CONSENT FORM
(sample)

TITLE

YOU ARE INVITED TO PARTICIPATE IN A RESEARCH STUDY TO EVALUATE IF AN INVESTIGATIONAL DRUG ( ) IS SAFE AND EFFECTIVE FOR THE TREATMENT OF ( ). AN INVESTIGATIONAL MEDICATION MEANS THAT THE DRUG HAS NOT YET BEEN APPROVED BY THE FOOD AND DRUG ADMINISTRATION (FDA) FOR COMMERCIAL USE AND IS AVAILABLE ONLY FOR RESEARCH. PARTICIPATION IS ENTIRELY VOLUNTARY. IF YOU CHOOSE NOT TO PARTICIPATE OR WITHDRAW AT A LATER TIME, THIS WILL IN NO WAY JEOPARDIZE THE QUALITY OF CARE YOU RECEIVE.

Why have you been selected?

You have been selected to participate in the study because .........

What is the purpose of this study?

The purpose of this research study is to evaluate the safety and effectiveness of three different doses of ( ) when compared to placebo (a tablet containing no active medication) in outpatients with ( ).

What does the study consist of?

This study will be about (#) weeks long and will require (#) clinic visits. Before you enter the study, screening procedures will be performed to determine your eligibility to participate. You will have a complete physical examination, a medical history, an electrocardiogram (also known as an ECG, a painless heart tracing on paper), and a number of psychological tests for anxiety. In addition, blood (# of tablespoons or ounces) will be drawn for laboratory tests and a pregnancy test, if appropriate.

If eligible, you will be randomly assigned (like flipping a coin) to receive one of (#) doses of the drug, ( ), or placebo for the duration of the study. The study medication will be taken twice each day and neither you nor your doctor will know which medication you are receiving. However, this information is immediately available should it be needed in an emergency.

At each visit, you will have a brief physical exam and blood work (volume in lay terms). At visit (#), a physical exam, an ECG, and psychological tests will be repeated.

Are there any benefits to me?

If the treatment is effective, you may experience some relief of your symptoms of ( ). It is possible, however, that no therapeutics or other direct health benefit may result from your participation. If you are assigned to receive placebo, you would not be expected to benefit. At the end of the study, ($ . . .) will be offered for each completed clinic visit as reimbursement for your travel expenses.
Are there any side effects or risks involved?

The most common side effects that occur with the drug ( ) include sleepiness, unsteady walking (gait), poor coordination, lack of concentration, sleep disturbance, and dizziness. Other possible side effects include nausea, dry mouth, headache, restlessness, visual disturbance, changes in blood pressure, and elevations in liver enzyme levels. It is possible that other unknown or unforeseen side effects, including allergic reactions, could occur. Blood drawing may be associated with discomfort (stinging), a slight bruising where the needle is inserted into your vein and the remote chance of infection.

Will compensation be made for any injury from this research?

In the event that injury occurs as a result of this research, the University of Wisconsin would not automatically provide reimbursement for medical care or offer other compensation. In the event of such an injury or for more information, please contact the investigator in charge, (name), at (608)(#). For further information on patient rights, please call the hospital patient representative at (608) 263-8009.

Are there other costs involved?

The study medication and all tests and examinations required as part of this study will be provided at no cost to you. All other routine costs associated with your continuing care will be your responsibility.

Are there other treatments available to me if I do not participate in this study?

Should you decide not to participate, there are other FDA approved medications to treat your symptoms. These include . . . .

Who will receive the results from this research?

All research records will remain confidential. However, representatives from the study sponsor and the FDA may inspect your medical records and the information collected during the study. The results of these studies may also be used for medical and scientific publications, but you will not be identified personally.

If you change your mind

Take as much time as you need to think this over. Before signing this form, please ask questions on any aspect of this study that remains unclear. We will attempt to fully answer any questions you may have prior to, during, or following the study.
AUTHORIZATION

I have read the information in this consent, reviewed my questions with my physician, and I voluntarily agree to participate in this study. I have received a copy of the entire document.

__________________________________________  ______________
Signature of Patient                          Date

__________________________________________  ______________
Signature of Investigator                     Date

__________________________________________  ______________
Signature of Witness                          Date
the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.

§ 46.115 IRB records.

(a) An institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects

(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities

(4) Copies of all correspondences between the IRB and the investigators.

(5) A list of IRB members in the same detail as described in § 46.103(b)(3).

(b) Written procedures for the IRB in the same detail as described in § 46.103(b)(4) and § 46.103(b)(5).

(c) Statements of significant new findings provided to subjects, as required by § 46.116(b)(5).

The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner.

(Approved by the Office of Management and Budget under control number 9899-0020)

§ 46.116 General requirements for informed consent.

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understood by the subject or the representative.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) 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;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) 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;

(6) The approximate number of subjects involved in the study.

(b) Consent procedure. An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, if the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:

(a) Public benefit of service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) The research could not practically be carried out without the waiver or alteration.

(c) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practically be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(d) Documentation. The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional pertinent information to be disclosed in order for informed consent to be legally effective.

(e) The requirement in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

(Approved by the Office of Management and Budget under control number 9899-0020)

§ 46.117 Documentation of informed consent.

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.