Standard Operating Procedure

UHBW HOSTED RESEARCH AMENDMENTS

SETTING Trustwide

AUDIENCE Research staff submitting research study amendments for UHBW hosted research and R&D staff processing UHBW hosted research amendments

ISSUE To describe the process of reviewing and implementing research study amendments for UHBW hosted research

QUERIES Contact Research & Development department: 0117 34 20233 or research@uhbw.nhs.uk

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Document History

Review date	Version number	Version date	Effective date	Author/ Reviewer	Authorised by
N/A	1.0	19/JAN/2018	14/FEB/2018	Jess Bisset	Diana Benton
SEP/2020	1.1	21/SEP/2020	20/NOV/2020	Sandra Mulligan Karen Morgan	Jess Bisset
OCT/2022	1.2	17/OCT/2022	22/FEB/2022	Jake Harley Karen Morgan	Jess Bisset
FEB/2023	1.3	21/FEB/2023	01/APR/2023	Lucy Riddolls	Nicola Manning
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Version Number	Reason for change
Original V1.0	N/A original
V1.1	Minor clarifications and updates as part of biennial review
V1.2	Minor clarifications and updates as part of biennial review
V1.3	Departmental name change from Research & Innovation to Research & Development. Updated throughout SOP as a minor amendment.
V 1.4	Minor clarifications and updates as part of biennial review

1. Introduction

During a research study, it may become necessary for the sponsor to amend study specific documents and processes. Where UHBW are a participating site, the sponsor will need to submit the amendment to ResearchAmendments@uhbw.nhs.uk for review.

2. Purpose

This SOP is to describe the processes for both UHBW research staff and R&D staff in reviewing, authorizing, and implementing amendments for UHBW hosted research.

3. Scope

In Scope: Amendments submitted for UHBW hosted research.
Out of scope: Amendments submitted for UHBW sponsored research (please see *SOP_019 UHBW sponsored research amendments*)

4. Responsibilities

External sponsors and research staff are responsible for preparing amended study documents and submitting them to ResearchAmendments@uhbw.nhs.uk for review in line with national processes as described on the HRA and MHRA website.

UHBW research staff are responsible for reviewing submitted amendments for capacity and capability in liaison with UHBW R&D staff.

UHBW R&D staff are responsible for reviewing submitted amendments initially for completeness and subsequently for ongoing capacity and capability assessment and for issuing confirmation to sponsor.

5. Abbreviations and Definitions

Abbreviations	
CTIMP	Clinical Trial of an Investigational Medicinal Product
HRA	Health Research Authority
IRAS	Integrated Research Application System
iCT	Interactive Costing Tool
ISF	Investigator Site File
MHRA	Medicines for Healthcare products Regulatory Agency
REC	Research Ethics Committee
R & D	Research and Development
RMF	Research Management Facilitator
RPA	Research Projects Assistant
RPM	Research Projects Manager (Sponsored Trials)
SMT	Senior Management Team
TMF	Trial Master File
UHBW	University Hospitals Bristol and Weston NHS Foundation Trust

Definitions	
Amendment Category A	Implications for, or affects, all participating NHS/HSC organisations hosting the research project.
Amendment Category B	Implications for, or affects, specific participating NHS/HSC organisations hosting the research project.
Amendment Category C	No implications that require management or oversight by the participating NHS/HSC organisations hosting the research project. However, the amendment should still be submitted for information.
Substantial Amendment	A substantial amendment is a change to the terms of the request for clinical trial authorisation or the REC application, or to the accompanying particulars or documents, which significantly affects one of the following: - The safety or physical or mental integrity of study participants - The conduct or management of the study - The scientific value of the study - The quality or safety of any investigational medicinal product used in the study **For CTIMPs or a regulated investigation of a medical device,** the addition of new non-NHS/HSC trial sites or changes to investigators at non-NHS/HSC trial sites listed in the initial applications to MHRA and the REC qualify as substantial amendments. (Source IRAS - further guidance is available both on IRAS and HRA websites)

6. Procedure

6.1 Receipt of amendment documents into UHBW

- For any studies which UHBW are hosting, sponsors should submit amendment paperwork to **ResearchAmendments@uhbw.nhs.uk**. If amendment paperwork is incorrectly submitted through differing routes e.g. into **research@uhbw.nhs.uk** or to the PI/local study team/allocated RMF, personnel receiving the amendment should send the paperwork to **ResearchAmendments@uhbw.nhs.uk** to trigger the amendment process as described in the flowchart below. (Flowchart A).

