St George's University Hospitals NHS
NHS Foundation Trust

Standard Operating Procedure (SOP)

Confirmation of Capacity and Capability for St George's Hosted Research

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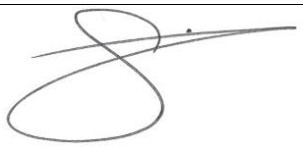
Signature of Authoriser			

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The master document is posted on the JRES website and any print-off will be classed as uncontrolled.

Researchers and their teams are responsible for checking the JRES website for the most recent version.

They may print off this document for training and reference purposes.

SOP Chronology		
SOP Version Number:	**Reason for Change:**	**Author:**
V1.0	Original Version	Ailsa Withers
V2.0	The above SOP was amended to the recent changes made to the process and to implement the new numbering system for SOPs.	Ira Jakupovic
V3.0	Review of Version 2.0	Ira Jakupovic
V4.0	Re-write to incorporate new JREO process, change to new numbering	Nadia Azzouzi
V5.0	Updated to reflect use of JREODOC0100 for CGL & BM approvals	Debs Rolfe
V6.0	Review of version 5.0. Updated Logo and Trust Name	Anika Kadchha
V7.0	Review of version 6.0. Updated with information relating to HRA approval process	Nadia Azzouzi
V8.0	Complete re-write of Version 7.0. Update to approach and processes reflective of HRA approval pathway for local organisations	Subhir Bedi
V8.1	Clarification of Clinical Lead (Director) and Business Manager approvals requirements	Subhir Bedi
V9.0	Reflecting changes in JRES and job titles and changes to the process in line with HRA updates to PIC and Non-NHS site set up and introduction of OID. Also insertion of associated JRES documents.	Georgia Bullock
V10.0	Updated to reflect changes to study review and approval post-COVID.	Joe Montebello / Deidre Callahan

Associated JRES documents

SOPs	WPDs	Docs	LOGs
JRESGOVSOP0003 Sponsorship for CTIMPs JRESGOVSOP0028 Applying for Sponsorship for Non-CTIMPs	JRESWPD0023 General Research Definitions		

Contents

1. Background

The Health Research Authority (HRA) was established in December 2011 under the UK Government's Plan for Growth, to streamline the regulation of research in healthcare whilst promoting and protecting the interests of patients. In line with the Health and Care Act 2014, the HRA was established as a statutory Non-Departmental Public Body (NDPB) as of the 1st January 2015.

HRA Approval is the current process for the NHS in England that brings together the assessment of governance and legal compliance, undertaken by dedicated HRA staff, with the independent Research Ethics Committee (REC) opinion provided through the UK Health Departments' National Research Ethics Service (NRES). The HRA has taken over the responsibility for ensuring that each new study complies with all applicable regulatory requirements in England. It replaces the need for local checks of legal compliance and related matters by each participating organisation in England. This allows participating organisations to focus their resources on Assessing, Arranging and Confirming (AAC) their Capacity and Capability (C&C) to deliver the study. The decision to formally confirm an organisation's C&C to deliver a specific study is normally issued by the organisation's Research and Development (R&D) function[1]. For St George's University Hospitals NHS Foundation Trust (SGHFT) patients and/or site(s), confirmation can only be issued by the Joint Research and Enterprise Services (JRES).

2. Joint Research and Enterprise Services (JRES) Policy

All JRES SOPs will be produced and approved in accordance with the JRES SOP on SOPs and must be used in conjunction with local NHS Trust and University policies and procedures.

The JRES acts as the representative of both St George's University of London (SGUL) and St George's University Hospitals NHS Foundation Trust (SGHT). St George's will be the official name used on all SOPs to represent either institution acting as Sponsor.

3. Scope

This SOP outlines the procedure for confirming capacity and capability (NHS R&D "Approval") of healthcare research being hosted at St George's. Research undertaken at St George's University Hospitals NHS Foundation Trust and/or involving Trust patients as participants will require

[1] http://www.hra.nhs.uk/research-community/hra-approval-the-new-process-for-the-nhs-in-england/

confirmation of capacity and capability (when directed by the HRA). This is subsequent to HRA and REC approval (and any other necessary approvals, e.g. MHRA approval) and before the project can commence.

