Reference Number: UHB 448 **Version Number:** 4.0	**Date of Next Review: 22/10/2029** **Previous Trust/LHB Reference Number:** *N/A*

Obtaining Capacity & Capability Confirmation for Research to Start
STANDARD OPERATING PROCEDURE

1. Introduction and Aim

The purpose of this SOP is to describe the process for obtaining Capacity & Capability (C&C) from the Cardiff Joint Research Office (JRO) for research to take place within the Health Board.

From April 2018 C&C has replaced NHS permission. Formal confirmation of C&C is required for all studies where Cardiff and Vale UHB is acting as a research site, unless otherwise specified in the HRA/HCRW approval letter.

Objectives

- To assist researchers with obtaining capacity and capability from the JRO for research projects.

Scope

This procedure applies to all researchers in all locations, including those with honorary contracts who are applying to conduct research within CAVUHB.
This SOP is not for use if the proposed project is an audit or service evaluation. For further information about classification of your project please use the HRA, 'Is my study research?' link: http://www.hra-decisiontools.org.uk/research/

Equality Health Impact Assessment	An Equality and Health Impact Assessment (EHIA) has not been completed as this is an administrative procedure.
Documents to read alongside this Procedure	HCRW SOP 2 Good Clinical Practice (GCP) Training Requirements (all-Wales)UHB 525 Cardiff Joint Research Office (JRO) Applying for Sponsorship – Medium and Low risk UHB 543 Cardiff Joint Research Office (JRO) Applying for Sponsorship- Higher Risk studies UHB 317 Research Training Requirements including Good Clinical Practice (GCP)
Approved by	Joint Research Governance Group
Accountable Executive or Clinical Board Director	Medical Director
Author(s)	Deputy R&D Manager

