center. This form provides you with information so you can understand the possible risks and benefits of participating in this study; so that you can decide whether or not you want to be a part of this research study.

Before deciding whether to participate in this study, you should read the information provided on this document and ask questions regarding this study. Once the study has been explained and you have had all your questions answered to your satisfaction, you will be asked to sign this form if you wish to participate. You are being invited to participate in this study because...

- **(explain succinctly and simply why the prospective subject is eligible to participate)**

PURPOSE OF THE STUDY

This study involves research. The purpose of the research is

- **Provide a description of the project.**
- **Provide a statement that explains how many subjects will be participating in the research, at the Rush site.**

RESPONSIBILITIES/ EXPECTATIONS AND PROCEDURES

- **Outline the responsibilities of the subject. These responsibilities must include:**
 - **the total duration of the subjects participation (for example, you will be asked to come to the clinic 3 times a week for 4 weeks, fill out a subject diary, etc.).**
- **Include a description of the procedures (for example, blood draws (list amount in teaspoons), electrocardiogram- electrical tracing of your heart, etc.) and**
 - **description of the different kinds of information that will be collected, (for example, personal, medical, etc.).**
- **Explain clearly and simply which procedures are considered standard of care and which are considered experimental.**

Tissue Repository/Storage of Tissue/blood sample for future testing

- **Suggested language:**

“As part of this study, researchers would like to do additional laboratory testing on your tissue/blood samples to find out as much as possible about **(insert disease, for example, cancer)** and how this treatment might affect the disease. This tissue will be stored by **(insert information, for example, the study sponsor)** in a repository. As a result of these activities, a financial gain may be derived by the study Sponsor, and Investigator. However, you will not receive any financial gain from these activities. Please indicate below if you will allow for your excess tissue/blood sample to be kept and used for future research purposes.” **(If these future research studies are known, they must be**

RUSH UNIVERSITY MEDICAL CENTER
Subject Information Sheet and Consent Document

listed in the consent). Also, be sure to indicate whether the samples can be withdrawn from the repository, or if the samples will be stored anonymously (and cannot be removed).

1. I agree to the use of my specimens for research and teaching purposes related to my disease.
___ Yes ___ No Initial _____
2. I agree to the use of my specimens for future genetic research.
___ Yes ___ No Initial _____
3. I agree to the use of my specimens for future research purposes unrelated to my disease.
___ Yes ___ No Initial _____

POTENTIAL RISKS AND DISCOMFORTS

- **Include a description of any reasonably foreseeable risks or discomforts, inconveniences, and how these will be managed.**
- **Studies involving investigational drugs/devices or new combinations of drugs must include a statement regarding the possibility of unforeseeable risks.**
- **List all known and/or expected foreseeable side effects linked to the procedure or drug in order from greatest to the least. Also include all discomforts associated with a particular treatment or therapy (for example, if drawing blood then the following language is suggested: “You may experience pain or discomfort, and/or bleeding, and bruising at the site the needle enters the body, and in rare cases, fainting or infection.”**
- **In addition to physiological risks/ discomforts, describe any psychological/ emotional or financial risks that might result from participating in the research.**
- **For studies that involve the risk of allergic reactions, the following language is suggested:**
There may be risk of allergy to one or more of the drugs used in this study. Signs of an allergic reaction may include redness, itching, swelling or (in rare cases) difficulty with breathing, and lightheadedness. Severe allergic reactions may result in death. If you feel that you are experiencing a severe allergic reaction, first seek treatment and then call **(insert appropriate contact)** at **(insert phone number)**, this number is available 24 hours a day.

PREGNANCY RISKS-if applicable (modify as needed).

Women

If you are pregnant or breastfeeding, you cannot take part in this study. A pregnancy test (**maybe/is**) required. You must use an effective birth control method such as birth control pills, barrier method, intrauterine device (IUD), hormone implants or surgical sterility while you are taking part in this study. Once you have completed treatment, you may discontinue birth control after **(insert amount of time. For example, 3 months after completion of treatment)**. If you become pregnant, you must notify the study doctor immediately.

Men

You must use effective birth control methods, such as the ones listed above. If you are a male and your female partner becomes pregnant, you must notify your study doctor immediately. Once you have completed treatment, you may discontinue birth control after **(insert amount of time. For example, 3 months after completion of treatment)**.

- **Make a statement if known problems have previously been reported or are suspected with study drug or class of drugs in pregnancy or breast-feeding.**

RUSH UNIVERSITY MEDICAL CENTER

Subject Information Sheet and Consent Document

- Make clear that if a pregnancy test is given, it is stated **when** it will be given.

