**Project Forms and Documents**

**CPI Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Trial Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |  |  |
| --- | --- | --- |
| **Instrument name** | **Sub Instruments** | **Comments** |
| Study Protocol | ProtocolProduct Information/Investigational Brochure |  |
| PICFs | ParticipantWithdrawalCarerSub-studies |  |
| Worksheets | One instrument for each worksheet |  |
| Other Patient Facing Documents | InstructionsDiariesContact CardsSafety Posters |  |
| ISF Master Documents | SSDLTraining LogShort CV templateProtocol Violation Form (Template 7) |  |
| Ethics and Regulatory | Trial RegistrationCTNInsurance and indemnityLead HREC initialAmendment (submission and approval)Secondary HRECUTS HREC |  |
| Advertising and Marketing | Staff posterPatient posterReferral formArticles |  |
| Assessment Tools | QuestionnairesOther assessments to be given to and completed by participants |  |
| Guides and Instructions | Adverse Event Coding SheetCCI scoring instructionsCOVID script |  |
| Site initiation training slides | Training program and record of attendance1. Pharmacy training
2. Regulations
3. Monitoring and management
4. Protocol and implementation
5. Data management
 |  |

See also TEMPLATE Study Forms and Documents in REDCap Projects (copy and paste into new study and adapt as required).