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**APPENDIX B**

ELEMENTS OF CONSENT

**Written informed consent for research must have these elements.**

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of subject's participation, a description of what procedures will be followed, and which ones are experimental;
2. A description of any foreseeable risks or discomforts;
3. A description of benefits to the subject or others who may benefit;
4. Disclosure of appropriate alternative procedures or treatments that may be advantageous to the subject;
5. A statement describing the extent of confidentiality of records identifying the subject;
6. Research involving more than minimal risk must include explanations regarding
* Whether any compensation is available for participation
* Whether medical treatments are available for injuries, and if so, a description of them or where more information is available;
1. Whom to contact for answers to questions about the research; answers to questions about subject's rights; if a research-related injury occurs;
2. A statement that participation is voluntary, that refusal to participate will not penalize the subject, and consent to participate can be withdrawn at any time.

**Additional Elements of Informed Consent - When Appropriate:**

1. 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 current unforeseeable;
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
3. Any additional costs to the subject that may result from participation in the research;
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. 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; and
6. The approximate number of subjects involved in the study.