STU-SOP-TS-007 – Standard Operating Procedure on Regulatory Green Light Process

1. Purpose

This Standard Operating Procedure (SOP) describes the procedure of obtaining a green light for regulatory release for a Clinical Trial of an Investigational Medical Product (CTIMP). It does not describe the technical release of a medicinal product (MP) by a Qualified Person (QP).

A risk assessment will identify the need for a green light process for interventional research projects which are not CTIMPs.

2. Background

Under the Clinical Trial Regulations the Sponsor must not start a CTIMP until a Clinical Trial Authorisation (CTA) has been granted, a favourable REC opinion has been received and the Sponsor is satisfied with the manufacture and release of the MPs for the research project. This process can be divided into technical and regulatory release steps but is referred to overall as the 'regulatory green light'.

Before recruitment at any trial site, each site must have completed local capacity and capability (C&C) checks.

MP cannot be released by sites until the regulatory green light approval is in place.

3. Roles and Responsibilities

The **Sponsor** is responsible for reviewing the information submitted and ensuring a green light approval notification is issued to the Chief Investigator.

Swansea Trials Unit (**STU**), when assigned by Sponsor, is responsible for ensuring that the green light process is completed. This may involve liaising with expert Sponsor staff e.g. Clinical Trials Pharmacist.

The **Chief Investigator (CI)** is responsible for overseeing that tasks and approvals are completed, , and liaising with expert Sponsor staff where required. The CI may delegate responsibilities as appropriate.

The **Trial Manager (TM)** when delegated, is responsible for compiling relevant information and liaising with all required parties. The TM will disseminate green light approval to the research project team and staff at sites and have responsibility for coordinating site initiation.

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

4.1 CTIMP Regulatory Green Light process

Where responsibility for managing the regulatory green light process has been delegated to the CI and TM. The Sponsor will retain oversight of the process.

For CTIMPs with only one site, the trial and site checks are combined into a single review. When delegated by the Sponsor, the CI/TM will complete the green light form (STU-AD-FRM-022) or a Sponsor green light form as appropriate. A copy of the form and any other documentation pertinent to the review will be forwarded to the Sponsor.

The Sponsor should confirm in writing/by email that the process has been completed or requires revision. Any issues raised with the CI must be rectified. The CI cannot initiate sites until a regulatory green light approval is received.

Sponsor will advise when the MP can be shipped to the investigator site in readiness for local checks and site activation and may be held in quarantine until the green light has been given to release the MP.

All communication and documentation relating to the regulatory green light process must be filed in the Trial Master File (TMF) and Investigator Site File (ISF) as appropriate.

4.2 CTIMP Multi-Site Regulatory Green Light Process

When a CTIMP is multicentre, a regulatory green light process is required for each site.

The CI/TM will complete a site green light form (STU-AD-FRM-021) for the second and subsequent sites to be initiated.

The procedure as described in 4.1 will be followed in relation to Sponsor review and release of MP.

4.3 Non-CTIMP Research Project Green Light Process

This process and documentation may be used for research projects which are not CTIMPs but still require oversight of a MP. The Sponsor will indicate their involvement in either performing the green light or requiring oversight only.

For all other research projects, the responsibility for a green light process may be delegated to the CI. ADs may be adapted if required.

5. 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

Number	Title	Location
STU-AD-FRM-022	Trial Green Light Form	Q-Pulse
STU-AD-FRM-021	Site Green Light Form	Q-Pulse

7. Abbreviations

List of Abbreviations	
CAPA	Corrective and Preventative Action
CI	Chief Investigator
CRF	Case Report Forms
CTU	Clinical Trials Unit
GCP	Good Clinical Practice
MP	Medicinal Product
ISF	Investigator Site File
MHRA	Medicines and Healthcare products Regulatory Agency
PI	Principal Investigator
QP	Qualified Person
SIV	Site Initiation Visit
SOP	Standard Operating Procedure
STU	Swansea Trials Unit
SU	Swansea University
TM	Trial Manager
TMF	Trial/Project Master File
TMG	Trial Management Group
TSC	Trial Steering Committee

8. Appendices

Appendix 1: Document History

Version No:	3	Effective Date:	20-Jun-2024
Description of changes:	Update to procedure		