University College London Hospitals
NHS Foundation Trust

FAQS FOR RESEARCHERS WISHING TO INITIATE NEW STUDIES RELATING TO COVID- 19 (UCL AND UCLH)

CONTENT (15/04/2020)

I have an idea for a Covid-19 study. What should I do?

Contact the Joint Research Office (JRO) asap. If your study idea involves the use of existing or new drugs or devices contact the JRO via uclh.randd@nhs.net

All studies at UCL and UCLH in Covid-19 are seen by the UCLH Covid-19 Research Strategy and Compassionate Care Committee prior to being approved to submit to the regulators or open at UCLH. The Committee meets at least once a week (more so if required). For further information about the Committee, please contact r.khengar@ucl.ac.uk

Please note, the JRO has halted the review of all MSc and BSc student research studies. This is in line with national HRA guidance. s

I've been approached by a non-UCLH or non-UCL organisation regarding participation in or acting as a Principal Investigator (PI) on a Covid-19 study. What should I do?

Contact the JRO asap (uclh.randd@nhs.net), with as much detail as possible - including your view on whether UCLH should participate/you would wish to act as PI. The JRO will aim to get back to you within the day where possible.

Data studies: I'd like to collect health data or human tissue at UCLH about Covid-19 patients and/or their characteristics. Is this research and what should I do next?

You first need to determine if the study is defined as "research" which needs a national regulatory approval. Consult the national decision making tool at: http://www.hra-decisiontools.org.uk/research/ or refer to the table at: http://www.hra-decisiontools.org.uk/research/docs/DefiningResearchTable_Oct2017-1.pdf

Whatever the outcome, drop an email to the JRO (uclh.randd@nhs.net) letting the JRO know that you have completed the decision tool. All Covid-19 related work (defined under any of the categories within the decision tools) are being logged within UCLH R&D. The JRO will make sure your project is reviewed by the UCLH Covid-19 Strategy and Compassionate Care group.

Should the study be classified as research, the JRO will support you with getting the study into the right regulators and onto opening asap.

Should the study be classified as a category other than research, you should, at the same time as you inform the JRO for their log, speak to the UCLH Information Governance Team (Matthew Hall) to discuss the logistics and IG requirements for the study.

Consent to use personal data: Do we need to obtain consent to access and use Patient Identifiable Information for research into Covid-19?

The Department of Health and Social Care have released four temporary notices under the Control of Patient Information Regulation 2002 requiring the processing of confidential patient information and including specific directives on consenting requirements during the COVID-19 pandemic, until the date of expiry (currently 20th September 2020). The Notices can be found here, where the specific letter for organisations providing health services is here.

In summary:

- The Secretary of State for Health has directed Organisations providing health services, General Practices, Local Authorities and Arm's Length Bodies of the Department of Health and Social Care to process confidential information COVID-19 Purposes; The Purposes are defined in the Notice here and include research to support these purposes;
- Individual patient consent is not required for this processing;
- Confidentiality Advisory Group support under Section 251 of the NHS Act 2006 is not required for this processing;
- The National Data Opt Outs will not be enforced;
- Data Security and Protection Toolkit submissions will not be expected;
- All processing under the COVID-19 Notice must be recorded;

When the Notice expires CAG Support or other mechanisms to uphold the duty of confidence will need to have been put into place for any processing under the COVID-19 Notice

GDPR: UCLH's privacy policy is currently being updated in regard to COVID-19 and will be publicly available on the UCLH website.

Consent in Emergencies: How should I go about consenting Covid-19 patients to research studies if they are too ill, or lack the capacity to go through full consent procedure themselves?

Where a patient can provide consent, they should provide so themselves. There is no relaxation of the requirements or expectations around ensuring full, informed consent is obtained. However, in some Covid-19 studies, sponsors will make provision (within the protocol) for the use of emergency research consent processes and where required, the use of consultees. These measures should not be used unless there is an agreement with the sponsor and the procedures are outlined in an approved (by regulators) protocol.

Further information about emergency research can be found at:
https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/research-emergency-settings/

National Priority Studies: What are the priority studies and how can my study be considered as part of this list?

COVID-19 Urgent Public Health Research is being prioritised to gather the necessary clinical and epidemiological evidence that will inform national policy and enable new diagnostic tests, treatments and vaccines to be developed and tested for COVID-19.

Government support is available to prioritise, coordinate and deliver these studies, regardless of sponsorship and funding source. This support includes expedited identification of sites to ensure appropriate geographical distribution of Urgent Public Health Research to maximise recruitment and minimise over-commitment of resource

National priority studies are determined by a central, government team. Applications to be considered onto the national priority list can be made at any time. The JRO or the Clinical Trials Unit supporting you in the set-up of your study, will help you submit to the appropriate body for consideration.

Further information can be found at:
https://www.nihr.ac.uk/researchers/collaborations-services-and-support-for-your-research/run-your-study/government-support-for-research-related-to-covid-19.htm

Expedited Regulations: Which regulations need to be in place before a Covid-19 study can begin?

There have been no changes to the type of regulations that need to be in place for studies deemed "research". However, all regulators have expedited processes in place for the review of new studies.

At UCLH/UCL, all studies are seen by the UCLH Covid-19 Research Strategy and Compassionate Care Committee. Following such, the JRO or a UCL CTU will support the CI or PI with any regulatory submissions. JRO processes are also expedited for all Covid-19 studies.

Local site approval (for UCLH) is managed by the JRO or the UCLH Cancer Clinical Trials Unit or the UCLH Clinical Research Facility. All three units are working together, with trials pharmacists, radiologist and pathologists at UCLH to ensure all UCLH Covid-19 host studies are expedited for local review in parallel to regulatory submissions.

Details of the fast track HRA process for Covid-19 studies (including amendments) can be found at: **https://www.hra.nhs.uk/covid-19-research/**

Details of the fast track MHRA process for Covid-19 studies can be found at:
https://www.gov.uk/guidance/clinical-trials-applications-for-coronavirus-covid-19

Any queries regarding the expedited review of UCLH host approval (or decision to deliver) should be sent to uclh.randd@nhs.net

Further information about regulations more generally can be found at www.ucl.ac.uk/jro

Honorary contracts: I work for UCL, but intend to support UCLH COVID-19 work; how can I get an honorary UCLH contract quickly?

Substantive UCL staff intending to support with COVID-19 clinical or research activity at UCLH can apply to become a **COVID Response Worker,** rather than go through the usual honorary contracts or research passports process (excluding UCL students or honorary UCL staff; please continue to follow the standard processes). This expedited process accepts pre-employment checks already completed at UCL, provided they meet the requirements of the UCLH role. UCL staff must then complete the **COVID Response Worker Template** form, and submit it to the UCLH Additional Workers team for processing. The UCLH Additional Workers team will then add to the relevant HR system and ensure relevant access is provided, and will liaise with relevant departments for training etc. (**Note:** electronic health record system training will be delivered virtually via webinars or eLearning from 14th April 2020; a UCLH Learning Portal account will be required to access these).

Please contact uclh.jro-communications@nhs.net for further information on how to apply to become a COVID Response Worker.

This process should only be followed by current UCL staff supporting UCLH COVID-19 clinical/research work. UCL Student researchers, or researchers involved in non-COVID-19 research should continue following the current JRO Research Passports process via the Joint Research Office (uclh.jro-communications@nhs.net). If you are a clinician joining UCLH for non-COVID-19 work, please follow the standard honorary contracts application process via uclh.honorarycontracts@nhs.net.