**Re-opening studies – process for consideration during COVID19 pandemic**

Re-opening studies will relate to studies that were categorised as 3 or 4 in the exercise undertaken in March 2020.

1 urgent research contributing evidence to the understanding of the Pandemic
2 clinical studies where the study protocol contributes to essential clinical care, or where patients would not otherwise receive an essential treatment
3 research studies where protocol driven changes in immunosuppression or other interventions may potentially render patients at a higher risk of Covid-19
4 other
5 non UPH COVID related research

These studies will have been impacted with the initial move to close non-COVID19 related work. Particular attention will be required for Category 3 studies as these entail a higher risk to patients visiting hospital for appointments. It is likely that re-opening of studies will be on a case by case basis based on the following considerations:

a) Is this a decision that can be taken in Leicester?
- Where UHL / UOL are the Sponsor, a local decision could be made after consultation. Where external, the sponsor is responsible and confirmation from the trial sponsor will be needed before further action taken. In cases of student research, confirmation and written agreement from the academic supervisor will be required.
- If this is a NIHR portfolio study have the points raised in the NIHR 'A framework for restarting research studies funded or supported by NIHR which have been paused due to COVID-19' been considered?
- Does the Sponsor consider that the study remains viable?
- Can study delivery be aligned with re-opening of routine NHS service in the relevant clinical service, or would it conflict in any way?
- Is staffing currently available to re-start the study? This may be a particular issue if staff have been re-deployed to other priority studies.

b) Does re-opening a study expose participants to avoidable risk?
- are patients seen in outpatients appointments or are they in-patients
- If out-patients, is it possible to amend the study process to accommodate alternative virtual appointments removing the need to attend hospital. If the answer is NO here, will it be possible to run a risk assessment to minimise risks? (PPE use, social distance/minimal contact)
- Can study requirements be encompassed within 'restoration to normal' of clinical services
- Re-open with a re-design of tools to minimise risks e.g. paper based questionnaires or web-based tools instead of existing?

c) Can value be added by adding COVID-related questions to existing protocol by amendment and can any such changes be easily accommodated into existing data collection tools (CRF's)

Where studies are ready to be submitted for Sponsor review the following should be noted:

I) It may be possible to submit new studies for Sponsor review prior to submission to HRA / REC / MHRA etc – however, non COVID research is not being prioritised so may be a longer time for approval. Need to consider if we can open the study once approved.

II) New Student studies are not currently being reviewed by HRA but could be worked up to the point of submission. Keep one eye on the HRA website for changes in restrictions.

**Re-opening study process:**

It will be more time consuming to re-open studies than it was to pause them. Not all studies will be able to re-open at the same time and some internal prioritisation of workload will be required. Therefore whilst we will process your requests as quickly as possible, there may be delays due to volume of work – your patience and understanding is appreciated.

**Principle Investigator / Study Team requirements**:

There is an expectation that the clinical research areas will have a comprehensive list of studies, their current status and a priority classification within the service for re-opening. It is expected that the clinical service will make their own assessment as to the priority based on internal criteria.

It is expected that an appropriate risk assessment will be carried out for each study which refers to Trust and National guidelines.

Appendix 2 Re-Opening studies during pandemic provides a flowchart and further guidance for clinical areas.

Once internal priorities have been confirmed, an email to the R&I office requesting restart of an individual or group of studies will trigger the start of the procedures. Please use RIAdmin@uhl-tr.nhs.uk marking the email clearly as 'COVID Re-open'.

Answers to the following questions along with relevant evidence should be provided to R&I prior to a study or group of studies re-opening:

- Does the study remain viable post COVID-19 – a statement from the sponsor, or a re-open request directly from the sponsor will be sufficient

- Email confirmation from Clinical Service managers that they are supportive of the research re-opening
- Confirmation that plans are in place should a further re-pause be required
- Confirmation that research staff are available to work on the study with no impact on Urgent Public Health COVID-19 study delivery
- Confirmation that any necessary amendments to protocols are being or have been processed through the relevant regulatory authorities – NB studies will not be re-opened until amendments have been appropriately approved
- All necessary precautions are in place for both participants and staff for a safe restart.

NB: When providing information for more than one study please ensure each aspect is covered for each, and the identifiers for each study are clearly marked in your correspondence.

**R&I Office process**

The R&I Office will commence re-opening procedures on a study by study basis. The PI/study team will alert the R&I office of the intention to re-open.

The EDGE attribute COVID-19 has been adapted to accommodate re-open and should be populated to confirm receipt of relevant information as listed above. Once a week, the R&I Office will send a list of requests to any relevant support departments and the CRN EM requesting that any objections or concerns about the studies re-opening is made within 72 hours of receipt. Provided no objections are received, the list of requests will be provided to the 'Re-Opening Research Panel' on a weekly basis. The panel will consist of senior members of R&I, clinical managers and PIs. The panel will make a decision about opening. Only when the attribute is complete may the re-opening be confirmed by the R&I Team.

A list of NIHR Portfolio studies expressing interest in restarting will be provided to the CRN EM on a weekly basis. CRN EM will report to UHL on an exceptions basis highlighting any intelligence that may affect the ability of a study to re-open as planned.

In cases where there is a conflict that exists within the Specialty, the 'Re-Opening Research Panel' will review cases and make an independent decision.