1. Introduction

This Standard Operating Procedure (SOP) describes the procedures to be implemented within the research community when the UHL Pandemic Plan is triggered, and the preparation and planning required to ensure smooth initiation of the 'sleeping' studies that the UHL will undertake.

1.0.1)
The Department for Health & National Institute for Health Research have processed a number of research protocols through the approvals process in preparation for announcement of a national pandemic. They are collectively referred to as 'sleeping studies'. These studies are implemented only during a Pandemic and will be identified on the EDGE database as 'Pandemic Studies'.

2. Scope

This SOP applies to all research activity that is 'live' at the time of the announcement of a national pandemic, and includes implementation of the NIHR 'sleeping' studies to be hosted by the University Hospitals of Leicester NHS Trust (UHL).

3. 'Sleeping' Studies

To obtain an accurate listing of all studies that have been categorised as 'sleeping studies' please request a report from the EDGE database.

4. Research Continuity

This SOP should be read within the context of the UHL Pandemic Influenza Plan (v10 September 2016) and alongside the Urgent Public Health Research Delivery Plan v2 produced by the Clinical Research Network: East Midlands. This SOP is designed to help to facilitate research that must continue where ever possible during a pandemic while also making suggestions on how resource that cannot continue with the 'day job' can make a difference to the 'sleeping studies' and their delivery.

4.0.1)
A pandemic is defined in both other referenced documents and these definitions are adopted here. A pandemic will be activated by NHS England and Clinical Research Networks will additionally be notified by the Department for Health. It is unlikely that a pandemic will be a surprise to anyone involved as it is likely to hit the world press.

4.1)
Staff absence within the Research Community

Staff absence is covered in both the previously referenced documents and it is therefore thought unnecessary for a repeat in this document.

4.2)
Expedited contingency and rapid set up of research studies

A pandemic situation may be called at any time. It will be important to understand the impact on studies that are progressing through the R&I Authorisation process at the earliest possible opportunity.

4.2.1)
Resource may need to be diverted to set up studies specifically focusing on the pandemic, in addition to waking up the 'sleeping studies'.

4.2.2)
The R&I Corporate senior management team will liaise with the clinical management groups (CMG's) and make decisions where to divert the resource most appropriately. A series of Operational meetings will be called and will happen on an 'as needed' basis to assess the status of research awaiting Trust authorisation.

4.2.3)
In addition, an assessment will need to be made about the continuation of research within each Clinical Management Group and speciality. Deployment of resource within the Research Community must be done with the discretion of the team managers. An assessment of studies requiring on-going support must be made a priority e.g. studies requiring administration of drugs to patients within tight timelines. Similarly, where the patient flow has stopped because of the pandemic, staff may wish to utilise their skills to assist in other studies where resource is required.

5. Pandemic Feasibility

The 'sleeping studies' that are already waiting for a pandemic call should be worked up to the point of confirmation of capacity and capability, or as far as is possible to do so. It is recommended that the Specialty or CMG that employs the Principal Investigator (PI) will lead the feasibility process. Feasibility of a 'sleeping study' is no different to that of a 'usual' study; it's simply that actual delivery of the study will not be required for a period of time.

5.1)
The outcome of the feasibility will be that all contacts are known, all departments are fully appraised and 'ready'. The existing feasibility documentation can be utilised. There is no need to do anything additional except that there is an expectation that the feasibility be repeated on an annual basis.

5.2)
Some of the 'sleeping studies' are trying out 'dry runs' in advance of the declaration of a pandemic. These 'dry runs' are designed to test the readiness of the trusts, in a similar way to the testing of an emergency system. It is the intention at UHL to be 'ready' as far as is possible to activate these studies should such a test be requested.

6. Responsibilities

	Responsibility	Undertaken by	Activity
1	UHL R&I	R&I corporate senior management team	Make informed decisions about reallocation of resource at the notification of a pandemic
2	UHL R&I	R&I Information Manager	Provide report on 'sleeping' studies when requested
3	CMG/Specialties	Research Teams	Make informed decisions about reallocation of resource at the notification of a pandemic
4	CRN EM	CRN EM	Make UHL R&I Aware of studies that will be 'woken up'
5	R&I Office	Study Support Officers	Process studies in an expedited way
6	CMG/Specialities	Research Teams	Conduct feasibilities and revisit annually

7. Who Guideline Applies To

All staff within UHL and external to UHL who are delivering research.

8. Education and Training

The SOP is detailed so the process can be clearly followed. No flowchart is provided / required.

9. Education and Training

None

10. Monitoring Compliance

What will be measured to monitor compliance	How will compliance be monitored	Monitoring Lead	Frequency	Reporting arrangements
Sponsor Audit	Randomly chosen for audit	Carolyn Maloney	As and when	A report will be produced

11. Supporting Documents and Key References

CRNEM Urgent Public Health Research Plan v2.0

UHL Pandemic Influenza Plan v10

12. Key Words

Research, Innovation, EDGE, REC, MHRA, HRA, Pandemic, Influenza, Sleeping Studies, Covid

13. Contact and Review Details

CONTACT AND REVIEW DETAILS	
Guideline Lead (Name and Title) Lisa Wann R&I manager	**Executive Lead** **Medical director**
Details of Changes made during review: **Review and update**	

14.

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

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Author / Lead Officer:	Carolyn Maloney	**Job Title:** Head of Research Operations
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REVIEW RECORD			
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