Regulatory Green Light Process for NuTH Sponsored High Risk Studies

NJRO-REG-SOP-005

Contents

1. Background/Introduction

Prior to authorising the start of a clinical trial and the initiation of research sites, the sponsor must ensure that all approvals, contracts, and necessary documentation are in place. Records must be available to verify that all necessary documents have been received by the sponsor prior to the authorisation to start the trial at each site. This should include confirmation that they have been reviewed by an appropriately delegated representative of the sponsor. Once this check is complete, the trial activities at site can commence. This process is referred to as the 'regulatory green light'.

2. Purpose

This Standard Operating Procedure (SOP) describes the regulatory green light process for all high-risk studies that fall under the Regulatory Compliance Team (RCT) where The Newcastle upon Tyne Hospitals NHS Foundation Trust (NuTH) is acting as research sponsor. It does not describe the processes for technical release or regulatory release of Investigational Medicinal Products (IMPs) by a Qualified Person.

3. Scope of Document

The SOP is applicable to Chief Investigators (CI) and delegated trial team members involved in the management of high risk NuTH FT-sponsored studies falling under the RCT.

Where a Clinical Trials Unit (CTU) has been delegated responsibility to perform aspects of the regulatory green light process, this SOP is also applicable to the assigned Trial Manager (TM).

The SOP is also applicable to the RCT.

4. Definitions

CI – Chief Investigator
CTU – Clinical Trials Unit
RCT – Regulatory Compliance Team
SIV – Site Initiation Visit
TM – Trial Manager
NuTH – The Newcastle upon Tyne Hospitals NHS Foundation Trust

5. Roles & Responsibilities

For those trials where a CTU is employed to manage the trial, the responsibility for performing the regulatory green light process will be delegated to the assigned Trial Manager (TM).

For those trials not managed by a CTU the responsibility for performing the regulatory green light process will be delegated to the CI and trial management team.

The RCT is responsible for issuing green light on behalf of Sponsor.

6. Procedures

6.1. Regulatory Green Light Template Agreement

Prior to the opening of sites, the template green light checklist (see NJRO-REG-T-005) must be prepared by the trial management team and agreed with the RCT. For trials where CTUs wish to use their own regulatory green light checklist template, this must be reviewed by the RCT to ensure this meets sponsor requirements.

When the checklist is agreed the documents that must accompany a green light request will also be agreed. At a minimum this will include the signed and dated CV and GCP of the PI and the SIV Report with an accompanying confirmation that all actions identified have been completed.

6.2. Regulatory Green Light Procedure

The party who has been delegated responsibility to perform aspects of the regulatory green light process as per the sponsor delegation of duties agreement will complete the regulatory green light checklist for each site. The completed checklist will then be sent to the RCT (via tnu-tr.sponsormanagement@nhs.net) accompanied by the other agreed documents.

Upon receipt the checklist and all accompanying documents will be reviewed by an appropriately delegated member of the RCT ensuring all required actions have been completed. As part of this review the SIV report will be reviewed and signed (if applicable) and the professional registration of the PI checked (as appropriate). If there are any items outstanding, the trial management team will be informed and will rectify any issues prior to resubmission.

When the review is completed and all required documentation is in place, the checklist will be signed and returned to the trial management team. The return of the

signed checklist and signed SIV Report (if applicable) using NJRO-REG-T-008 will represent the green light to initiate recruitment activity at site.

Copies of the green light correspondence will be retained in the Trial Master File, Investigator Site File and Sponsor Oversight File.

7. References

MHRA Good Clinical Practice Guide, 2012 - https://www.gov.uk/guidance/good-clinical-practice-for-clinical-trials

8. Appendices

NJRO-REG-T-005 – NuTH Template Regulatory Green Light Checklist
NJRO-REG-T-008 – Green Light Template Email