Reference Number: UHB 448 **Version Number:** 1.1	**Date of Next Review: 30/01/2022** **Previous Trust/LHB Reference Number:** N/A

OBTAINING CAPACITY & CAPABILITY CONFIRMATION FOR RESEARCH TO START

1. Introduction and Aim

The purpose of this SOP is to describe the process for obtaining Capacity & Capability (C&C) from Cardiff and Vale UHB Research & Development office (R&D) for research to take place within the Health Board.
From April 2018 C&C has replaced NHS permission, all research studies that are conducted within The UHB need confirmation of C&C along with the other appropriate regulatory approval

Objectives

- **To assist researchers with obtaining capacity and capability from the UHB R&D office.**

Scope

This procedure applies to all researchers in all locations, including those with honorary contracts who are applying to conduct research within the UHB.
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	GR-RG-008. Applying for Cardiff and Vale NHS University Health Board Sponsorship Procedure. HCRW SOP 2. Good Clinical Practice (GCP) Training Requirements (all-Wales) UHB 317 Training Requirements for Research Staff, including Good Clinical Practice (GCP)
Approved by	Research Governance Group

Accountable Executive or Clinical Board Director	Medical Director
Author(s)	Commercial Trials 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

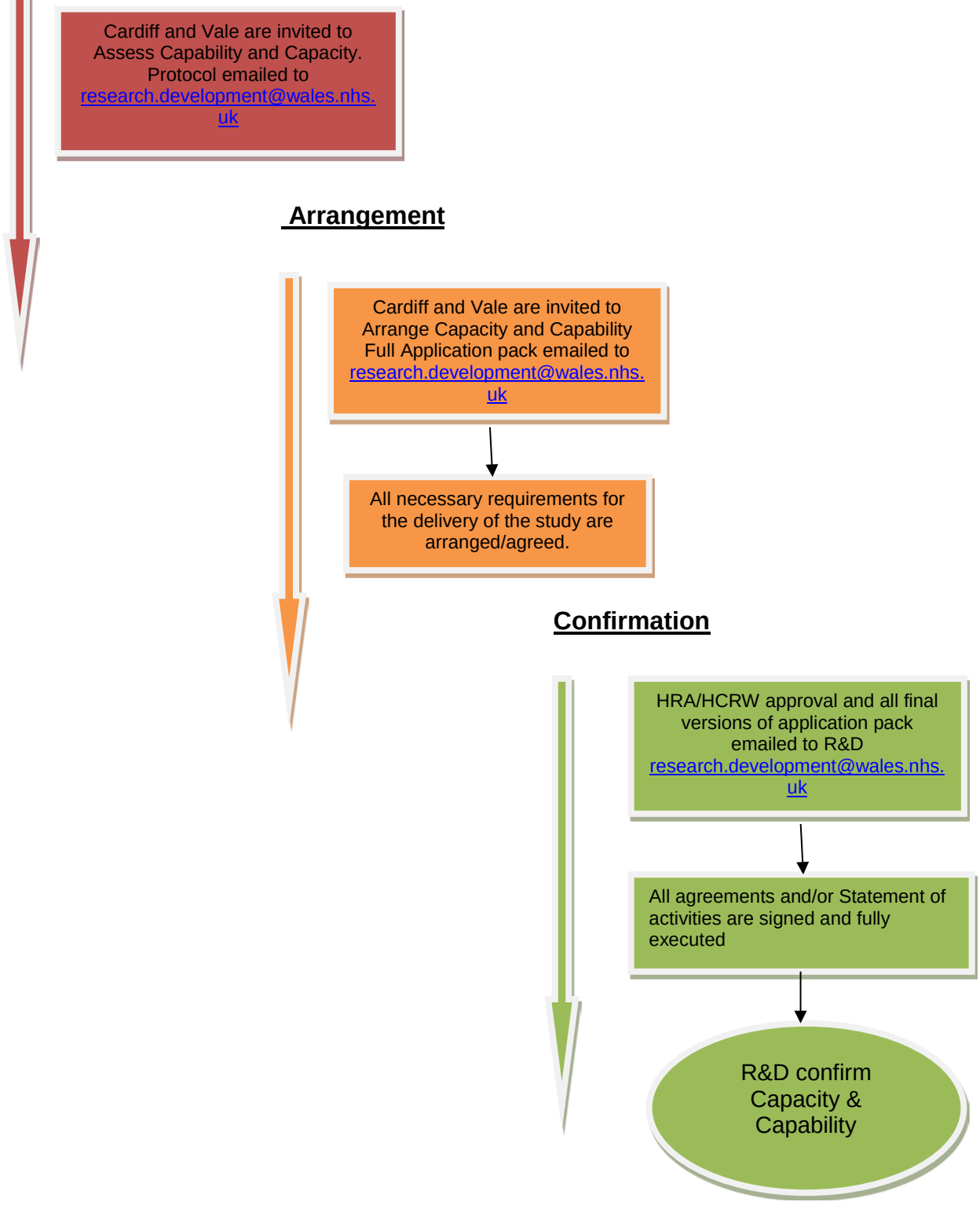
Version Number	Date of Review Approved	Date Published	Summary of Amendments
1.0	30/01/2019	29/04/2019	New document adapted from the North Bristol NHS Trust SOP Obtaining R&I Confirmation for Research to start with their kind permission.

