Standard Operating Procedure

CONFIRMATION OF CAPACITY AND CAPABILITY TO DELIVER RESEARCH AT UH BRISTOL

SETTING Trustwide

AUDIENCE All staff who wish to undertake research at UH Bristol

ISSUE The local process to approve clinical research at UH Bristol

QUERIES Contact Research Operations team 0117 342 0233 or email research@uhbristol.nhs.uk

Document History

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Version Number	Reason for change
Original V1.0	N/A
2.0	Major update to processes and restructuring of the SOP

Review date	Version number	Version date	Effective date	Author/ Reviewer	Authorised by
N/A	1.0	17/OCT/2016	31/OCT/2016	Jess Bisset	Diana Benton
19/JAN/2018	2.0	19/JAN/2018	13/FEB/2018	Trusha Rajgor & Jess Bisset	Diana Benton

1. Introduction

Introduced in April 2016, Health Research Authority (HRA) approval is the process within England which replaces the requirement of researchers to obtain NHS permission from each NHS Trust where they plan to deliver their research. Instead, sponsors or delegated others, will apply for HRA approval which centralises the assessment of governance, legal compliance and required regulatory reviews, currently excluding MHRA approval which will still need to be sought separately. NHS Trusts in England will no longer issue NHS permission, but instead provide confirmation of capacity and capability (C&C) for a proposed research study.

This SOP describes the processes within the UH Bristol Research & Innovation (R&I) department to review and confirm C&C of the trust to deliver a proposed research study. The process is separated into the following scenarios:

- studies which are notified to R&I as not requiring C&C review
- studies notified to R&I where UH Bristol is a potential participating site (Host) requiring C&C review
- studies sponsored by UH Bristol requesting C&C review from participating sites (including UH Bristol as a site).

2. Purpose

The purpose of this SOP is to describe the processes undertaken by UH Bristol R&I department to review and confirm C&C to deliver research at the Trust.

3. Scope

In Scope: Research undergoing HRA approval involving UH Bristol premises, staff or patients.
Out of scope: Research that does not involve UH Bristol premises, staff or patients and does not require HRA approval. This includes research tissue banks, research databases and any other non-research projects e.g. audit, service evaluation, service improvement.

4. Responsibilities

The sponsor is responsible for submitting the correct documents to UH Bristol for C&C review. The allocated RMF in R&I is responsible for reviewing submitted documents for C&C and where applicable confirming C&C at UH Bristol.

5. Abbreviations

Abbreviations	
C&C	Capacity and Capability
CI	Chief Investigator
HRA	Health Research Authority
IRAS	Integrated Research Application System
QMS	Quality Management System
R&I	Research & Innovation
REC	Research Ethics Committee
RMF	Research Management Facilitator
RPM	Research Projects Manager
SoA	Statement of Activities
SoE	Schedule of Events

6. Procedure

6.1 Studies which are notified to R&I as not requiring C&C review

- The HRA will email the Research Approvals inbox (ResearchApprovals@UHBristol.nhs.uk) any research which has been assessed as not requiring C&C review by local NHS organisations and where UH Bristol has been listed as a participating site on the IRAS form.
- Within this email the HRA will state whether the research can be implemented immediately at site or whether a 35 day review for 'no objection' is required.
- The R&I projects officer who monitors the Research Approvals inbox will therefore either;
    - Immediately file the email by creating an electronic sub folder on the R drive in the folder entitled 'HRA – studies where capability and capacity not required' using the IRAS number to label the folder, and notify the local team (where required) for information

    Or

    - Send the email to one of the Research Management Facilitators (RMF) who will review within the 35 day timescale whether there is any objection to the research taking place at UH Bristol. The review by the RMF will involve assessing the documentation provided by the HRA in the email to establish whether any resource

needs or funding is identified. Where applicable the RMF will liaise with the local team/service where the research will take place and discuss whether there are any objections.

- Where a review of 'no objection' takes place the RMF will communicate by email the outcome to the CI, Sponsor and relevant local team. There is no template for this communication and it will be dealt with on a study by study basis.
- As above the RMF will then create an electronic sub folder on the R drive using the study IRAS number to label the folder, and will store all of the applicable documentation and correspondence.
- In some instances research may be emailed to the ResearchApprovals inbox directly from researchers or sponsors rather than by the HRA. The Projects Officer will review these and where the HRA letter indicates that sites do not need to confirm capacity and capability will pass to an RMF to review as detailed above.

