Covenant Medical Center
Institutional Review Board

Basic Elements of Informed Consent

	***=Omit if not applicable. May not apply to some expedited minimal risk research**
	REQUIRED ELEMENTS
1	A statement that the study involves research
2.	An explanation of the purposes of the research
3.	The expected duration of subject participation
4.	A description of any procedures which will be followed
5.*	*Identification of any experimental procedures (only if applicable)
6.	A description of foreseeable risks and discomforts to the subject
7.	A description of foreseeable benefits for the subject, or others
8.*	*A disclosure of any appropriate alternate procedures
9.	A description of how and to what extent confidentiality
10.*	*A statement that the FDA may inspect the project records, if FDA regulated research
11.*	*An explanation of compensation and the availability of medical treatments with research-related injury, for research involving greater than minimal risk
12.	An explanation of whom to contact if questions should arise about the research or the subjects's rights, should injury occur
13.	A statement that participation is voluntary
14.	A statement that refusal to participate shall involve no penalty or loss of benefits to which the subject is otherwise entitled
15.	A statement that the subject can discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled
	ADDITIONAL ELEMENTS OF INFORMED CONSENT
	When appropriate, one or more of the following elements of information shall also be provided on each subject
16.	A statement that the procedure may involve unforeseeable risk
17.	A description of the circumstances under which the subject participation may be terminated by the investigator without the subjects consent
18.	A statement regarding any additional costs to the subject resulting in participating in the research
19.	A statement regarding the consequences of a subjects decision to withdraw from research
20.	A statement that significant new findings developed during research which may relate to the subjects willingness to continue participation will be communicated
21.	A statement regarding the approximate number of subjects involved
22.	A statement that includes the Covenant IRB Chairperson or designee and telephone number as a contact for subjects
23.	Statement that addresses investigator conflict of interest or explanation why such a statement is not necessary for the protection of human subjects
24.	*If FDA Clinical Trial after March 7, 2012, must have the statement: **"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."**