IRB FORM 6

Consent Form Template

Consent To Take Part In a Research Study

[All items not bracketed must be included in consent]

1.**Subject Name**: _____

2. **Title of Research**: *[Must be identical to protocol]*

3. **Purpose of Research**:

You are being asked to take part in a research study. The purpose of this study is to find out if----------

[Remember to use lay language and explain unavoidable technical language. Make sure this tracks throughout the protocol. Be sure to avoid any implied pressures or coercive statement.]

[Indicate why participant has been asked to take part. Include the approximate number of subjects expected to be enrolled in this study.]

[It is important for the participant to know why they are in the study (even if only as a control) and why their participation may end. Also important is a listing of the exclusion criteria about which the patient would have knowledge from the study. This should be clearly indicated. You should also discuss possible prior treatment or medication which may affect the participant's risks or benefits of taking part in the study. They must know that they may choose not to be part of the study or may withdraw when they wish. They should also know what conduct or circumstances may end their participation in the study and any resulting loss or changes in treatment.]

4. **Procedures and Duration:**

You understand that the following things will be done to you. (Experimental procedures are underlined) [OR] You understand that all of the following things that will be done to you are experimental. (Don't underline)

[The subject's participation should be described in detail, underline any experimental procedures (unless all are experimental) and include at least the following:

- types of procedures, the number of each procedure, individual and cumulative durations, up to years of treatment, if appropriate: time and effort requirements for the patients, in terms of visits, their duration and frequency (a chart or graph may be helpful if the treatment protocol is particularly difficult to describe in words only. This chart may be an appendix to the consent form).
- whether hospitalization will be involved, or if an extension of hospitalization will be caused by participation in this study.
- What the participant will experience during the study, particularly indicating whether more invasive procedures (such as biopsies, endoscopies, intra arterial placements or the like) are principally research procedures or whether these procedures are clinically indicated, complemented by research procedures. Include number of blood draws and how much in tsp.]

5. **Risks and Discomforts/Constraints**

[List all potential risks and discomforts and their frequency and maximum possible severity. Refer to your protocol and make sure that the consent form is consistent with the protocol.

- Risks should include any risks of radiation, other minor procedures which may be part of the study, side effects or other unknown effects of a drug, particularly if the drug is investigational. (If possible relate such risks to interventions about which the risks are more commonly known like chest x-ray, aspirin, etc.).

- Discomforts may include physical or mental discomfort, such as those of venipuncture, of answering personal questions, of remaining in the same position for a long time, or the like.

- In discussing probability, try not to use odds such as "one in a thousand."

- Include risks from washout periods or placebo arms or risks of discontinuing current medications.

- Indicate if the participant's regular activities may be affected by participation in the study. For example, if a drug may promote drowsiness, or may react with alcohol, the participant should be advised of these risks. More minor changes of daily routine, such as the timing of meals or sleep should also be discussed even if these are only inconveniences.

- Include precautions to minimize risks or to protect subjects from adverse events. This must be presented in a balanced way.]

6. **PREGNANCY WAIVER SECTION (Titled on Consent)**

*[Include this section **only if** there are risks known or unknown of physical or genetic damage to a fetus or to the genes of a fetus. Wording may be modified to meet more stringent/requirement of sponsors or if only one gender participates.]*

"We do not know what impact this drug will have on your fertility (your ability to conceive a child or impregnate a female). We also do not know what effect this drug will have on a pregnancy. We recommend that you use effective birth control throughout the course of this study and for _____ months after. If female, you should avoid getting pregnant. If you are now pregnant, you should not enter this study. If you become pregnant while in the study, you must inform the doctors conducting the research. If male, you should avoid impregnating a female."

_____

Subject Signature Date

[It is anticipated that this wording would apply to most phase III and late phase II studies in which women can be enrolled after baseline animal fertility studies have been completed. It may also be applied to earlier studies if appropriate.]

7. **BENEFITS**

[Begin this section by stating there may be no benefits. Indicate possible benefits to the participant, if any including no benefits or condition may worsen by taking part in this study, if appropriate.

Benefits should be discussed in conservative terms in order to avoid undue expectations or coercion of the participant. If a drug is investigational and a therapeutic benefit is experienced, discuss whether treatment may continue after the end of the study, or whether a relapse or loss of benefit impossible during or after withdrawal.]

8. **ALTERNATIVE PROCEDURES/TREATMENTS**

[Describe other procedures or courses of treatment which are available to the participant in place of this one. This should include current therapies as well as the option not to participate if there are no alternatives.]

9. **REASONS FOR REMOVAL FROM STUDY**

You may be required to stop the study before the end for any of the following reasons:

a. Change in your medical condition;
b. If all or part of the study is discontinued for any reason by the sponsor or government ` agencies; or
c. Other reasons, including new information available to the investigator or harmful reactions experienced by others in this study.

