The Northern Care Alliance (NCA) NHS Group

COVID-19 Pandemic

Guidance for NCA Investigators and Research Staff (#1)

Introduction

You will be aware of the rapid spread of the COVID-19 virus. On 17 March 2020 we circulated an email which outlined a number of measures that needed to be implemented with immediate effect. These measures were:

1. Recruitment of new patients to all studies to be suspended (unless it is a COVID-19 study).
2. Prioritise COVID-19 studies.
3. Continue with essential follow-up activity e.g., for safety monitoring or when stopping the follow-up activity would be detrimental to the patient.

The above measures will be reviewed on an on-going basis and the guidance is subject to change at short notice. Where guidance from external organisations proves inconsistent, instructions from the NCA should take precedence.

General advice for research staff

- Recruitment to COVID-19 studies will be prioritised.
- As the COVID-19 crisis escalates it will be necessary for many Research & Innovation (R&I) colleagues with clinical skills to provide essential clinical support where necessary across the NCA. We have already had discussions with research delivery team leads regarding the resource required to safely deliver essential research activity. It is now necessary to identify those specific colleagues who can support COVID-19 research, as well as those who can provide much needed support to the wider clinical team.
- Non-clinically qualified staff may be requested to support delivery of COVID-19 studies by providing admin support including data entry. Appropriate activities will vary widely given the various qualifications, skills and experience of research staff.
- Site set up of any new or on-going studies (including those sponsored by the NCA) that are not prioritised COVID-19 studies will be paused.

Monitoring, Site Initiation Visits (SSVs) and Site Selection Visits (SSVs)

- R&I colleagues should review all non-essential visits to the organisation, including monitoring visits. With agreement of the study sponsor, where possible, monitoring should be undertaken remotely in line with recent emergency MHRA recommendations. Where this is not possible, monitoring visits should be cancelled. They can be rescheduled at a later stage once normal clinical services resume. https://mhrainspectorate.blog.gov.uk/2020/03/12/advice-for-management-of-clinical-trials-in-relation-to-coronavirus/
- All SIVs and SSVs should be cancelled until further notice unless they relate to a COVID-19 study.

Specific Guidance

- **Recruitment of new patients to all studies to be suspended (unless it is a COVID-19 study)**
- Continue with essential follow-up activity e.g., for safety monitoring or when stopping the follow-up activity will be detrimental to the patient (use flexibility of the visit windows where necessary). Chief and Principal Investigators, and Research Delivery Teams, should identify all essential follow-up activity. All follow-up related decisions should be made by clinically qualified staff based on clinical criteria.
- Non-essential follow-up activity that has been scheduled can continue in the short term provided this does not require patients to come on site. Only non-clinical colleagues should support this activity. Further non-essential follow-up activity should not be scheduled beyond 27 March 2020.
- Any decisions should be communicated to the Research Management and Support (RM&S) team who will liaise directly with sponsor contacts.
- The categorisation system below will help facilitate decision making regarding the actions that are required.

LEVEL	DESCRIPTION	ACTION
1	COVID-19 studies and/or other urgent health studies relating to COVID-19.	Recruitment to and delivery of these studies will be prioritised.
2	Studies open to recruitment when suspension of protocol activity would be detrimental to the patient.	Delivery to continue for patients already recruited but recruitment of new patients should be suspended.
3	Studies where patient care could be compromised by not seeing the patient but where this does not provide a risk to patient safety.	Delivery to continue for patients already recruited should continue. Recruitment of new patients should be suspended.
4	Studies that involve patient care but where patient care is not compromised if the study is suspended.	Recruitment of new patients should be suspended. Non-essential follow-up activity can continue in the immediate short-term provided this can be undertaken remotely (patients should not come on site). Only non-clinical colleagues should support this activity. **Further non-essential follow-up activity should not be scheduled beyond 27 March 2020.**
5	Studies that do not provide direct patient care e.g., registry studies, sample collection/bio bank studies.	These studies will be suspended unless they relate specifically to COVID-19.

- Where possible, maintain contact with participants as per the study schedule.
- For essential visits where that visit might not be possible or if participants do not attend appointments, attempts should be made to schedule a telephone or electronic call within the visit window to review participant status, collect safety information and perform any study assessments that can be completed remotely. Consider posting questionnaires to participants' homes, where appropriate. CI and PI oversight should be maintained.
- Serious Adverse Events (SAE's) should be reported in the usual way (reported to the sponsor immediately and certainly within 24 hours) of an Investigator site becoming aware of an SAE.
- All participant contact should be fully recorded in their medical notes/electronic patient record and CRF.
- All protocol deviations (e.g. out-of-window visits, missed assessments, missed visits) should be recorded on the deviation log, as per normal practice.
- Once visits to clinic become viable again, schedule participants to be seen as soon as possible to complete any missed assessments.
- **Contact the trial sponsor through normal routes if you require protocol specific guidance.**

Contracting and finance

- The temporary suspension of clinical research will make it difficult for the NCA to meet some contractual obligations. Whilst this is a concern for commercial research, initial discussions with our external partners indicate that they fully understand the current exceptional circumstances.
- It is considered that, in contracts for both commercial and non-commercial research, the NCA could invoke *Force Majeure* clauses in the event of temporary suspension due to COVID-19.
- Where necessary, when decisions are taken to suspend study activities, notices will be sent to the sponsor to notify them of this decision in order to avoid a breach of contract. The RM&S Team will ensure such notices are issued promptly.
- UKRI and NIHR have confirmed that no financial penalties will be enforced if a study is suspended. It is anticipated that AMRC registered charities will fall in line with the main UKRI guidelines. However, the requirement remains to notify funding bodies on a project by project basis.
- The requirement for clinical staff aligned to research projects to be enlisted to support NHS resource demands has also been anticipated and understood by these funding bodies.
- A short-term reduction in our financial activity and cash flow as a result of the above should be expected. This should ease when we return to business as usual.

The above points are subject to regular change as the COVID-19 pandemic develops and further updates will be issued.

Northern Care Alliance – Joint Research Office
24 March 2020