STANDARD OPERATING PROCEDURE

S21 – Confirmation of Capacity and Capability

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Signature	
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Controlled document

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DISCLAIMER

This generic R&D Standard Operating Procedure (SOP) must be followed unless a study specific SOP exists.

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Full History			
Version	**Date**	**Author**	**Reason**
1.1	3 January 2014	Anoushka Tepielow	No significant changes. Corrected general typographical errors. Replaced "patient" with "participant" as per NIHR guidelines. Removed authorised signatory's name from appendix 4 & 5. Removed "(for portfolio adopted studies only)" from the "Impact Form" row under "Feasibility Documents" in appendix 5.
1.2	2 September 2016	Lisa Treeby	Updated in line with new HRA processes/ terminology.
2	25 February 2020	Lisa Treeby	Updated to give more simplified overview of processes.
3	February 2021	Lisa Treeby	Update to section 6 to include information on costing.

Associated Trust Policies/ Procedural documents:	*S26 – Training for Researchers* *S08 – Costing Non Commercial Network Studies* *S29 – Letters of Access and the Research Passport* *S09 – CTIMP Sponsorship* *S48 – Non-CTIMP Sponsorship* *All up-to-date SOPs can be found on the Royal Devon website*
Key Words:	*Research, Research and Development, Ethics, HRA, CTIMP, Confirmation of Capacity, Sponsor*
In consultation with: This SOP has been reviewed by the Governance Oversight Group (GOG).	

Contents

1. INTRODUCTION

All research must be undertaken following the standards set out in the UK Policy Framework for Health and Social Care Research:

https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/

All research in England is required to be reviewed and approved by regulatory authorities prior to being carried out at individual sites. The Health Research Authority (HRA) manages the approval process and co-ordinates an assessment of governance and legal compliance (HRA approval), with an independent review by a Research Ethics Committee (REC approval). Studies involving the use of a Clinical Trial of Investigational Medicinal Product (CTIMP) or Clinical Investigation of a Medical Device (CIMD) may also require review by the Medicines and Healthcare products Regulatory Agency (MHRA approval).

HRA Approval only applies to the NHS in England. The HRA has compatibility arrangements in place with the national NHS Permission coordinating function in Northern Ireland, Scotland and Wales.

*HRA Approval **may** be needed for project-based studies that use research tissue from registered banks, depending on the activities in the NHS and the scope of the ethics favourable opinion for use of research tissue by the Bank. However, they will all require approval from the Research Tissue Bank steering committee and confirmation of capacity and capability from the Trust. Studies building a tissue collection only do not require confirmation of capacity and capability.*

Only when all regulatory approvals are in place, can a site look to provide its own approval for a project, also known as Confirmation of Capacity and Capability (CC&C).

Where a Trust is also acting as Sponsor, it will have additional responsibilities in ensuring compliance for the overall project across its own organisation and other organisations providing care. Please refer to sponsorship SOP's S48 and S09.

2. PURPOSE

This Standard Operating Procedure (SOP) outlines the process for assessing, arranging and confirming capacity for a project being delivered at the RD&E.

All research projects must be registered with the R&D Department and must not commence until R&D have provided email CC&C to deliver the project.

In order for sites to be able to assess the feasibility of running a project and make the necessary arrangements to be able to deliver it, they must first be sent the project documentation (Local Information Pack).

The level of governance review required for each project will depend upon the project complexity and the outcome of a risk assessment. Final Review and sign off of all projects, including Non Commercial Contract sign off, is done by the Research Governance and Quality Manager (RG&QM). Commercial projects however, require their Contracts to be signed by a Trust Executive Director.

RD&E may refuse permission for a research project to proceed, even if regulatory approvals have been granted.

3. SCOPE

This SOP relates to research proposed to be undertaken at RD&E sites, involving patients, staff, patient data, tissue, facilities or premises.

It applies to all individuals with a role in assessing, arranging and confirming capacity for research.

This SOP does not apply to projects that are not classed as research such as audit, service evaluation or service improvement. The HRA decision tool can be used to identify whether a project is research: http://www.hra-decisiontools.org.uk/research/

Not all projects require a site to provide CC&C (this will be indicated on the HRA approval letter).

Not all studies require HRA approval (ie Research Database, Tissue Bank projects).