This SOP will not cover obtaining Sponsor approval, which is required before the project can be booked into Ethics. For sponsorship guidance, please refer to JRESGOVSOP0003 and JRESGOVSOP0028.

4. Definitions

For general research management related acronyms used in this SOP, please refer to General Research Definitions Working Practice Document (JRESWPD0023).

5. Responsibilities

In respect to the process outlined in this SOP, the following responsibilities are applicable:

- *Sponsor/ CI:*

It is the responsibility of the Sponsor (or CI if delegated to him/her) to ensure the formal steps of HRA approval are followed.

It is the responsibility of the Sponsor (or CI if delegated to him/her) to ensure that an HRA local document package is simultaneously submitted to the study delivery team (PI) and the JRES (and to the Local Clinical Research Network, where applicable) once they have received the HRA Initial Assessment letter (or HRA Approval Letter where no Initial Assessment letter is issued). The HRA local document package is outlined in section 6.1.
It is the responsibility of the sponsor to provide an Investigator Site File (ISF) and relevant documents. Where not provided, the PI at St Georges should utilise JRES templates.

- *JRES*

It is the responsibility of the assigned JRES Research Governance and Facilitation Officer (RGFO) to operationally manage the local process for studies being proposed within SGHFT.

Only the Director of the JRES, Head of Research Governance and Delivery (HRGD) and / or Head of Funding for the JRES may authorise any formal clinical research site agreements/contracts on behalf of St George's (as Sponsor and / or participating centre).

The Research Governance team (RDGT), is made up of the HRGD, Research Development and Delivery Manager (RDDM), Research Development and Governance Manager (RDGM), Clinical Research Associates (CRA) and Research Governance and Facilitation Officers (RGFO), all of whom are authorised to give written (email) confirmation of C&C on behalf of St George's for research to commence, once all requirements are met.

It is the responsibility of the HRGD to ensure that this SOP is updated and audited where necessary.

In accordance with the UK Policy Framework for Health and Social Care Research, **it is not** the role of the JRES to repeat compliance checks carried out and confirmed by the HRA as part of HRA Approval for hosted sites.

- *Principal Investigator (PI)*

It is the responsibility of PI to actively contribute to the set-up process locally to ensure the studies s/he takes on can ultimately deliver. This will include participating in feasibility meetings and discussions among other activities.

Please note, SGHFT acts as "one site" overall and there can only be **one** named PI per study proposed and undertaken within the Trust. Additional investigators can and should be added to the study team and delegation logs as sub/deputy-PI, however the main named PI has overall responsibility for onsite study conduct.

6. Procedure

The HRA has defined the 4 stages that Sponsors and participating sites must go through to support and review local C&C to deliver a study (study set-up). Some of these stages are used to identify time points which the Trust must measure in order to examine where barriers to study set-up and delivery occur (see flowchart Appendix 9.3).

The 4 stages are:

1. **Identify**: Identification of potential study (of interest) by PI and then to initiate discussions with Sponsor, or identification of potential site by Sponsor. Start of site level feasibility which can be supported by NIHR CRN Expression of Interest (EOI) and or Site Intelligence (SI) processes if applicable. Supported by final/draft protocol and or protocol synopsis.
2. **Assessing:** Assessing the feasibility of a study and whether or not the Trust has the capacity and capability to participate in the study. Supported by final/draft protocol and or protocol

synopsis. The sponsor should outline any trial specific arrangements and or training required at this stage. Potential site target should be set at this stage.

Please note: Stage 1 and 2:

- May occur simultaneously (to avoid duplication).
- May not be required/ be minimal in certain types of studies where it is expected that the site will participate, for example urgent public health research or studies involving minimal local activity such as distributing questionnaires online. In these instances, the HRA assessment/approval letter(s) will detail the status and nature of the local review requirement.

