1. Introduction

This Standard Operating Procedure (SOP) describes the process required to open or reopen research activity during a World Health Organisation (WHO) categorised pandemic at University Hospitals Of Leicester NHS Trust (UHL). This SOP is designed to be generic. Responses to individual pandemics may require different approaches and as such are added as appendices.

Many research studies will have closed or set up delayed due to a pandemic having been called. This is due to the fact that many staff will be redeployed to assist on pandemic research or to the clinical front line, but also because many clinical services will be suspended to help to manage the Public Health Crisis.

When the initial pandemic cases have peaked, some clinical services will begin to be brought back on line. In the same way, it may be possible for some research to be re-opened with appropriate changes to the method of delivery or patient visits.

2. Scope

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

3. Categorisation of Research

Prior to and during the initial / developing stages of the pandemic; all research activity at UHL will be categorised in accordance with the SOP C-2026 UHL Pandemic Categorisation for research hosted by the UHL during a pandemic. The categories are as follows:

1.	Urgent research contributing evidence to the understanding of the pandemic and listed on an Urgent Public Health Research portal. The category 1 studies were further divided to reflect the UHL priority: 1A – UHL First Priority and 1B - all other UHL studies.
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 infection.
4.	Other
5.	Research contributing evidence to the understanding of the pandemic but not listed on the Urgent Public Health Research portal.

Research that is categorised within numbers ‘2’, ‘3’ and ‘4’ may cease activity. This SOP is targeted mainly at these studies.

4. Re-opening / Opening Research

There are a number of important questions to ask before re-opening research. The first of these should be addressing the viability of the research in a post pandemic age. Each clinical service or area may have different needs and it is expected that all relevant individuals will be engaged during the conversation.
The appendices provide a pandemic specific outline of considerations and questions that should be asked before any individual research study is re-opened. This may change depending on the type of pandemic faced. It is expect that the Chief Investigator (CI), along with wider study

management will engage in conversation across the speciality and consider these points as a minimum.

5. Study Re-Opening 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. Re-opening will commence on a study by study basis. This equally applies to recommencing set up of studies that were paused.

5.1 Single Centre Studies

Studies that are open only at UHL will be covered by the internal SOP C-2027 UHL. However additional confirmation will be required to assure that the study:

- Remains viable post pandemic.
- Funders are in agreement
- Trial Steering Group has been consulted (where necessary)
- Clinical Trials Units are in agreement (where necessary)

The EDGE database will be updated to confirm receipt of all relevant information as detailed above. Once these have been satisfied, no objections have been raised by the CRN EM and the local services are in agreement Sponsor green light to re-open will be provided.

5.2 Multi Centre Studies

The sponsor should not seek to influence the decisions of local sites. It is anticipated that similar requirements to UHL will be needed by each site and the Chief Investigator should be prepared to reassure and provide further information as requested by the site Principal Investigator or the local R&I/D office. Evidence to show host site readiness to re-open will be required. An email from the R&I/D Office from the site will be adequate.

Attention to patient and researcher safety must be a high priority. Creative options to continue involvement may be required. Each study may need different flexible, solutions but all options should be explored.

6. Responsibilities

	Responsibility	Undertaken by	Activity
1	Principal Investigator / Study Team	PI/Study Team	Confirm all aspects considered and alterations in place to commence re-open or opening of studies
2	Sponsor	Sponsor/delegate	Work closely with PI/study team to ensure all required actions/confirmations are in place.
3	Sponsor	Sponsor/delegate	Update EDGE attribute and provide email confirmation of re-opening study.

7. Legal Liability Statement

Guidelines or Procedures issued and approved by the Trust are considered to represent best practice. Staff may only exceptionally depart from any relevant Trust guidelines or procedures and always only providing that such departure is confined to the specific needs of individual circumstances. In healthcare delivery such departure shall only be undertaken where, in the judgement of the responsible healthcare professional it is fully appropriate and justifiable – such a decision to be fully recorded in the patient's notes and in the research site file.

8. Supporting Documents and Key References

SOP C-2026 UHL Pandemic Categorisation for research hosted by the UHL

SOP S-1047 Appendix 1

9. Key Words

Research, Innovation, Prioritised, Expedited, Pandemic, Covid, Reopen, Feasibility, C&C, Categorisation, Urgent Public Health, UPH

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This table is used to track the development and approval and dissemination of the document and any changes made on revised / reviewed versions

DEVELOPMENT AND APPROVAL RECORD FOR THIS DOCUMENT		
Author / Lead Officer:	Carolyn Maloney	**Job Title:** Head of Research Operations
Reviewed by:	UHL Research Management Meeting	
Approved by:	Professor Nigel Brunskill	**Date Approved:** 20/11/20

REVIEW RECORD			
Date	**Issue Number**	**Reviewed By**	**Description Of Changes (If Any)**
November 20	2	CM	Addition of 1A & 1B categorises, formatting

DISTRIBUTION RECORD:			
Date	**Name**	**Dept.**	**Received**