- The study type (e.g., CTIMP, regulated investigation of a medical device etc.) and amendment type (substantial, non- substantial) will determine what types of approvals are required for amendments (e.g. MHRA, HRA, REC etc.). It is the responsibility of the sponsor to ensure the appropriate approvals are sought for the amendment. HRA assessment will review whether required regulatory approvals are in place and participating sites will only need to assess whether they have the ongoing capacity and capability to implement the approved amendment.

- The RPA is responsible for reviewing received correspondence to identify whether the local PI and study team have been informed of the amendment. If not, the RPA will send on necessary paperwork to local study team (*TMPL_088 Amendment notification email*). This e-mail also informs the local study team of the35-day period from the date of the notification to raise an objection about the amendment (if applicable).

6.2 Deciding who in R&D should review the amendment

- On receipt of an amendment the Research Projects Assistant (RPA) will decide whether full review of the amendment is required by an RMF. This will be based on the following;
  - If the amendment is a Category A or B and is substantial and;
  - If the amendment involves an additional arm or;
  - If the amendment has implications for funding or;
  - If the amendment has implications for support department authorisation or;
  - If the amendment has implications for contractual arrangements
  - If the amendment has any other major impact on the Trust
- The RMF will then take over review of the amendment and completion of the EDGE workflow (*R&D-Host-Amendments workflow*) The RMF will seek input from the Senior Management Team as required for processing of the amendment.
- Otherwise, the RPA retains responsibility for the processing of the amendment.

6.3 Review of the amendment by an RMF

- If a review of the amendment is required by an RMF the following will be carried out:
  - RMF to review whether all support departments have been informed. If not, the amendment should be sent immediately with a request for authorisation of the amendment from any support departments affected.
  - RMF to review any amended contracts, liaising initially with the Senior Management Team for advice and with the UHBW legal department as required. The RMF will arrange for the signature of the contract amendment document.
  - RMF to review any changes to funding and where these are negative discuss with the local PI/study team the feasibility of continuing the study on reduced funding. For commercial studies, additional actions relating to the interactive Costing Tool (iCT) may be required.
  - RMF to review whether the capacity of the current PI/study team will be affected by the proposed amendment and discuss feasibility of continuing the study.
  - RMF to review any other capacity or capability impact by the proposed amendment.

6.4 Confirming ongoing capacity and capability

As described in the flowchart below, where all the checks are satisfactory and the required authorisation is in place, the RPA or RMF will email the sponsor with the local PI and study team cc'd to confirm ongoing capacity and capability confirmation.

- There is a template email for this: *TMPL_089 Continuing confirmation of C&C*. The RMF/RPA must ensure the Study title, IRAS ID, R&D reference number and Amendment number is clearly referenced in the email.

Flowchart A – Submission Process of Amendments for UHBW Hosted Studies

Amendment submission received into researchamendments@UHBW.nhs.uk

Category A

RPA reviews received correspondence to identify whether local PI and study team have been informed of the amendment. If not, RPA will send on necessary paperwork to local study team

RPA will also review whether the review required by an RMF. Further details on when a review may be required can be found in section 6.2 above.

RMF/RPA liaises with the local PI and study team to confirm ongoing capacity and capability at this site. Further details of this review can be found in 6.3 above.

When RMF/RPA & local PI & local study team have confirmed ongoing capacity & capability, RPA to review whether all approval paperwork has been received (i.e., HRA approval, REC approval, MHRA approval etc)

Where continued capacity and capability cannot be confirmed RMF/RPA emails sponsor with local PI & study team cc'd confirming the explanation and details for site closure

Category B

RPA reviews whether we are listed as one of the sites affected by the proposed amendment. If not RPA to follow process for Category C amendments.

If we are an affected site, the RPA reviews received correspondence to identify whether local PI and study team have been informed of the amendment. If not, RPA will send on necessary paperwork to local study team.

RPA will also review whether the review required by an RMF. Further details on when a review may be required can be found in section 6.2 above.

RMF/RPA liaises with local PI and study team to confirm ongoing capacity and capability at this site. Further details of this review can be found in 6.3 above.

Category C

RPA checks that local PI/study team have been sent the amendment paperwork (if not RPA to send) and files the paperwork in the electronic study folder.