Figure 1. Summary of process for obtaining Capacity and Capability

Research must have sponsorship already in place, for UHB Sponsored Studies please refer to Applying for Cardiff and Vale UHB Sponsorship SOP

Assessment

This stage of the process can be an informal step which consists of the sponsor having an early conversation with R&D to identify any obstacles which would stop the study from being undertaken.



2. .Definitions/Abbreviations

C&C	**Capacity and Capability**
The UHB	**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**
LIP	**Local Information Pack**
LIT[1]	**Local Information Template**
MHRA	**Medicines and Healthcare Products Regulatory Agency**
PI	**Principal Investigator**
R&D	**Research and Development**
REC	**Research Ethics Committee**
SOP	**Standard Operating Procedure**
SoA	**Statement of Activities**
SoE	**Schedule of Events**
SoECAT[2]	**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**

[1]References to the Statement of Activities will refer to the Local information Template when it is introduced

[2] As part of the HRA/Health and Care Research Wales approvals process a SoECAT can be submitted instead of a Schedule of Events.

3. Who Should use this SOP

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

4. When Should this SOP be used

This SOP should be used when applying for Capacity and Capability confirmation.

5. Procedure

5.1 Before Requesting C&C confirmation

The R&D office may be contacted at any point for help and support. R&D can be reached on 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 C&V to act as a Sponsor, please refer to the Applying for Cardiff and Vale University Health Board Sponsorship SOP.

b. The proposed project needs to be a research project. It should be assessed whether the proposed activity is 'research' 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 classification.

c. All research studies will have to be submitted for HRA/HCRW[3] approval[4] and HRA/HCRW guidance must be followed www.hra.nhs.uk www.healthandcareresearch.gov.wales. Application and submission will occur via IRAS. For further details

[3] The Lead nation will be where the lead site is based. If this is Wales then the study will be submitted to HCRW, if the lead nation is England then this will be HRA.

[4] HRA/HCRW Approval is the new single application process for the NHS in England and Wales that brings together the assessment of governance and legal compliance, undertaken by the HRA/HCRW, with the independent REC opinion provided through the UK Health Department's Research Ethics Service. All project-based research taking place in the NHS in England or Wales is required to obtain HRA/HCRW approval. Studies with sites in Northern Ireland or Scotland will be supported through existing UK-wide compatibility systems, by which each country accepts the centralised assurances, as far as they apply, from national coordinating functions without unnecessary duplication.

