Great Western Hospitals NHS
NHS Foundation Trust

Standard Operating Procedure: Capacity and Capability

Audience: All staff who wish to undertake research at GWH

SOP NUMBER: 009 Version Number & Date: V1 01/04/2017 Superseded Version Number & Date(if applicable):	Effective Date: 01/04/2017 Review Date: 01/04/2019

Author:

Name: Jean Kordula Position: R&I Facilitator Signature: J. Kordula Date: 01-04-2017

Approved by:

Name: CHRIS CLARK Position: R+I MANAGER Signature: [signature] Date: 1 APR '17

Name: ELIZABETH PRICE Position: R & I DIRECTOR Signature: [signature] Date: 1/04/2017

1. BACKGROUND

This SOP sets out to provide clarity about the process to be followed before Confirmation of Capacity and Capability is given to deliver a research study in Great Western Hospitals NHS Foundation Trust (the Trust) for studies receiving HRA Approval. Obtaining Confirmation is an essential precondition to the conduct and delivery of any portfolio or non-portfolio study.

HRA Approval is now 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 previously known as local governance review. This allows NHS organisations to focus their resources on assessing, arranging and confirm their capacity and capability to deliver the study.

HRA Approval applies only 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 that mean that the HRA will share information with those national coordinating functions to benefit study set up in participating NHS/HSC organisation across the UK where applicable. Further information about this can be found at http://www.hra.nhs.uk/about-the-hra/ourplans-and-projects/assessment-approval/

DEFINITIONS/ABBREVIATIONS

C&C	Capacity and Capability
CI	Chief Investigator
RM&G	Research Management and Governance
Sr. RDF	Senior Research Delivery Facilitator
RDF	Research Delivery Facilitator
HRA	Health Research Authority
REC	Research Ethics Committee
R&I	Research & Innovation
SoA	Statement of Activities
SoE	Schedule of Events

2. PURPOSE

The purpose of this SOP is to describe the processes undertaken to review and confirm capacity and capability to deliver research at the Trust.

3. APPLICABLE TO

Members of Great Western Hospitals NHS Foundation Trust R&I Department and Research Teams, Principal Investigators and Support Departments.

4. PROCEDURE

The HRA has defined the different stages that sponsors and participating organisations (the Trust) go through on the way to mutually agreeing that the study can open at that organisation (the Trust).

These stages can be used to identify time points which the Trust may wish to measure in order to examine where barriers to study set up and delivery occur (see flowchart Appendix 1).

- **Assessing:** Assessing whether or not 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 questionnaires, on line 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.

- **Arranging:** Putting any practical arrangements in place to provide the capacity and capability to deliver the study

- **Confirming:** Confirming that the Trust 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 statement of activities for non-commercial studies or sign-off on an agreement.

Confirmation of Capacity and Capability

Assess:

- The sponsor/CI/study co-ordinator invites the Trust to assess their local capacity & capability to participate in a study. This invitation will come via the Research Approvals mailbox or directly from the PI/research team and will consist of the protocol (commercial study – protocol, industry costing template and agreement, non-commercial –protocol, Statement of Activities/trial agreement and Schedule of Events). If either of these documents are missing request from the sponsor.

- The RDF will cascade the documentation to the relevant research team for them to assess. Once the PI and research team have reviewed and assessed their capacity and capability to deliver the study as per its protocol, they must feed back to the R&I Manager or delegate who will then progress with the assessment. Support departments will be approached to confirm they are willing and able to support the research study in question. The R&I Manager is responsible for the oversight of all research activity within the Trust and once all information has been collated will review and confirm if the study is feasible or not.

- If deemed feasible, the Sr.RDF/RDF will confirm with the sponsor and request the Local Information Pack (see appendix 2).

  (NB) This invitation must only happen after an application for HRA Approval has been made but can also occur after HRA Approval is in place.

- If capacity or capability does not allow for delivery of the study an email will be sent to the sponsor to notify them of this decision.

- If the decision is made to deliver the study, the RDF will process the study using the Confirmation of Capacity and Capability Checklist and will add the study to EDGE.

- Consider with the research team when the first patient first visit (FPFV) will take place.

Assess : Actions

- Create a new EDGE record for the study as well as a new study folder on the T Drive
- Obtain the Local Information Pack from the sponsor ensuring it is complete (see appendix 2) which may include requesting the pharmacy and/or lab manual as appropriate to the study
- Undertake an assessment of the study agreement/statement of activities and industry costing template/schedule of events
- Review NHS cost and resource implications
- If happy with the study agreement, localise and return to sponsor requesting hard copies signed by the sponsor
- If happy with statement of activities complete relevant section and hold until issue of Confirmation of Capacity and Capability email.
- Request authorisation from the relevant support departments
- Identify (check the Schedule of Events) honorary employment contract / letter of access requirements and ensure that all relevant research passports/honorary contract (or letter of access) application forms and/or copies of NHS substantive contracts are available (or are obtained).

