(n) That the monitor, the auditor, the IRB/IEC, and the regulatory authority will be granted direct access to the subject's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the subject or the subject's legally acceptable representative is authorizing such access.

(o) That records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, the subject's identity will remain confidential.

(p) That the subject or the subject's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the subject's willingness to continue participation in the trial.

(q) The person to contact for further information regarding the trial and the rights of trial subjects, and whom to contact in the event of trial-related injury.

(r) The foreseeable circumstances and/or reasons under which the subject's participation in the trial may be terminated.

(s) The expected duration of the subject's participation in the trial.

(t) The approximate number of subjects involved in the trial.

IV. ETHICAL DOCTRINES

Ethical doctrines relevant to consent forms include the Belmont Report (1979), the Declaration of Helsinki (1964), and the Nuremberg Code (1947). The Belmont Report arose from an Act of the U.S. government, namely, the National Research Act of 1974. This Act created the *National Commission for Protection of Human Subjects of Biomedical and Behavioral Research*, which issued the *Belmont Report*. These ethical doctrines arose, in part, as reactions to notoriously unethical experiments on human subjects. As reviewed by Rice (20) these notorious studies include experiments by Nazis on prisoners, the Willowbrook Hepatitis Studies, and the Tuskegee Syphilis Study.

While the *Belmont Report* was not codified as any law or rule of the United States government, it did serve as a basis for parts of the CFR that concern consent forms used for clinical trials (21). These parts are Title 21 CFR Sections 50 and 56, and Title 45 CFR Section 46. The combination of 21 CFR 50 and 45 CFR 46 is called *The Common Rule* (22,23,24).

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