Standard Operating Procedure

CONFIRMATION OF CAPACITY AND CAPABILITY TO DELIVER RESEARCH AT UHBW

SETTING Trustwide

AUDIENCE All staff who wish to undertake research at University Hospitals Bristol and Weston NHS Foundation Trust (UHBW)

ISSUE The local process to approve clinical research at UHBW

QUERIES Contact Research Operations team on 0117 34 20233 or email research@uhbw.nhs.uk

Document History

SOP number	SOP 017	**SOP Version**	3.3
Effective Date	11/DEC/2024	**Review Date**	11/DEC/2026

Version Number	Reason for change
Original V1.0	N/A
2.0	Major update to processes and restructuring of the SOP
3.0	Major update to remove reference to specific High Level Objectives (HLOs), changes to how studies not requiring Capacity & Capability (C&C) review are managed and clarification on processes as part of biennial review.
3.1	Minor updates and clarifications as part of biennial review including studies in the CRF that do not require HRA approval
3.2	Departmental name change from Research & Innovation to Research & Development. Updated throughout SOP as a minor amendment.
3.3	Minor updates and clarifications as part of biennial review

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
SEP/2020	3.0	19/OCT/2020	16/NOV/2020	Jake Harley Becky Lambert Jess Bisset	Diana Benton
NOV/2022	3.1	18/JAN/2023	23/JAN/2023	Jess Bisset Sandra Mulligan Amelia Lowe Karen Morgan	Jake Harley
FEB/2023	3.2	16/FEB/2023	01/APR/2023	Lucy Riddolls	Nicola Manning
DEC/2024	3.3	06/DEC/2024	11/DEC/2024	Sandra Mulligan Simon Cavan Owen Collings	Jess Bisset

1. Introduction

Introduced in April 2016, Health Research Authority (HRA) approval became the process within England which replaced the requirement of researchers to obtain NHS permission from each NHS Trust where they planned to deliver their research. In 2018 HRA Approval became HRA and Health and Care Research Wales (HCRW) Approval and now applies to all research taking place in the NHS in England and Wales. HRA Approval assesses governance and legal compliance, with an independent ethical opinion by a Research Ethics Committee (REC) where required. It is mandatory for any research carried out on NHS premises and where the NHS organisation has a duty of care to participants, either as patients or NHS staff. See https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/hra-approval/ for full details. MHRA approval for required trials will still need to be sought separately. As a result of HRA and HCRW Approval NHS Trusts in England 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 UHBW Research & Development (R&D) 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&D as not requiring C&C review
- studies notified to R&D where UHBW is a potential participating site (Host) requiring C&C review
- studies sponsored by UHBW requesting C&C review from participating sites (including UHBW as a site).

2. Purpose

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

3. Scope

In Scope: Research undergoing HRA approval involving UHBW premises, staff, or patients.

Out of scope: Research that does not involve UHBW 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. Research conducted on NIHR Bristol CRF premises which does not require HRA approval or any other UHBW resources other than room rental only.

4. Responsibilities

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

5. Abbreviations

Abbreviations	
ATIMP	Advanced Therapy Investigational Medicinal Product
BTC	Bristol Trials Centre
C&C	Capacity and Capability
CI	Chief Investigator
HLO	High Level Objective
HRA	Health Research Authority
HCRW	Health and Care Research Wales
IRAS	Integrated Research Application System
mNCA	Model non-commercial agreement
OID	Organisation Information Document
QMS	Quality Management System
R&D	Research & Development
REC	Research Ethics Committee
RMF	Research Management Facilitator
RPM	Research Projects Manager
SMT	Senior Management Team
SOP	Standard Operating Procedure

6. Procedure

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

- The Sponsor will email the Research Approvals inbox (ResearchApprovals@uhbw.nhs.uk) with the study documentation including the letter from the HRA confirming their assessment that it does not require C&C review by local NHS organisations,
- Within the HRA letter, it will detail whether a 35 day review for no objection is required.
- The R&D Research Projects Assistant who monitors the Research Approvals inbox will therefore either;
    - Immediately file the email by creating an electronic sub folder on the shared 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 and add the study to the Excel spreadsheet 'HRA – capacity and capability review not required' in the same folder on the shared drive **Or**
        - Review the study within the 35-day timescale to ascertain whether there is any objection to the research taking place at UHBW. The Research Projects Assistant will liaise with the Research Operations Manager or Research Management Facilitators as required for this process. The review will involve assessing the documentation provided by the Sponsor in the email to establish whether any resource needs or funding are identified. Where applicable the Research Projects Assistant 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 Research Projects Assistant 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 Research Projects Assistant will then create an electronic sub folder on the shared drive using the study IRAS number to label the folder and will store all of the applicable

documentation and correspondence and add the study to the excel spreadsheet 'HRA – capacity and capability review not required'.

