Restart and Reset for Research

Dear Research Community

As you are aware the Trust has asked PIs and Team Leads to investigate and assess the safety and practicality of studies reopening at Newcastle. There is a capacity and capability form available to complete and return to NJRO. We have already received a number of forms and we will begin to review as of the 1st June.

All required documents can be found on the NJRO website. https://newcastlejro.com/covid-19/

We understand the pressures on you to re-open, recruit and complete your research. The below explains the approach we have taken in R&D to manage safety, capacity and demand. R&D will endeavour to review as swiftly as is possible but due to capacity we cannot offer a fixed timeline.

I understand that due to the nature of research; some studies may need to be treated in a different manner. If this is the case please e-mail me (sean.scott@nhs.net) to discuss further.

1. **Hosted Research**

Capacity and capability will be reviewed and a green light e-mail issued to restart if safe to do so. It is highly likely that priority 3 studies will be the first to open. Mainly due to the lack of (or significantly reduced) PPE requirements and ability to amend easily incorporating virtual access to patients and/or staff. However; all priorities will be looked at case-by-case. As a Trust we have a large portfolio and we simply cannot provide green light for all studies at once. Trials that have a direct bearing on care will be given due assessment in-line with the directorates restart procedures.

Please note that at this time University Labs are not open and therefore green light cannot be given to such trials if the primary endpoint requires these facilities or we are unable to legally store material on Trust premises.

2. Newcastle Hospitals Sponsored Research

The below explains the requirements for Newcastle Sponsored trials and studies. Please note that Sponsor green light does not mean the trial/study can open at all participating sites. Investigators need to work with their Principal Investigators (PIs) across the UK to ensure all involved can restart. Chief Investigators (CIs) must have an awareness of other Trusts policies and opening of all sites will, in most cases, be staggered.

a. CTIMPs, Devices and ATIMPs
Trials that require Competent Authority approval must complete a risk assessment. CIs are requested to work with your Senior Trial Manager from Newcastle Clinical Trials Unit to complete and return to Sponsor. For trials managed by other CTUs please contact tnu-tr.sponsormanagement@nhs.net to gain a copy of the approved risk assessment.

b. Randomised Control Trials (RCT)
For trials classified as RCT or 'Trial' on ReDA a risk assessment is available on the NJRO website. CI's should work with their Team Leads to complete and return to nuth.nuthsponsorship@nhs.net

A Sponsor representative will review and respond with an e-mail confirming green light if appropriate at this time. For trials that require this risk assessment a NuTH capacity and capability form is not required as local governance will be completed at the same time.

c. All Other Studies
Sponsor is not requiring the completion of a separate risk assessment for all other trials. The capacity and capability form should still be completed as per section 1 of this document. A Sponsor representative will review both site and Sponsor restart using this document.

3. Submitted Studies for Capacity and Capability

R&D has continued to accept capacity and capability forms for new studies during the close-down of recruitment. The team has been working to ensure they are ready for a quick approval once the Trust is in a position to restart activities.

Such studies will not be opened before the hosted and sponsored activities have been restarted. This is to ensure that we are in a position to complete our current contractual and legal requirements of the current portfolio. We will contact PIs when we are in the position to restart and confirm that you and the team are able to safely run the study. There is no requirement to complete the additional capacity and capability form.

Of course, we understand the need to assess on a case-by-case due to the variety of complexity and pressures on research. If you would like to discuss restart of submitted studies (section 3) please e-mail me in the first instance.

Many Thanks
Sean Scott
Regulatory Compliance Manager