4. DEFINITIONS

CC&C	Confirmation of Capacity and Capability
CI	Chief Investigator
CIMD	Clinical Investigation of a Medical Device
CTIMP	Clinical Trial of an Investigational Medicinal Product
CTU	Clinical Trials Unit
GCP	Good Clinical Practice
GOG	Governance and Oversight Group
HRA	Health Research Authority
IRAS	Integrated Research Application System
MHRA	Medicines and Healthcare products Regulatory Agency
NIHR	National Institute for Health Research
PI	Principal Investigator
R&D	Research & Development
REC	Research Ethics Committee
SOP	Standard Operating Procedure
Sponsor	An individual, company, institution or organisation which takes responsibility for the initiation, management and financing of a clinical trial. Sponsorship activities may be delegated to the Investigator, CTU and/ or other organisations as appropriate

5. DUTIES AND RESPONSIBILITIES OF STAFF

The Chief Investigator (CI) has overall responsibility for the design, conduct and reporting of a project across all sites.

The Sponsor is an individual organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance a project.

The Principal Investigator is responsible for the conduct of a project at an individual site.

The Delivery Team and Service Departments at sites are responsible for assessing the feasibility of a project and making necessary arrangements to be able to deliver it.

The R&D Finance Team is responsible for undertaking costing of projects.

The R&D department is responsible for reviewing the research governance and providing final confirmation of capacity for a project to start.

6. PROCEDURES

6.1 Dissemination of '*Local Information Pack'*

In order for a site to provide Confirmation of Capacity and Capability for a project they must receive the project 'Local Information Pack. The pack should be sent to the RD&E R&D generic mailbox rde-tr.Research@nhs.net. It is the Chief Investigator / Sponsor Representative's responsibility to ensure that sites receive this. For RD&E sponsored research, R&D will already have access to the Local Information Pack via the Research Facilitator who is responsible for assessing sponsored research. For further details on obtaining sponsorship please refer to SOP 09 & SOP 48

The local information pack is defined by the HRA; a list of contents can be found on their website:
https://www.hra.nhs.uk/planning-and-improving-research/best-practice/nhs-site-set-up-in-england/

As Sponsor, when sharing a local information pack with sites, the following template email must be used; available on the IRAS website:
https://www.myresearchproject.org.uk/help/hlptemplatesfor.aspx#UK-Local-Information-Pack-Info-Templates

The study documentation required for each study will vary. This is dependent on the level of research activities taking place at the site and the type of study in set up i.e. Observational or Interventional, Commercial or Non Commercial, Single or Multicentre. You will see differing versions of the following templates: Model agreement, Costing Template, Organisational Information Document*. The documents required for Tissue Bank studies may differ from other studies. For instance, they may not require a Costing Template but there will be need to be evidence of funding to cover the study. Tissue Bank studies may also not require an Organisational Information Document.*

Timelines for the review of costs and contracts for studies will comply with NIHR contractual obligations. In line with NIHR guidelines, sites are required to open a project and recruit their first patient within 70 days of receiving the full local information pack.

6.2 *Assess and Arrange – What is Required?*

R&D Staff work alongside their local Delivery Teams and Support Departments in the set up and delivery of projects. The areas focused upon during set up are:

Delivery Team

- Review suitability of research team, adequacy of facilities, local arrangements required to support participants and compliance of delivering practical aspects of Protocol
- Impact Form (feasibility) – complete, obtain PI and Research Nurse signatures Send to R&D

- Localise relevant project documentation
- Ensure research CVs and GCP certificates (where required) are up-to-date
- Arrange Site Initiation Visit (SIV) – study start/training date

Service Departments

- Review and sign relevant page of Impact form and return to R&D
- Review Project Documentation
- Review adequacy of facilities, local arrangements and compliance of delivering practical aspects of Protocol

R&D Finance

• Costing meeting to be held with the CI/PI/Research Nurse, where a review of the Protocol and SoECAT/Industry Costing Template (ICT) will be undertaken. Ensure all costs have been included in the costing template and that cost attribution is correct. All Service Support Costs, Research Costs and Treatment Costs must be attributed in line with DOH guidelines Attributing the costs of health & social care Research & Development (AcoRD). Any missing costs should be added to the costing template. Cost negotiations will need to be made with the Sponsor to ensure that all costs are recovered where possible. Where a study is a CTIMP, Pharmacy will be asked to review any excess treatment costs. Not all studies will come with funding; however, all activities should still be documented on a costing template to capture costs which are being absorbed. A final review of the study and its costing template will be completed by the Research Governance & Quality Manager.