6.2 Studies notified to R&D where UHBW is a potential participating site (Host) requiring C&C review

- On receipt of any communication to the R&D department at UHBW regarding a new proposed research study, the recipient will ensure this is sent to the Research Approvals inbox for assessment by the Research Projects Assistant who will review the HRA assessment letter (if available) to determine whether C&C review is required. If C&C is not required the Research Projects Assistant will follow the process described in section 6.1
- For commercial studies, study feasibility enquiries and Local Information Packs may also have been sent to the R&D Joint Commercial Managers via the Commercial Research Inbox. In this instance, the Joint Commercial Managers will liaise with the Research Projects Assistant.
- For studies that require C&C review the Research Projects Assistant will, as a minimum, request the latest version of the protocol and will contact the applicable local research team(s) 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 Research Projects Assistant will assign a local UHBW R&D project reference number to the study using the standard format: Clinical Division/Year/number e.g. for an oncology study, ON/2020/XXXX using the number allocation spreadsheet on the R&D shared drive. Where there are several research teams involved (e.g. an adult and a children's team) the Research Projects Assistant will make a decision on an ad hoc basis as to which clinical division to use as the reference number. They will then add the study to EDGE completing the required fields as described in *GD_010 EDGE field listing* and will create an electronic folder on the shared drive under 'Active Studies' using the template in the folder, saving all correspondence and documentation received to date.
- The Research Projects Assistant will then liaise with the Research Management Facilitator Team Leader and Joint Commercial Research Manager to allocate the study to an RMF and will update the local R&D host data form on the study's local EDGE record.
- Where no local team is identified or the UHBW personnel sits outside of a dedicated research team, the Research Projects Assistant 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 UHBW research priorities (see *GD_012 Research Priorities at UHBW,and GD_016 Priority of applications into the inbox*).
- During exceptional circumstances e.g. a global pandemic, our priorities may have to be amended and the Research Projects Assistant will send an applicable template email to all requests for Capacity and Capability assessments received into the Research Inbox (e.g. using *TMPL_098 Prioritisation email during COVID-19 Pandemic*).
- Once allocated, the RMF will ensure appropriate site records have been set up on EDGE (where there is more than one hospital site in UHBW taking part) and liaise with the local team(s)/personnel and sponsor/lead site to undertake C&C review by completing the applicable workflows on EDGE.
- These workflows act as standalone templates in the R&D Quality Management System and are maintained by the Research 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 will be made public by the RMF so that they can be viewed at

any time by UHBW personnel allocated to that study record on EDGE. This allows transparency in the capacity and capability review process.

- Updates to the workflows will be documented on an ongoing basis on the 'Database Update Requests' spreadsheet which will be maintained by the Research Information Officer in the Quality Management System folder on the shared drive. Any requested updates to the workflows will need to be brought for discussion at the weekly R&D Operations team meeting and agreed by a member of the R&D Senior Management Team (SMT) before they are implemented.
- For specialist trials e.g. Advanced Therapy Investigational Medicinal Products (ATIMPs) additional reviews are required and these are described in *SOP_021_UHBW review of clinical trials involving ATIMPs.*

6.2.1 The National Institute for Health and Care Research (NIHR) High Level Objectives (HLOs)

- The NIHR sets HLOs every year which each Partner Organisation is measured against and influences funding received in future years. When completing Capacity and Capability Assessments the RMF must be mindful of the current HLOs set by the NIHR which will be communicated by the SMT in R&D. The RMF must ensure all data fields are fully completed in EDGE in order to accurately record required data points for metric reporting and the Research Information Officer will advise each year on which fields are required. The Research Information Officer will also report against the HLOs in the R&D Operations report (both weekly and monthly).

6.2.2 Confirmation of C&C at UHBW

- Once all the applicable workflows for the study have been completed for each UHBW site 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 the following R&D documents as a guide
        - *GD_010 EDGE field listing*
        - *GD_041 RMF Quality Manual*
    - For **non-commercial studies**, complete the required sections of the Organisation Information Document (OID) or mNCA as applicable and using *TMPL_054 Confirmation of Capacity and Capability at UHBW* send an email confirming C&C to the sponsor, PoC in lead research team, local PI, local PoC and applicable support departments attaching the OID and partially or fully executed model non-commercial agreement where applicable. Where there is more than one site at UHBW, this C&C confirmation will detail which UHBW sites have Capacity and Capability. Where the University of Bristol (UoB) is the Sponsor, the UoB Research Governance Team should also be included in the C&C e-mail (research-governance@bristol.ac.uk).
    - For **commercial studies**, provide a copy of the fully executed contract along with an email confirming C&C using *TMPL_054 Confirmation of Capacity and Capability at UHBW* to sponsor (or representative of the sponsor), local PI, local PoC and applicable support departments. The RMF will also arrange for original wet ink contracts to be returned to sponsor if this is still required. Where there is more than one site at UHBW, this C&C confirmation will detail which UHBW sites have Capacity and Capability.
- Where there is insufficient capacity or capability to deliver the study at UHBW the RMF will email the sponsor, PoC at lead research team, local PI (if identified), local PoC(s) 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)
    - any applicable HLO metrics
    - any other outstanding documents (i.e. Letter of Access)
- After the sponsor has issued green light for the study to open at UHBW, the RMF will remove it as an 'RMF active study' on EDGE. The Research Information Officer will then take over responsibility for data maintenance of that study on EDGE which includes gathering First Patient First Visit (FPFV) and recruitment to time and target information. If the RMF becomes aware of any delays to FPFV or recruitment to time and target they should ensure the applicable RTT notes field on EDGE is updated and the communication saved in the study folder on the R&D shared drive. They should liaise with the Research Information Officer as applicable.

