Insert the title of the SOP here

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| Document Detail | |
| Document type | Standard Operating Procedure |
| Document name | Enter the number and title of the SOP |
| Document location | Q-Pulse \ CRF Documents |
| Version | Enter the version number (eg: 1.0) |
| Effective from | Enter the date when the SOP will become effective |
| Review date | Enter a review date (usually 2 years from the effective date) |
| Author | Enter the name and job title of the author |
| Approved by | Enter the name and job title of the approver |
| Authorised by | Professor Peter Goadsby, CRF Director |
| Related documents | List any related documents (eg: other CRF SOPs, CRF forms, KCH policies, user manuals etc) |
| Keywords | Enter a few key words from the SOP |
| Supporting references | Enter any relevant references (eg: websites) if applicable or state ‘See Section 6.0’ |

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| Change History | | |
| Date | Change details, since approval | Approved by |
|  | Enter a numbered list of the changes made to the previous version (leave blank if this is version 1.0) |  |

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| --- | --- | --- |
| Review History | | |
| Date | Review details | Approved by |
|  | Review of v1.0 conducted by XXXX, due to XXX. Changes made as per ‘Change History’ and re-issued as v2.0 (leave blank if this is version 1.0) |  |

1. **Background**
   1. Brief statement / introduction providing the background / context of the SOP.
2. **Purpose** 
   1. Brief statement outlining the purpose of **the SOP** (eg: to describe the procedure for performing xxx).
3. **Scope** 
   1. Brief statement outlining who the SOP applies to (eg: all core CRF staff and users of the CRF), any exceptions and any limitations of the SOP. This should include the standard statement that CRF SOPs apply to the CTF and EMF only and not the CTU.
4. **Responsibilities** 
   1. Statement detailing the persons responsible for the major tasks within the SOP and what their exact responsibilities are.
5. **Procedure**
   1. Details of how the task / process is performed. This must be written in a logical, methodical and unambiguous manner. The information must be clear and concise and easily understood. It must comply with current regulations and organisational policies. It should include references to any relevant SOPs/forms/policies etc.
6. **Related documents & References**
   1. Documents with an impact on the procedure including other CRF SOPs, CRF Policies, CRF forms, KCH policies/documents, websites, journals, user manuals, regulatory documents/references, publications plus anything else referenced in the SOP.
7. **List of Appendices** 
   1. List each appendix in this section or if none, enter ‘N/A’. Appendices (eg: diagrams, flowcharts) should be numbered and added at the end of the document after the signature page.
8. **Approval and sign off**

The paper Master Copy of the SOP must be signed off by the authorised signatories prior to becoming effective.

**Author:**

Name:

Position:

Signature: Date:

**Approved by:**

Name:

Position:

Signature: Date:

**Authorised by:**

Name: Professor Peter Goadsby

Position: CRF Director

Signature: Date: