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| **SOP TITLE** | |
| **SOP ID: XX-XXX-XX** | |
| **Effective Date**: XX-XXX-XX | **Review Date**: XX-XXX-XX |
| **Author**  Name:  Title:  Signature: ON FILE  Date: XX-XXX-XX | **Approver**  Name:  Title:  Signature: ON FILE  Date: XX-XXX-XX |

**Document History**

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| **Version** | **Description of Update** | **Date Effective** |
| X.X | *If v1.0 state ‘first release’. If an update to an existing document include all changes made to the original version.* | XX-XXX-XX |

1. **Purpose**

*State the purpose for the creation of the SOP*

1. **Scope**

*Which groups does this SOP apply to? – e.g. all staff; CI; PI; Trial Managers; Data Managers; Sponsor Representatives; SCRGM; Statisticians.*

1. **Responsibilities**

*Describe the specific responsibilities of groups/staff members that this SOP involves*

1. **Procedures**

*This is the main body of the SOP. Make details as clear and concise as possible. Any abbreviations must be included in section 6 of the SOP.*

1. **Referenced and Related Documents**

*Include all forms, guidelines or template documents that have been created or to which this SOP has a link to. Consider including related documents such as GCU policy papers or national legislation if it will provide the reader with further information.*

1. **Abbreviations and Definitions**

*Include all abbreviations and definitions used within the body of the SOP*