

(Please leave this area blank)

WakeMed Health & Hospital Systems

CONSENT TO PARTICIPATE IN A CLINICAL STUDY

Title:

Principal Investigator: <Name>
<Address>
<Telephone Number>

Co-Investigator(s): <Name>
<Address>
<Telephone Number>

Faculty Sponsor: <Name>
<Address>
<Telephone Number>

Clinical Coordinator: <Name>
<Address>
<Phone Number>

Instructions: In order to review your proposal, the WakeMed Institutional Review Board must have all the following information, unless a heading does not apply. Each topic must be titled using the **boldface headings** listed below. Address each topic independently in the sequence listed without reliance on information covered under other headings. Define all abbreviations and terms not part of common language and use simple, straightforward sentences directed toward an eighth-grade reading level.

PURPOSE OF RESEARCH:

What are the specific scientific objectives (aims) of the research? Clarify for subject whether or not this study is for an investigational device or drug.

Include background and identify information that the research is intended to fill. Describe any previous work human studies that provide a basis for the proposed research and that would support the expectation of obtaining useful results without undue risk to human subjects.

(Include how many study subjects you estimate will be participating nationally and at WakeMed.)

TESTING AND EXAMINATION:

TREATMENT:

Describe the study design and all procedures that subjects will undergo. Identify all procedures that are considered experimental and/or procedures that will be exclusively for research purposes (i.e., research medications, to be administered and method, dose and frequency, post-treatment follow-up, diary card, questionnaires). Also include any additional diagnostic/follow-up tests that will be performed.

(Include the following statement:)

Those tests that are only part of the study protocol may be performed and interpreted at another facility and those results may not become part of your WakeMed records. Your study records may be available to you through your Principal Investigator.

DURATION OF STUDY PARTICIPATION:

Expected duration of subject's participation.

INCLUSION CRITERIA: (Include all listed in study protocol in simple words.)

Begin with the following statement:

You will be eligible to participate in the study if you meet all of the following criteria:

Include the following statements, when applicable:

Women of childbearing potential: *If you are female of childbearing potential, you must use reliable methods of birth control; for example: oral or barrier method contraceptives, birth control pills, intrauterine device (IUD), condoms, and/or diaphragm, if applicable.*

Women of non-childbearing potential: *If you have been surgically sterilized or are a minimum of one (1) year post-menopause, you can participate in the study.*

EXCLUSION CRITERIA: (Include all listed in study protocol in simple words.)

Begin with the following statement:

You will not be able to participate in the study if you meet any of the following criteria:

RISKS/DISCOMFORTS/SIDE EFFECTS: (Include all listed in study protocol.)

Describe all reasonably foreseeable risks and discomforts to the subject. If this is a medication study, include all side effects that have been reported for each medication involved in the study.

Include statement that some risks may be unforeseeable.

For studies that include blood draws, include the statement that the following could occur: localized bleeding, pain, bruising, infection, and/or dizziness or fainting while having blood drawn.

BENEFITS FROM PARTICIPATING IN THE STUDY:

Describe any benefits to the subject or others that may reasonably be expected from the research.

Note: The FDA does not consider it a "benefit" to the subject that the study drug/device is being provided free-of-charge.

ALTERNATIVE THERAPIES/TREATMENTS:

Disclose appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subject. If none, so state.

(If the subject chooses to use one of the alternatives mentioned, information should be available for the subject.)

NEW INFORMATION:

A statement that any significant new findings developed during the course of the research which may relate to the subjects willingness to continue participation will be provided to the subject.

FINANCIAL COSTS OF THE STUDY:

Any additional costs to the subject that may result from participation in the research; i.e., what will the subject have to pay for; what will the study sponsor pay for; what will the subject's insurance company be billed for.

Include the following statement:

*Any medical care determined to be necessary and usual by your physician for the treatment of your diagnosis not covered by this study will be billed to you or your insurance carrier. Some insurance carriers and/or third-party reimbursement mechanisms may not pay for participation in research studies that use investigational drugs (**use the word "devices" when applicable**). If you are unsure what your insurance covers, you may want to call your insurance carrier.*

COMMERCIALIZATION AND CONFLICT OF INTEREST:

Disclose any Significant Financial Interest: anything of monetary value from a business entity including salary, payment for services, consulting fee, honoraria, equity ownership (stocks, options, notes, etc.) and royalty-bearing intellectual property rights (patents, copyrights, trademarks). If none, so state.

The research consent form should briefly describe any apparent, actual or potential conflict of interest on the part of the Principal Investigator, co-investigators, facility sponsors, clinical coordinators, their institutions or study sponsors and any possibility of commercialization of the research findings. If none, so state.

PAYMENTS TO STUDY PARTICIPANTS:

Detail any payments made to the subject for participating in the study. Include when and how the payments will be made. If no payments will be made, so state.

