

## **UCL and UCLH Sponsored Clinical Research Studies.**

### **Covid-19 Guidance**

This guidance outlines the requirements regarding continuation of clinical research studies sponsored by UCL and UCLH during the current Covid-19 pandemic. All researchers are expected to halt new recruitment and follow-up visits (which physically take place at NHS or social care sites) unless there are exceptional circumstances to continue or the research relates to Covid-19. Follow-up of expected, pre-booked protocol visits can, where possible, be conducted remotely.

The reasons and context for the suspension include:

#### **1: Changing priorities within the NHS and Social Care**

In response to the evolving Covid-19 situation, and under the guidance of the NHS, NIHR and regulators, the majority of research studies involving the NHS and social care have been suspended by host organisations.

UCLH, as the major host organisation for UCL and UCLH sponsored studies, has released its statement regarding the continuation of research

([https://www.ucl.ac.uk/joint-research-office/sites/joint-research-office/files/uclh\\_research\\_covid\\_19\\_policy\\_v1.6\\_20.03.2020.pdf](https://www.ucl.ac.uk/joint-research-office/sites/joint-research-office/files/uclh_research_covid_19_policy_v1.6_20.03.2020.pdf)).

#### **2: Redeployment and availability of research staff**

Growing numbers of research, clinical and technical staff are redeployed to focus on Covid-19 research or to provide support to NHS and social care services. Many hospital sites require staff, facilities, and services such as pharmacy, imaging and pathology to focus on essential clinical care and the response to Covid-19 only.

#### **3: Safety of staff and participants**

Most NHS and UCL staff are working from home. A significant percentage of staff will likely be in self-isolation. NHS organisations are minimising or completely halting all non-essential contact with patients, and have restrictions in place for visitors and other non-essential staff.

#### **Sponsored studies**

The following is expected for all UCL and UCLH sponsored studies.

#### **Continuation of in-progress studies (recruiting or in follow-up)**

All Chief Investigators should have mechanisms in place to risk assess/oversee the impact of any changes at host sites and their research teams upon their study. These risk assessments should have been completed in response to Covid-19.

We recommend the suspension of all UCL and UCLH studies with the exception of those studies where:

- The treatment is essential for serious, or life-threatening conditions
- The withdrawal of study treatment will have a serious or life-threatening consequence for the participant
- Studies of Covid-19
- Studies where there is no requirement for participant or researcher attendance at NHS, academic, social care or prison sites (UK and international sites)

All UCL and UCLH studies will be considered automatically suspended unless CI's advise otherwise (fall under the above exceptions). CI's of such studies should inform the Joint Research Office immediately on [uclh.randd@nhs.net](mailto:uclh.randd@nhs.net) (non-ctimps) or [ctimps @ucl.ac.uk](mailto:ctimps@ucl.ac.uk)

All studies will be marked on EDGE as "suspended due to Covid-19) from Wednesday 8th April, unless the JRO is otherwise informed.

Studies where researchers are visiting participants within their homes or where participants meet with researchers in community settings should be suspended.

However, studies falling into these 4 exception categories should only continue with permission/in line with the Covid-19 research policy for the host site.

Studies which involve the observation, interviewing or surveying of NHS, social care, prison (or other key worker) staff, should consider suspension unless specific re-approval from the local service or clinical leads at the host site has been sought.

### **New studies making applications for UCL and UCLH sponsorship:**

Regulators are prioritising Covid-19 and high priority studies only. Research funders have largely paused the submission of new funding applications.

Sponsorship approval for studies at UCL and UCLH will be suspended unless the studies are for:

- The treatment is essential for serious, or life-threatening conditions
- Studies of Covid-19

The Joint Research Office (JRO) and the UCL Clinical Trials Units (CTU) may (subject to availability of staff and guidance from regulators) continue to receive new applications in preparation for future (post Covid-19) submissions to the HRA and MHRA. However, the

priority for all units will be the support of Covid-19 studies. No student (MSc or BSc) projects will be supported. PhD applications relating to serious or life threatening conditions or studies of covid-19 will be prioritised.

## **Further guidance**

All researchers should regularly check the JRO website for updates from regulators and other relevant information

Researchers working with CTU's should continue to liaise with/manage their studies with the CTU in line with the above recommendations

Any concerns or points of clarification (from CIs or CTUs) relating to Pharmacovigilance, safety reporting, contracting or other high risk or safety issues should be referred immediately to the JRO via email to [ctimps@ucl.ac.uk](mailto:ctimps@ucl.ac.uk)

Any escalations of major issues or guidance requirements from CTUs should be sent to the sponsor office

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.

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](http://www.hra.nhs.uk/coronavirus). Enquiries about existing or planned studies should be made to the Joint Research Office ([uclh.randd@nhs.net](mailto: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>).