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. To facilitate this process please ensure that when you have received these other regulatory approvals, you forward them on to the HRA assessment team via hra.approvals@nhs.net or HCRW permissions service via research-permissions@wales.nhs.uk

5.2 Requesting C&C confirmation

Submission and review of requests occurs in 3 main stages: ***Assessment, Arrangement*** and ***Confirmation*** (see Figure 1)***.*** The sponsor (or nominated delegate) is responsible for submitting the relevant paperwork to allow each stage to commence. If the study is sponsored by The UHB, the CI is responsible for submitting these documents. All documents should be submitted to research.development@wales.nhs.uk. Each section is outlined below, including details of the relevant paperwork to be submitted at each stage, and what subsequently happens at each stage.

a. ASSESS:

i. Initial *Assessment* is an informal process which involves researchers liaising with R&D to see if there are any barriers to C&C.

ii. This assessment can occur when a protocol is submitted to R&D via email.

iii. Assessment will consider the following:

- Staffing Requirements
- PI performance
- Patient population
- The equipment/space/specialist services/emergency processes/IT etc needed to deliver the study
- If there will be high cost resources needed.

iv. If the initial Assessment is positive and the site is selected then further documentation will be needed for the Arrangement stage.

v. If the assessment outcome is that The UHB are unlikely to have the capacity and capability to deliver the research study then this will be communicated to the sponsor and CAV will not be set up as a site.

b. ARRANGE:

i. R&D must make arrangements to enable local capacity and capability to deliver the research study. To initiate this stage, the Sponsor (or delegate) must submit all documents (Local Information Pack) as indicated below to R&D by email once the research study has received a HRA/HCRW Initial Assessment Letter (or HRA/HCRW Approval Letter where no Initial Assessment letter is issued):

- Copy of IRAS Form (combined REC and R&D form) as submitted for HRA Approval
- Protocol
- Any Amendments
- Participant information and consent documents
- SoA/LIT relevant to the participating NHS organisation (non-commercially sponsored studies only)
- Relevant template contract/model agreement (for commercial studies and or non-commercial if needed in addition to SoA/LIT).
- Costing template (commercially sponsored studies only) or SoE/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.

If a local PI has been identified, the sponsor should provide their name and contact details to R&D.

ii. R&D will assess the study to identify what arrangements are needed, and the PI needs to work with the sponsor and research team to ensure that those arrangements are put in place.. These arrangements may include but are not limited to:

- Ensuring any HRA guidance (as indicated in Initial Assessment/Approval) is acted on;
- Putting in place any contractual arrangements;
- Negotiation and agreement of financial arrangements;
- Ensuring that there are adequate resources available at The UHB 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 research and ensuring ICH GCP compliance is met by staff as per Health Board Policy. See SOP UHB 317 Training Requirements for Research Staff, including Good Clinical Practice (GCP)
- Ensuring that appropriate HR arrangements are in place for all staff.

iii. Local research personnel may be asked to submit the following
- Curriculum Vitae signed and dated within the last 12 months
- A valid Good Clinical Practice (GCP) certificate (if the study is a CTIMP) – CAV policy indicates these are valid for **2** years from date of issue. See SOP on Research Staff Training (HCRW SOP 2)
- Evidence of substantive or honorary employment by CAV.

iv. It is likely that R&D will need to contact the research team and Sponsor with queries during the arrangement process. It is essential that the PI/Sponsor co-operate fully with any such queries, as this prevents delay during study set up. Meetings (face-to-face, telephone, video-conference) may also be required to facilitate discussions.

c. CONFIRM:

i. In order for *Confirmation* of local capability and capacity to be obtained, the following should be in place:

i. final HRA/HCRW approved versions of the study documents
ii. an agreed site agreement or SoA/LIT
iii. HRA/;HCRW Approval
iv. All arrangements in place to be able to deliver the study.

ii. Subject to all relevant actions being completed, R&D Confirmation of Capacity and Capability will be issued alongside the agreed SoA/LIT or fully executed study agreements. It is issued electronically via email to the PI, Sponsor, research team and other relevant stakeholders.

iii. Once R&D Confirmation is given, the research can proceed at The UHB, subject to relevant compliance as indicated on the confirmation email.

6. Dissemination and Training

This SOP and any associated templates and forms will be uploaded to the Health Boards 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.

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
  Research Route Map
  www.healthandcareresearch.gov.wales/research-route-map/

- The following R&D documents are available

	Applying for Cardiff and Vale, University Health Board Sponsorship.
HCRW SOP 2	Good Clinical Practice (GCP) Training Requirements (all-Wales)
UHB 317	Training Requirements for Research Staff, including Good Clinical Practice (GCP)