Guidance on managing open research studies at UCLH during the Covid-19 pandemic
(*Version 1, 2nd April 2020*)

Introduction

The Research Directorate at UCLH have advised that all studies at UCLH cease until further notice unless they fall into three categories:

- 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

Studies falling into those categories remain open and treating patients at UCLH. These studies must inform the Joint Research Office (JRO) if they remain open.

These studies will be open at a time where the pressures upon service support, and other departments is considerable, and often significantly impaired due to redeployment of support to Covid-19. This document outlines any changes in practice which may affect the progression, treatment or testing of participants on these open studies.

Studies using Pathology Services

When conducting and developing your research programmes, please consider that there is currently an unprecedented demand and shortage of viral collection swabs, transport media and other associated consumables specifically used for the collection of respiratory virus samples and for COVID-19 testing.

In addition, some routine sample types have had their handling requirements upgraded whereby laboratories are required to handle those samples within biological safety cabinets.

Therefore where possible;

1) Minimising additional routine or specialist sample collection pathways beyond what is needed for standard of care testing. Where possible additional samples for research should not be taken.

2) Do not collect additional respiratory virus swab samples beyond standard of care and when compatible and appropriate consider pooling of multi-site samples so ensure that hospital consumables and downstream COVID-19 testing reagents in pathology are maximised for patient and healthcare worker testing and management.

3) Through appropriate data protection routes and authorisation pathways researchers are encouraged to utilise existing standard of care data held in the Trusts electronic data patient management systems to support your research programme.

Studies using Pharmacy Services

When conducting and developing your research programmes please consider that there is currently a demand on the research pharmacy team to support the NHS due to unprecedented levels of operational vacancies following a number of staff required to self-isolate.

In accordance with the NIHR position statement on prioritizing funding and support for COVID-19 research across the UK, the Research Pharmacy Clinical Trials Unit (PCTU) is ensuring that they make the best use of limited resources and capacity available to support research. There are a number of CTIMP trials in the pipeline to open at UCLH.

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UCLH is an NHS Foundation Trust comprising: University College Hospital (incorporating the Elizabeth Garrett Anderson Wing, the Macmillan Cancer Centre and University College Hospital at Westmoreland Street), Royal London Hospital for Integrated Medicine, Royal National Throat, Nose and Ear Hospital, National Hospital for Neurology and Neurosurgery at Queen Square and Cleveland Street, Institute of Sport, Exercise and Health, Hospital for Tropical Diseases, The Eastman Dental Hospital.

In addition to this, NHSE have made a request for each organization (including UCLH Pharmacy) to provide staff to the NHS Nightingale Hospital which further causes an impact on operational delivery.

To comply with the departmental business continuity plan, where staff numbers have decreased beyond the level required, the PCTU team is required to redeploy staff to other arms of the pharmacy service in order to ensure that the core medicines supply process is maintained. Across the department, across all sites, we are doing our best to maintain services at 50% staffing level. The consequence of this being that there is extremely limited support available for non-COVID trials.

Please therefore ensure that any new or continuing research activity meets that above criteria.

Studies using Radiology Services

In order to manage the Covid-19 response, the Radiology department have a reduced CT/MRI/US imaging service. All scans are vetted for clinical urgency/need. Non-urgent scans for patients on studies, i.e. scans which are over and above the normal routine be delayed/cancelled at this time.

Please keep to the routine booking process for research studies. The Research Bookings team remains staffed and is able to help to schedule those scans that remain necessary. If a scan is cancelled/delayed for a patient on a trial and it is essential that it be performed, please contact research bookings and the team will try to help to resolve this.

Please note that there is a daily updated spreadsheet of actively recruiting studies and those with patients actively in follow-up provided by R&D. For any scan that is booked, the Research Bookings team will review this list to confirm that the patient is on an authorized study. If your study is not listed, the Bookings Team should advise you to contact R&D to discuss further.

New study set-up support will be provided in accordance to the Covid-19 guidance issued by R&D. When planning new studies, please bear in mind the reduced imaging capacity at this time.

Remote monitoring via EpicCare link

Where sponsors and Principal Investigators determine a need to request remote access for monitors (in line with the guidance from the HRA, MHRA and UCLH), they should firstly consult the COVID-19 UCLH Remote Monitoring Arrangements guidance document. Please, check all the information on the JRO link. https://www.ucl.ac.uk/joint-research-office/news/2020/mar/covid-19-important-updates-researchers.

Completing Case Report Forms (CRFs) whilst working from home

UCLH staff working from home have access to secure UCLH-approved applications and systems (e.g. electronic health records systems) and shared drives via remote working software (Citrix). UCLH systems have been approved for use (e.g. review of patient records) and can be accessed remotely for completion of sponsor CRFs. Study teams should check with their sponsor in the first instance for guidance on how to complete, sign and send these electronically to sponsors (e.g. where paper CRFs are still being used).

Research Incident Reporting

Please continue to report research incidents on the UCLH Datix system, accessible from the myUCLH homepage via Citrix or a VPN token: http://riskmanagement/datix/live/index.php. If you are unable to open the reporting form remotely, please raise an incident with UCLH IT Services, keep a local record of the incident details, and report as soon as you're able to login. For further details on what type of research incidents to report, please refer to the UCLH Research Incidents SOP.

Communication tools whilst working from home

Some study teams may have existing communications using Microsoft Teams, Slack, WhatsApp, Hospify, or Trello. There's no need to abandon these – the hospital will support you using what works.

Remember three principles:

- We have no audit or archive of these platforms, so makes notes of decisions on official systems, e.g. Epic, documents on shared drives, NHSMail, etc.
- You should never discuss identifiable patient information over any of these other channels – only use Epic, and other secure UCLH-approved applications
- Let UCLH know, via uclh.remote@nhs.net, if you are using tools not in the list above.

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