INFORMED CONSENT REQUIREMENTS

NAME OF STUDY: _____

BASIC ELEMENTS	REQUIRE-MENT SATISFIED YES/NO
1. A statement that the study involves: a) research, b) an explanation of the purposes of the research and the expected duration of the subject's participation, c) a description of the procedures to be followed, and d) identification of any products which are experimental.	a) ____ b) ____ c) ____ d) ____
2. A description of any reasonably foreseeable risks or discomforts to the subject.	
3. A description of any benefits to the subject or to others which may reasonably be expected from the research.	
4. A disclosure of appropriate alternative procedures or courses of treatment, if any that might be advantageous to the subject.	
5. A statement describing a) the extent, if any, to which confidentiality of records identifying the subject will be maintained and b) that notes the possibility that the Food and Drug Administration may inspect the records.	a) ____ b) ____
6. For research involving more than minimal risk, a) an explanation as to whether any compensation and b) an explanation as to whether any medical treatments are available if injury occurs and, if so, c) what they consist of, d) or where further information may be obtained.	a) ____ b) ____ c) ____ d) ____
7. An explanation of a) whom to contact for answers to pertinent questions about the research subjects' rights, and b) whom to contact in the event of a research-related injury to the subject.	a) ____ b) ____
8. A statement that a) participation is voluntary, b) that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and c) that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. [As to GH] d) that termination or desire not to participate will not jeopardize treatment at the hospital.	a) ____ b) ____ c) ____ d) ____
9. 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.	
10. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.	
11. Any additional costs to the subject that may result from participation in the research.	
12. The consequences of a subject's decision a) to withdraw from the research and b) procedures for orderly termination of participation by the subject.	a) ____ b) ____
13. 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.	
14. The approximate number of subjects involved in the study.	
15. a) A statement that the study does not involve a conflict of interest on behalf of the Principal Investigator, any study team member, sponsor either of the study or products/services associated with the study, or Griffin Hospital.	a)_____ b)_____
16. A statement that all investigators and facilitators have completed Human Subjects Research Training.	
17. A statement that all subjects have the right to contact the Griffin Hospital Privacy Officer with questions or concerns about their privacy rights, or file a complaint if they believe their privacy rights have been violated.	
18. Reading level of consent (Flesch-Kincaid reading level) (Reading level should be no higher than 8th grade)	_____