

- ◆ Consent form must relate to specific proposal and not be a “standard form.”
- ◆ Consent form should be written in ordinary language, easily understood by persons with no medical or scientific background.
- ◆ Consent forms are most understandable if they are written just as the clinical investigator would give an oral explanation to the subject; that is, the subject is addressed as “you” and the clinical investigator as “I/we.” Use active tense rather than passive tense verbs (e.g., “We did” rather than “It was done”)
- ◆ Make clear the links of logical sequences and of cause-and-effect, even if doing so makes the sentence much longer (e.g., “We will do this, because that happened”)
- ◆ Subjects are not in a position to judge whether the information provided is complete. Subjects may certify that they understand the statements in the consent form and are satisfied. They should not be required to certify completeness of disclosure (e.g., “This study has been fully explained to me,” or, “I fully understand the study.”)

Sections (see Template):

1. Put at top, title of the research project.
2. Name, address and telephone number of Principal Investigator (PI)
3. Name, address and telephone number of Faculty Sponsor (if P.I. not a member of WakeMed Medical Staff)
4. Name, address and telephone number of Clinical Coordinator, if applicable
5. A statement that the study involves research.
6. An explanation of the purpose of the research, identifying procedures that are experimental.
7. Identify the number of estimated subjects nationally and at WakeMed.
8. An explanation of the procedures to be followed.
9. Specify the expected duration of subject’s participation, frequency of trips to study site required, etc
10. Specify inclusion and exclusion criteria.
11. Describe all discomforts and risks to be reasonably expected; include a statement that some risks may be unforeseeable.
12. Describe benefits to be reasonably expected.
13. Disclose any alternative procedures available.
14. 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.
15. A statement of any costs to the subjects (clinical fees, professional fees, diagnostic and laboratory studies, drugs, devices, transportation, hospitalization)
 - In the case of studies involving investigational devices or drugs, a statement indicating that some insurance carriers may not pay for participation in research studies.

16. Disclose any significant financial interest of the principal investigator or any potential conflict of interest.
17. A statement of any payments to the study participant for being in the study and when and how these payments will be made
18. A statement that subject may see other caretakers and should inform them of study participation
19. A statement that the subject's participation is voluntary and that refusal to participate will not affect the subject's access to care from his/her physician or WakeMed
20. A statement that the subject is free to withdraw from the research activity at any time without penalty.
21. A statement describing confidentiality of participant's health information.
 - If reviewed or sponsored by the manufacturer of a drug or device, include a statement that such manufacturer as well as the Institutional Review Board here at WakeMed may review all records.
 - If reviewed or sponsored by the FDA or HHS, include a statement that the FDA and the HHS may review all records, as well as the Institutional Review Board here at WakeMed
22. The following statement MUST be included in all consent forms (Federal and WakeMed regulations): In the event of physical injury directly resulting from this research, 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.
23. A statement that this research has been approved by the Institutional Review Board and instruction that if the subject feels there is any infringement upon his/her rights, subject may contact the IRB Chair, Miriam P. Rogers, Ed.D, RN, through the WakeMed IRB office at 919-350-8795.
24. A statement indicating whom the subject may contact if questions about the research and research-related injuries arise (this should include the investigator's name and telephone number).
25. A statement of the subject's agreement and that the subject will receive a copy of the consent form.
26. Signature of subject and date indicating consent (include printed name of subject under the signature line). [Signature of parent(s) or signature of guardian/legally authorized representative and date for subjects who cannot legally represent themselves.]
27. Signature of witness and date.
28. Signature of investigator or person obtaining consent and the date.

**ESSENTIAL ELEMENTS FOR CONSENT FORMS
FOR HUMAN SUBJECTS IN RESEARCH**

APPENDAGE II

Signature EXAMPLE

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

Date

Printed Name of Patient

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

Date

Signature of Witness

Date

Signature of Investigator or Person Obtaining Consent

Date