Research Directorate Covid-19 recommendations SPONSORSHIP (UCL and UCLH acting as Sponsor)

Update 19th October 2020

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

This guidance informs Chief Investigators (CI's) of their responsibilities should (and only if) clinical services be fully or partially suspended due to measures introduced under this new approach or under subsequent national or local (sites) Covid-19 management policies.

The guidance also covers research in community setting or within participants homes.

This guidance should inform study pandemic contingency plan and should be enacted in the event it is required.

Unlike the first wave of Covid-19, a universal approach to managing the pandemic within host sites and localities is unlikely. Host sites/localities are likely to respond in different ways - depending on tier rating within their locality and/or the policies or priorities of the host organisation. Change maybe rapidly and frequently imposed – as areas and organisations manage increases and decreases in infection.

It is essential for CI's to enable the regular communication between themselves and each host site and keep risk assessments actively updated.

Multicentre studies should consider the change at each host site and may be required to adopt different approaches for each site.

CI's should work with the JRO or their supporting UCL CTU (as applicable) on any adjustments to study management plans and risk assessments including the supply of drugs/devices and the availability of labs and essential services at each site

This guidance continues by making recommendations on how to manage potential scenarios within host organisations. Should CI's encounter other scenarios, they should speak to the JRO or their supporting UCL CTU (as applicable).

Studies currently approved to actively recruit patients or conduct follow-up visits within NHS or Social Care facilities in the UK

Where the host site halts all non-essential treatment at site

- Participants on active treatments should continue to be treated where possible - in line with the relevant host site's guidance and that of the applicable regulators
- No new recruitment should take place without the explicit agreement of the authorised department within the host organisation (e.g., the R&D function)
- In all cases remote methods should be deployed for the delivery of drugs, devices, and follow-up of patients

- The JRO or CTU will support with the submission of any regulatory requirements and approve any change
- The JRO or CTU should be informed immediately if the site or research team are unable to enact/fulfil the agreed approach, where the study is halted or suspended by the host organisation, in the event of any harm or distress to participants or deviations from the protocol, regulations or host site requirements.

Where the host site enacts a partial closure or restrictions to visitors and patients

- The CI should consult with the JRO or supporting CTU to determine the viability of continuing recruitment or follow-up at site
- The host site's guidance should be sought, and any study amendments made in line, and in agreement with, the host site
- Where possible, remote methods should be deployed for the delivery of drugs, devices, and follow-up of patients
- The recruitment of new participants should follow the policies/guidance of the host organisation and with explicit written approval from the relevant authority within the host organisation (e.g., the R&D office)
- Where visits continue, the CI should consider and make arrangements for participants travelling between their homes and sites and/or between research sites
- The JRO or CTU will support with the submission of any regulatory requirements and approve any change
- The JRO or CTU should be informed immediately if the site or research team are unable to enact/fulfil the agreed approach, where the study is halted or suspended by the host organisation, in the event of any harm or distress to participants or deviations from the protocol, regulations or host site requirements.

Where the host site continues to treat patients at site (and sits within tier 2 and 3)

- The CI should consult with the JRO or supporting CTU to determine the viability of continuing recruitment or follow-up at site
- Remote methods for non-clinical procedures are strongly recommended
- The host site's guidance should be sought, and any study amendments made in line, and in agreement with, the host site
- Where viable and safe, remote methods should be deployed for the delivery of drugs, devices, and follow-up of patients
- The recruitment of new participants should follow the policies/guidance of the host organisation and with explicit written approval from the relevant authority within the host organisation (e.g., the R&D office)
- Where visits continue, the CI should consider and make arrangements for participants travelling between their homes and sites and/or between research sites
- The JRO or CTU will support with the submission of any regulatory requirements and approve any change
- The JRO or CTU should be informed immediately if the site or research team are unable to enact/fulfil the agreed approach, where the study is halted or suspended by the host organisation, in the event of any harm or distress to participants or deviations from the protocol, regulations or host site requirements.

Studies currently approved to actively recruit patients or conduct follow-up visits within community (public) settings or within participants homes (including focus groups)

- CI's should continually review the tier level (and other restrictions) in place within the locality of the research activity
- The CI should consult with the JRO or supporting CTU to determine the viability of continuing this activity and should wherever possible, to revert to remote methods to complete research activity
- Where visits continue, the CI should consider and make arrangements for participants travelling between their homes and sites and/or between research sites
- The JRO or CTU will support with the submission of any regulatory requirements and approve any change
- The JRO or CTU should be informed immediately if the site or research team are unable to enact/fulfil the agreed approach, where the study is halted or suspended by the host organisation, in the event of any harm or distress to participants or deviations from the protocol, regulations or host site requirements.

Studies not yet active (i.e., had yet to initiate at sites or have yet to receive regulatory approvals)

- The CI should consult with the JRO or managing CTU and with proposed sites
- Studies which have received full regulatory and sponsor approvals but have yet to initiate at sites should be managed in line with the guidance above
- CI's with studies in set-up (within the JRO or CTU) but have yet to receive all approvals should discuss the continuation of the studies set-up with the relevant coordinator/manager in the JRO or CTU. A decision as to the viability of continuing will be dependent upon the host sites circumstances and policies and the priorities of regulators
- The continuation of any study should follow the guidance listed in the relevant sections above
- A decision may be influenced by the re-deployment of JRO or CTU staff to Covid-19 clinical support or to support Covid-19 research