NIHR | University College London Hospitals Biomedical Research Centre

NHS University College London Hospitals NHS Foundation Trust

University College London Hospitals
Research Directorate Covid-19 Recommendations

Version 1.7 3rd April 2020

Introduction

UCLH is a major research active organisation, currently with over 1,000 active clinical studies, involving over 15,000 patients and over 25,000 research encounters per year. The Covid-19 infection is rapidly evolving and this is likely to be the case over the coming months. This document outlines guidance for all staff involved in research at UCLH to ensure the safety of our patients and our staff until the situation resolves. It complements other guidance related to Covid-19 provided by UCLH and UCL and is subject to regular review as the National situation evolves. Updates will be provided via our usual multiple communication channels.

Advice for Research Staff regarding Clinical and Non-Clinical Duties

- In the event that UCLH has a substantial increase in demand for its clinical services due to a serious Covid-19 outbreak, we would expect clinical trained research staff with substantive or honorary contracts at UCLH, to support the provision of patient care. Other research staff with relevant skills e.g. laboratory, pharmacy, technical support services and other non-clinically qualified research staff e.g. administrative, may also be requested to support UCLH in its provision of care.

- All clinically qualified research staff working on hospital premises should discuss what their appropriate clinical activities might be on an individual basis and should acquaint themselves with the latest guidance issued within their clinical service with respect to infection control measures.

Advice on initiating new research studies

Initiating new studies at this time is going to be challenging. Evidence already suggests that potential participants will be increasingly reluctant to attend the hospital, research staff may be diverted to other duties and research space may be used for other purposes. We are establishing the *UCLH Research Directorate Covid-19 Response Group*, meeting on a weekly basis, to consider the initiation of new clinical trials at UCLH on a case-by-case basis, during this period but a general principle is;

- **New research studies should not be initiated until further notice – effective immediately**, unless;
- The treatment is essential for serious, or life-threatening conditions
- Studies of Covid-19
- Studies where there is no requirement for patient attendance at UCLH

We will expect the administration of studies already in set up to continue, but stop short of awarding decision-to-deliver and signed contracts.

If a study requires the set-up of a new diagnostic test, platform or pathway outside of services currently provided it should not go ahead for the time being.

Advice on existing active research studies

This is challenging because of the wide range of studies, of varying complexity, at various stages of their life cycle and the fact that the implications for patients involved in these studies may be significant if the study is discontinued. Nevertheless, the same concerns apply with respect to patient attendance, staff availability and research space. There are two elements to existing research studies; (i) whether new screening and recruitment should take place; and (ii) what to do with patients who are already actively involved in studies.

(i) Screening and recruitment of new participants into existing studies:

Our general principle is:

- **New screening, recruitment (including consenting, post-consent screening procedures) should not take place – effective immediately**, unless;
- The treatment is essential for serious, or life-threatening conditions
- Studies of Covid-19
- Studies were there is no requirement for patient attendance at UCLH
  *This applies to both new participants and existing participants whom have already consented but have not been **randomised or initiated IMP treatment.**

(ii) Continuing review and/or treatment of Patients in existing studies:

- **Priority 1 Studies** (studies we must endeavour to maintain): Open studies in which recruited patients would be at risk of serious harm or imminent life-threatening deterioration if the study is paused, or studies of Covid-19. **These studies should continue for patients who have already been recruited.**

- **All other interventional studies** can continue but only if non-dosing visits are conducted remotely (e.g. by telephone) and Service Support Departments (Pharmacy) confirm that there is continued capacity. Dosing visits may continue on site but only for non-oral IMPs that need to be delivered by the parenteral route (e.g. IV or IT) and not by patient self-administration (e.g. orally or by SC route), if continued clinical capacity is confirmed. As per MHRA Covid-19 Guidance, the delivery of IMP to a patient's home and the omission of non-essential per-protocol assessments (including blood and/or imaging tests) is acceptable, if in the medical opinion of the Investigator patient safety is not put at risk.

- All other research requiring patient attendance at UCLH (e.g. non-interventional observational/biomarker/longitudinal cohort studies) **must not** continue until further notice.

- UCL students' studies involving UCLH staff may continue, subject to discussion with the relevant clinical leads, providing the studies fully utilise remote methods only (no face to face interactions with staff and/or patients).

The portfolio will continue to be reviewed on an on-going basis.

The decision to book research visits should always be made in line with UCLH policy which is currently subject to change at short notice. In the event a PI considers a research visit may be required to minimise risk to the patients care or safety, the PI should:

- Make contact with the study sponsor. The sponsor will advise on their contingency plan for the delivery of essential medicines/IMP
- Discuss with Service Support Departments such as Pharmacy and Imaging to ensure there is continued capacity
- Use phone calls instead of protocol-directed in-person study visits. The omission of non-essential per-protocol assessments (including blood and/or imaging tests) is accepted, if in the medical opinion of the Investigator patient safety is not put at risk. Protocol deviations in relation to Covid-19 will not constitute a serious breach, therefore there is no need to report to the MHRA or submit a substantial amendment. However any protocol deviations should be well documented
- Consider the use of alternative consultation methods where appropriate (as advised by the Trust or local clinical department)
- Ensure patients are informed, in good time, of any change to their requirement to visit UCLH

Monitoring ongoing studies

- Facilities for remote monitoring of research studies is available at UCLH. Guidance can be found at: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/covid-19-guidance-sponsors-sites-and-researchers/ and the Medicines and Healthcare Products Regulatory Agency (MHRA) https://mhrainspectorate.blog.gov.uk/2020/03/12/advice-for-management-of-clinical-

trials-in-relation-to-coronavirus/ and https://www.gov.uk/guidance/managing-clinical-trials-during-coronavirus-covid-19

- Information on access to remote monitoring can be located on the JRO Website.

Contracting and Finance

- Temporary pausing of clinical studies would often have implications for contractual obligations, particularly for commercial research. Our review of contracts for commercial and non-commercial research suggests that UCLH could rely on Force Majeure clauses in research contracts in the event of temporary study suspensions due to COVID-19.
- In the event of study suspension, the Principal Investigator or their nominated delegate, should inform the study sponsor. This advice is in line with MHRA advice for management of clinical trials issued 12th March 2020 (see link above)
- UKRI and NIHR have confirmed that no financial penalties will be enforced if a project is suspended. It is anticipated that AMRC registered charities will follow UKRI guidelines.
- The Grant holder should inform funding bodies about any study suspension on a project by project basis.

Implications for Dedicated Clinical Research Facilities (CRFs)

- There are two NIHR CRFs, one at 170 Tottenham Court Road and one at Queen Square. These facilities remain open and will continue to operate in line with the recommendations above and existing UCLH guidance on visiting UCLH during the Covid-19 outbreak.
- Any additional changes to the use and availability of the CRF facilities during the Covid-19 outbreak will be communicated if the situation changes.

Further Information

Information will be regularly updated on the Joint Research Office and BRC Websites and via UCLH communications and the HRA www.hra.nhs.uk/coronavirus. Enquiries about existing or planned studies should be made to the Joint Research Office (uclh.randd@nhs.net). This guidance document is in line with national guidance issued by the NIHR (https://www.nihr.ac.uk/news/dhsc-issues-guidance-on-the-impact-on-covid-19-on-research-funded-or-supported-by-nihr/24469).

Professor Bryan Williams
UCLH Director of Research, Director of NIHR UCLH Biomedical Research Centre

Dr Nick McNally
Managing Director, Research UCLH/UCL