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**Version Control**

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## SOP 051: Confirmation of capacity and capability for non- Harmonised Studies

### Contents

<b>Section</b>		<b>Page</b>
1	Introduction	4
2	Objective	5
3	Definitions	5
4	Scope	5
5	Equality statement	6
6	Duties	6
7	Details of procedure	7
8	Policy	10
9	Risk management/liability/monitoring & audit	10
10	Forms/templates to be used	11
11	Flowchart of obtaining statement of capacity and capability	11
<b>Appendices</b>		
Appendix (1)	Full submission checklist for non-harmonisation studies	12
Appendix (2)	SOP reading log	13
Appendix (3)	Equality analysis guide and tool	14

## 1. INTRODUCTION

This document sets out the procedures to be followed by all Staff members who are involved in the initiation, set-up and running of research.

HRA Approval is the process for the NHS in England that comprises 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 by each participating NHS organisation. This allows these participating NHS organisations to focus their resources on assessing, arranging and confirming their capacity and capability to deliver the study.

The HRA process replaced the NHS Permission or 'R&D approval' process and letter that was previously issued by R&D

The HRA has defined the different stages that Sponsors and participating organisations go through on the way to mutually agreeing that the study can open at that organisation. These stages can be used to identify time points which NHS organisations may wish to measure in order to examine where barriers to study set up and delivery occur. These stages are:

### **Assessing:**

Assessing whether or not the NHS organisation has the capacity and capability to participate in the study.

This stage may not be required, or will be minimal, for some types of studies where it is automatically expected that the NHS organisation will participate unless there is a significant reason why not. The HRA will indicate such studies on their HRA approval letters. These study types include emergency public health research, studies involving minimal local activity such as distributing questionnaires 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.

This stage may not be required where the NHS organisation is also the Sponsor of the study. For Royal Free single-site Sponsored studies this process is undertaken via during the Sponsorship review and the Trial Feasibility Committee (TFC) review. For further information on these processes, see SOP 029 and 051 respectively.

### **Arranging:**

Putting any practical arrangements in place to provide the capacity and capability to deliver the study.

Again, this stage may be very brief where the activities at the local organisation are minimal. At RFL, this process is included in SOP051 Trial Feasibility Committee Approval

**Confirming:**

Confirming that the NHS organisation has the capacity and capability in place to deliver the study and will deliver the study.

This confirmation is given through the mutual confirmation of the contents of the organisational document for non-commercial studies or sign-off on an agreement. For a commercial study, confirmation would be through a signed agreement or a mutually agreed costing template.

**2. OBJECTIVE**

The propose of this document is to outline the procedure obtaining confirmation or capacity and capability for studies which are **not** being managed by the North Thames CRN harmonisation process. These studies are those which have **not** been adopted by NIHR Portfolio, for example because they are ineligible as they have not secured full funding i.e. education projects (see NIHR website for eligibility criteria) [www.nihr.ac.uk/funding-and-support/study-support-service/eligibility-for-nihr-support/](http://www.nihr.ac.uk/funding-and-support/study-support-service/eligibility-for-nihr-support/)

Studies which will not be confirmed via the processes outlined in this SOP are NIHR Adopted studies and commercially Sponsored studies, e.g. those studies that are insured and managed by pharmaceutical companies i.e. GSK. These studies will be managed via the North Thames CRN harmonisation route (see SOP 052 Confirmation of Capacity and capability for Harmonised studies)

**3. SCOPE**

This SOP describes the procedure for confirming capacity and capability of healthcare research being conducted at a RFL site. Confirmation of capacity and capability is mandatory. It is required in addition to HRA approval, REC approval (and any other necessary approvals e.g. MHRA approval) before the project can commence. This SOP is concerned with confirmation of capacity and capability at RFL of non-harmonised studies that has been or is being submitted for ethical approval and should be used in conjunction with SOP029 Applying for Royal Free Sponsorship.

