General Requirements for Informed Consent - CHECKLIST

1. A statement that the study involves research
2. An explanation of the purposes of the research and the expected duration of the subject’s participation
3. A description of the procedures to be followed
4. Identification of any procedures which are experimental
5. A description of any reasonably foreseeable risks or discomforts to the subject
6. A description of any benefits to the subject or to others which may be expected from research
7. A disclosure of appropriate alternative procedures or courses of treatment, if any that might be advantageous to the subject
8. A statement describing the extent, if any, to which confidentiality of records identify the subject will be maintained
9. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs, and if so what they consist of or where further information can be obtained
10. An explanation of whom to contact for answers to pertinent questions about research and research subjects’ rights and whom to contact in the event of a research related injury to subject
11. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Additional Elements

1. A statement that the particular treatment or procedure may involve risks to subject (or to embryo or fetus, if subject is or may become pregnant) which are currently 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 research and procedures for orderly termination of participation by 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
6. The approximate number of subjects involved in the study