

Monday 22 June

Dear Research Colleagues,

We have been keeping in contact with you regularly to update on progress with the COVID-19 research response and more recently the beginning of our restart in the second phase of the NHS response. The response from you all to both of these challenges has been overwhelmingly positive reminding us all that research is both an important and integral part of Newcastle Hospitals offering to patients. Rest assured we are keen to support you all to get as much new and paused research up and running as soon as possible – our only delaying factors being demand and the constraints laid out in the risk assessments.

Research Restart, Reset and Recovery

As we already passed on, in the 11 May communication update, the Trust is undergoing a significant programme of **Restart, Reset and Recovery** in all clinical services. Research is integrated with, and effected by, this project and we are taking part in this directly to ensure that services have research in place wherever possible in a safe, sustainable and collaborative way.

The project details clearly the 3 different areas – Restart, Reset and Recovery and describes them as follows:

Restart - a short term switch back on with minor alterations to pre COVID

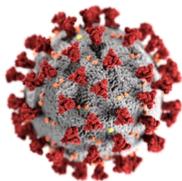
Reset - recommence but with adoption of new ways of working which are defined by the COVID legacy constraints such as need for PPE, testing, shielding, social distancing and workforce fatigue.

Recovery - a longer term programme, where we embed our new transformative ways of working, recover our performance and clear backlogs

Primarily at this time the focus is on the **Restart** phase with some **Resets** where possible – it is clear that we have an opportunity to not just restart research safely but also to essentially reboot research and ensure it is as functional, efficient and effective as possible going forwards. To that end we aim to have at least some research activity open within as many clinical areas as possible, offering patients research as an option of treatment.

At the current time there have been 76 submitted risk assessments to restart research projects, with 12 already approved and running – focussing initially on paused studies, but in parallel we are keen to review on a case by case basis new research which was paused during set up and also new research which has come about since the advent of the COVID-19 pandemic. We are keen that you, as clinical and delivery experts, review your entire research portfolio and prioritise your applications to the NJRO on the basis of viability, safety (staff and patient), capacity (support services and research delivery), finances, reputation (contract delivery), spread of research and clinical care options, end dates and target numbers and potential impact.

Risk assessments to un-pause research remains the same process which can be found on the NJRO website here: <https://newcastlejro.com/covid-19/>



The documents can be found under the [COVID-19 Guidance tab](#) – please see the table below:

Type of Research	Study Restart Capability Form	Trial Restart Risk Assessment	CTU Risk Assessment Form
CTU Managed (Chief Investigator at Newcastle)	X		X
Newcastle Trust Sponsored Trial (RCT)		X	
All other Research (Observational, Host-ed, Trust Sponsored non-RCT)	X		

On submission of your risk assessment(s) or forms you can expect to receive a confirmation email back within 48 hours confirming which member of staff in NJRO will be reviewing your study, and we hope that the process of actual review will speed up over time.

Common concerns, locally and nationally, include:

- **Capacity** of support departments – this has been escalated centrally and conversations are underway to negotiate a position and access to services for research.
- **Impact of social distancing** in order to see patients is adding significant time to each consultation which is likely to effect the number of patients who would be able to undertake research – you need to factor this in to either the end dates of your research or the target number of participants.
- **Shielding** is a significant constraint in relation to many of our research participants – amendment of protocols to limit the risk to shielded patients, but still ensure that they are not excluded from research will be a point of ongoing discussion and planning for all teams.

[Team Leads & Clinical Leads Forums](#)

We recognise that there may be common issues in relation to restart and so have organised a weekly report and brief meeting for team leads to provide an update on their progress and concerns, and also a fortnightly forum for clinical colleagues to share and ask questions. With our focus on supporting research in as many areas as possible, there may be decisions to take in relation to restarts that span teams and specialities. It is important to keep you informed as to the Trust position overall and how that in turn effects your own research.

Delivery Team Leads Meeting will be held on Mondays 2-3pm

Clinical Research Leaders Meeting will be held fortnightly on Tuesdays – the first 2 dates are Tuesday 30 June and 13 July 12-1pm

We will continue to keep you updated on a regular basis by email bulletin fortnightly and please do contact us with any queries directing them as follows:

[Stephen Wright](#) – clinical concerns

[Morag Burton](#) – staff capacity and support services issues

[Sean Scott](#) – research governance feedback or questions

Our Steering Group will be meeting weekly on Tuesday afternoons where common escalations will be discussed and actions taken to resolve these going forward.

Morag Burton and Dr Stephen Wright
Research Operations Manager | Clinical Director R&D