Once all approval paperwork in place, EDGE workflow (*R&D-Host-Amendments workflow*) is completed and email confirming ongoing capacity and capability is submitted to the sponsor with local PI and study team cc'd in.

6.5 Objecting to the amendment

- In some instances, it may not be feasible to confirm ongoing capacity and capability for an amendment. In this instance, this will be communicated to the sponsor via email with the local PI and study team cc'd in and it will be discussed as to whether the site should be withdrawn from the study or to continue using the unamended protocol.

6.6 Filing and Information Processing within R&D

- **Filing**
  All correspondence relating to amendments in R&D must be saved in the electronic study folder in the 'Amendments' section. Each amendment will be assigned its own folder with a label describing amendment type and number with a short description e.g. 'Substantial Amendment 1 Protocol v2.0'. This will enable easier access to these documents by other members of the R&D department.

- **EDGE records**
  Not all study amendments are required to be recorded on EDGE. However, an amendment workflow should be initiated on the study EDGE record (site level) if the changes described in the amendment are applicable to the UHBW study site. (See Flowchart A above)

  Category A or B amendment (depending on whether the change affects some or all sites).
  - If the change(s) affect the UHBW site, an Amendments workflow (*R&D-Host-Amendments workflow*) is to be added to EDGE and required information completed until confirmation of C&C is issued. This may be the responsibility of the RPA or RMF following the initial RPA assessment (See Section 6.2 above).

  Category A or B amendment – Financial changes
  - If the amendment changes are financial, the RPA adds the Amendments workflow to EDGE and allocates this to the study RMF to review and update the Amendment workflow.

  Category C amendments - No further study wide review required.
  - EDGE workflow not required. These amendments received are passed on to the study team and filed in the Active study folder/Amendments

6.7 Implementing the amendment at UHBW site

- After R&D has issued ongoing capacity and capability confirmation for the amendment the local PI/study team at UHBW will implement the amendment on the advice of the sponsor. The sponsor may have previously confirmed that the amendment can be implemented as soon as ongoing capacity and capability is issued by R&D.
- The PI/local study team will ensure correct versions of documents are implemented and all team members can access latest versions. The PI/local team will file correspondence in the Investigator Site File (ISF) which may be hard copy or electronic.
- Please note further information on how the REC and HRA process amendments can be found on the HRA website: https://www.hra.nhs.uk/approvals-amendments/amending-approval/ Please refer to the website for latest guidance

7. Dissemination and training in the SOP

Plan Elements	Plan Details
The Dissemination Lead is:	Research Operations Manager
Is this document: A – replacing the same titled, expired SOP, B – replacing an alternative SOP, C – a new SOP:	A – replacing the same titled, expired SOP
If answer above is B: Alternative documentation this SOP will replace (if applicable):	N/A
This document is to be disseminated to:	All applicable research staff (including R&D)
Method of dissemination:	For major updates to the SOP dissemination will be: 1. To Chief Investigators of UHBW Sponsored CTIMPs 2. Research unit leads across UHBW 3. Head of Research Governance at UoB (where SOP is applicable) All updates (major and minor to the SOP) will be: 1. Updated on the trust MyStaffApp 2. Updated on the R&D website 3. Cascaded in the R&D e-bulletin
Is Training required:	All staff whose activities are subject to this SOP should ensure that they read and understand the content of the SOP. The personal training log of the individual (and the Investigator Site File/Trial Master File if required) should be completed to document that the content of this SOP has been read and understood as described in *SOP_007 Research Training UHBW*

REFERENCES	https://www.hra.nhs.uk/approvals-amendments/amending-approval/substantial-and-non-substantial-amendments/ https://www.hra.nhs.uk/approvals-amendments/amending-approval/ IRAS: https://www.myresearchproject.org.uk/help/hlpamendments.aspx
RELATED DOCUMENTS AND PAGES	SOP_007 Research Training SOP_019 UHBW Sponsored research amendments TMPL_088 Amendment notification email TMPL_089 Continuing confirmation of C&C Latest versions can be found on the Research & Development Department section of UHBW's website: http://www.uhbristol.nhs.uk/research-innovation/for-researchers/templates-and-sops/
AUTHORISING BODY	Trust Research Group
SAFETY	N/A
QUERIES AND CONTACT	Research & Development department 0117 34 20233 or research@uhbw.nhs.uk
AUDIT REQUIREMENTS	Departmental Quality Management System audits are undertaken annually.