

NEWS FROM THE INSTITUTIONAL REVIEW BOARD

CHANGES TO THE IRB PROTOCOL APPLICATION FORM

The Federal Regulations for the Protection of Human Subjects establish specific criteria for IRB approval of research (45CFR46.46.111). To ensure that the IRB receives and considers information needed to determine that these criteria are satisfied, the Protocol Application Form has been revised. The new Protocol Application Form is available on the IRB web page and should be used for **all** full IRB submissions, expedited submissions and exempt submissions beginning February 1, 2003.

In order to approve a research study, the IRB must determine that all of the following criteria are satisfied:

- Risks to subjects are minimized
- Risks to subjects are reasonable in relation to anticipated benefits (if any) to subjects, and the importance of the knowledge that may reasonably be expected to result from the research is described
- Selection of subjects is equitable
- Informed consent will be sought from each subject or the subject's legally authorized representative
- Informed consent will be appropriately documented
- The research plan makes adequate provisions for monitoring data collected to ensure subjects' safety
- There are adequate provisions to protect the privacy of subjects and to maintain data confidentiality
- When some or all of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards have been included to protect the rights and welfare of these subjects.

In a recent review of operations, the IRB has identified the need for a more systematic presentation and review of information related to these criteria. Thus, the Protocol Application Form and the IRB Reviewer Form have been revised to ensure that information required to determine if these criteria are met is provided by the investigator and reviewed by the IRB. The IRB must determine that these criteria are met regardless of whether the research study is reviewed by the full IRB or reviewed through expedited or exempt procedures. Other forms are available on the IRB web page which provide additional information that the IRB must consider for specific types of research (e.g., research involving drugs or devices, children or other vulnerable populations), expedited or exempt review or waiver of informed consent. When applicable these forms should be completed and included with the Protocol Application Form.

COMPLETE SUBMISSIONS REQUIRED FOR REVIEW

IRB submissions that are incomplete, that do not have the required number of hard copies, or that lack electronic copies will be returned **without** review. The IRB uses a primary reviewer system for new protocols and continuing review of existing protocols. For new submissions, three primary reviewers are assigned to each protocol. A single primary reviewer is assigned to each continuing review submission. Primary reviewers are provided hard copies of each new or continuing review submission, and are responsible for an in-depth review of all pertinent documentation related to the submission. All IRB members are expected to review each submission and informed consent to determine that the criteria for IRB approval of research are satisfied. Information need to allow IRB members to determine that the criteria are satisfied is provided electronically. To ensure appropriate review of new and continuing review submission, the required information, including the requested number of hard copies, and electronic copies must be provided.

INFORMED CONSENT TEMPLATE AVAILABLE

Informed consent documents are required to provide specific information to research subjects. To assist investigators in writing informed consent documents, a template is now available on the IRB web site. This template may help investigators ensure that all elements of informed consent are included, and provides example wording for specific issues often encountered when writing an informed consent.

Required Informed Consent Elements

- Wake Forest University Health Sciences (WFUHS) header or letterhead
- Study Title
- Use of lay language, defined as language understandable to the people being asked to participate (usually 6th to 8th grade). The use of second person (e.g., “You will receive...”) is preferred; the use of the first person (e.g., “I understand that...”) is discouraged. Individual involved in the study should be referred to as subjects or participants not patients. The informed consent should state facts rather than require attestations on the part of the subject.
- A statement that a research study is being performed.
- An explanation of the purpose of the study.
- The expected duration of the subject’s participation.
- A description of the procedures to be followed.
- Identification of any procedures or interventions which are experimental.
- A description of any reasonably foreseeable risks or discomforts to the subject.
- A description of any benefits to the subject or to others that may reasonably be expected from the research.
- Disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained. Include all entities that might review the records of the subject, such as the IRB, FDA, the sponsor, DHHS, and OHRP as appropriate.
- A statement of any additional costs, if any, to subjects that may result from participation in the research and an explanation of those costs
- An explanation as to whether any compensation is available to subjects for participation.
- Disclosure of any actual or potential conflicts of interest.
- An explanation of whom to contact, with phone number, for answers to pertinent questions about the research and whom to contact in the event of a research-related injury.
- A statement that the chairman of the WFUHS Institutional Review Board should be contacted at 336-716-4542 for answers to questions about research subjects’ rights.
- A statement that participation is voluntary, refusal to participate will not involve penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled.
- If appropriate, 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 and/or a pregnancy clause (Use of WFUHS standard pregnancy clause is preferred).
- Appropriate liability clause containing 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 (WFUHS standard language is preferred).
- A line for the subject’s signature and date.
- A line for the name or signature of the person obtaining consent and date

Additional elements to included as appropriate

- Anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent
- The consequences of a subject’s decision to withdraw from the research and procedures for orderly termination of participation by the subject.
- 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.
- The approximate number of subjects involved in the study at this site and/or at all sites.