If your study has already been adopted onto the NIHR portfolio or maybe eligible for adoption, please refer to SOP 053 Applying for NIHR adoption in addition to SOP052 Confirmation of Capacity and capability for Harmonised studies)

**4. DEFINITIONS**

**GCP** – Good Clinical Practice is an international ethical and scientific quality standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

**HRA** – Health Research Authority

**RFL** - Royal Free London Hospital NHS Foundation Trust

**R&D** - Research & Development

**Sponsor** - Individual, organisation or group taking on legal responsibility for securing the arrangements to initiate, manage and finance a study. A group of individuals and/or organisations may take on Sponsorship responsibilities and distribute them by agreement among the members of the group, provided that, collectively, they make arrangements to allocate all the responsibilities in this research governance framework that are relevant to the study.

**CI** - Chief Investigator (CI) is the authorised health care professional who takes primary responsibility for the conduct of the trial. There is only one Chief Investigator per Member State.

**Confirmation of Capacity and Capability** – formerly known as Trust host site approval

**ICF** – Informed Consent Form

**IRAS** - The Integrated Research Application System (IRAS) is a single system for applying for the permissions and approvals for health and social care / community care research in the UK.

**Harmonisation** - In this process which is being run across CRN: North Thames Trusts. CRN: North Thames will be doing the contracts; costing and all governance to give NHS Permission confirm capacity for all those Trusts which have been listed for that study within CRN: North Thames.

**NIHR Portfolio** – National Institute of Health Research’s registry of adopted studies

**PIS** – Patient or Participant Information Sheet

## **5. EQUALITY STATEMENT**

The Royal Free London NHS Foundation Trust is committed to creating a positive culture of respect for all individuals, including job applicants, employees, patients, their families and carers as well as community partners. The intention is, as required by the Equality Act 2010, to identify, remove or minimise discriminatory practice in the nine named protected characteristics of age, disability (including HIV status), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex or sexual orientation. It is also intended to use the Human Rights Act 1998 to treat fairly and value equality of opportunity regardless of socio-economic status, domestic circumstances, employment status, political affiliation or trade union membership, and to promote positive practice and value the diversity of all individuals and communities.

This document forms part of the trust’s commitment. You are responsible for ensuring that the trust’s policies, procedures and obligation in respect of promoting equality and diversity are adhered to in relation to both staff and service delivery.

The equality analysis for this SOP is attached at Appendix (3).

## **6. DUTIES**

The Trust is committed to the delivery of world class care and expertise to both staff and patients, and our values of positively welcoming, actively respectful, visibly reassuring and clearly communicating are fundamental to the delivery of this. This policy has been developed with our values in mind, and is intended to be implemented within the spirit of these values.

This SOP applies to all personnel that are conducting research at the Trust including: staff that are full or part-time employees of the Trust, those working at the Trust with employment contracts funded partially or wholly by third parties, those working at the

## SOP 051: Confirmation of capacity and capability for non- Harmonised Studies

trust under honorary contract or under the remit of a valid research passport, those seconded to and providing consultancy to the Trust, and to students undertaking training at the Trust.

Staff's working on a research study are all responsible for ensuring that the study has confirmation of capacity in place for it to be undertaken at RFL before research activity takes place

The Principal Investigator, or their delegated personnel, is responsible for the submission of all the required information to the R&D Team, during the Trust Confirmation of Capacity process.

### 7. DETAILS OF THE PROCEDURE

The R&D Office at RFL will only accept **one** investigator for Royal Free London Hospital NHS Foundation Trust as the main PI. If the CI is based at a RFL site, then they must also be named as the Principal Investigator. Other researchers can be named as co-investigators. However, a deputy PI **MUST** be named to facilitate appropriate clinical cover for the clinical management of the study participants in the absence of the lead PI/study CI.

