

INFORMED CONSENT (SAMPLE FORM)**TO: PARTICIPANTS IN THIS STUDY:****1. Introductory Statement**

The following information will describe the study and your role as a participant. The investigator will answer any questions you may have about this form and about the study. Please read carefully and do not hesitate to ask anything about the information provided below.

2. Purpose of the Study

_____ is a (disease, condition, syndrome) which causes _____ (or) results in _____.

The purpose of this study is to determine if _____ (name of drug) (an investigational drug) (a marketed drug being tested for a new use) is safe and effective in the (cure, mitigation, or treatment) of this disease or condition. (Describe any other purpose for which the drug is being studied.)

3. Procedures to be Followed

After your medical history and a complete physical examination are taken, you will receive either the drug or placebo. During the course of the study you will be administered _____ (quantity) of the drug or (active control drug, placebo) at _____ (state intervals). In addition, you will have (blood drawn, X-rays taken, urine samples taken, blood pressure taken, etc.) at _____ (state intervals). You will be asked to make _____ visits to the (hospital) (clinic). You may be requested to remain at the (hospital) (clinic) (laboratory) for a period of time during or following the study.

4. Prior Experience With Drug

This drug has been tested in approximately _____ (animals) (humans). The results of this study are _____. (or) This is the first study. The number of participants involved is approximately _____.

5. Discomforts and Risks

Certain side effects and discomforts associated with the drug may occur. Some of the side effects and discomforts reported are _____. (List should be in lay language.) There may also be side effects and discomforts which are not yet known. In addition, there may be some discomfort from the procedures including _____ (e.g., slight pain associated with venipuncture and bruises).

6. Alternatives

The following other drugs or procedures are available as alternatives to the drug which is now being studied: _____.

7. Exclusions

If you are any one of the following, you should not participate in this study: (e.g., pregnant or nursing women, persons allergic to compound, persons with history of heart attacks, etc.)

8. Benefit to Participants

If the test drugs are effective, you may benefit by _____.

It is possible, however, that no therapeutic or other direct health benefits may result during or following completion of this study.

9. Payment for Participation in Study (if Applicable)

You will be paid for participation in this study as follows _____. (Amount and terms should be described.)

10. Compensation for Medical Treatment

(Compensation, if any, provided by Investigator/Hospital.) If you suffer any adverse drug experience resulting directly from the Merck study drug, Merck & Co., Inc., will provide reimbursement for the reasonable costs of medical treatment to the extent such costs are not covered by your medical or hospital insurance or by third-party or governmental programs providing such coverage. No other form of compensation is available.

11. Confidentiality

Unless required by law, only the investigator, the sponsor, Merck & Co., Inc., and government regulatory agencies will have access to confidential data which identifies you by name. You will not be identified in any reports or publications resulting from the study.

12. New Findings

You will be told of any significant new findings developed during the course of this study which may relate to your willingness to continue your participation.

13. Parties to Contact

The investigator or his designate has answered all your questions. If you have additional questions during the course of this study about the research or your rights as a research subject, you may address them to _____ at _____. In the event of a research-related injury or if any other problems arise, please contact (insert investigator's name) at (investigator's phone number).

14. Voluntary Participation

Your participation in this study is voluntary. You may refuse to participate or may discontinue participation at any time during the entire duration of the study without penalty or loss of benefits to which you are otherwise entitled. If you terminate your participation, you may receive a standard medication and no prejudice will be shown toward you for medical care or participation in future research studies. In addition, your participation may be terminated by the investigator or the sponsor without regard to your consent if you need additional medication, violate the study plan, experience a study-related injury or for administrative reasons. Any time your participation is terminated you shall go through the termination procedures--physical, blood and urine tests, etc., for your own safety.

I have read and understand this consent form. My questions have been answered. I voluntarily consent to participate.

(Signature of Volunteer)

(Date)