

## STANDARD OPERATING PROCEDURE:

### Confirming Capacity and Capability

<b>SOP REFERENCE NUMBER</b>	CLPG19 SOP 5	
<b>VERSION NUMBER</b>	Version 1	
<b>REPLACES SEPT DOCUMENT</b>		
<b>REPLACES NEP DOCUMENT</b>		
<b>KEY CHANGES FROM PREVIOUS VERSION</b>	New document	
<b>AUTHOR</b>	Research & Development Manager	
<b>CONSULTATION GROUPS</b>		
<b>IMPLEMENTATION DATE</b>		
<b>AMENDMENT DATE(S)</b>		
<b>LAST REVIEW DATE</b>		
<b>NEXT REVIEW DATE</b>		
<b>APPROVAL BY CLINICAL GOVERNANCE &amp; QUALITY SUB-COMMITTEE</b>	March 2018	
<b>RATIFICATION BY QUALITY COMMITTEE</b>	April 2018	
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<b>SOP SUMMARY</b>		
<p>This SOP outlines the procedure for the R&amp;D office to issue Confirmation of Capacity and Capability, following Health Research Authority (HRA) approval of a research study seeking permission to go ahead at EPUT. Issuing of a confirmation email indicates to the Research Sponsor that the study is authorised to begin at the Trust.</p>		
<b>The Trust monitors the implementation of and compliance with this policy in the following ways:</b>		
<p>Monitoring of implementation and compliance with this procedure will be undertaken by the Executive Medical Director, Research manager, Research lead, R&amp;D department staff and R&amp;D group.</p>		
<b>Services</b>	<b>Applicable</b>	<b>Comments</b>
Trustwide	✓	
Essex MH&LD		
CHS		

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## 1. INTRODUCTION

Health Research Authority (HRA) approval is the new process for the NHS in England. HRA approval includes a review by a NHS Research Ethics Committee (REC) (where required) as well as an assessment of regulatory compliance and related matters undertaken by dedicated HRA Staff. In England, it replaces the need for local checks of legal compliance and related matters previously known as local governance review. This is intended to allow NHS organisations to focus resources on assessing, arranging and confirm their capacity and capability to deliver the study.

This SOP describes the process to be followed before Confirmation of Capacity and Capability is given to deliver a research study in Essex Partnership University NHS Foundation Trust (EPUT) for studies receiving HRA approval, in line with HRA guidance for NHS Trusts in England.

## 2. SCOPE

This SOP should be used by members of the EPUT R&D department responsible for Research Governance and applies to all research seeking permission to go ahead within the Trust.

## 3. DEFINITIONS

**Confirmation of Capacity and Capability:** The local feasibility procedure undertaken by an NHS Organisation to assess and confirm whether the organisation has the resources, policies and service users required to successfully deliver the research study to time and target.

**Health Research Authority (HRA):** The national non-departmental public body established by the Government to oversee health and social care research. HRA approval has replaced the need for individual organisational approvals for research.

**Integrated Research Application System (IRAS):** An integrated web-based application system, in which one information dataset is completed by the researcher to apply for multiple research approvals, as required for the needs of the study.

**Research Ethics Committee (REC).** RECs safeguard the rights, safety, dignity and well-being of people participating in research in the NHS. A favourable opinion from REC to conduct a research project involving NHS patients or identifiable patient data must be obtained prior to the start of any research activity involving direct contact with participants.

## 4. DUTIES AND RESPONSIBILITIES

### **Sponsor:**

The organisation/Institution with overall responsibility for the conduct of the study in the UK.

The sponsor will arrange:

- Indemnity, financial and contractual arrangements for the whole study.

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- Necessary approvals required to be in place by the start of the study.
- Study set-up and provide full trial documentation and study training to local research teams.
- Continued communication about updates to study and documentation to the local site.