Person Responsible	Task
Sponsor/CI/Study Coordinator/ Research Portfolio Manager/ PI/ Research teams/	<p><u>7.1 Submission of documentation to R&amp;D</u></p> <p>The Sponsor/ CI/ Study Coordinator formally invite the NHS organisation (Research Management Team) to assess their local capacity and capability to participate in a named study. This should be done by email to the R&amp;D contact. All study documents should be submitted electronically via <a href="mailto:rf.randd@nhs.net">rf.randd@nhs.net</a> The submission should include the full document set outlined in Appendix 1.</p> <p>The formal invitation should be made after a final protocol is ready for regulatory applications and may take place before or after the application to HRA. The purpose of this step is site selection – the Royal Free site may previously have put forward an expression of interest and the Sponsor may want to identify which NHS organisations have enough potential participants and the right equipment. Some Sponsors may choose to undertake site selection visits as part of assessing the capacity and capability of the potential site.</p> <p>For CTIMPs in particular, Sponsors should be assessing site suitability and may conduct a site selection visit in this stage. The outcome of that site selection would be a decision by both Sponsor and site to set up the study.</p> <p>It is likely, but not necessary, that early or informal collaborative discussions may have taken place with PI/ research team/support departments prior to this formal invitation, e.g. through early Expressions of Interest.</p> <p>Where a local Principal Investigator or Local Collaborator is required at Royal Free they should be named if known by Sponsor, or a request to identify a local research team should be made to the organisation. Where no local</p>

SOP 051: Confirmation of capacity and capability for non- Harmonised Studies

	<p>Principal Investigator or Local Collaborator is required, the Sponsor should make this clear. HRA will confirm whether this is appropriate based upon the study type and activities proposed for that organisation.</p> <p>Research management staff and local research delivery staff (where applicable and may include LCRN funded staff) work together to identify if the NHS organisation has the capacity and capability to deliver the study – or can put that capacity and capability in place –for example:</p> <ul style="list-style-type: none"> <li>- The participant population required</li> <li>- The equipment/ space/ specialist services/ emergency processes/ safety reporting processes/ IT etc. needed to deliver the study</li> <li>- The staff required to deliver the study</li> </ul> <p>For some studies a site selection visit by the Sponsor may be part of the activity. Initial discussions about finance may begin.</p> <p>All projects are assigned a unique identifier by the R&amp;D team. This should be used in all correspondence.</p> <p>It is encouraged, that Investigators make contact with the R&amp;D office regarding advice on the content of, and requirements for first submissions to R&amp;D. The R&amp;D office is able to advise the researcher on the requirements of an R&amp;D submission through sending the checklist of documents (Appendix 1).</p>
<p>Research Portfolio Manager/CI/PI/Research Teams</p>	<p><u>7.2 Confirmation of Capacity timelines</u></p> <p>The national targets for Trusts to get first patient recruited for NIHR portfolio studies is set at 70 days. RFL aims for this target to be used for all studies, not just those on the Portfolio.</p> <p>The clock starts once the study has been to Trial Feasibility Committee and is approved. A valid submission consists of the following. It is also known as the HRA pack. Please see Appendix 1 for full details of what is required.</p> <p>For the Trial Feasibility Committee approval process, see SOP048 Trial Feasibility Committee Approvals</p>
<p>Sponsor, or delegate i.e. trial manager or CI</p>	<p><u>7.3 Confirmation of Capacity Assessment</u></p> <p><u>Selection of site:</u> Joint decision by Sponsor and organisation that the organisation has been selected to participate in a study.</p> <p>This should happen after an application for HRA Approval has been made but may also occur after HRA Approval is in place. The NHS organisation should be listed in Part C of the IRAS form. If the site is added after HRA Approval has been granted then the new site must be added via an amendment.</p>

