

University College London Hospitals Research Directorate Covid-19 Recommendations

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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 and recruitment should not take place – 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

(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 harm if the study is paused, or studies of Covid-19. **These studies should continue for patients who have already been recruited.**
- **For all other studies, the Principal Investigator should consider very carefully whether they should be continued at this time.** The portfolio will continue to be reviewed on an on-going basis.

Monitoring ongoing studies

- Facilities for remote monitoring of research studies is available at UCLH. However, sponsors should ensure patients have specifically consented to remote monitoring (outside of UCLH) access by non-UCLH staff. 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/>.
- 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).

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