1. Introduction

This Standard Operating Procedure (SOP) describes the process that Corporate Research & Innovation office will use to confirm that the University Hospitals of Leicester NHS Trust (UHL) has the Capacity and Capability (C&C) to deliver research studies.

1.1)
The process to achieve confirmation of C&C is delivered by appropriately trained and authorised personnel within individual clinical specialities or corporate directorates. The process outlined within SOP C-2023 UHL was developed following a Listening into Action process in June / July 2019 where it was identified that duplication was causing unnecessary delays to the set up and confirmation process.

1.2)
This SOP details processes to be followed by authorised personnel within Corporate R&I and includes a Quality Assurance check to give wide assurances that the relevant internal and regulatory permissions have been confirmed, prior to any research study commencing at UHL.

1.3)
Trials of this new process began on 2nd March 2020 and will be rolled out as appropriate achieving full take up by end of June 2020. As a result, a parallel process will exist until all research approvals are managed by the new approach.

2. Scope

This SOP applies to all research activity that is hosted by the University Hospitals of Leicester NHS Trust (UHL).

3. Quality Assurance Checks

The Support Services personnel completing workup of a study will be expected to ensure that all necessary Attributes, Workflows, Support Departments, Files, Study Teams, Dates, Targets and Status are completed prior to sending an email to request that UHL Capacity and Capability is Confirmed. Completion of a Confirmation of C&C request workflow must be done prior to the request being made.

3.0.1)
The Quality Assurance Check will confirm that all areas have been completed. It will not confirm that all the information within the system is accurate. This is confirmed through the Data Verification process.

3.1 Attribute Checks

All study set up attributes will be checked for completeness. A check will be made to ensure that Support departments and their relevant attributes have been appropriately added. This can be verified by simply checking that the Support department has been ticked in Mandatory 1, and the corresponding attributes added.

3.1.1)
A check will also be made to ensure that attributes that may be required in the future have also been added. Appendix 1 Additions to every study

3.2 Workflow checks

All study set up workflows will be checked for completeness. A check will be made to ensure that Support departments and their relevant workflows have been appropriately added and completed. This can be verified by simply checking that the Support department has been ticked in Mandatory 1, and the corresponding workflows added. Completed workflows are indicated as a Green Flag.

3.2.1)
A check will also be made to ensure that workflows that may be required in the future have also been added. Appendix 1 Additions to every study

3.3 Support Department Checks

A check will be made against the list within Mandatory Category 1 attribute which details all Support Departments that are required for the study.

3.3.1)
It is expected that all Attributes / Workflows on both Green and Red levels are added and completed as required.

3.3.2)
A list of attributes / workflows for support departments that are required prior to confirmation of C&C can be found at Appendix 2.

3.4 Uploaded Files check

A random check to ensure that key documents have been uploaded to the RED level will be made. It is expected that the email request sent for confirming C&C will included a list of approved documents. This should mirror the documents listed on the HRA letter. The HRA letter will not be verified during this check but will be included in the Data Verification processes. The uploaded files will be checked against the detail in the email

3.5 Study Team check

It is expected that all personnel working on the study are added to EDGE during the workup process. It is additionally expected that specialty teams will ensure that all staff working on the study have the appropriate evidence of training and contract with UHL.

3.6 Study dates check

It is expected that all relevant dates are entered on the RED level of EDGE. Where it is identified that the GREEN level have incorrect information, Corporate R&I must be contacted for the owner of the record to be approached for the information to be updated.

3.6.1)
Further guidance on Dates, Target is available at Appendix 3.

3.7 Target check

The site target should reflect the lowest number on the contract.

3.7.1)
Where a range for recruitment is identified, the range details must be added to the RED level notes and where appropriate included in the Support Services applications. The range should be as reflected in the Contract.

3.8 Study status check

Details about study 'status' and when to change from one status to the next is detailed at Appendix 4.

3.8.1)
Where a status is identified as incorrect on the GREEN Level, Corporate R&I must be notified in order for the owner of the record to be approached and a request for changes to be made.

3.9 Green Level checks

The GREEN level can only be updated by the owner of the record. This should managed through Corporate R&I. Do not ignore errors in the data, always notify.

4. Confirming Capacity & Capability

Capacity and Capability may be confirmed by the following individuals:

- Director of R&I
- Associate Director of R&I
- Deputy Director of R&I
- Head of Research Operations
- R&I Manager

4.1)

The workflow 'Corporate R&I CC&C' must be completed. It is possible for workflow items 1 – 7 to be completed by an administrative assistant authorised by the authoriser. The workflow items 8 – 10 must be completed by the individual providing C&C on behalf of UHL. Each of the workflow items must be completed in turn. Once all items in the workflow have been completed an email will be sent from the RIConfirmCC email address to relevant individuals. Workflow item 2 can be completed after confirmation of C&C. This workflow item will be tracked for completeness using the Power BI solutions employed in the R&I Office.

4.2)

The email must be copied to RIContracts & RIAdmin in addition to individuals listed within the request email.

5. Responsibilities

	Responsibility	Undertaken by	Activity
1	R&I Corporate / Authorised signatories	R&I Corporate / Authorised signatories	Complete RED Level date and status
2	R&I Corporate / Authorised signatories	R&I Corporate / Authorised signatories	Complete Corporate R&I CC&C Workflow
3	R&I Corporate / Authorised signatories	R&I Corporate / Authorised signatories	Send confirmation of capacity and capability email

7. Supporting Documents and Key References

Appendices 1, 2, 3, 4

8. Key Words

Research, Innovation, Capacity, Capability, Feasibility, Contract, C&C, CC

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