3. **Arrange**: Putting and approving (internal) all practical arrangements required to support effective and timely study delivery. This is based upon the nature of the study, its timelines and target population and will require interactions with internal service support departments such as imaging, pharmacy, pathology and the Clinical Research Facility (CRF). This stage is initiated formally by the submission of the local submission package/addition of site, marking the start of the 40-day formal set up timeline**.** Site target should be formalised at this stage (if not previously).
4. **Confirming:** Final confirmation notification marking that the Trust has the capacity and capability in place to deliver the study and that all practical arrangements are in place. This confirmation is given through the agreement of the contents of the Organisation Information Document (for non-commercial studies) and sign-off on relevant site agreement where applicable.

It is the role of the RGFO to coordinate, oversee and deliver this process for their portfolio of studies within established timelines.

6.1 Local HRA Information Package

- IRAS application form, PDF (signed) version.
- Protocol (final HRA/REC submitted version).
- Patient information sheet and consent form (final HRA/REC submitted version).
- Relevant template contract/model agreement (if needed in addition to OID).
- Costing template (commercially sponsored only) or Schedule of Events/ SoECAT (non-commercially sponsored only).
- Any amendments.

- Copy of HRA Initial Assessment letter (if one is issued) and (when issued) HRA Approval letter and final document versions.
- Delegation log (Sponsor can share this at a later date).
- Relevant documents to support site set up e.g. pathology manual, Investigator Brochure etc.

Additional documentation may be required to support study review within specific departments i.e. CRF, imaging review form(s). **These are Trust internal documents not to be sent to the sponsor for completion**. The RGFO should collectively work with the PI/research team and relevant department to ensure the relevant form/information is conveyed in a timely and proportionate manner.

6.2 R&D Database Registration

To ensure effective oversight, any newly proposed study should be registered on the JRES R&D database – EDGE - at the earliest opportunity (during the Identify and/ or Assess phase). At the very latest the study has to be registered at the point of HRA Local Package submission to the PI and JRES (and LCRN if applicable). For details of EDGE database registration and management please refer to working practice document JRESWPD0019.
"R&D number generator" is to be used to create the local/Sponsor R&D/JRES reference number.

6.3 Metrics

Please note, only once the (initial) HRA local information pack (all relevant documents listed in section 6.1) has been received, does the formal 40-day set-up clock commence. The JRES aims to confirm C&C within this timeline. Please see Appendix 9.4 outlining study set-up metrics.

Study feasibility and assessment discussions should continue regardless of formal submission (and where a protocol/protocol synopsis has been provided) to avoid unnecessary delays and duplication (this should include interactions with internal support departments).

6.4 Confirmation notification

Once the local assessment and arrangement of study requirements have been completed (and a site target agreed with the PI and agreed with the Sponsor based on these), the relevant member of the JRES will be able to formally confirm capacity and capability on behalf of St George's.

Final JRES sign-off is dependent on the following reviews/approvals being in place internally:

- ✓ Feasibility review detailing study requirements and relevant arrangements to support study target and timelines- this is to include confirmation of any study specific training required by the sponsor
- ✓ Relevant site agreement(s) signed off by the JRES and Sponsor organisation (if applicable) in line with section 4 'Responsibilities'. **Fully signed contracts need to be in place before confirmation can be issued**.
- ✓ Approved site contract (mCTA, CRO-mCTA, mNCA or OID depending on study type) completed with confirmed site target.
- ✓ Authorisation of support from applicable support department's e.g. imaging, pathology, pharmacy & CRF.
- ✓ Authorisation from the Head of Research Governance and Delivery for the study to resume post-COVID
- ✓ Confirmation of NIHR Clinical Research Network (CRN) eligibility status.
- ✓ Care Group Lead (and where relevant Business manager) (email) notification/ agreement (email template Appendix 9.1).
  (*Care Group Leads are notified of study intention and provided 7 days to respond otherwise approval is assumed. Business Manager Notification is required ONLY when there is a financial burden to the clinical unit, i.e. instances of excess treatment costs. For all commercially funded research, Business Manager Notification is not required as there is income generation*).