IF YOU SEEK CARE FROM ANOTHER PHYSICIAN:

Include the following statement:

If you seek care from another healthcare provider or facility during your study participation, you should inform the other caretaker of your study participation and give them a copy of this informed consent.

VOLUNTARY PARTICIPATION:

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.

Suggestion: You hereby freely and voluntarily consent to participate in the study described above. This consent is given based on verbal and written information provided to you and on the understanding that you are medically and physically qualified to participate in this study. You understand that you do not have to participate in this study and that choosing not to participate will not affect your current or future medical care by your physician or this institution.

RIGHT TO WITHDRAW FROM STUDY:

A statement that subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. Also include any anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to subject's consent.

Suggestion: You acknowledge that your participation is voluntary and you have been told that you are able to withdraw your consent and authorization to stop your participation in this study at any time. If you do withdraw, it will not affect your current or future medical care by your physician or this institution. You understand that your participation in this study may be terminated without your consent if (list reasons here).

Include the following statement: You can revoke (take back) your consent by a written notice sent to the Principal Investigator (include address) at any time but you will no longer be entitled to participate in this study.

CONFIDENTIALITY:

A statement describing extent to which confidentiality of records identifying the subject will be maintained. A statement that acknowledges the possibility that various entities (including the FDA) may inspect the records.

Include the following statement:

You authorize your protected health information to be used and disclosed in accordance with the study protocol. Your identifying information (e.g. name, address, social security number, date of birth) will not be revealed in reports or publications resulting from this study without your expressed consent. WakeMed and/or the Principal Investigator for this study will allow monitors from the Food and Drug Administration (FDA), the study sponsor (identify the study sponsor), members of the Institutional Review Board (IRB) at WakeMed, and the Office for Human Research Protections in the U.S. Department of Health and Human Services to review your medical records (which include identifying information) created and maintained in conjunction with the research study when appropriate and necessary. These entities will treat such information as confidential; however, absolute confidentiality cannot be guaranteed. Medical records created after the end of the research study or after you revoke this authorization will not be used or disclosed without your expressed consent except when required by state or federal law.

Include statements clarifying where subject data will be stored and for how long; how subject data will be protected and who will have access.

If audio an/or videotaping will occur, include a statement about what safeguards will be taken to ensure confidentiality.

COMPENSATION IN CASE OF INJURY:

Clearly state whether any compensation and/or medical treatments will be available if a research-related injury occurs and who will be responsible (i.e., if financial compensation will be provided by the study sponsor). When applicable, explain financial compensation provided by the study sponsor.

Include the following statement:

You have been informed that should you suffer any physical injury as a result of participation in this research study, financial compensation cannot be provided by WakeMed. However, every effort will be made to make available to you the facilities and professional skills of WakeMed. By

signing this consent form, you acknowledge that you have not waived any of your legal rights or released any party from liability for negligence.

INSTITUTIONAL REVIEW BOARD (IRB) APPROVAL:

Include the following statement:

The Institutional Review Board (IRB) at WakeMed has reviewed the protocol for this project in the context of certain federal laws relating to research and experimentation involving human subjects. Approval of this protocol by the WakeMed IRB does not constitute an endorsement of this project or its consequences.

CONTACTS:

Explain whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.

Include the following statement:

If you have any questions about the study or if you experience a research-related injury, you may contact Dr. (insert P.I. 's name here) at (919) (insert telephone number here). If you have any questions about your rights as a research subject or if you are not satisfied with the manner in which this study is being conducted, you may contact (anonymously if you choose) the IRB Chair, Miriam P. Rogers, Ed.D, RN, through the Board office at (919) 350-8795.

STUDY SUBJECT'S AGREEMENT:

I have read the information provided in this consent form and have been given the opportunity to ask any questions concerning the study. I hereby authorize Dr. (*put last name here*) or the physicians/investigators he/she may designate to administer the drug regimen under investigation. I will receive a signed copy of this informed consent.

Your authorization will expire at the completion of the research study.

Signature of Patient (including minor, if capable of consent)

Date

Print name of Patient

****If your study uses minors and adults unable to sign the consent, include the following line:***

If patient is unable to sign or is a minor, complete the following: Patient is (minor _____ years of age or is unable to sign because): _____

****If your study uses adults only and they are unable to sign the consent, include the following line: Patient is unable to sign because: _____***

Signature of Guardian/Legally Authorized
Representative (required for all unemancipated
minor study participants)

Date

Signature of Witness

Date

“Either I have or my designee has explained to the study subject named above (or guardian/legally authorized representative) the nature of the research described above. To the best of my knowledge, the study subject (or the guardian/legally authorized representative) signing this consent form understands the nature, demands, benefits and risks involved in participating in this research study.”

Signature of Investigator or Person Obtaining Consent

Date

Note: A copy of your informed consent will go into your medical record. The original copy of your informed consent will go into your study file with the Principal Investigator.

*only use if criteria applies

(Rev. 6/28/99, 5/24/00, 1/09/02, 4/9/02, 10/23/02, 5/7/03, 12/06)