SOP 051: Confirmation of capacity and capability for non- Harmonised Studies

	<p>The Sponsor/ CI/ Study Coordinator should supply the organisation with the documentation submitted to the HRA (or approved by, depending on timing).</p> <p>These documents should be supplied electronically simultaneously to the local study delivery team and the research management function.</p> <p>A full submission or notification of a new study must be received in the R&amp;D inbox <a href="mailto:rf.randd@nhs.net">rf.randd@nhs.net</a> or to the Portfolio Manager responsible for the research project (if known).</p>
<p>Research Coordinator</p>	<p>The R&amp;D Coordinator who is the R&amp;D staff responsible for managing the R&amp;D inbox will allocate study to the appropriate Research Portfolio Manager and ensure a minimum dataset is entered onto the R&amp;D database (ReDa),</p>
<p>Portfolio Manager</p>	<p><u>Where Trial Feasibility Committee approval has not been received</u></p> <p>The R&amp;D office will check the completeness of the submission.</p> <p>The relevant member of the R&amp;D team will email the PI/study team informing them that they will be the point of contact for the study and requests any deadlines/milestones for which the confirmation of capacity and capability is required to meet (e.g. SIV).</p> <p>The organisation must be listed in the application to the HRA, or added via a substantial or minor amendment (as appropriate)</p> <p>Suitability of an investigator is assessed and confirmed through the TFC process and the submission of an up to date CV (signed and dated within 2 years for CTIMPs). Failure to provide an updated CV will prevent the investigator participating in the study and could cause delays to the study opening at a RFL site.</p> <p>As per SOP 048 work with the PI to gain TFC approval</p> <p><u>Upon Receipt of TFC approval</u></p> <p>Check to ensure that all regulatory and ethical approvals are in place. It is the Sponsor’s responsibility to ensure that all conditions of the regulatory bodies have been met. The R&amp;D office will check that all regulatory and ethical approvals are in place before confirmation of capacity can be given for the study.</p> <p>Update ReDA with relevant data and correspondence</p> <p>Check that all CVs, GCP certificates and research passports have been issued as per SOP 002 (Research passports and letters of access)</p> <p>Check with R&amp;D Costing and Contract Manager that all</p>

## SOP 051: Confirmation of capacity and capability for non- Harmonised Studies

	relevant contracts have been fully executed including but not limited to site, material transfer or service level agreements.
Portfolio Manager and PI	<p><u>Studies with Relevant material</u></p> <p>Each study will be assessed to ascertain details of any tissue samples collected during the course of the research. Material Transfer Agreements (MTA) will be required for all studies transferring samples to another site in accordance with national legislation and guidelines.</p> <p>For studies where samples taken are to be retained and stored at RFL beyond the end of the study (and therefore beyond the period of the Research Ethical Approval), the Human Tissue Authority (HTA) regulations will become applicable. At this point samples should be transferred to the tissue bank or further REC approval should be sought.</p> <p>The PI must also keep a log of relevant material samples taken from patients or participants. This log must record from collection to destruction of the samples. RFLRDLOG0014</p>
R&D Costing and Contract Manager	<p>If it is determined that a contract, such as Clinical Trial Agreement or Material Transfer Agreement is required, the member of the Portfolio will inform the Contracts Manager and allocate the study to them. The Contracts Manager will then commence contract negotiations with the Sponsor.</p> <p>As per SOP 014 Contract negotiation and review.</p> <p>The study will also be assessed for cost by the R&amp;D Office.</p>
Research Performance and Data Analyst	Upon confirmation of capacity and capability, the Research Performance and Data Analyst will ensure that the correct recruitment target and key dates are entered on ReDa and EDGE and assign the correct study team to the project and open the study on both EDGE and ReDA.

### 8. POLICY

This SOP is mandatory and non-compliance with it may result in disciplinary procedures.

### 9. RISK MANAGEMENT/ LIABILITY/MONITORING & AUDIT

- The SOP Working Group will ensure that this SOP and any future changes to this document are adequately disseminated.
- The R&D Department will monitor adherence to this SOP via the routine audit and monitoring of individual clinical trials and the Trust's auditors will monitor this SOP as part of their audit of Research Governance. From time to time, the SOP may

