**Project Forms and Documents**

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

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| **Instrument name** | **Sub Instruments** | **Comments** |
| Study Protocol | Protocol  Product Information/Investigational Brochure |  |
| PICFs | Participant  Withdrawal  Carer  Sub-studies |  |
| Worksheets | One instrument for each worksheet |  |
| Other Patient Facing Documents | Instructions  Diaries  Contact Cards  Safety Posters |  |
| ISF Master Documents | SSDL  Training Log  Short CV template  Protocol Violation Form (Template 7) |  |
| Ethics and Regulatory | Trial Registration  CTN  Insurance and indemnity  Lead HREC initial  Amendment (submission and approval)  Secondary HREC  UTS HREC |  |
| Advertising and Marketing | Staff poster  Patient poster  Referral form  Articles |  |
| Assessment Tools | Questionnaires  Other assessments to be given to and completed by participants |  |
| Guides and Instructions | Adverse Event Coding Sheet  CCI scoring instructions  COVID script |  |
| Site initiation training slides | Training program and record of attendance   1. 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).