Arrange: Actions

- Clarify with the sponsor and team if there is study specific training required
- Confirm SIV date
- Confirm IMP delivery date
- Any other arrangements e.g. Service Level Agreements, freezer, drug cabinet etc

Confirm: Actions

- Ensure HRA Approval has been received and upload latest versions of documents to the study folder onto the T Drive and EDGE.
- Ensure study agreement is fully executed or SoA is completed
- Pharmacy confirmation of readiness has been received (IMP studies)
- Laboratory confirmation of readiness has been received (if relevant)
- All required honorary contracts/letter of access ready to issue
- Confirmation of Site Initiation received.
- If the above are confirmed agree a start date/drug delivery date with the sponsor (if available) and issue confirmation of capacity and capability email to sponsor and copy in all appropriate personnel. If using the SoA as the agreement (non-commercial studies) attach this to the email or the fully executed contract as appropriate.
- Confirm with the PI and Research Team when the FPFV (first patient first visit) date will be ensuring this it fall within the 70 day target (from receipt of local document package)
- Lastly, ensure the route for entering recruitment on to edge has been agreed.

5. SUPPORTING DOCUMENTS

Appendix 1 – Assessing Arranging & Confirming Capacity and Capability

Appendix 2 – Local Information Pack

Appendix 1

Step	Name	STEP START	Actions	STEP ENDS	Recording	CRN	DH/NIHR (PII/PID)
1	Identify	First approach about study but no protocol	Early discussions between sponsor, PI, team and R&I Review study Synopsis/Summary	Email from PI/R&I/team confirming interest	Nothing	N/A	N/A
2	Assess	Date participating organisation invited receipt by R&I of a protocol from sponsor	Carry out quick check of study Have we got PI/team in place? Have we got required facilities/support depts.? Have we got required patient/participant type?	Email response sent to sponsor acknowledging receipt of protocol	Record "Participating Site Invited" date on EDGE Create EDGE record Use IRAs number as study identifier Include PI name, Sponsor, Funder etc.	3 Days (Expectation not a measured metric)	N/A
3	Arrange	Date Participating Site Selected Receipt of 'Local Information Pack' from Sponsor Includes HRA Initial Assessment Letter Includes all associated documents Includes statement of activities (non – commercial) Includes schedule of events Includes costing template/mCTA etc.	R&I Staff Carry out site checks for capacity and capability by email R&I review costings, contract, SoA etc. Negotiate terms of contract/SoA where required Send investigator agreement to PI and inform PI/team about EDGE reporting requirements		Record "Participating Site Selected" data on EDGE Save all study documents in study folder For each completed review save email chain/confirmation in study folder	Start of CRN 40-day "selected to site confirmation" metric HLO 4 40 Days	Start of DH 70-day "selected to first patient" metric 70 Days
		Receipt of HRA Approval Letter from sponsor			Record "Date of HRA approval letter" on EDGE		
		Date Participating organisation confirmed by sponsor	First party signs contract/mCTA or Sponsor emails final agreed SoA to site (R&I generic mailbox)	Date of the FIRST signature on the agreement/contract Or date final SoA received by email from sponsor	Record "Date participating organisation confirmed by sponsor" date on EDGE		

4	Confirm	Date participating organisation confirmed	Fully executed study agreement/mCTA Or emails confirming acceptance of SoA from both Sponsor and site R&I emails Sponsor using template email confirming capacity and capability (attaching fully executed agreement/mCTA orSoA)	Date of the LAST signature on the agreement/contract or date SoA accepted by both site and Sponsor (evidence by email)	Record 2Date participating organisation confirmed" on EDGE Ensure EDGE record is complete including status, start and end dates etc.			
		Date participating organisation ready to start	Date sponsor confirms that recruitment can begin at the site (by email)		Record date in 'open to recruitment' field on EDGE	Start of CRN 30 day confirmed by sponsor to first patient metric HLO 5		
						30 Days		RTT Recruit-ment tc time and Target
		Non-confirmation	Sponsor declines site or site confirms no capacity and capability	Site unable to take part in study	Record 'Non-confirmation' on EDGE			
5	First Patient Recruited	First Patient is recruited at site	*Patients consented but failing screening do not count*		PI/team to record first patient recruited on EDGE	End of CRN 30 days to 1st patient metric	End of 70 day selected to 1st patient metric	

DURING RECRUITMENT WINDOW	Patients recruited at site	R&I to review amendments R&I to check that the recruitment is being uploaded by PI/team Where study payments are due, R&I to check that invoices are raised at agreement timepoints		PI/team to maintain recruitment record on EDGE	

6	Last Patient Recruited	Last patient recruited at site	R&I to check the PI/team have fully recorded recruitment on EDGE		PI/team to record date of last patient recruited on EDGE	

Appendix 2

LOCAL INFORMATION PACKAGE

The Sponsor should provide the following information to the site:

- Copy of the HRA Initial Assessment Letter
- Copy of IRAS application form(R&D) form
- Protocol
- Any amendments
- Participant Information and Consent documentation
- Schedule of Events – non-commercial studies
- Relevant model agreement and/or Statement of Activities non-commercial studies
- NIHR Costing template validated by the Clinical Research Network – Commercial Studies
- Contract must be provided for all Commercial Studies