6.2 Studies notified to R&I where UH Bristol is a potential participating site (Host) requiring C&C review

- On receipt of any communication to the R&I department at UH Bristol regarding a new proposed research study, the recipient will ensure this is sent to the Research Approvals inbox for assessment by the projects officer who will review the HRA assessment letter (if available) to determine whether C&C review is required. If C&C is not required the projects officer will follow the process described in section 6.1
- For studies that require C&C review the projects officer will, as a minimum, request the latest version of the protocol and will contact the applicable local research team to enquire whether they are aware of the proposed research study.
- On receipt of confirmation from the research team that appropriate feasibility has been conducted (in line with the guidance from the HRA) and there is a documented joint decision between the local research team and sponsor to proceed with set up, the projects officer will assign a local project reference number to the study. They will then add the study to EDGE completing the required fields as described in *GD_010 EDGE fields* and will create an electronic folder on the R drive under 'Active Studies' using the template in the folder, saving all correspondence and documentation received to date. The projects officer will then allocate the study to an RMF. Where no local team is identified or the UH Bristol personnel sits outside of a dedicated research team (see *GD_011 UH Bristol research teams/units*) the projects officer will make enquiries with the applicable clinical team about feasibility of set up before it is allocated to an RMF. As a minimum the clinical team should confirm that they wish to undertake the study and have suitable capacity to do so. The order in which studies are allocated for review from the Research Approvals inbox will follow UH Bristol research priorities (see *GD_012 UH Bristol research priorities*).
- Once allocated, the RMF will liaise with the local team/personnel and sponsor/lead site to undertake C&C review by completing the following workflows on EDGE:
    - R&D – RMF Set Up Workflow
    - R&D – Capacity & Capability Review Workflow
- These workflows act as standalone templates in the R&I Quality Management System and are maintained by the Information Officer. The workflows consist of a set of numbered questions that the RMF has to work through (like a checklist). Each question has a 'show procedure' button which provides further information on what review is required by the RMF. Comments during the review must be documented in the comments box with the date the comment was made. As each question is completed the RMF must mark it as completed with the date. These workflows can be viewed at any time by UH Bristol personnel allocated to that study record on EDGE. This allows transparency in the capacity and capability review process. Further guidance for RMFs on completing the workflows can be found in *WI_005 Capacity & Capability review for RMFs.*

- Versions of the workflows will be documented on an 'EDGE workflow log' which will be maintained by the Information Officer in the Quality Management System folder on the J drive. Any requested updates to the workflows will need to be authorised by a member of the R&I senior management team before they are implemented.
- Further information on the key checks made during capacity and capability review can be found in 6.2.2 below.

6.2.1 Triggering the National Institute for Health Research (NIHR) 70 day benchmark metric

- The NIHR 70 day metric to promote 'faster easier clinical research' will be triggered from the point that a complete HRA pack (see HRA website for details) is submitted to the Research Approvals inbox and the applicable research team.
- The RMF should check that the version and dates of the contents of the local information pack matches with the documents listed on the HRA approval letter and any amendment documents.
- As described in section 6.2 there must be a documented joint decision between the local research team and sponsor to proceed with set up prior to the pack being submitted. However, C&C review must be initiated by the RMF at the earliest stage possible (i.e. receipt of protocol/any information about the study) and should not wait for submission of the complete pack. As the RMF works through the applicable workflows on EDGE for C&C review they will request that any missing documents are submitted to the Research Approvals inbox and the research team in line with the process described above.
- Where a complete pack has not been received at once, receipt of the last document to complete the pack will act as the trigger point for the 70 day metric. The RMF will record this on EDGE in the HRA entity as 'Date Site Selected' in accordance with NIHR guidance.

6.2.2 Confirmation of C&C at UH Bristol

- Once the workflows have been completed by the RMF on EDGE and all reviews are satisfactory (i.e. there is the capacity and capability to deliver the proposed research), the RMF will:
    - For **all studies**, ensure all applicable fields on EDGE have been updated using *GD_010 EDGE fields* as a guide.
    - For **non-commercial studies**, complete the green and white sections of the 'Statement of Activities' (SoA) as applicable and using *TMPL_054 Confirmation of Capacity and Capability at UH Bristol* send an email confirming C&C to the sponsor, PoC in lead research team, local PI, local PoC and applicable support departments attaching the SoA and partially or fully executed model non-commercial agreement where applicable.
    - For **commercial studies**, provide a scanned copy of the fully executed contract along with an email confirming C&C using *TMPL_054 Confirmation of Capacity and Capability at UH Bristol* to sponsor, local PI, local PoC and applicable support departments. The RMF will also arrange for original wet ink contracts to be returned to sponsor as required.
- Where there is insufficient capacity or capability to deliver the study at UH Bristol the RMF will email the sponsor, PoC at lead research team, local PI (if identified), local PoC and applicable support departments to notify them of the reasons why C&C cannot be confirmed. There is no template for this email as it will be on a study by study basis.
- Once C&C confirmation has been issued the RMF will keep the study listed as an 'RMF active study' on EDGE in order to chase:
    - when the study has been opened by the sponsor (in order to update the details page in EDGE)
    - the 70 day benchmark
    - any other outstanding documents (i.e. Letter of Access)

