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| **COVID STEROID 2 Unblinded Trial Folder Index** | | |
| **Section** | **Section Heading** | **Comments** |
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| **2** | **Protocol & Manuals** | optional |
| **2.1** | Protocol (Current only) |  |
| **2.2** | COVID Steroid 2, Manual for Unblinded Study Staff (India sites only) |  |
| **3** | **Investigators & Study Staff** |  |
| **3.1** | Unblinded Site Signature, Training & Delegation Log |  |
| **4** | **Monitoring - Unblinded CRA** |  |
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| **4.2** | Monitoring (Unblinded) Visit Reports and Correspondence | Including virtual visits |
| **4.3** | Close-out Visit Report and Correspondence |  |
| **5** | **Correspondence - emails, letters, fax** |  |
| **6** | **Notes to File** |  |
| **7** | **Study Tools & Forms (Templates/blank forms)** |  |
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|  | Unblinded Study Drug Preparation Form |  |
|  | Unblinded Drug Reconciliation and Destruction Log |  |
|  | Randomisation notification |  |
| **8** | **Completed logs** |  |
| **8.1** | Patient Allocation Log |  |
| **8.2** | Unblinded Drug Reconciliation and Destruction Log |  |
| **9** | **Individual Patient files (create a new section for each patient as per study Patient ID)** |  |
| **9.1** | Randomisation notification |  |
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| **9.3** | Protocol Deviation |  |
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