POSSIBLE BENEFITS

There may be no direct benefit to you for participating in this study.

- **Provide a description of any and all benefits to the subject that may reasonably be expected from the research. Explain why the investigator/sponsor believe this to be true. In cases where no direct benefit is anticipated, explain what benefit may be gained and by whom.**
- **Also remember that being paid for their participation is not a benefit!**

ALTERNATIVES TO PARTICIPATION

Instead of participating in this study, you may choose another form of treatment such as:

- **List the possible alternatives to participation. If the subject can receive the same intervention without participating in the research, this fact must be stated.**
- **Also, if there are no alternatives currently available list the following statement: “The only alternative to participating in this study is not to participate.”**

NEW FINDINGS –delete if not applicable.

You will be informed if new information develops during the course of this study that may change your willingness to continue participation in this study. You should discuss further options with the study doctors at that time.

COST AND COMPENSATION

Required Text for treatment studies –delete this header once text is in place

All costs that are part of your usual medical care, such as **(state what these costs might be)** will be charged to you or your insurance company. You will be responsible for all costs that are not paid by your insurance company. You should check with your insurance company before you enroll in this research study.

- **Indicate what is provided free of charge by the study, for example, medications, X-rays, blood tests, device, study visits, etc.**
- **Clearly state and list what the financial burden (if any) there will be for the subject**
For example: There is no cost to you for the study drug - Brand X, 3 clinic visits on these dates, the MRI, or laboratory tests for pneumonia, nor will you have to pay for parking.
- **State whether the subject will be paid or offered other compensation (such as free baby-sitter, cab fare, parking or public transportation costs, etc.) for his/her participation in the study.**
- **State what the payment schedule will be. If the subject is expected to continue participation over time, the payment should be pro-rated (for example, you will receive bus fare for each visit or you will receive \$25.00 for filling out the questionnaire).**

Suggested language-Please omit if not applicable to your study:

(Insert Doctor’s name) is being paid by the sponsor of the study, (Insert Sponsor’s Name), to conduct this research study. This payment will be used to pay for the costs of the study, which may include such things as tests, medications, physical exams, etc. Also, a portion of the money will be given to Rush University Medical Center. One example of what this payment will cover would be the cost of rent for office space within the medical center.

RUSH UNIVERSITY MEDICAL CENTER
Subject Information Sheet and Consent Document

VOLUNTARY PARTICIPATION

Participation in this research study is voluntary. There is no penalty if you decide not to take part in this study. You will not be penalized if you decide to stop participating in this research study.

RESEARCH RELATED INJURIES

If the sponsor provides any coverage for these costs, amend this paragraph appropriately:

If you experience any injury or illness as a direct result of your participation in this research study, immediate treatment will be provided. However, the cost of that treatment will be billed to your insurance company. Your insurance company may not pay.

Note: The following language must be stated in the consent form-DO NOT DELETE:

“Rush University Medical Center has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study.”

Note: It is also recommended that the Investigator use the statement above when referring to the sponsor, for example: "Novartis has no program for financial compensation for..."

TERMINATION/WITHDRAWAL-delete if not applicable.

You may be removed from this study without your consent for any of the following reasons: the study doctor decides that continued participation in the study will be harmful to you, you will need a treatment not allowed on the study, your disease becomes worse, you are unable to take the treatment as indicated, or the study is canceled.

CONFIDENTIALITY

Records of participation in this research project will be maintained and kept confidential as required by law.

- **(State the methods that will be used, for example, coded names or identification numbers, removal of all identifying information, etc. If the study is sponsored, name the sponsor and explain the sponsor’s access to the study files. Include access by regulatory bodies such as the FDA and the NIH.)**

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews human research to check that the rules and regulations are followed. Your identity will not be revealed on any report, publication, or at scientific meetings.

QUESTIONS

Questions are encouraged. If there are any questions about this research project or suffer a research related injury, please contact: **[Investigator’s name, area code and phone number]**. Questions about the rights of research subjects may be addressed to the Rush Office of Research Affairs at 312-942-5498.

By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study personnel. You do not waive any of your legal rights by signing this consent document. You will be given a copy of the signed and dated consent form for your records.

RUSH UNIVERSITY MEDICAL CENTER
Subject Information Sheet and Consent Document

Signature of Subject Date

Minor Assent - *delete if not enrolling minor subjects* Date

Parent or Legal Guardian's Signature- *Delete if not needed for this study* Date

I observed the signing of this consent document.

Witness to Signature Date

Signature of Principal Investigator or Individual Obtaining Consent Date