## SOP 051: Confirmation of capacity and capability for non- Harmonised Studies

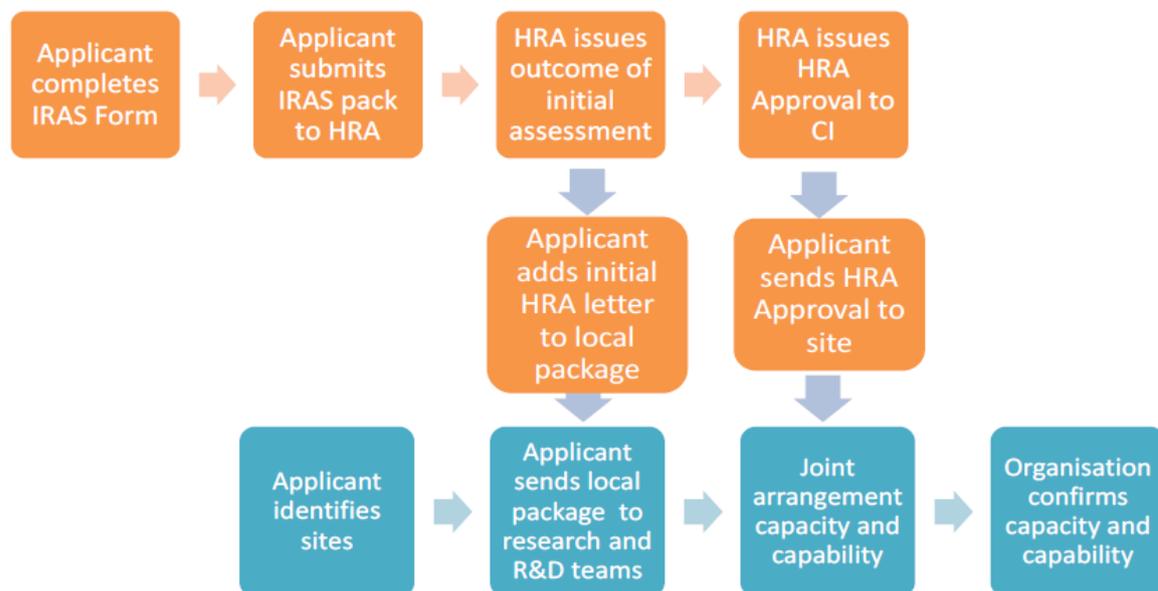
also be inspected by external regulatory agencies (e.g. Care Quality Commission, Medicines and Healthcare Regulatory Agency).

- In exceptional circumstances it might be necessary to deviate from this SOP for which written approval of the R&D Manager/Deputy R&D Director should be gained before any action is taken.
- SOP deviations should be recorded including details of alternative procedures followed and filed in the Investigator and Sponsor Master File.
- The Research and Development Directorate is responsible for the ratification of this procedure.

### 10. FORMS/TEMPLATES TO BE USED

[www.myresearchproject.org.uk](http://www.myresearchproject.org.uk)

### 11. FLOWCHART



This flowchart shows the process of obtaining a statement of capacity and capability

**APPENDIX 1****Full submission checklist for non-commercial, non-harmonisation studies**

No	Document	Received	Note
1	IRAS form, PDF form <b>Must be the final signed version.</b> We will accept hard copy of the final submitted document (no watermark)		
2	Signed and dated summary CV (no more than 2 years old) of PI and anyone listed as part of the research team. If a summary CV has not be created , suggest RFLRDDOC001		
3	GCP Certificate of the PI and anyone else listed as part of the research team ( no more than 2 years old)		
4	Protocol (final HRA/REC approved with date and version)		
5	Patient information sheet and consent form (final HRA/REC approved with date and version)		
6	Study specific documentation approved by the REC and the HRA (e.g. patient diary cards)		
7	Evidence of insurance (if applicable)		
8	Evidence of funding (if applicable)		
9	Evidence of agreement confirming site and Sponsor Responsibilities if applicable		
10	Schedule of events and organisational document (for non-commercial studies where there is more than site)		
11	Certificate of ARSAC (if applicable)		
12	Final HRA approval letter when available (submission can be made with HRA initial assessment letter)		
13	REC favourable option letter (including provisional opinion and all correspondence		
14	Confirmation of REC favourable option for any substantial amendments ( if applicable)		
15	MHRA CTA Approval or MHRA confirmation of Notification (if applicable)		
16	Confirmation of authorisation from MHRA for any substantial amendments (if applicable)		
17	Any other approvals documentation that is relevant to the study (CAG approval etc.)		