When everything is in place, the template email in Appendix 9.2, confirming capacity and capability, should be edited and issued for the study addressed to the Sponsor/CI, copying in the PI, study team, support department(s) and LCRN (if applicable). The study can now open (providing, where applicable, relevant the Sponsor green light has been given).

A copy of the approval email (PDF) along with all attachments should be placed in the electronic R&D file (on EDGE or shared drive depending on the study).

EDGE data points and status should be updated to reflect study status in real time.

7. Study Site Types

Study site type will be defined based on the nature of activity conducted on site and in agreement with the Sponsor.

- **Research sites** (recruitment and study delivery): responsible for participant-related research procedures specified in the protocol including recruitment and informed consent and intervention delivery. Each site should have its own OID/Contract, SoE/SoECAT and C&C approval.
- **Shared /Continued Care site**: where two or more organisations are is responsible for the conduct of some protocol procedures and/or management of the routine care pathway of a research participant. Some aspects of a single protocol may need to be delivered by different NHS Trusts. Each site should have its own OID/Contract, SoE/SoECAT and C&C approval. Where facilities or equipment at a different location from the main site are used, but the participant remains under the responsibility of the main site Trust, separate approval is not required, for example, Moorfields Eye Clinic at St George's is the responsibility of Moorfields NHS to manage fully.
- **Participant/Patient Identification Centres (PICs)**: identifies potential research participants by processing personal data (e.g. through carrying out a search of patient records database to identify individuals that meet a study's eligibility criteria) and is, following the Sponsor(s) instructions, responsible for identifying potential research participants and directing these potential participants elsewhere without undertaking any further research activity for that study (i.e. the research occurs at another legal entity). Sites are not PICs where they are responsible for the delivery of any protocol-driven research activities including additional screening procedures (e.g. blood tests and X-rays), as they would be full research sites, or where they are identifying potential patients through routine clinic referral pathways, or advertising opportunities to participate in a specific study, e.g. via posters in waiting rooms (where they are not any site type). PICs are set up through a sub-contracting arrangement with the participating NHS/HSC organisation that the PIC supports. Appropriate data processing arrangements should be put in place by using the appropriate model agreement published on the IRAS and/or HRA website.
  https://www.myresearchproject.org.uk/help/hlpsitespecific.aspx#PIC
  PIC referral funding requires approval from the HRGD or Head of Research Funding before agreement with PIC site.

7.1 Non-NHS Sites

These sites are organisations undertaking protocol-driven procedures with participants outside of an NHS setting, for example, St George's Vaccine Institute (under St George's University of London). An assessment of the suitability of the site and Principal Investigator needs to be undertaken for *Clinical Trials of Investigational Medicinal Products (CTIMPs) and Clinical*

Investigations of Medical Devices only via the completion and submission of a non-NHS/HSC Site Assessment Form to the Ethics Committee/HRA. Documents required for submission include:

- Notice of Substantial Amendment Form
- Non-NHS/HSC Site Assessment Form
- Short CV for the Principal Investigator(s)
- Any other supporting documents for addition of new non-NHS/HSC site (e.g. Evidence of insurance or indemnity (not required for Phase 1 trials in healthy volunteers where the site is accredited by the MHRA); local versions of documentation if they are significantly different to the main version)

For all other study types, including research involving adults lacking capacity, the Sponsor should list the sites in Part C of the application form for ethical review and or notify the HRA/ethics of new non-NHS site at the next routine amendment/progress report. No additional documentation or forms need to be submitted for non-NHS/HSC sites in this instance.

For forms, visit IRAS website:

https://www.myresearchproject.org.uk/help/hlpsitespecific.aspx#non-NHS-sites)

For non-NHS site confirmation for St George's University of London, C&C approval is still required prior to site activity starting. The procedure in this SOP should be followed with feasibility, capacity and capability discussions with PI/local research team undertaken and evidence prior to formal St George's University of London confirmation. St George's University of London should be set up as a site on EDGE.