### **Chief Investigator (CI):**

The lead researcher with responsibility for the conduct of the clinical trial across all research sites, including but not limited to the following areas:

- Qualifications and agreements (Good Clinical Practice (GCP) Training, delegation of trial-related duties)
- Arrange adequate resources to conduct the overall study – time, funding, demonstrate ability to recruit (via pilot etc.)
- On-going communication with research approving bodies throughout the trial.

### **Principal Investigator (PI):**

A person that has overall delegated duty for the conduct of the research study at each individual participating research site. The PI will be selected and/or confirmed by the R&D office. Duties will include:

- Study feasibility on behalf of the Organisation in conjunction with the R&D office
- Reasonable assessment of potential recruitment numbers
- Highlighting any difficulties or challenges in delivering the study.
- Assessing and organising training needs of the supporting research team.
- Attending site selection, set-up and initiation visits.
- Identify co-investigators as required for each research study.

### **Chief Pharmacist:**

The Chief Pharmacist is responsible for reviewing the local feasibility of conducting a study involving Investigational Medicinal Products (IMPs) from a pharmaceutical perspective. This review should take place as early as practically possible in the feasibility process.

### **Research Nurse (RN), Clinical Studies Officer (CSO), Research Assistant (RA) and Research Delivery Co-ordinator (RDC):**

Research practitioners employed by the research team, Trust or research body with delegated duties to carry out specific allocated duties as identified in Trust approval documentation and supported by the delegation log. Duties could include:

- Input on study feasibility and capability as required by the PI and R&D office
- Organising training and attending study set-up meetings as required.
- Identifying any delivery challenges of the study, based on prior experience.
- Communicate with PI and investigators about study feasibility and set-up.

### **R&D Office:**

The R&D office will review the local feasibility of conducting research studies in the relevant NHS premises. Duties Include:

- Lead on confirmation of capacity and capability assessment

- Agree potential participant numbers and targets with the PI and CI/Sponsor.
- Assign research team members to support the PI.
- Review and sign any financial and contractual arrangements
- Report details of new studies to R&D Lead, Executive Medical Director and R&D Group as appropriate
- Liaise with any internal departments required for conduct of study (e.g. Pharmacy)
- Agree outsourcing arrangements with partner organisations for clinical support services
- Register details of approved studies on EDGE (R&D database), including HRA timelines and NIHR Time to Target data where appropriate.
- Process applications for external researchers to conduct research at EPUT, in line with the NIHR HR Good Practice Pack, and arrange for sign off of Letters of Access / Honorary Research Contracts from the Trust HR department.

### 5. OBTAINING PERMISSION FOR RESEARCH STUDIES AT EPUT

#### 5.1 Site Invitation

It is expected that researchers contact the Research Manager to invite EPUT to act as a research site. Assessment of feasibility may be informed by a draft or final protocol or summary of the study, but a full study documentation set is not expected at this stage. The invitation will provide an opportunity to start engagement and discussion with clinical and research teams across the Trust. Expressions of interest to assess potential EPUT involvement may occur prior to HRA approval being obtained. For commercial studies, a Non-Disclosure Agreement or Confidentiality Agreement may be requested in order for the site to see study documentation. These may be signed by the potential PI but generally should be forwarded to the Research Manager for review and sign-off.

#### 5.2 Site Selection

Once the sponsor has selected EPUT as a Research Site, the sponsor should send the local documentation set to the Research manager, copying in CRN North Thames ([sss.crnnorththames@nihr.ac.uk](mailto:sss.crnnorththames@nihr.ac.uk)) where appropriate.

The date that the local document set is received is defined as the 'start point' for assessing, arranging and confirming capacity and capability of the research study. This 'start point' is expected to occur after the research has submitted final versions of study documentation to HRA for approval.