SOP 051: Confirmation of capacity and capability for non- Harmonised Studies

**APPENDIX 3**

**Royal Free London NHS Foundation Trust Equality Analysis guide and Tool**

An equality analysis is a review of a policy, practice, function, business case, project or service change which establishes whether there is a negative effect or impact on particular social groups. This In turn enables the organisation to demonstrate it does not discriminate and, where possible, it promotes equality to meet the needs of the diverse patients and communities we serve.

This check list is a way to help you think carefully about the likely impact on equality groups and take action to improve services. This is also an opportunity to evidence positive practices in our services and demonstrate strategic integrity to ensure that our services and employment practices are fair, accessible and appropriate for all patients, visitors and carers, as well as our talented and diverse workforce.

Name of the policy / function / service development being assessed	The process for obtaining NHS Permission for Non-Commercial Harmonisation studies
Briefly describe its aims and objectives:	This document defines the procedures used to obtain permission for research studies including the preparation and submission of the relevant documentation to ensure that the correct approvals are in place.
Directorate and Lead:	Medical Directorate
Evidence sources: DH, legislation. JSNA, audits, patient and staff feedback	Medicines for Human Use (Clinical Trials) Regulations 2004 and all associated amendments. UK Policy Framework for Health and Social Care (2017)
Is the Trust Equality Statement present?	Yes if no do not proceed with Equality Analysis (EA)

If you are conducting an EA on a procedural document please identify evidence sources and references, who has been involved in the development of the document, process or strategy, and identify positive or negative impacts. It is the discussion regarding the equality impact of the document that is important.

SOP 051: Confirmation of capacity and capability for non- Harmonised Studies

**Equality Analysis Checklist**

Go through each protected characteristic below and consider whether the policy, practice, function, business case, project or service change could have any impact on groups from the identified protected characteristic, involve service users where possible and get their opinion, use demographic / census data (available from public health and other sources), surveys (past or maybe carry one out), talk to staff in PALS and Complaints and Patient Experience.

Please ensure any remedial actions are Specific, Measureable, Achievable, Realistic, and Timely (SMART).

Equality Group	Identify negative impacts	What evidence, engagement or audit has been used?	How will you address the issues identified?	Identifies who will lead the work for the changes required and when?	Please list positive impacts and existing support structures
<b>Age</b>	None identified	R&D administrative document	N/A	N/A	This SOP includes the Trust Equality Statement, as well as the results from the Equality Assessment for this SOP.  These actions are designed to embed the equality agenda and promote equality compliance within the Trust.
<b>Disability</b>	None identified	R&D administrative document	N/A	N/A	
<b>Gender Reassignment</b>	None identified	R&D administrative document	N/A	N/A	
<b>Marriage and Civil Partnership</b>	None identified	R&D administrative document	N/A	N/A	
<b>Pregnancy and maternity</b>	None identified	R&D administrative document	N/A	N/A	
<b>Race</b>	None identified	R&D administrative document	N/A	N/A	
<b>Religion or Belief</b>	None identified	R&D administrative document	N/A	N/A	

SOP 051: Confirmation of capacity and capability for non- Harmonised Studies

Equality Group	Identify negative impacts	What evidence, engagement or audit has been used?	How will you address the issues identified?	Identifies who will lead the work for the changes required and when?	Please list positive impacts and existing support structures
<b>Sex</b>	None identified	R&D administrative document	N/A	N/A	
<b>Sexual Orientation</b>	None identified	R&D administrative document	N/A	N/A	
<b>Carers</b>	None identified	R&D administrative document	N/A	N/A	

It is important to record the names of everyone who has contributed to the policy, practice, function, business case, and project or service change.

Equality Analysis completed by: (please include every person who has read or commented and approval committee(s). Add more lines if necessary)	Organisation	Date
Sop Working Group	Royal Free London NHS Foundation Trust	27/09/2017
R&D Committee	Royal Free London NHS Foundation Trust	26/10/2017