



M I G R A N T C L I N I C I A N S N E T W O R K

INSTITUTIONAL REVIEW BOARD GUIDELINES FOR INFORMED CONSENT

NOTICE: Regulations require that all consent forms, and all pages of the consent forms, be kept for a minimum of 3 years after the completion of the study, even if the subject does not continue participation. The consent form must be written in language that can easily be read by the subject population and any use of jargon or technical language should be avoided. Use lay language understandable to the subject. **The consent form should be written at no higher than an 8th grade reading level**, and it is recommended that it be written in the third person.

A two-inch by two-inch blank space must be left on the bottom of each page of the consent form for the IRB approval stamp.

Basic elements required for all consent forms:

1. An introduction of the principal investigator
2. A statement that the study involves research, e.g., "...this research study...", an explanation of the purposes of the research; the expected duration of the subject's participation; a description of the procedures to be followed; and identification of any procedures which are experimental.
3. A description of reasonably foreseeable risks, pain, or discomforts to the subject.
4. How the sample was selected and why.
5. The expected duration of the subject's participation.
6. A brief summary of the project procedures.
7. A description of any benefits to the subject or to others which may reasonably be expected from the research. If none, so state.
8. Rationale for study; literature review, social and or scientific value. How study adds to the knowledge base.
9. A disclosure of appropriate alternative procedures or courses or treatment, if any, that might be advantageous to the subject.
10. Methodology

11. Data entry and analysis appropriate to study goals and rationale and addition to the knowledge base.
12. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained. Indicate that the data and consent forms will be stored separately for at least three years following the completion of the study. Indicate where, in general, the data and consent documents will be stored and who will have access. The following statement must be included in all consent forms and informational letters: "Only the researcher, the advisor (if applicable) and people who audit IRB procedures will have access to the data." Please make appropriate additions to the persons that may have access to your research data. Indicate how the data will be disposed of. Be sure to list any mandatory reporting requirements that may obligate breaking confidentiality. For drug studies, the sponsor and the Food and Drug Administration have access to medical records.
13. For research involving more than minimal risk, an explanation as to whether compensation and/or medical treatment is available if an injury occurs. If so, what liability is assigned or where further information may be obtained.

An explanation of at least two people to contact in the event of a research-related injury or for answers to questions about the research, usually the investigator, with name and telephone number. Also, give contact for questions regarding the rights of research subjects. This information should be included in the following statement: "If you have questions about the research, please call (insert Principal Investigator's name) at (insert phone number of Principal Investigator) or (Co-PI or advisor) at (insert Co-PI or advisor's phone number). If you have any other questions or concerns, please call the Chair of the MCN IRB- Sara Quandt 336-402-1022 or email Squandt@wakehealth.edu.

14. If applicable: an explanation of who to contact in the event of a research-related injury to the subject.
15. If applicable: an explanation of financial interest must be included.
16. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled
17. A statement that the subject may withdraw at any time without negative consequences with an explanation of how the can discontinue participation.
18. An explanation of circumstances which may result in the termination of a subject's participation in the study.
19. A description of any anticipated costs to the subject.
20. A statement indicating whether the subject will be informed of the findings of the study.
21. A statement indicating that the subject will receive a copy of the consent form.

Additional elements Consider each, one or more may be appropriate to the study:

1. A statement about payment to subjects who take part in the study:

There is no payment to you for participating in this study.

OR

You will be paid \$_____ for taking part in this study (describe any conditions for payment, e.g., payment will be made after completion of stated parts of the study or payment will be made at the completion of the study).

2. 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.
3. If women of childbearing potential will take part in the study, consider the need for negative pregnancy test and use of a reliable method of birth control.
4. If vulnerable populations are the research subjects, discuss specific assurances.
5. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
6. Disclose use of a placebo. When a study is double blind, mention that, neither subject nor physician will know identity until the study is over. However, in case of an emergency, the identity may be learned.
7. If assignment to treatment is random, define random as like the flip of a coin.
8. Discuss additional costs to the subject that may result from participation in the research. Costs can include social costs such as time away from work or family. If there are no additional costs, so state.
9. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
10. With end of care relationships and with negative effects
11. A statement that significant new findings developed during the course of the research which may be related to the subject's willingness to continue participation will be provided to the subject.
12. The approximate number of subjects involved in the study.

Other Information:

The subject must have the form available in his primary language.

The subject must have ample time to read and ask questions.

If functionally illiterate, the subject should have the form read to him/her.

A copy of the consent form must be given to the person giving consent. A witness to the signature must also sign the form. If the subject is a child or an incompetent person, a signature block is needed for the parent or guardian rather than for the subject.

Special circumstances may preclude signed consent by the subject when there is a perceived risk associated with signing one's name. If such circumstances apply, the applicant must give a detailed description of an alternate assurance of the completion of informed consent.

Records relating to human research studies must be kept for 3 years following completion of the study. Consent forms should be incorporated into the patient's permanent record. (N.B. FDA requires records to be kept for 2 years following marketing of a new drug or device, or 2 years after the IND is withdrawn if the product is not marketed.)

CONSENT FORM CHECK LIST

- Letterhead of institution
- Lay language
- Research study
- Study description
- Procedures
- Risks
- Benefits
- Alternatives
- Confidentiality
- Costs to patient
- Patient compensation
- Contact for study questions
- Contact for subjects' rights questions
- Right to refuse or withdraw without negative consequences
- Pregnancy clause, if appropriate
- Appropriate liability clause