**FORM 3.5A STUDY FOLDER CONTENT CHECKLIST**

|  |  |  |  |
| --- | --- | --- | --- |
| **TITLE OF DOCUMENT** | **YES** | **NO** | **N/A** |
| **INVESTIGATOR BROCHURE** |[ ] [ ] [ ]
| **SIGNED PROTOCOL, AMENDMENTS, IF ANY,** |[ ] [ ] [ ]
| **INFO. GIVEN TO TRIAL PARTICIPANT** |  |  |  |
| INFORMED CONSENT FORM |[ ] [ ] [ ]
| ANY OTHER WRITTEN INFORMATION |[ ] [ ] [ ]
| ADVERTISEMENT FOR PARTICIPANT RECRUITMENT |[ ] [ ] [ ]
| **SIGNED AGREEMENT BETWEEN INVOLVED PARTIES** |[ ] [ ] [ ]
| **DATED, DOCUMENTED APPROVAL/ FAVORABLE OPINION OF IDI REC OF THE FOLLOWING:** |  |  |  |
| Protocol and any amendments |[ ] [ ] [ ]
| CRF (if applicable) |[ ] [ ] [ ]
| Informed Consent Form(s) |[ ] [ ] [ ]
| Any written information to be provided to the participant(s) |[ ] [ ] [ ]
| Advertisement for participant recruitment (if used) |[ ] [ ] [ ]
| Participant compensation (if any) |[ ] [ ] [ ]
| Any other documents given approval/ favorable opinion |[ ] [ ] [ ]
| **INVESTIGATOR BROCHURE/PRODUCT DESCRIPTION UPDATES** |  |  |  |
| **ANY REVISION TO:** |  |  |  |
| - Protocol/amendment(s) and CRF |[ ] [ ] [ ]
| - Informed Consent Form |[ ] [ ] [ ]
| - Any written information provided to participants |[ ] [ ] [ ]
| - Advertisement for participant recruitment (if used) |[ ] [ ] [ ]
| **SIGNED INFORMED CONSENT FORMS** |[ ] [ ] [ ]
| **NOTIFICATION BY SPONSOR AND/OR INVESTIGATOR, IF NEEDED, TO REGULATORY AUTHORITY(IES) AND IDI REC OF UNEXPECTED SERIOUS ADVERSE REACTIONS AND OF OTHER SAFETY INFORMATION** |  |  |  |
| **NOTIFICATION BY SPONSOR TO INVESTIGATORS OF SAFETY INFORMATION** |[ ] [ ] [ ]
| **PERIODIC REPORTS TO IDI REC** |[ ] [ ] [ ]
| **COMPLETION REPORT BY INVESTIGATOR TO IDI REC** |[ ] [ ] [ ]