

## **Q&As for researchers Existing UCLH studies only**

**The Q&A below should be read in conjunction with the UCLH Covid-19 recommendations from the Research Directorate at UCLH.**

**I have read the advice published by R&D. Has R&D let sponsors know about the UCLH recommendations for researchers?**

At this stage, sponsors have not been independently emailed by R&D. We advise that Principal Investigators let their sponsors know and discuss the implications upon individual studies.

**I currently have a study going through the feasibility approvals process at UCLH. Will it be able to open at UCLH?**

Initiating new studies will be challenging for UCLH as a service and for our patients. New research studies have been paused until further notice unless the study relates to treatment for a serious or life-threatening condition; does not require patient attendance at UCLH; or is related to Covid-19.

If your study has not yet been approved to start at UCLH but was in a feasibility review, the UCLH coordinator will continue to progress the feasibility assessment as much as is possible - including contract and finance negotiations. However, no approval, greenlight or decision to deliver will be issued as yet so you will not be able to start at UCLH. Anticipated start dates cannot be provided at this stage.

**I believe my active study falls into the category of “treating a serious or life-threatening condition.” Do I need to let anyone know that I will carry on recruiting?**

Yes. Email the JRO on [uclh.randd@nhs.net](mailto:uclh.randd@nhs.net) and let them know the IRAS number (or other identifier if you cannot locate the IRAS) and mark as urgent. You should also ensure your pharmacy contact, clinical director and general manager are aware.

Make sure you have informed your sponsor.

**I think my study should go ahead but the Research Directorate guidance advises otherwise. Can I talk to someone about this?**

Yes. First email the JRO at [uclh.randd@nhs.net](mailto:uclh.randd@nhs.net). Your email will be reviewed at the weekly Research Covid-19 response group. The group will advise. Until you hear back from the group, you should follow the Research Directorate’s guidance

**I am concerned about potential legal or financial consequences arising from the commercial sponsor of the study should I need to suspend activity. What should I do?**

A statement regarding the rationale for site suspension at UCLH can be sent to the sponsor to explain the circumstances behind the decision to pause research activity. All commercial contracts do contain a Force Majeure clause. You should consult with sponsors as soon as possible whenever there is a change to activity at UCLH, particularly if there are implications upon the contract and upon the protocol. The Joint Research Office legal team can support with these communications. They can be contacted via [uclh.randd@nhs.net](mailto:uclh.randd@nhs.net). It would be helpful if your query is marked as “legal advice” in the subject header.

**External monitors need to access patient records at UCLH. The current practice is for them to do so through EpicCare Link but from UCLH computers. How should I advise the monitors in the event that visitors are restricted to UCLH?**

On-site monitoring visits are suspended until further notice. Monitors can however access EpicCare Link remotely during this period, from Monday 23<sup>rd</sup> March 2020. Monitors will be required to sign a 'remote monitoring' code of conduct, which has been developed in accordance with MHRA, GDPR and UCLH Information Governance requirements. The UCLH SOP for Monitor Access to Epic (via EpicCare Link) should continue to be followed. Requests for monitor access should follow the current arrangements as outlined at: <https://my.uclh.nhs.uk/Interact/Pages/Content/Document.aspx?id=13495>. Please refer to the JRO's COVID-19 page for further updates.

If remote monitoring is not practical for whatever reason, we recommend halting monitoring activities until on-site monitoring resumes. If you are involved in a high risk trial (or COVID-related trials) where monitoring must continue, please contact [research-incidents@ucl.ac.uk](mailto:research-incidents@ucl.ac.uk) to discuss further.

**Can I contact patients remotely for follow up protocols?**

Yes. As long as the Trust has the correct facilities to do so and the sponsor has been consulted and agreed, it may be possible to consult remotely.

**Participants on my trial are reporting flu related AEs/SAEs. Do we record these on CRFs?**

The MHRA advise that they are recordable, unless the sponsor can justify a substantial amendment to the protocol to exclude these events. Speak with your sponsor immediately.

**Should we continue to report SUSARs, ASRs and other events required by Sponsors?**

Yes.

**Key procedures required by the protocol cannot be met. What should we do?**

Contingency plans should be in place to minimise impact upon patient safety and data integrity. Protocol deviations should be recorded in the CRF/EHRS/Site File as appropriate. Consult the study sponsor for further guidance. UCLH is currently suspending research scans and blood tests, as these are considered to be 'non-critical'. PIs are responsible for notifying their sponsors of this and recording and reporting protocol deviations accordingly. PIs are to use their clinical judgement regarding whether to continue any protocol related activities during this period.

**A patient on my trial needs to be re-consented following an amendment, but will not attend their next appointment at which this was due to occur. How should this be managed?**

Please discuss with the Sponsor immediately, who may choose to follow up with relevant Ethics committees for further advice. It may be appropriate to delay re-consent depending on the nature of the amendment (e.g. if it is not linked to safety). If re-consent is linked to safety, or it is important to obtain it as soon as possible, it may be permissible to do so over the phone. However, before proceeding to do so, please consult the study Sponsor for guidance. In all cases, any delays or deviations from normal consent processes should be well documented.

## **Should I continue to call patients into UCLH for research visits if their routine appointments have been cancelled?**

The decision to book research visits should always be made in line with UCLH policy which is currently subject to change at short notice.

In the event a PI considers a research visit may be required to minimise risk to the patients care or safety, the PI should:

- - Make contact with the study sponsor. The sponsor will advise on their contingency plan for the delivery of essential medicines/IMP
- - Consider the use of alternative consultation methods where appropriate (as advised by the Trust or local clinical department)
- - Ensure patients are informed, in good time, of any change to their requirement to visit UCLH.