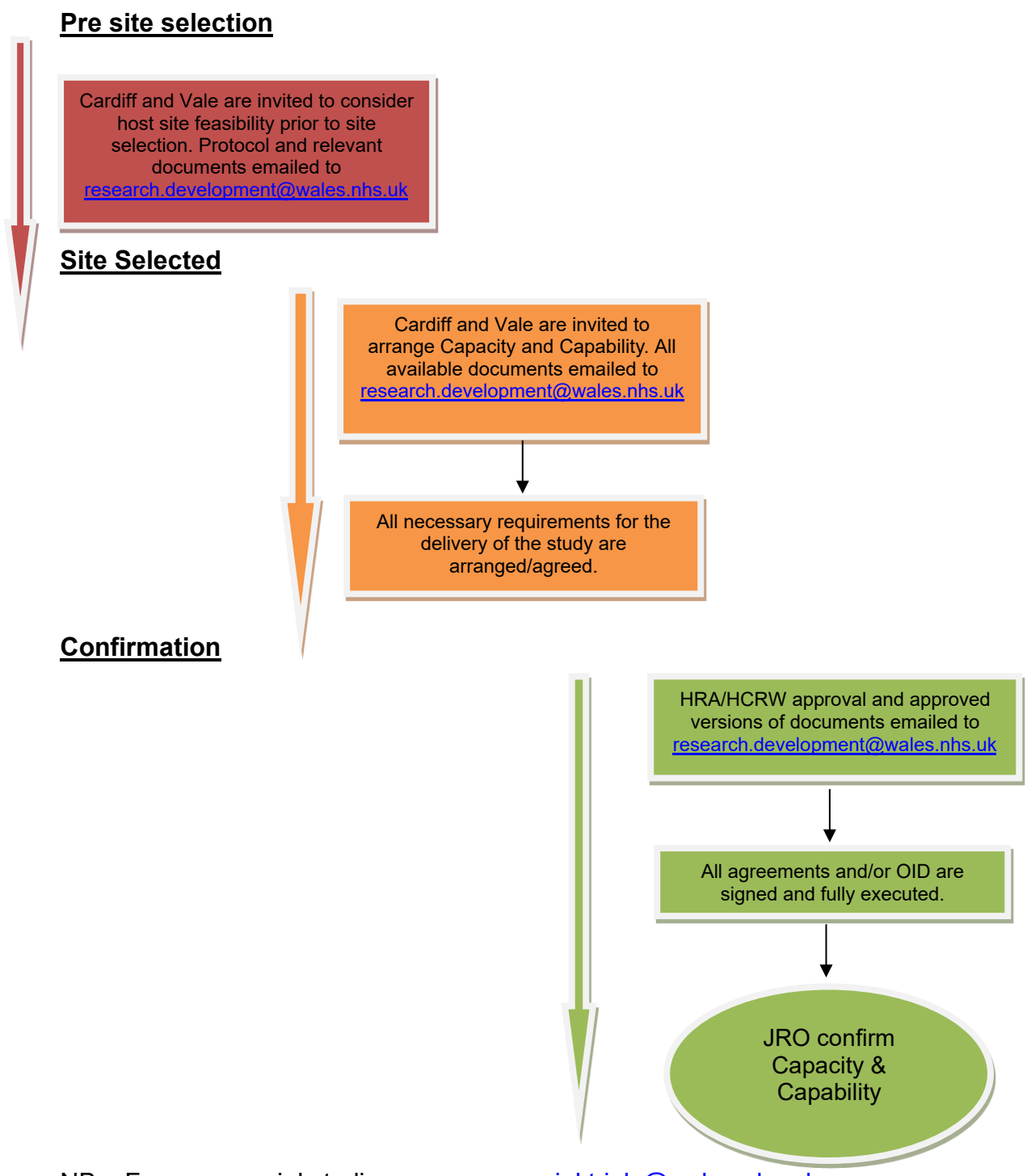
Disclaimer

If the review date of this document has passed please ensure that the version you are using is the most up to date either by contacting the document author or the Governance Directorate.

Summary of reviews/amendments

Version Number	Date of Review Approved	Date Published	Summary of Amendments
1.0	*30/01/2019*	*29/04/2019*	New document adapted from the North Bristol NHS Trust SOP Obtaining R&I Confirmation for Research to start with their kind permission.
2.0	20/01/2022	25/03/2022	All links checked and corrected. Updated guidance on the Assess process to include the new research assessment form. Terms no longer in use removed, references to R&D changed to JRO.
3.0	30/01/2025	07/04/2025	All links checked and correct, minor grammar updates and reference to the Research Assess Form guidance made
4.0	22/10/2026	10/11/2026	New process detailed in line with new metrics and set up process.

Figure 1. Summary of process for obtaining Capacity and Capability



NB – For commercial studies use commercial.trials@wales.nhs.uk

Research must have sponsorship already in place if using this SOP; for JRO Sponsored Studies please refer to UHB 543 Applying Sponsorship of Higher risk studies (inc. CTIMPS and Medical device studies) and UHB 525 Cardiff Joint Research Office (JRO) Applying for Sponsorship- Low and Medium risk studies.

2. Definitions/Abbreviations

C&C	**Capacity and Capability**
CAVUHB	**Cardiff & Vale University Health Board**
CI	**Chief Investigator**
CTIMP	**Clinical Trial of an Investigational Medicinal Product**
HCRW	**Health and Care Research Wales**
HR	**Human Resources**
HRA	**Health Research Authority**
ICH GCP	**International Conference on Harmonisation Guidelines for Good Clinical Practice**
IRAS	**Integrated Research Application Service**
JRO	**Joint Research Office**
MHRA	**Medicines and Healthcare Products Regulatory Agency**
PI	**Principal Investigator**
REC	**Research Ethics Committee**
SOP	**Standard Operating Procedure**
OID	**Organisational Information Document**
SoECAT[1]	**Schedule of Events Cost Attribution Template**
Sponsor	**The individual, company, institution or organisation, which takes on ultimate responsibility for the initiation, management (or arranging the initiation and management) of and/or financing (or arranging the financing) for that research**

3. Who Should use this SOP

This SOP should be used by anyone wishing to conduct research activities at Cardiff and Vale UHB.

