

## **UCLH/UCL Research Directorate Covid-19 recommendations: Update 19th October 2020**

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 beginning to rise. In response, the UK government has announced a three-tier approach to managing local outbreaks.

This guidance informs Principal Investigators (PI's) of their responsibilities should (and only if) the need arise for clinical services at UCLH to be fully or partially suspended because of measures introduced under this new approach or under subsequent national or local (UCLH specific) Covid-19 management policies.

This guidance is aimed at researchers and sponsors conducting research at UCLH and should inform sponsor pandemic contingency plans. PI's at UCLH should review the guidance with the sponsor for each of their studies and should enact any elements in the event it is required .

### **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 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 national or local Covid-19 measures.

### **Where the Trust (UCLH) halts all non-essential treatment at site**

- Participants on active treatments 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 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– including any change in local tier ratings
- The Divisional Research Lead and the JRO should be informed (via a joint email) of the change which has been imposed (including confirmation of approval from the sponsor)

### **Where the Trust (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 Divisional Research Lead and 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)

### **Where the Trust (UCLH) continues to treat 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 – including any change in local tier ratings
- The Divisional Research Lead and 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)

### **Studies not yet active at UCLH**

#### **Where the Trust (UCLH) halts all non-essential treatment at site**

- The applicable sections of the Research Directorate Covid-19 recommendations (March 2020 version 1.6) will be re-instated. Specifically, no further studies will be approved to re-start or initiated at UCLH
- Exceptions will be considered for studies in Covid-19, those considered priority by the NIHR, those treating serious and life-threatening conditions and those where no patients or on-site activity is required
- Researchers requesting exceptions should make a clear case for such (in line with the Research Directorate Covid-19 recommendations March 2020) and submit jointly to the JRO and the applicable Divisional Research Lead (for re-start of studies). The Research Directorate Covid-19 response group will consider each study with the Divisional Lead
- PI's should additionally demonstrate that the management of the study and patient experience are in line with the applicable restrictions, and the relevant UCLH, division and regulatory policies, directives, and guidance (including any change in local tier ratings)

### **Where the Trust (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 opening at UCLH
- Should the PI and sponsor wish to re-open at UCLH, the UCLH research re-start procedure should be followed (<https://www.ucl.ac.uk/joint-research-office/covid-19-important-updates-researchers>)

- PI's should additionally demonstrate that the management of the study and patient experience are in line with the applicable restrictions, and the relevant UCLH, division and regulatory policies, directives, and guidance (including any change in local tier ratings)

#### **Where the Trust (UCLH) continues to treat patients at UCLH**

- The PI should consult with the sponsor and determine the viability of opening at UCLH
- Should the PI and sponsor wish to re-open at UCLH, the UCLH research re-start procedure should be followed (<https://www.ucl.ac.uk/joint-research-office/covid-19-important-updates-researchers>)
- PI's should additionally demonstrate that the management of the study and patient experience are in line with the applicable restrictions, and the relevant UCLH, division and regulatory policies, directives, and guidance (including any change in local tier ratings)