The Newcastle upon Tyne Hospitals
NHS Foundation Trust

Restart, Reset and Recovery in clinical research: guidance for local investigators and research delivery teams.

Effective from Monday 11th May 2020

NB this guidance supersedes the COVID-19 pandemic: R&D action plan from Monday 30th March 2020.

As we move into the second phase of the COVID-19 pandemic, clinical research will – like other services in the Trust – need to begin to restart, reset and recover. In the short term, we will look to restart paused research studies based on a balanced assessment of risk vs. benefit, capacity within the research team, and the impact on other services in the Trust. The restart will be gradual and there may be setbacks if there are other peaks in the number of cases of COVID-19. We should also take this opportunity to incorporate many of the positive changes we have seen in research over the last two months. In the longer term we will need to work towards recovering our full capacity and developing and delivering a new research strategy for the Trust. We are expecting national guidance on research restart in the coming days and this will need to be considered alongside this document.

Overarching principles

1. Clinical research is core business for the NHS and patients should be offered the opportunity to participate in research where it is safe and feasible to do so.
2. Research teams should work with their clinical colleagues to ensure that research is restarted in step with the clinical services.
3. Given the uncertain future, research teams should be cautious when opening/restarting studies to retain some flexibility in the system.
4. Principal Investigators should work with their Team Lead, Clinical Research Lead and the Study Sponsor to consider whether a study could be opened or restarted.
5. The NJRO will adopt a proportionate approach, enabling studies to restart as quickly as possible, while also maintaining oversight of the necessary governance, financial and reporting requirements.

Factors to consider when discussing whether a study could open or restart:

1. **Priority*:** 1a and 1b studies remain the highest priority but priority 2 and 3 studies should be considered equal and decisions should be made on a study-by-study basis. For example, it may be preferable to quickly restart an observational study ahead of a clinical trial, while submitting a protocol amendment to allow telephone follow up.
2. **Urgency of care:** as urgent care services have been prioritised clinically these may be the easier areas to open or restart clinical research.
3. **Protocol alignment with clinical pathways:** studies where the protocol requirements fit, or can be amended to fit, with clinical care pathways will be preferred. As before, hospital visits should be kept to a minimum and follow up should be undertaken by telephone or videoconference whenever possible. Investigators are reminded of the pragmatic guidance from the HRA and MHRA about conducting research and submitting protocol amendments during the pandemic.
4. **National guidance on testing/social distancing:** this is likely to change over time and will be reflected in Trust information and guidance but research teams should ensure that participants are able to comply with national guidance where relevant.

5. **Patient group:** careful consideration will be required for studies which recruit patients who are defined on medical grounds as extremely vulnerable to COVID-19 and are shielding.
6. **Impact on other services:** it is important to consider the impact on other services, such as clinical trials pharmacy, radiology and laboratory/pathology. It may be that some registry studies for example can be restarted immediately with no impact on other services.
7. **Location of research activity:** some studies may be able to open or restart away from the main hospital sites at the Freeman Hospital and RVI e.g. the CAV or Centre for Life.
8. **University collaboration:** some studies may require collaboration with academic and laboratory staff at Newcastle University and/or the use of university facilities.
9. **Projected recruitment numbers and financial aspects:** it is important to consider restarting studies which will recruit well and/or which will bring a financial return to the Trust, either through accrual-based funding from the CRN or per patient fees from commercial or non-commercial studies.
10. **Capacity of the research delivery team:** finally, and most importantly, we need to consider the capacity in the research delivery team and local PIs to recruit and follow up study participants. At this time our clinical research delivery team is greatly reduced – due to redeployment, shielding and sickness – and this will limit the number of studies we can restart immediately.

Oversight of restart by NJRO

The NJRO will maintain oversight and work closely with research teams, Sponsors and the CRN to ensure a rapid but coordinated restart. The restart process will be proportionate, with a 'light touch' approach for hosted, low-risk studies and a more detailed review for studies where NUTH is the sponsor.

SIVs, monitoring and follow-up visits.

Wherever possible, site assessment, training and initiation visits should be done remotely. If this is not possible, visitors should follow current Trust information and guidance to minimise the risk to themselves, patients and staff. Similarly, monitoring visits should be kept to a minimum but if they do need to go ahead appropriate measures should be taken.

Wherever possible, follow-up visits should be done remotely, face-to-face visits should be kept to a minimum and ideally combined with visits for clinical care. If patients are required to attend research teams should follow current Trust information and guidance to minimise the risk to patients and staff.

Next action for Principal Investigators

Over the next two weeks investigators are requested to work with their Team Lead, and Clinical Research Lead, to discuss which studies could safely open or restart and which of these would be their priority studies. To allow R&D the necessary oversight and to plan staffing accordingly, please forward the list of studies (with R&D numbers) to the NJRO nuth.genericqueries@nhs.net as soon possible and no later than 25th May. Requests to restart will be reviewed promptly and study teams will receive a 'reactivation' email from the NJRO for paused studies and the usual 'green light' email for studies opening for the first time.

*** Prioritisation criteria for clinical research studies in NUTH**

1a	Studies investigating COVID-19 including emergency public health studies.
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.
2	Studies where there is a safe and effective 'usual care' treatment option for patients not enrolled in the trial, e.g. a RCT of novel antihypertensive versus standard care, or a device study where an alternative device or treatment option exists.
3	Observational, tissue bio-bank, qualitative and other studies.