6.3 Studies sponsored by UHBW requesting C&C review from UHBW site

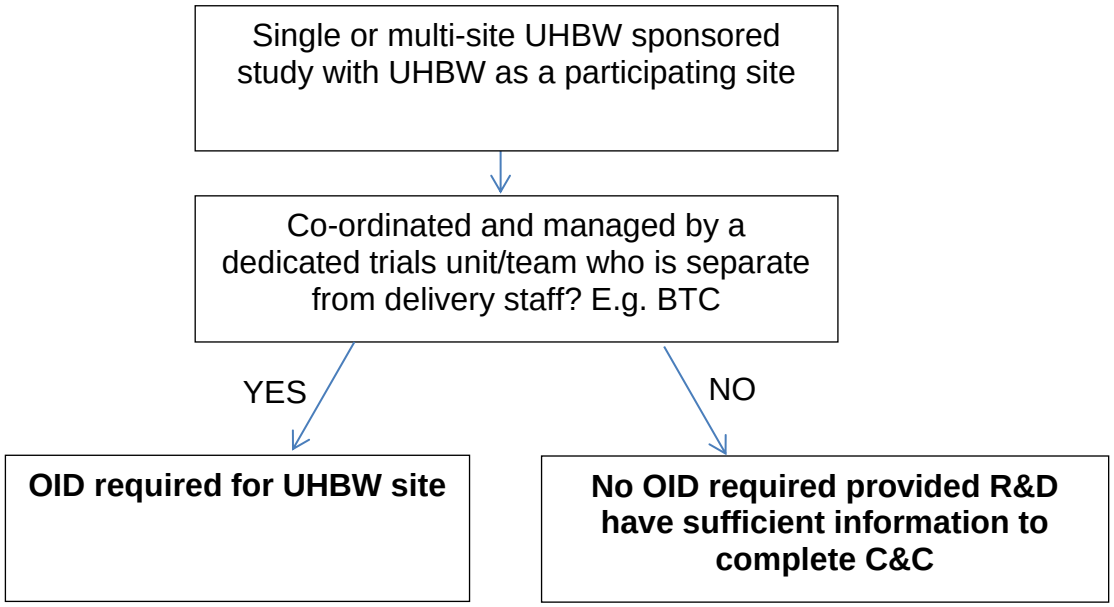
- Full details of the UHBW sponsorship process can be found in *SOP_002 Research Sponsorship at UHBW*. The processes described below details how C&C confirmation will be sought from UHBW site for studies where UHBW is the sponsor.

6.3.1 UHBW site

- The RMF or the Research Projects Manager (RPM) as applicable, will complete the applicable workflows on EDGE for UHBW sponsored studies e.g. (list not exhaustive):
    - R&D – RMF Set up workflow
    - R&D – Capacity and Capability Review

- The C&C review for UHBW 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 an OID is required for the UHBW site:



- The allocated RMF/RPM 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/RPM will issue confirmation of C&C. Depending on study type (e.g. non CTIMP, single

centre etc.) this email may include sponsor green light to commence recruitment. Full details of the green light process can be found in *SOP_002 Research Sponsorship at UHBW*.

- 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

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	N/A
RELATED DOCUMENTS AND PAGES	• GD_010 EDGE Field listing • GD_012 Research Priorities at UHBW • GD_016 Priority of applications into inbox • GD_041 RMF Quality Manual • SOP_002 Research Sponsorship at UHBW • SOP_007 Research Training UHBW • SOP_021_UHBW review of clinical trials involving ATIMPs • TMPL_054 Confirmation of Capacity and Capability at UHBWTMPL_098 Prioritisation email during COVID-19 Pandemic) These can be found on the R&D section of UHBW's website: http://www.uhbristol.nhs.uk/research-innovation/
AUTHORISING BODY	Trust Research Group
SAFETY	N/A
QUERIES AND CONTACT	Contact the Research & Development Department on 0117 34 20233 or research@uhbw.nhs.uk
AUDIT REQUIREMENTS	Departmental Quality Management System audits are undertaken annually.