4. When Should this SOP be used

This SOP should be used when applying for Capacity and Capability confirmation at Cardiff and Vale UHB.

The JRO will not be able to formally confirm C&C on behalf of GP practices or any other providers that are independent contractors but should still undertake of review of these studies.

5. Procedure

5.1 Before Requesting C&C confirmation

The JRO may be contacted at any point for help and support. The JRO can be reached on CAV_research.development@wales.nhs.uk

a. Before requesting C&C confirmation (or approval for any other regulatory bodies) a Sponsor for the research must be identified. If you require Cardiff University or C&V to act as a Sponsor, please refer to relevant JRO Applying for Sponsorship SOPs (UHB 543 and UHB 525)

b. The proposed project must be best defined as 'research'. It should be assessed whether the proposed activity meets the criteria for this as defined in the UK Policy Framework for Health and Social Care Research: www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/ Further information and guidance can be also found on the HRA website: www.hra.nhs.uk. Your project sponsor and local R&D office can help you determine this categorisation.

c. All research studies will have to be submitted for HRA/HCRW approval and HRA/HCRW guidance must be followed www.hra.nhs.uk www.healthandcareresearchwales.org . Application and submission will occur via IRAS. For further details see www.myresearchproject.org.uk . HRA/HCRW approval will not be issued until all other relevant regulatory approvals (e.g. REC/MHRA) are in place.

5.2 Requesting C&C confirmation

Submission and review of requests occur in three stages: ***Pre-site selection (feasibility), Site Selected/In setup*** and ***Confirmation*** (see Figure 1)***.*** The sponsor (or nominated delegate) is responsible for submitting the relevant paperwork at each stage. If the study is sponsored by CAVUHB or Cardiff University (CU), the CI is responsible for submitting these documents. All documents should be submitted to CAV_research.development@wales.nhs.uk. Each stage is outlined below, including details of the relevant paperwork to be submitted, and what then subsequently happens at each stage.

a. PRE-SITE SELECTION (FEASIBILITY):

i. Initial Assessment involves researchers/sponsors liaising with the JRO and key stakeholders to identify any barriers to delivering the study at site and within the required timescale.

ii. This assessment can occur when a near-final protocol and other relevant information (such as proposed role of CAVUHB, recruitment assumptions, target timelines) is shared with the JRO.

iii. Assessment will consider the following:

- Study summary and planned timelines
- Staffing requirements
- PI performance and engagement
- Patient population
- Equipment, facilities and services required
- Any funding/resourcing issues

iv. If the initial assessment by site and sponsor is positive and the site is selected, then an agreement will be made for a target site planned recruitment open date (within 60 days of the date site selected unless future date beyond this timeline has been agreed in writing with the Sponsor).

v. If the assessment finds that CAVUHB is unlikely to have the capacity and capability to deliver high-quality research activities to time and target and on budget, then this will be communicated to the sponsor, and site setup should not proceed.

b. SITE SELECTED:

i. The JRO will make all necessary arrangements for delivery of the research study at site. To initiate this stage, the PI and study team will be requested to complete the Site set up Pack (FRM-001-15) and any supplementary support forms needed. The Sponsor (or delegate) must submit all documents as indicated below to the JRO by email once the research study has received an HRA/HCRW Initial Assessment Letter (or HRA/HCRW Approval Letter where no Initial Assessment letter is issued).

- Final IRAS Form as submitted to HRA/HCRW

- Protocol
- Any subsequent modifications
- Participant information and consent documents
- OID relevant to the participating NHS organisation (non-commercially sponsored studies only)
- Relevant template contract/model agreement (for commercial studies and for non-commercial if needed in addition to OID).
- Access to Industry Costing Tool (ICT) (commercially sponsored studies only) or SoECAT (non-commercially sponsored studies only)
- HRA/HCRW Initial Assessment Letter (if one is issued) and (when issued) HRA Approval letter and final document versions.
- Any relevant additional approved study documents such as lab, radiology or pharmacy manuals.