•For Non Commercial studies involving CRF staff or resources, the CRF Trial Manager / CRF Lead Research Nurse are responsible for ensuring that an additional CRF costing template (CRF Intensity Tool) is completed. A copy of the completed form will be forwarded to R&D for information. The CRF are responsible for obtaining their own approval for allocation of Service Support Costs.

• Costs to be added to local database (Edge)
• Set up invoicing

R&D

- Documentation – ensure correct documentation and approvals received
- Impact Form – obtain signatures from relevant service departments
- Letters of Access (LOA) – external researchers coming on site with a completed Research Passport or NHS to NHS proforma will require a LOA to be issued: https://www.myresearchproject.org.uk/help/hlphrgoodpractice.aspx
- Contracting – review any changes from the NIHR model agreement. Obtain appropriate signatures (Trust Executive Director - Commercial, RG&QM - Non Commercial). R&D promote the use of the model contract, but will use their own judgement, seeking advice from the Trust's Legal Department where required when reviewing companies own contracts.
- IRMER/ARSAC – review IRAS Form and request appropriate local approvals from Radiology/Medical Physics.
- Risk Assessment
- Data Protection – HRA review this. Local review only to check that there are no additional requirements for site to follow ie software to be installed or identifiable data being used in a way that would warrant review by the Trust Information Governance Department.
- Edge – project to be added to and workflow completed on Edge.

6.3 *Confirmation of Capacity and Capability*

Confirmation of Capacity and Capability can only be provided when all 'assess and arrange' activities are complete.
A template email for Confirming Capacity and Capability can be found on IRAS: https://www.myresearchproject.org.uk/help/hlptemplatesfor.aspx
A signed CI or PI Responsibilities letter, Document Log, Organisational Information Document and/or signed Contract will be returned to the Sponsor at the same time as issuing email Confirmation of Capacity and Capability.
The site will wait for a Green Light activation email from the Sponsor before recruitment can begin.

7. DISSEMINATION AND TRAINING

7.1 This SOP and associated templates and forms will be uploaded to the Royal Devon website shortly after having been released.

7.2 All staff whose activities are subject to this SOP should ensure that they take time to read and understand the content of this SOP.

7.3 *If applicable, a training log within the Investigator Site File/Trial Master File should be completed to document that members of staff have read and understood the contents of this SOP.*

8. MONITORING COMPLIANCE AND EFFECTIVENESS OF THIS SOP

8.1 In order to monitor compliance with this SOP, the auditable standards will be monitored as follows:

No	Minimum Requirements	Evidenced by
1.	Study received all relevant REC and HRA approvals prior to opening.	Check approvals section of R&D study folder.
2.	Full document set received prior to opening.	Compare list on HRA website to R&D document log (for patient facing docs).
3.	Impact Form was fully signed by relevant delivery team and service departments prior to opening.	Check Impact Form in R&D study folder.
4.	Costing template was completed in full.	Check costing template in R&D study folder.
5.	The site has a fully signed Contract.	Check Contract in R&D study folder.
6.	Confirmation of capacity email has been issued and a copy saved in the R&D study file.	Check for confirmation of capacity and capability email in R&D study folder.

8.2 Outcomes from audit will be presented to the R&D Governance Oversight Group (GOG) which will monitor any resulting action plans until all issues have been addressed to satisfaction.

8.3 Issues identified via the audit process which require escalation will be referred to GOG.

9. ARCHIVING ARRANGEMENTS

9.1 The original of this document will remain with the R&D Quality Assurance Coordinator. An electronic copy will be maintained on the R&D section of the Q-Pulse document management system and a pdf copy on the Royal Devon website.

9.2 Archive copies must be maintained for any documents which have been superseded. Archive copies in electronic format should be retained indefinitely.

10. REFERENCES

UK Policy Framework (HRA) –
https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/

Is it research? HRA Decision Tool (HRA) –
http://www.hra-decisiontools.org.uk/research/

Local Document Pack (HRA) –
https://www.hra.nhs.uk/planning-and-improving-research/best-practice/nhs-site-set-up-in-england/

Local Document Pack Sponsor Template (IRAS) –
https://www.myresearchproject.org.uk/help/hlptemplatesfor.aspx#UK-Local-Information-Pack-Info-Templates

Research Passport and Letters of Access Guidance (IRAS) –
https://www.myresearchproject.org.uk/help/hlphrgoodpractice.aspx

Royal Devon Website –
https://www.royaldevon.nhs.uk/

Confirmation of Capacity and Capability Site Template (IRAS) –
https://www.myresearchproject.org.uk/help/hlptemplatesfor.aspx