COVID-19: Deviations to Current SOPs

NJRO-GEN-SOP-025

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1. Background/Introduction

COVID-19 has placed considerable pressure on clinical trials performed by and in the NHS. National organisations and government bodies have published guidance to ensure that best practice is maintained during this time. The Newcastle upon Tyne Hospitals NHS Foundation Trust (Trust) has a number of SOPs and guidelines to ensure preparedness and maintaining safety for patients and staff. As a research sponsor the Trust has a duty to maintain clinical trial activity where significant safety implications apply. As a result some trials will remain open during the pandemic.

2. Purpose

To describe how the Trust as sponsor will manage deviations to SOPs during the COVID-19 outbreak.

3. Scope of Document

Applicable to Newcastle Joint Research Office, Clinical Trials Units working with the Trust as Sponsor, Chief Investigators and Delivery/Support Teams.

4. Definitions

CMO – Chief Medical Officer
EHR – Electronic Health Record
HRA – Health Research Authority
NJRO – Newcastle Joint Research Office
SUSAR(s) – Suspected Unexpected Serious Adverse Event
USM – Urgent Safety Measure

5. Roles & Responsibilities

It is the responsibility of all staff working on research studies within or for the Trust to be aware of potential deviations to SOPs during the COVID-19 pandemic.

6. Procedures

All NJRO SOPs (or SOPs by individual units used in agreement with the Sponsor) should be followed as much as reasonably possible. In some cases, deviations to standard SOPs will be necessary to ensure the safety and integrity of the Clinical Trial.

6.1. Consent

Consent should be received in line with applicable SOPs. Where a change is required, for example; a paper copy cannot be retained because of biohazards other means can be implemented. A photograph of the form can be taken and retained for instance. Where this is a change to the current protocol the decision should be documented in a risk assessment.

6.2. Local Policies, SOPs and WIs

Where a participating site has changed local policy and procedures; staff should be aware of the impact on the clinical trial and the overarching sponsor SOPs. Changes that may result in Sponsor SOP deviations should be documented in a risk assessment.

6.3. Deviations, Violations, Urgent Safety Measures, Serious Breaches, Waivers and SUSARS

6.3.1. Deviations

Due to reduced hospital visits, self-isolation and shielding arrangements there will be an increase in deviations. All deviations are to be recorded during this time. Due to the potential number of deviations Sponsor has requested that the Trial Management teams collect information regarding deviations and collate in one document (for example: Excel spread sheet or usual reporting documentation). Trial Management teams should send the document to Sponsor at the end of each month until informed otherwise.

6.3.2. Violations

Any Violations should be reported in-line with the current SOP.

6.3.3. Urgent Safety Measure

Urgent Safety Measures (USMs) to trials that continue to follow-up must be reported in the usual way and CIs and PIs need to report any USM to sponsor immediately. To note: Regulation 3 amends the Medicines for Human Use (Clinical Trials) Regulations 2004 to allow for notice of urgent safety measures to be given as soon as possible to the licensing authority and an ethics committee.

6.3.4. Serious Breaches

Any serious breaches should be reported in-line with the current SOP.

6.3.5. Waivers

Prospective protocol waivers are unacceptable and should not be used to change a trial due to the pandemic (for example eligibility, patient safety and/or difficulties in assessments). CIs should discuss with R&D and consider use of USM, temporary halts or patient discontinuation.

6.3.6. SUSARS

Any SUSARs should be reported in-line with the current SOP.

6.4. Safety Reporting

Where a study is prioritised to continue follow-up on safety grounds all safety reporting should continue in-line with the applicable SOPs.

6.5. Risk Assessments

Risk assessments continue to be applicable to trials. To ensure compliance with the latest MHRA and HRA guidelines studies classified by Sponsor to be 1b "Studies where a patient's treatment depends on them being in the trial, e.g. early-phase cancer trials where the treatment is only available in the context of a trial and 'usual care' options are ineffective" or classified as high risk as Sponsor, a COVID-19 Specific risk assessment should be completed and returned to Sponsor. The current version of the risk assessment can be found on the NJRO website – www.newcastlejro.com.

6.6. Monitoring plans

After completion of the COVID-19 risk assessment it may be necessary to amend the monitoring plan. To ease the burden on trial management teams an appendix should be added to a monitoring plan detailing the changes. Consideration should be given to a reassessment date of the appendix to decide if the changes remain applicable or it is appropriate to revert back to the original monitoring plan. Reassessment and outcomes should be documented.

COVID-19 Monitoring plan appendix pages should be sent to sponsor for review.

6.7. Source Data

Scanning of Source data into a patient's EHR should continue as per applicable SOPs. All paper source data must be retained in an appropriate storage place until further development of a research policy linked to Paperlite.

The Trust will not supply PDF versions (full or redacted) of source data outside the Trust at this time.

6.8. Sponsorship

Sponsorship requests are required to follow the applicable SOPs. COVID-19 studies will be prioritised and reviewed in a timely manner. It is expected that Investigators wishing to conduct specific studies in relation to COVID-19 gain CMO approval. All potential related studies must be discussed with the NJRO Sponsor team at the earliest possible stage.

Non-COVID-19 sponsorship will continue to be reviewed and may be submitted to HRA/REC/MHRA, however, the review process may take longer.

6.9 SOP Approval in Q-pulse

In the absence of the Regulatory Compliance Manager and/or Quality Assurance Manager, SOP Authorisation within Q-pulse will be delegated to appropriate members of the NJRO.

7. References

N/A

8. Appendices

N/A