**STU-SOP-XXX-### – Standard Operating Procedure on *<Insert Title>***

*Delete/replace all highlighted text prior to finalising document.*

*Refer to STU-SOP-ADM-001 SOP on SOPs for further guidance on producing SOPs.*

**1. Purpose *<and Definitions>*** Please remove if not required

This Standard Operating Procedure (SOP) describes the procedure of *<Add a short introduction on the aim of the document.>*

|  |  |
| --- | --- |
|  | **Definitions** *Please delete table if not required* |
| ***<Term>****Add additional rows as required* | *<Definition of term>*  |

**2. Background**

*<Provide background information that may be related to the SOP, referencing applicable legal or regulatory requirements.>*

**3. Roles and Responsibilities**

*<Outline responsibilities of all positions involved in this procedure.>*

External use of SOP: this SOP and Associated Documents (AD) may be used for research projects not adopted by STU where Swansea University (SU) staff and associated NHS organisations require guidance. In such instances, oversight responsibility for any associated tasks will not be the responsibility of STU.

**4. Procedure**

*<Describe the steps required in plain English categorising steps with sequential numbering.>*

**5. References**

*Include all key references.*

* Health Research Authority website (HRA) - <http://www.hra.nhs.uk/>
* Medicine and Healthcare products Regulatory Agency website (MHRA) - <https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/services-information>
* UK policy framework for health and social care research (2017) - <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/>
* UK Medicine for Human Use (Clinical Trials) Regulations 2004 - <http://www.legislation.gov.uk/uksi/2004/1031/contents/made>

It is assumed that by referencing the principal regulations that all subsequent amendments are included in this citation.

**6. Associated Documents**

*Include any documents that might be relevant to the SOP and where these documents can be found.*

|  |  |  |
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| **Number** | **Title** | **Location** |
| STU-AD-XXX-### |  |  |

**7. Abbreviations**

*Add or Remove individual points as appropriate*

|  |  |
| --- | --- |
|  | **List of Abbreviations** |
| **AD**  | Associated Documents  |
| **HRA** | Health Research Authority |
| **MHRA** | Medicine and Healthcare Products Regulatory Agency |
| **NHS** | National Health Service |
| **QMS** | Quality Management System |
| **SOP** | Standard Operating Procedure |
| **STU** | Swansea Trials Unit |
| **SU** | Swansea University |

**8. Appendices**

**Appendix 1: Document History**

|  |  |  |  |
| --- | --- | --- | --- |
| **Version No:** |  | **Effective Date:** |  |
| **Description of changes:** | *Provide history of all document updates/versions.* |

*<Add additional if required.>*