**FORM 7.1A- INFORMED CONSENT CHECKLIST**

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| **Required Elements** | **Yes** | **No** |
| A statement that the study involves research |  |  |
| An explanation of the purposes of the research |  |  |
| Safety and efficacy defined as a purpose (for clinical trial) |  |  |
| The expected duration of participation (include active & follow-up) |  |  |
| Number of visits |  |  |
| A description of the procedures, including: Procedures at each visit matches protocol Procedures clearly described (in lay language) Laboratory adequately described Experimental procedures defined |  |  |
| The following described:  Reasonably foreseeable risks/discomforts of the study article Reasonably foreseeable risks & discomforts of the procedures Reasonably expected benefits to participants/others |  |  |
| Appropriate alternative treatments defined |  |  |
| Confidentiality Statement, including: Sponsor / funder and/or CRO access to records UNCST/ NDA access, IDI REC access, Other (e.g. interview service) |  |  |
| Injury statement (if more than minimal risk), including: Description of available compensation  Description of available medical treatments |  |  |
| Participation statement, including; What treatment consists of, if applicable Who to contact for a research related injury |  |  |
| Participation is voluntary Refusal to participate will involve no penalty or loss of benefits Participant may stop participation at any time - without penalty / loss of benefits | | |
| Who to contact for information about research |  |  |
| Contact for questions about research participant's rights |  |  |
| 24-hour emergency contact number? |  |  |

Comments:

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| **Additional Elements, as Appropriate:** | **Yes** | **No** | **NA** |
|  |  |  |  |
| Research may involve unforeseeable risks to the participant |  |  |  |
| Risks to pregnant women/ embryo/ fetus or nursing baby |  |  |  |
| Costs/additional costs to participant from participation |  |  |  |
| Circumstances under which the participant's participation may be terminated without regard to the participant’s consent |  |  |  |
| Payment for participation described (pro-rated, reasonable) |  |  |  |
| Procedures for orderly termination of participation |  |  |  |
| Medical /scientific terminology defined |  |  |  |
| A statement that significant findings during the course of research that might affect the participant’s willingness to continue participation will be provided to the participant |  |  |  |
| The approximate # of participants in the study |  |  |  |
| Legal guardian consent, if needed |  |  |  |
| REC volunteer statement included |  |  |  |
| Institutional/Organization Required Elements |  |  |  |

See informed consent form template (Form 7.1B) for suggestions for appropriate wording

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| Comments: | |
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| Primary Reviewer | Date |