Dorset HealthCare University
NHS Foundation Trust

Standard Operating Procedure for Local Assess, Arrange and Confirm

Objectives	The objective of this SOP is to outline the procedure for local assess, arrange and confirm.
Scope	Applies to the Research & Development Team.
Responsibility	It is the responsibility of the Research & Development Facilitator to ensure this SOP is adhered to.
Related Document	None.

1 Purpose

The purpose of this SOP is to describe the Health Research Authority (HRA) assess, arrange and confirm process which is undertaken by Dorset HealthCare as a participating organisation.

2 Introduction

Health Research Authority (HRA) Approval is the new process for the NHS in England that brings together the assessment of governance and legal compliance, undertaken by the HRA, with the independent REC opinion provided through the UK Research Ethics Service. 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 their capacity and capability to deliver the study.

3 Training

New users must read and understand this SOP before carrying out this procedure. Existing users must read and understand the Revisions section.

4 Revisions

This is the second version of this SOP.

5 Procedure

5.1 HRA Approval Notification

Once the HRA Approval letter has been issued to the Sponsor, the sponsor should inform the local or participating organisation that HRA approval has been given so that they can confirm local capacity through the assess, arrange and confirm process.

5.2 Allocation of Studies

As a participating organisation, Dorset HealthCare will be notified by the Sponsor of HRA approval. Dorset HealthCare may be contacted by the Sponsor before HRA approval is issued in order to initiate the local assess, arrange and confirm process.

The Research Support Co-ordinator will compile the documentation, register the study on EDGE (local management system) and initiate the required assess, arrange and confirm process.

5.3 Assess, Arrange and Confirm

ASSESS	Upon receipt of study protocol, conduct a brief check of study; consider a potential Principal Investigator (PI) and whether there are the facilities/support departments/patient/participant types available.
	Email the Sponsor to acknowledge receipt of protocol.
	Record 'Participating Site Invited' date on EDGE.
ARRANGE	Upon receipt of the local information pack from the Sponsor, record 'Participating site Selected' date on EDGE.
	R&D to carry out site checks for capacity and capability by email.
	R&D review costings, contract, SoA etc. – to negotiate terms of contract where required.
	Upload study documents to EDGE.
	Upon receipt of HRA Approval letter from Sponsor, record date on EDGE.
	Record 'Date participating organisation confirmed by Sponsor' date on EDGE (this is either the date of the first signature on the agreement/contract or Sponsor emails final agreed SoA to participating site).
CONFIRM	Record 'Date participating organisation confirmed' on EDGE when in receipt of either a fully executed study agreement/mNCA or email confirming acceptance of SoA from both Sponsor and site.
	Once Sponsor confirms that recruitment can begin at site, record date in 'Open to Recruitment' field on EDGE.
	If Sponsor declines site or site confirms no capacity and capability, record non-confirmation date on EDGE.

5.4 Statement of Activities and Schedule of Events

The Statement of Activities (SoA) and Schedule of Events (SoE) are sent to the participating organisation for local assessment, arrangement and confirmation of capacity.

In general, the SoA provides information relating to finance, material transfer provisions and confidentiality, data protection and freedom of information.

The SoE provides information relating to:

- Study set-up, study monitoring, study close-down
- Consent procedures, laboratory tests and investigations
- Medical exposure/imaging tests and investigations
- Pharmacy, interventions (clinical), interventions (non-clinical), other procedures/activities

The SoA and SoE are reviewed in conjunction with finance, the contracts team and other appropriate support departments.

As a participating organisation, the SoA and SoE may replace a site agreement or model non-commercial agreement (mNCA). This will be study dependent and agreed with the contracts team.

5.5 Local Confirmation of Capacity

The Research Support Co-ordinator, in conjunction with the R&D Facilitator, will review and verify completion of the SoA and SoE.

The SoA is signed by the R&D Facilitator. The approval of the SoA confirms local capacity to initiate the research study.

For external Sponsors, the Research Support Co-ordinator will email a copy of the approved SoA to the Sponsor.

If Dorset HealthCare is the Sponsor, the Research Support Co-ordinator will inform the Chief Investigator that Dorset HealthCare as a participating organisation has confirmed capacity.

6 Appendices

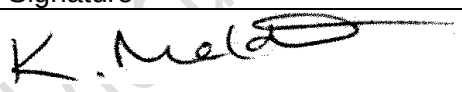
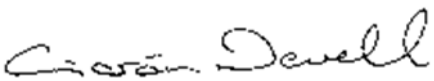
There are no appendices to this SOP.

7 Responsibilities

8 Review

This SOP should be reviewed every two years unless new guidance or legislation dictates a review any sooner.

Date reviewed: 12/04/2019 Date of next review: 12/04/2021

Written By	Signature	Date
Kim Meldrum		12/04/19
Reviewed By	Signature	Date
Dr Ciarán Newell		12/04/19
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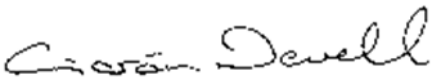
Dr Ciarán Newell		12/04/19