Standard Operating Procedure

UH BRISTOL HOSTED RESEARCH AMENDMENTS

SETTING Trustwide

AUDIENCE Research staff submitting research study amendments for UH Bristol hosted research and R&I staff processing UH Bristol hosted research amendments

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

QUERIES Contact Research & Innovation department: Ext 20233 or research@uhbristol.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

Version Number	Reason for change
Original V1.0	N/A original

1. Introduction

During the course of a research study it may become necessary for the sponsor to amend study specific documents and processes. Where UH Bristol are a participating site the sponsor will need to submit the amendment to ResearchAmendments@UHBristol.nhs.uk for review.

2. Purpose

This SOP is to describe the processes for both UH Bristol research staff and R&I staff in reviewing, authorising and implementing amendments for UH Bristol hosted research.

3. Scope

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

4. Responsibilities

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

UH Bristol research staff are responsible for reviewing submitted amendments for capacity and capability in liaison with UH Bristol R&I staff.

UH Bristol R&I 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
ISF	Investigator Site File
MHRA	Medicines for Healthcare products Regulatory Agency
REC	Research Ethics Committee
R & I	Research and Innovation
RMF	Research Management Facilitator
RPM	Research Projects Manager (Sponsored Trials)
SMT	Senior Management Team
TMF	Trial Master File

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 ethics committee 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,** addition of new trial sites or changes to investigators listed in the initial applications to MHRA and the ethics committee 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 UH Bristol

- For any studies which UH Bristol are hosting, sponsors should submit amendment paperwork to **ResearchAmendments@UHBristol.nhs.uk**. If amendment paperwork is

incorrectly submitted through differing routes e.g. into **research@uhbristol.nhs.uk** or to the PI/local study team, personnel receiving the amendment should send the paperwork to **ResearchAmendments@UHBristol.nhs.uk** to trigger the amendment process as described in the flowchart below.

- Study type (e.g. CTIMP, 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.

6.2 Deciding who in R&I should review the amendment

- On receipt of an amendment the 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. The RMF will seek input from the Senior Management Team as required for processing of the amendment.

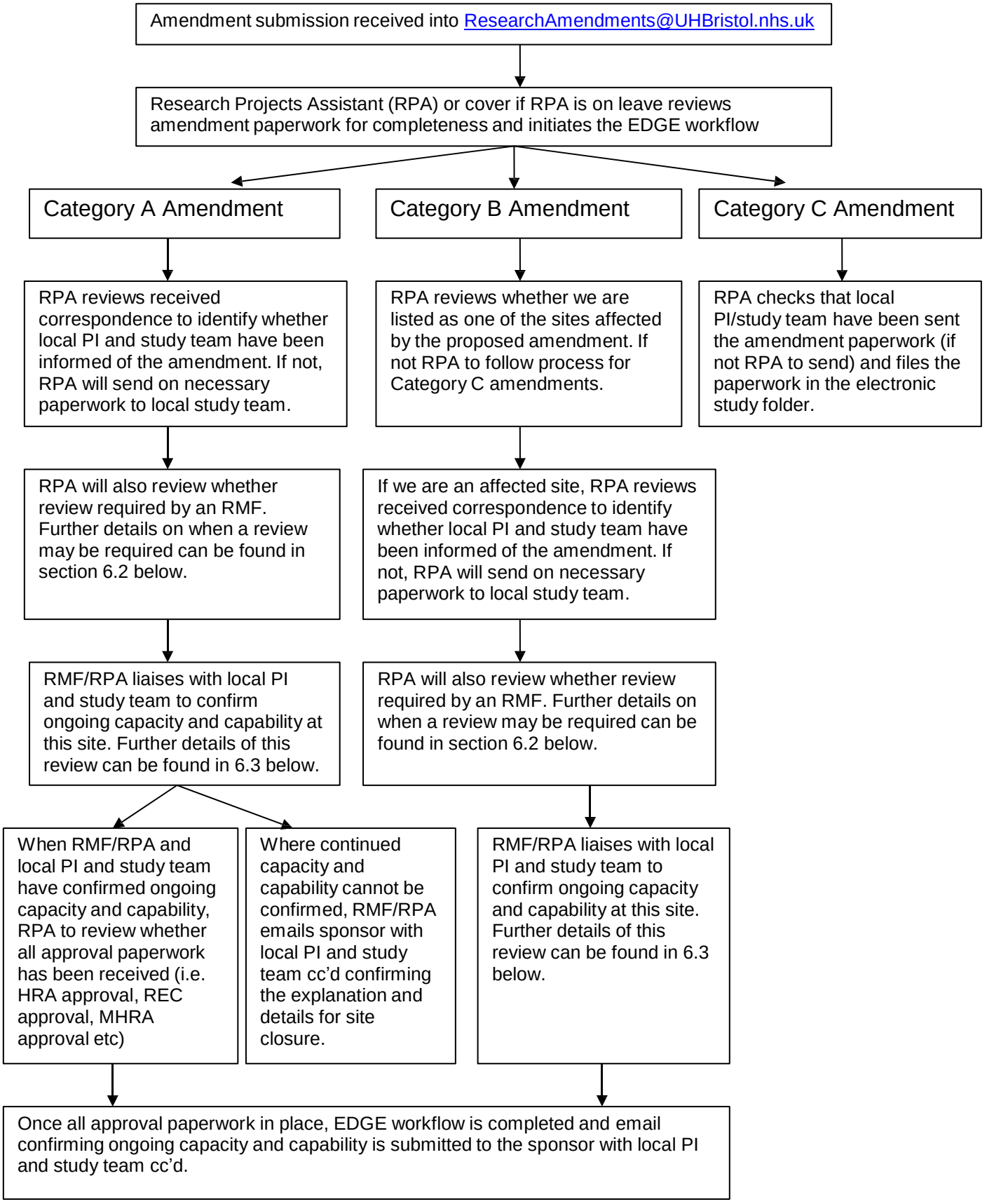
6.3 Review of the amendment by an RMF

- 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 UH Bristol legal department as required
    - 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.
    - RMF 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 review any other capacity or capability impact by proposed amendment.

6.4 Confirming ongoing capacity and capability

- As described in the flowchart below, where all of the checks are satisfactory and 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 no template email for this, however the RMF/RPA must ensure the Study title, IRAS ID, R&I reference number and Amendment number is clearly referenced in the email.

Flowchart A – Submission process of Amendments for UH Bristol hosted studies



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 within R&I

- All correspondence relating to amendments in R&I 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&I department

6.7 Implementing the amendment at UH Bristol site

- After R&I has issued ongoing capacity and capability confirmation for the amendment the local PI/study team at UH Bristol 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&I.
- 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

This SOP will be disseminated to applicable research staff (including R&I) and will be available on the R&I website.

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*.

8. Related documents

- SOP_007 Research Training
- SOP_019 UH Bristol sponsored research amendments