

COVID19 Research Guide – 7/10/20

Research Restart Guide

The National Institute for Health Research (NIHR) has published a [framework for restarting research activities](#) paused due to the COVID-19 pandemic. They have also published guidance for [a second wave of COVID](#).

These documents outline guiding principles for a coordinated restoration and ongoing management of the research portfolio. The essential points are reproduced below:

The Restart Framework recognises **three prioritisation levels**:

- **Level 1:** Essential studies providing evidence for pandemic management, i.e. nationally prioritised COVID-19 Urgent Public Health (UPH) Research studies
- **Level 2:** Studies where the research protocol includes an urgent treatment or intervention without which patients could come to harm. These might be studies that provide access to potentially life-preserving or life-extending treatment not otherwise available to the patient
- **Level 3:** All other studies (including new COVID-19 studies not in Level 1)

It should be noted that these classifications reflect the current situation as of the date of this document (i.e. the lack of an effective treatment or vaccine for COVID-19, the risk of further critical waves).

The Restart Framework also sets out three preconditions for restarting/starting research. In brief these are:

- **Study Viability:** Only research that is still viable should restart/start. Some studies that have been paused or have not yet started may no longer be viable, for scientific, clinical, financial or practical reasons.
- **Safety:** Research should only restart/start when safe to do so. Safety of research participants and staff is of paramount importance
- **Capacity and site readiness:** The pace of restart and the commencement of new studies should be commensurate with capacity and readiness.

The restart of a currently paused study and the start-up of new studies will be dependent on the above preconditions being met. It is the responsibility of the Sponsor, funder, Chief Investigator and Principal Investigator to assess that these are met before restarting/starting.

We encourage all research staff to follow the latest guidance from the Trust, Department of Health, NIHR and Health Research Authority (HRA) for guidance on how to appropriately manage research activity.

Current CNTW Research Status

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, or an IPC approved variation on this, to minimise the risk to patients and staff.

NIHR Funded Delivery Team Support:

The CNTW Research Delivery Team continue to work hard to support as many portfolio studies as possible. However, regional resource and capacity has begun to necessitate prioritisation of NIHR funded support, including the NIHR funded workforce within CNTW. Any studies categorised as Urgent Public Health (UPH) studies are an NIHR priority. Examples of UPH studies include work towards developing treatments for COVID, COVID vaccines and studies that address the impact of COVID on certain patient groups.

Delivery Team staff are supporting UPH studies regionally and over the coming months this may mean a reduction in our capacity to support the whole of the current CNTW NIHR portfolio. Some studies may be reallocated to alternative staff with very short notice and although we aim to avoid this, some may need to be paused. We will endeavour to support as many projects as possible, and will contact the PI if the delivery team support towards your study is affected.

Actions for Investigators:

PIs are encouraged to discuss their studies with the Research Team and to consider what the prioritisation level of their study is. This will allow the Research Team the necessary oversight to plan staffing accordingly. For CNTW Sponsored studies please contact CNTWSponsormanagement@cntw.nhs.uk and for Hosted studies please contact research@cntw.nhs.uk

Requests to restart will be reviewed promptly and study teams will receive a 'reactivation' email from R&D for paused studies and the usual 'green light' email for trials opening for the first time.

National Guidance:

MHRA and HRA have issued the following guidance:

<https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/covid-19-guidance-sponsors-sites-and-researchers/>

<https://www.gov.uk/guidance/managing-clinical-trials-during-coronavirus-covid-19>

Contact R&D using research@cntw.nhs.uk