

Thursday 9th July 2020

## Restart, Reset and Recovery Fortnightly Update

Dear research colleagues,

Work has continued apace throughout the Trust to restart all services and research has been no different. You have been reviewing your paused studies, renewing new study applications and working hard with the NJRO to get as much research up and running as possible.

The challenge of balancing competing priorities of Urgent Public Health research, Restart (both paused and new) and existing and potential vaccine studies will continue to flex as we enter a time of increased agility with our research workload. It is likely there will be movement forward and the potential to re-pause or re-evaluate these priorities, in tune with the clinical workload of the Trust.

The ask of Newcastle Hospitals in relation to more COVID 19 vaccine and antibody studies is still to be confirmed. However, as you can imagine, these studies would have an impact on the research trials and staff / space capacity in the Trust and would affect our Restart capability. Discussions in relation to this will continue at the Clinical Research Leaders Forum (the next one is Tuesday 14th July at 12:00) and the weekly Team Leads meetings.

It is important to work within your team to prioritise your studies to submit for Restart, and to make sure you keep the NJRO team up to date if that changes over time. I know some teams have already established some paused studies are no longer viable, or as new studies come in, they want them to take priority. Keep talking to one another to ensure we are all working on the most important studies first.

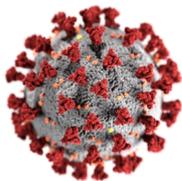
### Prioritisation Principles

The volume of applications submitted to the NJRO for Restart is still increasing weekly, with approximately **24% of all paused studies being submitted** so far. Concurrently, the team are looking to open the new studies submitted before the pandemic hit. There are around 35 studies currently classified as "on hold" at some stage in the set up process.

In order to effectively ensure all the studies are opened / un-paused in a timely and prioritised way, the following points will help us all to be as efficient as possible:

1. Prioritisation of your entire portfolio of research (paused and new) needs to be joined up – ensure you are clear which studies are most important for your team to open across all of these studies. Taking into account factors which are both relevant to your team and clinical area, staff capacity, support service capacity, deliverability, space and reputational impact.





2. The order in which your studies are submitted for review is being taken as an indication of priority – please make sure you state which your top priority studies are for review when submitting in your covering email. If this order changes, revise this information via email to the NJRO to ensure the right studies are opened in order.
3. Make sure you have reviewed the recruitment end date of the study and share the revised date (if applicable) before submitting the restart forms ([Study Restart Capability Form](#)) to the NJRO.
4. If the target recruitment for your study is changing this could lead to an amendment (particularly with commercial studies) – please ensure you share this information when submitting a study.
5. If there are studies which you either no longer want to open, or having paused them during the pandemic, have now decided they are no longer viable or a priority to open, please close them. This can be done by email to the NJRO.

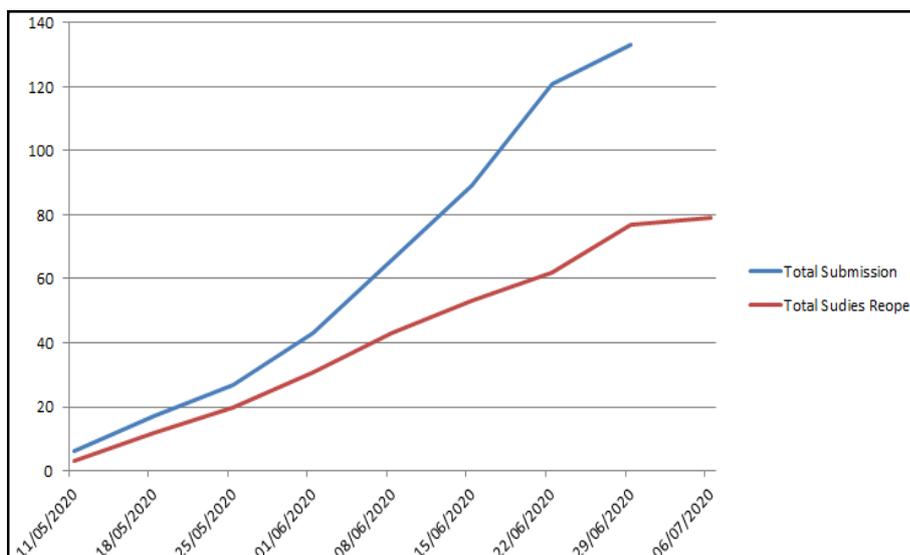
There are a number of generic emails for NJRO to ensure your application goes to the right place: [Nuth.genericqueries@nhs.net](mailto:Nuth.genericqueries@nhs.net) is for most Restart applications. [Nuth.amendments@nhs.net](mailto:Nuth.amendments@nhs.net) is for any Amended applications including changes to target and the method of delivering the study in light of COVID-19.

## RESTART Progress Update

The NJRO are working with increased staffing to support the re-opening of studies and have worked alongside every team in the Trust to open Restart studies.

As of the 6th of July, **79 studies have been assessed and re-opened, from the 133 submitted** for assessment.

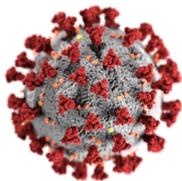
This equals around 24% of the Trust's studies paused due to the pandemic have been submitted, with 14% now restarted.



## Escalations & Resolutions

The current escalation process is that all issues are being reviewed and dealt with at weekly RRR meetings on a Tuesday. The major issues that have been escalated include concerns around commercial income flow, space due to social distancing, clinical need and changes in services for patients, shielding, support service capacity (in particular CT scanning and ECHO), research staff capacity and research prioritisation. These are being dealt with centrally, with two bespoke projects underway to review research space and workforce. These will feed into plans for the new Clinical Research Directorate.





Smaller scale operational issues have been resolved, including queries about NJRO risk assessment forms and processes, approach to Healthy Volunteers and Research Only appointments, and case by case study/site level queries.

Managing on-site CRA visits has also been raised, and the Pharmacy R&D team have emailed staff around tips to manage these remotely if possible to reduce department footfall and disruption.

In line with [restart information from R&D](#), where monitoring visits are necessary they may occur with the following, appropriate measures in place. This includes offering / providing as much as possible via email/remote visits – i.e.: temp logs, accountability documents etc – ensure all are non-identifiable to a participants details.

You should also consider if you are able to still socially distance or possibly relocate a staff member to another area to allow social distancing and accommodate a monitor on site. Do not feel pressured to accommodate all visits immediately. Only commit to visits in the dept where you feel current Trust COVID guidelines are able to be met.

A concern has been raised about potential capacity issues with Pharmacy production. Currently, Pharmacy's position for Restart is that if a study has already been open (paused) or remained open during COVID-19 and no changes are made to the Pharmacy requirements, then you should assume there is capacity. If you are finding individually that this is not the case, please raise this giving specific study level information.

### Newcastle University Campus Reopening

We are starting to accelerate the plans for more people returning to work at Newcastle University campus. As CARU and CRF remained open throughout the pandemic, it is important all staff are aware of the current plans for building reopening and becoming accessible. You can view the schedule [on NU Connect](#) – this is a working document so it is subject to change.

Please note the buildings listed will not be fully accessible immediately, they will be re-opened incrementally on a demand led basis to be agreed between Estates and the faculties.