8. References

- www.hra.nhs.uk
- NIHR CRN Study Support Services - CRN Principals for assessing, arranging and confirming local capacity and capability.
- UK Policy Framework for Health and Social Care Research.
- IRAS https://www.myresearchproject.org.uk/help/hlpsitespecific.aspx#non-NHS-sites
- NIHR Restart Framework https://www.nihr.ac.uk/documents/restart-framework/24886

9. Appendices

9.1: Clinical Director/Care Group Lead/ Business Manager email notification

9.2: Confirmation of Capacity and Capability notification email template

9.3: Phases of local Study Set up (1-4) as per HRA Approval guidance

9.4: Set Up and Delivery Metrics

9.1 Clinical Director/Care Group Lead/ Business Manager email notification

FROM: St George's JRES

To: Nominated Clinical Director/Care Group Lead/ Business Manager

CC: Site Principal Investigator, Site Research Team

Subject: IRAS ID-Short Title, PI Name- Request for clinical and/or trust authorisation

Attachment: Protocol, completed AAC review, completed site Schedule of events &/or Statement of activities (non-commercial), confirmed Costing Template (Commercial)

Dear XXXXXX

RE: IRAS ID-Short Title, PI Name- Request for departmental authorisation

I am writing to you notify you as clinical unit director/care group lead/business manager of the subjected research study to run at St George's:

Study Principal Investigator	
Site Target	
Study Duration (open and close date)	

The study is originating from (sponsor)

DELETE as appropriate

- Commercial [full cost recovery budget and clinical trials agreement, based on the UKCRN Model Clinical Trials agreement and costing template, with the company will be in place to ensure the hospital is reimbursed for all the activity associated with the study protocol.]
- Non-Commercial [based on the attribution information provided) the study activity attribution is outlined in the attached Schedule of Events. The study sponsor is providing XX to cover the following/is not providing any additional funding. As a NIHR CRN study the service support activity will be supported by CRN South London funding where appropriate

ADDITIONAL SERVICE/DELIVERY CONSIDERATIONS e.g. Outline of any onsite study management

I have attached the Protocol (and Schedule of events - non-commercial only) for your information.

Due to national study set up timelines we would appreciate your feedback (and confirmation) within **7 days**. If we do not hear back within this timeframe we will assume departmental approval.

Please do not hesitate to contact me should you have any questions or require additional information.

I look forward to your response

Best Wishes INSERT PERSONAL SIGNATURE

9.2 Confirmation of Capacity and Capability notification email template

From: St George's JRES

To: Sponsor representative/ Chief Investigator, Principal Investigator or Local Collaborator,

Cc: Clinical Trial Unit/Study Manager/Study Coordinator (where applicable), Lead Research Nurse/Coordinator, Support Departments, LCRN London South (NIHR CRN studies)

Subject: IRAS xxxxxx. Confirmation of Capacity and Capability at **St George's University Hospitals NHS Foundation Trust/ St George's, University of London**

Attachment: Signed agreement and/or agreed statement of activities, as appropriate

Dear Sponsor Representative,

RE: IRAS xxxxxx. Confirmation of Capacity and Capability at St George's University Hospitals NHS Foundation Trust/ St George's, University of London

Full Study Title:	
Site PI/LC	
Current Protocol version:	
Latest HRA Approval date:	

This email confirms that **St George's University Hospitals NHS Foundation Trust/ St George's, University of London** has the capacity and capability to deliver the above referenced study. Please find attached the signed agreement [and/or] agreed Statement of Activities as confirmation.

St George's Healthcare NHS Foundation Trust agrees to start this study on (INSERT DATE), as previously agreed OR on a date to be agreed when you as sponsor give the green light to begin. Please ensure the R&D office and local CRN contacts are provided with this date.

The local research team must ensure that the participant/patient medical records are clearly marked to indicate their study participation. For electronic medical records you are advised, where relevant, to utilise the system research flags or alerts and for paper records to affix an alert sticker to the front cover. Alert stickers can be obtained from the JRES.

You are required to record all participant recruitment on the Trust's EDGE database. If you are unable to access this please contact the JRES.