- After the study is opened and the 70 days has passed (regardless of whether a patient has been recruited or not) the RMF will remove it as an 'RMF active study'. The Information Officer will then take over responsibility for data maintenance of that study on EDGE.

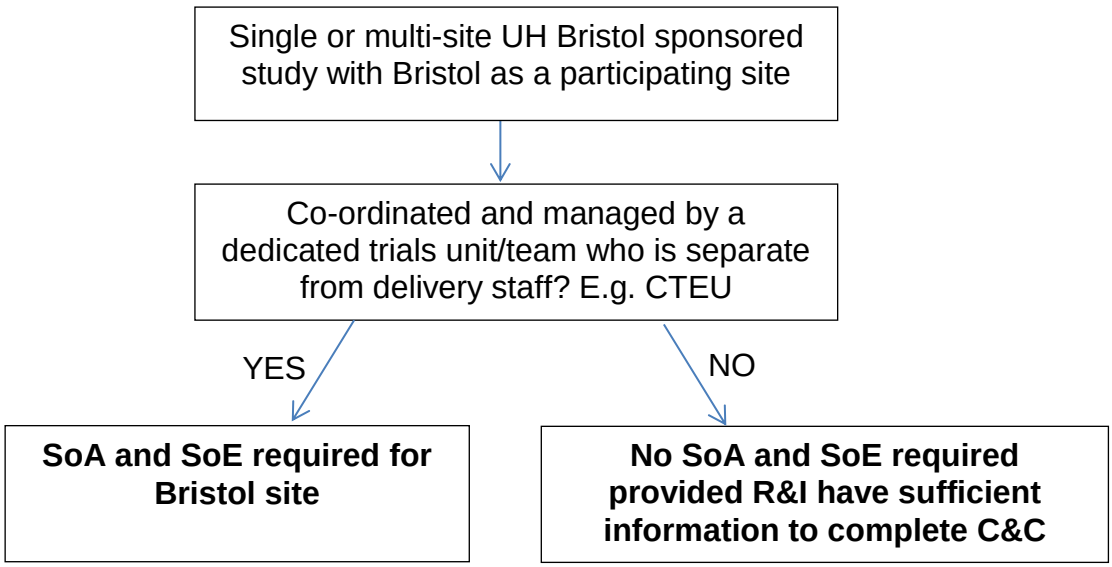
6.3 Studies sponsored by UH Bristol requesting C&C review from UH Bristol site

- Full details of the UH Bristol sponsorship process can be found in *SOP_002 Sponsorship*. The processes described below detail how C&C confirmation will be sought from UH Bristol site for studies where UH Bristol is the sponsor.

6.3.1 UH Bristol site

- The RMF in conjunction with the Research Projects Manager (RPM) as applicable, will complete the following workflows on EDGE for UH Bristol sponsored studies:
    - R&D – RMF Set up workflow
    - R&D – Sponsorship workflow
    - R&D – Capacity and Capability Review

- The C&C review for UH Bristol site can begin at any point during the sponsorship process to enable an efficient review.
- The following flow chart will be used to determine whether a Statement of Activities (SoA) and Schedule of Events (SoE) is required for the Bristol site:



- The allocated RMF will work through the EDGE workflows using the same process as described in section 6.2. When all of the applicable workflows have been completed the RMF will issue confirmation of C&C. Depending on study type (e.g. non CTIMP, single centre etc) this email may include green light to commence recruitment. Full details of the green light process can be found in *SOP_002 Research Sponsorship at UH Bristol*.
- This email will be sent to the CI, main PoC in study team and any other applicable personnel.

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

- GD_010 EDGE fields
- GD_011 UH Bristol research teams/units
- GD_012 UH Bristol research priorities
- SOP_002 Research Sponsorship at UH Bristol
- SOP_007 Research Training
- TMPL_054 Confirmation of Capacity and Capability at UH Bristol
- WI_005 Capacity & Capability review for RMFs.