[Indicate any resulting changes in treatment including necessity of weaning from drug/treatment, or other effects that the participant may experience in case of removal/withdrawal. This section may be deleted if the participation in this study is a one time event as so indicated in the section on procedures and durations. This should also be reinforced with participant with the signing of the consent agreement.]

10. **VOLUNTARY PARTICIPATION**

[Include paragraph (a) for patients or (b) for volunteers.]

a. Patients: "You understand that being in this study is voluntary. Your health care will not be affected in any way if you decline to be in or later withdraw from this study."

b. Subjects: "Participation in this study is voluntary, and you can refuse to be in the study or stop at any time without loss of the health care benefits to which you are entitled if you should suffer an injury as a result of this trial. Any fee you may be paid will be determined by the amount of time you spend in the trial and, if you do not complete the trial, the reason for leaving the study early."

[In the event that an individual requires treatment in order to withdraw from the study, e.g., weaning from a drug, this should be set forth with specificity in this paragraph.]

11. **RESPONSIBILITY FOR COST**

[Include who is responsible for costs of any treatment/procedures, especially if incurred by participant as opposed to the sponsor or third party payers.]

12. **STIPEND/REIMBURSEMEN**T (include only if appropriate)

[Include any monies a participant will receive and conditions related to payment.]

13. **IN CASE OF INJURY**

Except for studies involving only non-sensitive questionnaires, include the most appropriate of the following three paragraphs:

A. Sponsored Study, where the sponsor agrees to pay for care :

TREATMENT FOR INJURY. You have been told that if you have any questions or believe you have been injured in any way by being in this research project, you should contact Dr._____ at telephone _____. If you are injured by this research activity, which includes only those things that are being done to you which are

underlined in paragraph 4 above, [sponsor's name] will pay for your hospital care, if needed, and all related medical expenses. This agreement to provide free treatment does not include treatment for any complication or illness that might occur during the course of the study if that complication or illness is not a result of the research activity. No other payment will be made. If you are injured or have an adverse reaction, you should also contact the Institutional Review Board at the Ponce School of Medicine, telephone (787) 840-2575 Ext. 2158.

B. Studies Involved Critical/Terminally Ill Patients:

TREATMENT FOR INJURY. You have been told that if you have any questions or believe you have been injured in any way by being in this research project, you should contact Dr. __ __ _ __ ____ _____ __ __ __ at telephone _____. However, neither the Investigator nor Ponce School of Medicine will make any payment for injury, illness or other loss resulting from your being in this research project. If you are injured by this research activity, medical care including hospitalization is available, but may result in costs to you or your health insurance because the School does not agree to pay for each costs. If you are injured or have an adverse reaction, you should also contact the Institutional Review Board at the Ponce School of Medicine, telephone (787) 840-2575.

C. All Others:

TREATMENT FOR INJURY. You have been told that if you have any questions or believe you have been injured in any way by being in this research project, you should contact Dr. _____ at telephone _____ ___ _____. If you are injured by this research activity, which included only those things that are being done to you which are underlined in paragraph 4 above, you can obtain treatment at no cost to you, but only at one of the hospitals affiliated with the Ponce School of Medicine. This agreement to provide free treatment does not include treatment for any complication or illness that might occur during the course of the study if that complication or illness is not a result of the research activity. No other payment will be made. If you are injured or have an adverse reaction, you should also contact the Institutional Review Board at the Ponce School of Medicine, telephone (787) 840-2575.

[Exclude this language if treatment is not being provided, as in a questionnaire study.]

14. **CONFIDENTIALITY**

All data obtained in this study will be kept confidential. In any publication or presentation of research results your identity will be kept confidential but there is a possibility that records which identify you may be inspected by authorized individuals such as representatives of the Food and Drug Administration, the sponsor _____, the Ponce School of Medicine or employees conducting peer review activities. I consent to such inspections and to the copying of excerpts from my records, if required by any of these representatives.

[If applicable, explain that confidentiality may need to be broken because of legal reporting requirements if research disclosures reportable events such as infectious disease identification, presence of abuse, etc.]

15. **OTHER CONSIDERATIONS**

If new information becomes known that will affect you or might change your decision to be in this study, you will be informed by the investigator. If you have any questions at any time about this study or your rights as a research subject you may contact the Institutional Review Board at the Ponce School of Medicine, telephone (787) 840-2575 Ext. 2158.

16. **CERTIFICATION**

[If your sponsor request a section outlining inclusion and exclusion criteria, include only items of which the subject will have reasonable knowledge.

17. **CONSENT**

[This consent section, signatures section and list of individuals authorized to obtain consent should all be on one page.]

* I have been informed of the reason for this study.
* I have had the study explained to me.
* I have had all of my questions answered.
* I have carefully read this consent form, have initialed each page, and have received a signed copy.
* I give consent voluntarily.

_____ _____

Participant/Authorized Representative Date Relationship, if applicable

_____ _____

Investigator or Individual obtaining this consent# Date

_____ _____

Witness to Signature Date

List of Individuals Authorized to Obtain Consent

Name	Title	Day Phone	24 hour Phone