UCLH/UCL Research Directorate Covid-19 recommendations for UCLH research

19.04.2021

1. Updated guidance and general principals

The UCLH/UCL Research Directorate has continued to review the implications of Covid-19 upon the research portfolio at UCLH and UCL.

Nationally, the rates of Covid-19 infection are rising. In response, the UK government has announced that a national lockdown will commence in England on Thursday November 5th, subject to Parliamentary approval. Following the lockdown period, it has also been suggested that the previously announced, three-tier approach to managing local outbreaks will continue.

This guidance informs Principal Investigators (PI's) of their responsibilities should there be a change to clinical service delivery at UCLH because of any of the following:

- the lockdown,
- other national or local (UCLH specific) Covid-19 policies and guidance.

This guidance outlines the expected response from PIs where UCLH is required to halt routine clinical activity fully or partially. This guidance is subject to change (as the position at UCLH and/or nationally alter) PI's should review the JRO website weekly for updates.

This guidance is aimed at researchers and sponsors conducting research at UCLH and should inform sponsor pandemic plans and should be considered prior to the initiation of new studies at UCLH.

PI's at UCLH should review the guidance with the sponsor for each of their studies and enact in the event it is required . PI's should, in accordance with the guidance, apply the most appropriate guidance for the stage of the study (pipeline, actively recruiting, in follow up). Scenarios and the expected responses are outlined in sections 2 and 3 of this guidance.

For all studies, in all scenarios, PI's should:

- stay up to date with, and follow all UCLH, national and regulatory directives and guidance
- seek approval from the sponsor for all changes regarding the progression of their study
- ensure the delivery of the study is in line with the delivery of clinical care and infection control measures at UCLH
- use remote methods for follow-up of participants wherever it is possible to do so
- only conduct on-site research visits under approval from the sponsor and with the full knowledge of the clinical division. On site visits should, wherever possible, coincide with planned clinical appointments.
- communicate with research participants on the implications of Covid-19 measures on their participation and the conduct of the study. This should include information on any change (or not) to their personal participation, planning for remote and on-site visits, relevant changes to clinical delivery or patient visits to UCLH, change to the delivery or outputs of the study, any safety measures, and the opportunity to discuss their continued participation with the PI (or other lead from the research team)
- notify the Joint Research Office (JRO) where studies are suspended or altered and, in the event, of significant capacity issues which affect the delivery or compliance of the study (includes where the PI and lead researchers are redeployed to clinical support)
- regularly review the JRO website and messages and respond to requests for information from the JRO

- immediately enact the appropriate guidance (as below) and inform the JRO in good time (the next working day). The PI should not wait for a response from the JRO unless requested by the clinical division, the divisional research lead, or the sponsor, or where an amendment (or other) require a formal response from the JRO (as per UCLH or regulatory requirements - e.g., amendments or safety concerns)

Updates and enquires should be sent to uclh.randd@nhs.net. Urgent or significant safety concerns should be marked for the attention of Rajinder Sidhu and Ferdousi Chowdhary at the JRO.

2. Studies actively recruiting patients or conducting follow-up of patients on site at UCLH

The Research Directorate paused the recruitment of all new patients to research studies in March 2020 (Research Directorate Covid-19 recommendations, March 2020).

Exceptions to the policy were approved (by the JRO) for a defined group of studies – studies in Covid-19, treating serious and life-threatening conditions and those where no patients or on-site activity was required. A total of 230 studies fall into this exceptional group.

Following the end of the first national lockdown and the recovery of UCLH clinical services, some further studies have also been approved and re-opened at UCLH. Each study has been formally approved to re-open after an assessment by the relevant UCLH Clinical Divisions, service departments and the JRO.

PIs for these two groups of approved studies should follow the following guidance in the event clinical services are affected by (all) national or local Covid-19 measures (i.e., a lockdown, tiers, other guidance).

Where UCLH continues to treat all patients at UCLH

- The PI should consult with the sponsor and determine the viability of continuing recruitment or follow-up at UCLH
- Any actions should be in line with relevant UCLH, division and regulatory policies, directives, and guidance
- The JRO should be informed of the decision to continue, pause or amend the study (including confirmation of approval from the sponsor)

Where UCLH suspends all non-essential treatment at site or all clinical treatment within the division where the participant is recruited from

- Participants in follow-up and on active treatment should continue to be treated in line with sponsor requirements
- Remote methods should be deployed for the delivery of drugs, devices, and follow-up of patients
- Studies which were approved within the exceptional group (only) will be able to continue with new recruitment as per the agreements under the Research Directorate Covid-19 recommendations (March 2020 version 1.6)
- Any actions should be in line with relevant UCLH, division and regulatory policies, directives, and guidance

- The JRO should be informed (via a joint email) of the change which has been imposed (including confirmation of approval from the sponsor)

Where UCLH enacts a partial closure of clinical areas or partial restrictions to visitors and patients

- The PI should consult with the sponsor and determine the viability of continuing recruitment or follow-up at UCLH
- Any amendments to the conduct or management of a study should be approved by the Sponsor
- Any actions should be in line with relevant UCLH, division and regulatory policies, directives, and guidance– including any change in local tier ratings
- The JRO should be informed (via a joint email) of the decision to continue, pause or amend the study (including confirmation of approval from the sponsor)

3. Studies not yet active at UCLH

Studies not yet active at UCLH include:

- research studies which were previously issued D2D but had not started recruitment
- new studies currently in set-up at UCLH (i.e., have yet to be provided with an approval or d2d to start at UCLH)
- new study applications (i.e., are yet to be submitted for an approval at UCLH)

For these studies, the set-up process will continue at all times, but will stop short of issuing an approval to being at UCLH in the following circumstances **only**:

- in the event of a complete national lockdown
- where UCLH suspends all non-essential treatment at site or all clinical treatment within the division where the participant is recruited from

Should this be enacted, this would mean - the JRO, CRF and CCTU will continue to process the study paperwork, determine capacity and capability and draft/negotiate contracts and finances. However, the final approval (which allows the study to start at UCLH) will be with-held until the end of lockdown/when UCLH resume full clinical activity.

However, certain study types maybe exempt. Any exceptions will be guided by national DHSC advice. Researchers should check the JRO website and JRO communications for further information should the above circumstances apply. At all other times, researchers and sponsors should approach the JRO, CCTU or CRF (as applicable) and in accordance with normal processes.

4. On-site external research visits (monitoring, auditing, SIVs, close out visit, etc.)

- PI's should refer to the JRO website's COVID-19 page for the latest information.
- Remote monitoring of research patients medical records is available via EpicCare Link; please refer to guidance here for further information.