Interactive checklist for the restarting/starting of research

Due to the outbreak of COVID-19, most non-COVID related research and clinical trials have had to be stopped or paused. In order to support the restarting of research and trials, the National Institute for Health Research (NIHR) have published their 'Restart Framework', a set of guidance to support local decision-making in the resumption of NIHR funded or supported research. This guidance will continue to evolve in the context of learned experience and this tool will be updated in line with any changes to the guidance. More details and the most up to date guidance can be found by accessing the NIHR website.

Before research can be restarted or started, a number of preconditions must be met. Sponsors, funders and Investigators must ensure that they assess and consider the following key elements:

Study viability	Safety	Capacity and site readiness

We have created the interactive checklist below to help you ensure all of the necessary requirements have been met for your clinical trial or research study to restart.

Study viability requirements:

- ☐ Sponsor and funder have assessed and agreed to restart
- ☐ Regulatory approvals in place
- ☐ No impact on support for Urgent Public Health (UPH) COVID-19 studies
- ☐ All necessary research funding is confirmed
- ☐ Funding to meet any Excess Treatment Costs has been confirmed
- ☐ Sponsor and funder are satisfied with the arrangements for patient and public involvement in the study

Safety requirements:

- ☐ Risk of exposure to COVID-19 for patients and staff has been mitigated
- ☐ Physical access complies with government restrictions on social distancing
- ☐ Assessment of COVID-19 testing and PPE requirements completed
- ☐ Study arrangements comply with local organisation / site policies in respect of COVID-19
- ☐ Site compliance with regulatory requirements has been confirmed by the organisation's R&D Director or equivalent
- ☐ Clear guidance on safety issues and precautions has been provided to participants and staff
- ☐ Participants are asked and reassured about any concerns regarding COVID-19 and participants need to feel safe and confident

Capacity and site readiness requirements:

- ☐ Local clinical lead (Principal Investigator) confirmed and in place
- ☐ Research staff in place
- ☐ Health and care site / service 'open for business' to the full extent required for the study
- ☐ Research management and support in place (site R&D office, CTU, LCRN)
- ☐ All necessary supporting departments (e.g. pharmacy, pathology, radiology) have resource and capacity
- ☐ All necessary supplies have been procured and are in place (including IMPs and PPE)
- ☐ For paused studies, study data have been checked for data integrity to ensure that data remain robust and/or fit for purpose
- ☐ Physical access arrangements for participants have been assessed and are satisfactory
- ☐ Permission to restart from site legal entity

Prioritisation Guide

The NIHR's Framework also includes three levels of prioritisation for NIHR Clinical Research Networks support, with Level 1 being the highest priority/urgency. The three levels are:

- **Level 1:** Essential studies providing evidence for pandemic management, i.e. nationally prioritised COVID-19 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).

1. This information is based on guidance published by NIHR, Version: 2.0. 03 July 2020.