Re-activation of study activity

The general principles for planning any re-activation of study activity are:

- to ensure the safety of participants, the institutions hosting the study, and research teams
- research needs to control for any additional burden into NHS or social care (or other environments) and endeavour to mitigate such effects
- covid-19 measures should be followed
- service providers, sub-contractors, laboratories, support functions and funders should be consulted and agree to any re-start (as appropriate)
- regulatory requirements and advice are followed

CI's who wish to restart research activity at NHS and Social Care sites should make immediate contact with the CTU managing their study.

For non-CTU studies, CI's should contact the JRO. The JRO will request the CI completes a document which will outline the risk and mitigation plans for the study.

This plan will include (although not limited to):

- the rationale and timeline for the restart
- the impact upon existing participants should the study remain paused
- the view of the funder
- alignment with the recovery and covid-19 safety policies of the host organisation
- the availability of participants on-site and any potential risks of reintroducing research participants to host sites (where participants are not receiving routing care)
- covid-19 measures for participant travel and/or receipt of study materials, devices, or drugs
- the availability and readiness of sub-contractors, service providers, and other third parties
- the availability and readiness of laboratories and other support functions
- the availability of UCL and/or UCLH research staff and adherence to covid-19 measures for these staff (in line with UCL and UCLH guidance)
- the safe transportation and storage of study materials, samples, devices, drugs, and biological materials
- any revision in methodology to handle recruitment and attrition

The full risk assessment document for Clinical Trials managed by the JRO can be found here

The full risk assessment document for all other studies managed by the JRO can be found here

Amendments to protocol or study management maybe required. Any change should be articulated, where appropriate within the study protocol. The CTU or JRO will advise if regulatory submissions will be required. The plan should be clear on where protocol or study documents, contracts or costs will change.

Funders should be consulted in all cases. Including discussion and agreement regarding any cost and no cost extensions and any milestone or other deliverables.

No study should re-start without confirmation from the JRO or the CTU (as applicable)

Studies managed by CTU's will be approved by each CTU. No CTU study should re-start without confirmation from the CTU.

Studies overseen by the JRO will be approved by the JRO. No non-CTU study should re-start without confirmation from the JRO.