## 1. Introduction

This Standard Operating Procedure (SOP) describes the process during a World Health Organisation (WHO) categorised pandemic to confirm that University Hospitals Of Leicester NHS Trust have the Capacity and Capability to deliver a research study in accordance with the approved protocol and appropriate contract or agreement.

The SOP clarifies the processes required for studies that are 'PRIORITISED' and those that are 'EXPEDITED'.

## 2. Scope

This SOP applies to all staff and external individuals involved in research activity during a WHO categorised pandemic that is **HOSTED** by UHL or where UHL is a research **SITE**.

## 3. Confirmation of Capacity & Capability

A pandemic situation is a unique and complex status for all NHS Trusts. Speed of action and prioritised access to all services, systems and adequate staff across the whole Trust is paramount. It is important to recognise that while research will be focused in specialties most impacted by the pandemic, the usual specialty or Clinical Management Group processes are bypassed and replaced with a whole Trust solution. The solution at UHL will be managed by R&I Corporate Team.

Each pandemic is different. This SOP has been authored to address specific processes required to deal with the COVID19 pandemic (2020) but can be amended as required for future situations.

In normal circumstances, process detailed in SOP C-2007, an assessment to identify whether or not a specific specialty within the UHL have the capacity, capability, or are prepared to accept a research study is undertaken This takes into consideration the availability of staff, equipment, conflicting studies and follows a set process of governance. This can often take several weeks. Clearly to manage the pandemic situation these processes must be replaced with an appropriately flexible, proportionate and safe alternative. In order for the appropriate levels of scrutiny to be applied we have separated the COVID studies into the following categories:

- Prioritised studies – those studies added to the Chief Medical Officer (CMO) for England Urgent Public Health (UPH) research list via a national process

- Expedited studies – those studies that are important and supported locally, but not included in the CMO UPH lists

### 3.1 Prioritised Studies

The National Institute of Health Research formulated a process with the CMO for England to identify those studies that must be prioritised and have access to NIHR funded resources. These studies must be prioritised by NHS Trusts in receipt of NIHR funding, and supported by staff funded in this way.

Prioritised studies will have the approvals of all the relevant regulatory authorities and government bodies including (but not limited to)

- Health Research Authority (HRA)

- Research Ethics Committee (REC)
- Medicines and Healthcare Products Regulatory Agency (MHRA) (where required)

In addition, the studies will have received confirmation from the CMO office that they are a priority study.

### 3.1.1 Confirmation of Capacity & Capability for CMO UPH Registered Research

Approval of these studies will be achieved almost in reverse of the usual process. The priority is to ensure that Support Departments are able to provide the pharmaceutical products, testing, imaging etc. All other aspects of the process will be carried out retrospectively. Finance approval will not be required in advance of providing capacity and capability. The usual feasibility process is not required as all NIHR infrastructure across the Trust will be mobilised as far as is possible to support such studies. Completion of all EDGE attributes and workflows is required, but will be achieved after C&C has been confirmed.

## 3.2. Expedited Studies

These are studies that focus on the pandemic but have either not been through the CMO Priority process or have been identified by the CMO as important but not priority studies or have been delayed by processes. This includes amendments to existing studies to include a pandemic element. All relevant approvals as listed in 3.1 are required. Where possible, please submit documentation in parallel to submitting to the regulatory bodies. Otherwise, please send all documentation as soon as possible to RIAdmin@uhl-tr.nhs.uk.

A virtual local review panel has been convened to consider these research studies. All documentation submitted to the Health Research Authority and where appropriate the MHRA should be submitted to RIAdmin@uhl-tr.nhs.uk.

The documents required for review by the local panel will be disseminated by the Administrator team within the R&I Office. These include but are not limited to:

- Evidence of adequate funding
- Outline of proposed staffing required to deliver the activity with mitigation plan to reduce impact on NHS clinical staff or R&I staff delivering COVID-19 trials.
- Protocol
- Participant Information Sheet and Consent Form
- Prioritisation by local group i.e. within CVS/Respiratory/Cancer etc.

Once the virtual panel has agreed, the study will progress to Capacity and Capability review.

### 3.1.1 Confirmation of Capacity & Capability for Expedited Research Studies

A light-touch feasibility will be required within the primary specialty to confirm the following:

- Adequate funding
- Ability to deliver - no impact on NIHR priorities
- Support departments able to accommodate
- Prioritisation Process

In addition the following processes must be completed:

- Finance approval
- Contract review and sign off
- Data / GDPR review

Once all these factors have been satisfied, Capacity and Capability will be confirmed.

## 4. Responsibilities

| | Responsibility | Undertaken by | Activity |
|---|---|---|---|
| 1 | R&I Office | R&I Office & Specialty representatives | Confirm Capacity and Capability for Prioritised or Expedited studies. |
| 2 | Local Virtual review | Local Virtual Review panel | Review proposed studies or amendments to existing activity not accepted on CMO UPH lists. |

## 7. Supporting Documents and Key References

None Applicable

## 8. Key Words

Research, Innovation, Prioritised, Expedited, Pandemic, Covid, Capacity, Capability, Feasibility, Contract, C&C, CC

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