Office of Human Research Protection
Institutional Review Board
701 Grove Rd
ESC158
Greenville, SC 29605

Elements of Consent Disclosure Guidance

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Required: *(*Can be omitted if there are none.)* - The study involves research. - The purposes of the research. - The expected duration of the subject's participation. - The procedures to be followed. - Identification of any procedures, which are experimental.* - Any reasonably foreseeable risks or discomforts to the subject.* - Any benefits to the subject or to others, which may reasonably be expected from the research.* - Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.* - The extent, if any, to which confidentiality of records identifying the subject will be maintained.* - How to contact the research team for questions, concerns, or complaints about the research. - How to contact someone independent of the research team for questions, concerns, or complaints about the research; questions about the subjects' rights; to obtain information; or to offer input. - Whom to contact in the event of a research-related injury to the subject. - Participation is voluntary. - Refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled. - The subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
Required for More than Minimal Risk Research
- Whether any compensation is available if injury occurs and, if so, what it consists of, or where further information may be obtained. - Whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
Required for Clinical Trials
- The approval of the IRB. - The probability for random assignment to each treatment. - The subject's responsibilities. - When applicable, the reasonably foreseeable risks or inconveniences to an embryo, fetus, or nursing infant. - The important potential benefits and risks of the alternative procedures or courses of treatment that may be available to the subject. - When there is no intended clinical benefit to the subject, a statement to this effect. - The monitors, auditors, IRB, and regulatory authorities will be granted direct access to the subject's original medical records for verification of clinical trial procedures and data, without violating the confidentiality of the subject, to the extent permitted by applicable laws and regulations and that, by signing the consent document, the subject or LAR is authorizing such access. - If the results of the trial are published, the subject's identity will remain confidential.
Required for FDA-Regulated Research
- The possibility that the Food and Drug Administration may inspect the records. - The data collected on the subject to the point of withdrawal remains part of the study database and may not be removed. - The investigator will ask a subject who is withdrawing whether the subject wishes to provide further data collection from routine medical care.

- For controlled drug/device trials (except Phase I drug trials) and pediatric device surveillance trials: "A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."
Additional: (Include when appropriate).
- The particular treatment or procedure may involve risks to the subject, which are currently unforeseeable. - If the subject is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable. - Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent. - Any additional costs to the subject that may result from participation in the research. - The consequences of a subject's decision to withdraw from the research. - Procedures for orderly termination of participation by the subject. - 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. - Approximate number of subjects involved in the study. - Amount and schedule of all payments..