**Informed Consent Document (ICD) Review and Approval Checklist**

**A. General Protocol and ICD Information**

Protocol Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Protocol ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principle Investigator’s Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Study Site/Hospital: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Informed Consent Document (ICD) Version Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**B. Checklist of Required Elements in ICD**

Please review the ICD and indicate if each required element is included in the ICD

| **Basic Elements** | **Yes** | **No** | **N/A\*** | **Comments** |
| --- | --- | --- | --- | --- |
| 1. A statement that the study involves research | 🞎 | 🞎 | 🞎 |  |
| 1. An explanation of the purposes of the research | 🞎 | 🞎 | 🞎 |  |
| 1. The expected duration of the subject's participation | 🞎 | 🞎 | 🞎 |  |
| 1. A description of the study procedures to be followed, including all invasive procedures | 🞎 | 🞎 | 🞎 |  |
| 1. A description of subject’s responsibilities | 🞎 | 🞎 | 🞎 |  |
| 1. Identification of any procedures or treatment which are experimental | 🞎 | 🞎 | 🞎 |  |
| 1. A description of any reasonably foreseeable risks or discomforts to the subject (or to an embryo, fetus, or nursing infant when applicable) | 🞎 | 🞎 | 🞎 |  |
| 1. A description of any benefits to the subject or to others, which may reasonably be expected from the research. If there is no benefit the research participant should be made aware of this | 🞎 | 🞎 | 🞎 |  |
| 1. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject, including their important benefits and risks | 🞎 | 🞎 | 🞎 |  |
| 1. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained | 🞎 | 🞎 | 🞎 |  |
| 1. A statement that the monitor(s), auditor(s), IRB/IEC, and regulatory authority(ies) will be granted direct access to the subject original medical records for verification of study procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that by signing a written informed consent form, the subject (or the legally acceptable representative) is authorizing such access | 🞎 | 🞎 | 🞎 |  |
| 1. 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 may be obtained | 🞎 | 🞎 | 🞎 |  |
| 1. An explanation of whom to contact for answers to pertinent questions about the research | 🞎 | 🞎 | 🞎 |  |
| 1. An explanation of whom to contact for answers to pertinent questions about the research subjects' rights | 🞎 | 🞎 | 🞎 |  |
| 1. An explanation of whom to contact in the event of a research-related injury to the subject | 🞎 | 🞎 | 🞎 |  |
| 1. A statement that participation is voluntary, and that 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 | 🞎 | 🞎 | 🞎 |  |
| 1. The information given to the subject is in lay terms and in a language understandable to the subject | 🞎 | 🞎 | 🞎 |  |
| 1. The information given to the subject does not contain any language that causes the subject or the subject’s legally acceptable representative to waive or to appear to waive any legal rights, or that releases or appears to release the investigator, the institute, the sponsor, or their agents from liability for negligence | 🞎 | 🞎 | 🞎 |  |
| 1. A statement detailing study treatment(s) and the probability for random assignment to each treatment (if the study is a randomized clinical trial) | 🞎 | 🞎 | 🞎 |  |
| 1. A statement that the particular treatment or procedure may involve risks to the research participant (or to the embryo or fetus, if the participant is or may become pregnant), which are currently unforeseeable | 🞎 | 🞎 | 🞎 |  |
| 1. Anticipated circumstances and/or reasons under which the subject's participation may be terminated by the investigator without regard to the subject's consent | 🞎 | 🞎 | 🞎 |  |
| 1. Any additional costs or expenses to the subject that may result from participation in the research | 🞎 | 🞎 | 🞎 |  |
| 1. Any prorated payment to the subject for their participation in the study | 🞎 | 🞎 | 🞎 |  |
| 1. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject | 🞎 | 🞎 | 🞎 |  |
| 1. 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 in a timely manner. | 🞎 | 🞎 | 🞎 |  |
| 1. The approximate number of subjects involved in the study | 🞎 | 🞎 | 🞎 |  |

Note \* N/A = Not applicable

**C. Author of ICD**

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Signature Author’s Name Date

**D. Review and Approval of ICD**

Approved: ☐ Yes ☐ No

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature Principle Investigator’s Name Date