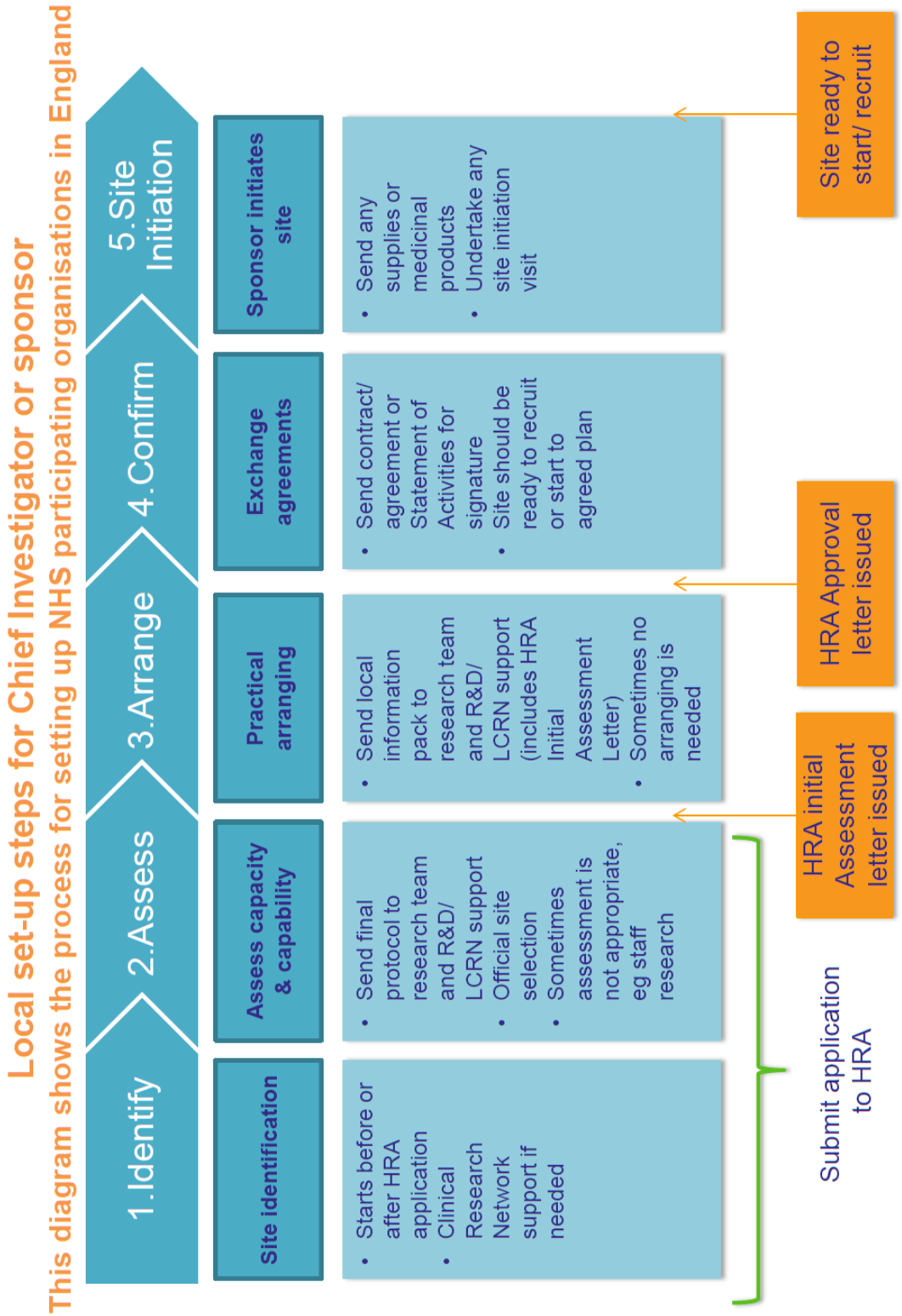
If you wish to discuss further, please do not hesitate to contact us and local team (cc above).

Please note, in line with the national HRA approvals process, you will no longer receive an NHS R&D Approval/Permission letter.

Kind regards

INSERT PERSONAL SIGNATURE

9.3 Phases of local Study Set up (1-4) as per HRA Approval guidance



9.4 Set Up and Delivery Metrics