**FORM 7.1A- INFORMED CONSENT CHECKLIST**

|  |  |  |
| --- | --- | --- |
| **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 compensationDescription 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:

|  |  |  |  |
| --- | --- | --- | --- |
| **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

|  |
| --- |
| Comments: |
|  |
|  |
|  |
|  |
|  |
| Primary Reviewer | Date |