Local document set:

- Copy of IRAS Form (combined REC and R&D form) as submitted for HRA Approval
- Protocol
- Any amendments
- Participant information and consent documents
- Statement of Activity relevant to the participating NHS organisation (non-commercially sponsored only) or delegation log (commercially sponsored only)
- Relevant template contract/model agreement (if needed in addition to Statement of Activity)

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- Costing template (commercially sponsored only) or Schedule of Events (non-commercially sponsored only)
- Any other documents that the sponsor wishes to provide to the site to support the set up and delivery of the study
- Copy of HRA Initial Assessment letter (if one is issued) and (when issued) HRA Approval letter and final document versions
- Documentation to support applications for HR access for external researchers, if required (see NIHR HR Good Practice Pack for details)

### 5.3 Research Capacity and Capability Assessment

The R&D office will conduct the following activities to formally assess feasibility of the research study, in accordance with the following procedures:

- a) Assessing – Assessing if the Trust has the capacity and capability to participate in the study

NB - this stage will not be required, or will be minimal, for some types of studies where it is automatically expected that the Trust will participate unless there is a significant reason why not. These study types include emergency public health research, studies involving minimal local activity such as distributing staff questionnaires / online surveys or supplying previously collected clinical data where consent is already in place, and studies where the clinical pathway has meant that a patient has been transferred for on-going clinical care but the responsibility for the research remains with the original Principal Investigator.

- b) Arranging – Put practical arrangements into place to provide the capacity and capability to deliver the study successfully

- c) Confirming – Confirm that the Trust has the capacity and capability to deliver the study to time and target, through mutual confirmation of the Statement of Activities for non-commercial studies, or sign-off of a formal agreement between the Sponsor and the Trust. The R&D office will issue a template email to the Sponsor representative, Trust PI, R&D lead and other contacts as appropriate as final confirmation (see Appendix 1)

The R&D office will adopt a risk proportionate approach to assessment with reference to the NIHR Research Support Services (RSS) guidance framework. Following R&D office assessment, agreement from the R&D Lead or Executive Medical Director will be sought prior to Confirmation of Capacity and Capability.

All new studies must have HRA approval in place before Confirmation of Capacity and Capability may be issued.

### 5.4 Non-Confirmation Status

The R&D office will confirm to Sponsor representatives via email if there is no capacity and capability to deliver the study. If the sponsor declines the site confirmation, the sponsor is expected to email the R&D office and the study will not proceed at the site.

## 6. REFERENCES

HRA guidance for NHS Trusts: <http://www.hra.nhs.uk/resources/hra-approval-nhs-organisation-guidance/>

HRA Statement of Activities: <http://www.hra.nhs.uk/resources/hra-approval-applicant-guidance/statement-activities-hra-approval/>

Commercial studies model agreements: <http://www.ukcrc.org/regulation-governance/model-agreements/>

NIHR HR Good Practice Pack: <https://www.nihr.ac.uk/about-us/CCF/policy-and-standards/research-passports.htm>

NIHR Research Support Services Framework: <https://www.nihr.ac.uk/about-us/CCF/policy-and-standards/framework-for-research-support-services.htm>

**Appendix 1: Template email for Confirming Capacity and Capability**

**From:** Participating NHS organisation  
**To:** Sponsor representative, Chief Investigator, Clinical Trial Unit/Study Manager/Study Coordinator (where applicable),  
**Cc:** Principal Investigator or Local Collaborator (where applicable)  
**Subject:** IRAS xxxxxx. Confirmation of Capacity and Capability at INSERT NHS ORGANISATION  
**Attachment:** Signed agreement and/or agreed statement of activities, as appropriate

**Body of Email:**

Dear Sponsor Representative,

**RE: IRAS xxxxxx. Confirmation of Capacity and Capability at INSERT NHS ORGANISATION.**

**Full Study Title:** Full study title

This email confirms that **INSERT PARTICIPATING NHS ORGANISATION** has the capacity and capability to deliver the above referenced study. Please find attached our **[add as appropriate either option 1]** signed agreement **[and/or option2]** agreed Statement of Activities **[end of options]** as confirmation.

We agree to start this study **[add as appropriate either option 1]** on **INSERT DATE**, as previously discussed **[or option 2]** on a date to be agreed when you as sponsor give the green light to begin **[end of options]**.

If you wish to discuss further, please do not hesitate to contact me.

Kind regards  
Participating NHS organisation  
Participating NHS organisation contact details