

## **CHECKLIST AND INSTRUCTIONS FOR CONSENT DOCUMENTS FOR INVESTIGATORS, IRB MEMBERS AND STAFF**

All MSSM consent documents **must** include the following 8 "**basic elements**" of informed consent and, when applicable, 6 "**additional elements**" of informed consent as required by Federal Regulations. This information **must** be written in a language that will be understandable to an individual with a sixth grade education. The information **must** be incorporated in the specific sections of the MSSM consent document as indicated below and, since the information is unique to the particular study, the specifics of the study must be written by the PI.

### **Title of Project:**

#### **A. Purpose of the Study:**

- A statement that the study involves research. [You (you/your child) are being asked to participate in a research project.]
- A statement of the purpose of research. [The purpose of this research is \_\_\_\_\_.]
- A statement why the subject qualifies for participation in research. [You qualify for participation because \_\_\_\_\_.]

#### **B. Description of the Research:**

- A description of the study and all of the procedures to be followed.
- The identification of any procedures, drugs or devices which are experimental and a statement that indicates whether they are approved by the Food and Drug Administration (FDA) for the purpose(s) they will be used in the proposed study.
- When applicable, the identification of any procedures that will be performed for clinically indicated, non-research-related reasons.
- An indication of the expected duration of a subject's participation.
- When applicable, an indication of the approximate number of subjects to be involved in the study.

#### **C. Costs/Reimbursements:**

- A statement whether or not subjects will be reimbursed for time and expenses. Include a statement whether or not reimbursement will be prorated. If prorated, indicate the anticipated prorated payments to the subjects.
- A statement as to whether there will be any costs to the subjects as a consequence of participation in the study. When applicable, clarify that costs for clinically indicated tests and procedures will be the responsibility of the patient or their insurance companies.

#### **D. Potential Risks and Discomforts:**

- A description of all-potential risks or discomfort to the subjects, and a statement of the reversibility of any potential adverse events.
- When applicable, 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.

## CHECKLIST AND INSTRUCTIONS FOR CONSENT DOCUMENTS (con't)

### **E. Potential Benefits:**

- A description of potential benefits to the subjects or to others.

### **F. Alternatives to Participation:**

- A disclosure of alternative procedures or courses of treatment that might be beneficial.

### **G. Confidentiality of Identity of Participant:**

- A statement describing how and the extent to which confidentiality of records identifying the subject will be maintained.

### **H. Compensation and/or Treatment in the Event of Injury:**

- A statement whether compensation and/or any medical treatment will be available if injury occurs, and if so what they consist of, or where further information may be obtained.
- A statement of whom to contact in the event of a research-related injury to the subject.

### **I. Voluntary Participation:**

- A statement that participation is voluntary and refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.
- When applicable, 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.

### **J. Termination of Participation:**

- A statement that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- When applicable, a statement of the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
- When applicable, a statement of anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

### **K. Contact Person(s):**

- A statement of whom to contact for answers to questions about the research and the rights of the research subjects.

### **L. Disclosure of Financial Interests:**

- A statement regarding financial interests of sponsoring agency, investigator(s), and/or department.