

Elements of Informed Consent

In seeking informed consent, the following information shall be provided to each subject. Please understand that these are suggestions formed by the Mercy IRC. This particular wording is not required but the content of each paragraph should have the same meaning.

1. 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.

Suggested: *"It has been explained to me that I have DIAGNOSIS. I have been invited to participate in this research study. This study involves treatment with NAME OF INVESTIGATIONAL DRUG OR PROCEDURE. The purpose of this study is to GIVE PURPOSE."*

2. A description of any reasonably foreseeable risks or discomforts to the subject.

Suggested: *Describe any reasonably foreseeable risks and discomforts to the subject with an assessment of the probability and seriousness of the risks. Please bullet out each risk making it easier for the patient to read them.*

3. A description of any benefits to the subject or to others which may reasonably be expected from the research

Suggested: *Describe any reasonably foreseeable benefit that the subject may have. Also list any benefit to the community or other subjects with the same diagnosis. List at least one benefit and bullet each benefit out if there are multiple benefits.*

4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

Suggested: *"You should be aware that there are alternatives to participation in this research study for the treatment of DIAGNOSIS. These include LIST OF ALTERNATIVES."*

5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records.

Suggested: *"Study records that identify you will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Except as otherwise addressed in this consent, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of NAME OF PRACTICE. For records disclosed outside of NAME OF PRACTICE you will be assigned a unique code number. The key to the code will be kept at NAME OF PRACTICE. Your information may be disclosed to persons associated with the following entities:*

- *Governmental agencies that have the right to see or review your health information, such as the Office of Human research protections and the Food and Drug Administration.*
- *Other institutions that are participating in the Study.*
- *The sponsor of the study and organizations that the sponsor may contract with.*
- *The Data Safety Monitoring Board.*

6. 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.

Suggested: “If you suffer any injury as a direct result of the proper use of NAME OF STUDY DRUG/DEVICE or the direct result of properly performed study procedures, and you have followed the investigator’s instructions, the sponsor will reimburse you for reasonable medical expenses incurred for treatments that are not covered by existing healthcare programs or insurance. No other forms of reimbursement will be available. By signing this consent you do not waive any rights you may have as a research participant.”

7. An explanation of whom to contact for answers to pertinent questions about the research and research subject’s rights, and whom to contact in the event of a research-related injury to the subject

Suggested: “If you have any questions or concerns about this clinical study, or if you develop an injury related to this study you should contact NAME OF PRIMARY INVESTIGATOR at 24-HOUR PHONE NUMBER.

If you have any questions or concerns regarding your rights as a research subject, you may contact the Mercy Medical center – Des Moines Institutional Review Committee and the Chair of the Committee, Dr. Prasad Palakurthy at (515) 247-3041.

If you have questions about the privacy or confidentiality of your medical information, you can call the Privacy Officer of Mercy medical Center at (515) 643-4557.”

8. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Suggested: “You may choose not to be in the study, or if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes. All data that have already been collected for study purposes will be sent to the study sponsor.

You or your legally authorized representative will be informed in a timely manner if new information becomes available that may affect your willingness to continue participation in this study.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at NAME OF PRACTICE.”

9. A statement that the particular treatment or procedure may involve risks to the subject’s embryo or fetus.
– Pregnancy Clause – please separate out under the “Risks and Discomfort” section.

Suggested: “This study may be hazardous to an unborn or nursing child. There is insufficient medical information available to determine whether there are significant risks to a nursing infant or to a fetus carried by a mother who is enrolled in this study. Therefore, appropriate methods to avoid pregnancy must be used by all participants or their sexual partners while participating in this study. Nursing mothers must discontinue nursing.

Women of child bearing age have the right to a pregnancy test prior to participating in this study. This requires that blood be drawn by venipuncture prior to the beginning of your participation. The risks involved with venipuncture are, but not limited to: bruising, swelling and skin irritation.”

10. Anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent.

Suggested: *“Your doctor may withdraw you from this study without your consent if:*

- *If the treatment is not effective*
- *If you have a bad side effect*
- *If the study is cancelled by the sponsor*
- *If the study is cancelled by the FDA*
- *For any other reasons that are in your best interest”*

11. Any additional costs to the subject that may result from participation in research.

12. The approximate number of subjects to be enrolled into the study both study wide and locally and the amount of time for the subject’s participation

Suggested: There will be approximately # OF SUBJECTS subjects enrolled in this study at a maximum of NUMBER OF SITES locations. The duration of your participation in this study including follow-up will be approximately AMOUNT OF MONTHS/YEARS.

13. Signature Clause

Suggested:

- I understand that I can refuse to participate in this research project.
- I understand that I can withdraw my consent and discontinue participation in the project at any time without penalty or loss of benefits to which I am otherwise entitled.
- My refusal will not affect my relationship to the institution involved in this research project.
- My signature below indicates that all of my questions have been answered to my satisfaction and in a language that I understand.
- I agree to participate in the project as described above.
- I agree to authorization of copying medical records for this trial.
- I understand that I will be given a signed copy of this form for my personal records.
- I understand that I am not waiving any of my legal rights.

Signature of Subject

Date Signed

Printed Name of Subject