ii. The JRO will coordinate all necessary arrangements to deliver the study, as identified in the Site Set-up Pack, working in conjunction with the sponsor, PI and local research team. These may include (but are not limited to):

- Ensuring any HRA/HCRW guidance (as indicated in Initial Assessment/Approval) is acted on;
- Putting in place any contractual arrangements;
- Review and agreement of financial arrangements;
- Ensuring that there are adequate resources available at CAVUHB from commencement to completion of the research – including finance, staff, and facilities (e.g. Pharmacy, Radiology, laboratories and other support departments);
- Ensuring that all research staff possess the necessary level of access and are trained by education and experience for their roles in the research, ensuring ICH GCP compliance is met by staff as per Health Board Policy. (See SOP UHB 317 Training Requirements for Research v5.)
- Ensuring that appropriate HR arrangements are in place for all staff undertaking research activities.

iii. Site research personnel may be asked to submit the following

- Curriculum Vitae signed and dated within the last 2 years.

- A valid Good Clinical Practice (GCP) certificate (if the study is a CTIMP) – CAVUHB policy indicates these are valid for 3 years from date of issue. See SOP Training Requirements for Research Staff, including Good Clinical Practice (GCP) (UHB 317)
- Evidence of substantive or honorary employment contracts held in CAVUHB.

iv. It is likely that the JRO will need to contact the PI, research team and Sponsor with queries during the arrangement process. It is essential that all parties co-operate fully with and are responsive to such queries, to prevent delays to study set up. This may include attendance at in-person and/or virtual meetings required to facilitate progress.

c. CONFIRM:

i. The following must be in place prior to formal confirmation of C&C at CAVUHB:
- Final HRA/HCRW approved versions of all study documents
- Fully executed site agreement and/or OID
- Evidence of HRA/HCRW approval (and REC favourable opinion where required)
- MHRA approval for CTIMP/Device studies
- Any additional specialist approvals e.g. CAG, GMSC
- All arrangements to be able to deliver the study.

ii. Subject to all relevant actions being completed, JRO Confirmation of C&C will be issued alongside the authorised OID and/or fully executed study agreements. This is issued via email to the PI, Sponsor, research team and other relevant stakeholders.

iii. Once JRO C&C is confirmed, research activities can proceed at CAVUHB, subject to relevant compliance as indicated on the confirmation email and sponsor-issued ‘green light’.

iv. Teams should ensure complete patient readiness before commencing recruitment

6. Dissemination and Training

This SOP and any associated templates and forms will be uploaded to the UHBs intranet site.

All staff whose activities are subject to this SOP should ensure that they read and understand the content of this SOP. The training log within the Investigator Site File/Trial Master File should be completed to document that members of staff have read and understood the content of this SOP.
Failure to comply with the SOP could lead to escalations and affect a teams ability to undertake future research.

7. Related SOPs and Documents

- Health Research Authority
  UK Policy Framework for Health and Social Care Research
  www.hra.nhs.uk

- Health Research Authority
  Decision Tool for Research
  www.hra-decisiontools.org.uk

- Health and Care Research Wales
  Support and guidance for researchers
  https://healthandcareresearchwales.org/researchers/support-and-guidance-researchers

- The following R&D documents are available

UHB 543	Cardiff Joint Research Office (JRO) Applying for Sponsorship of Higher Risk Studies (including Clinical Trials of Investigational Medicinal Products (CTIMPS) and Clinical Trials of Medical Devices (Medical Device Trials)
UHB 525	Cardiff Joint Research Office (JRO) Applying for Sponsorship- Low and Medium Risk Studies
HCRW SOP 2	Good Clinical Practice (GCP) Training Requirements (all-Wales)
UHB 317	Training Requirements for Research Staff, including Good Clinical Practice (GCP)
FRM-001-15	Site Set-up Pack
FRM-001-16	Site Set-up Pack Pharmacy
FRM-001-17	Site Set-up Pack Nuclear Medicine
FRM-001-18	Site Set-up Pack Radiology