Setting up new studies with your Research Facilitator

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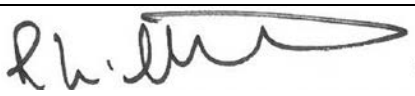
	Signature & Date	 28/07/20	
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1.0	24/07/23	Initial Document		
1.1	06/10/23	Minor additions	1.0	

1. Purpose

The purpose of this SOP is to describe the process at Swansea Bay University Local Health Board (SBU LHB) Research and Development office (R&D), to obtain confirmation of Capacity and Capability (C&C) in order for research to take place at the Health Board. The confirmation of C&C is required for all studies where it is noted on the Health Research Authority (HRA)/Health and Care Research Wales (HCRW) approval letter.

The R&D department has the authority from the Chief Executive, to Assess, Arrange and confirm Capacity and Capability for research to be conducted within the Health Board (HB). All research projects must obtain Confirmation of Capacity and Capability from the R&D department, before commencing any research at SBU LHB. The only exception to this are audits or service evaluations or research studies with specific exemptions as identified during the HRA/HCRW initial assessment. They do not require confirmation of Capacity and Capability from the R&D department.

For further clarification with regard to the classification of your project, please refer to the HRA website. “Is my study research?”

http://www.hra-decisiontools.org.uk/research/

2. Background

The HRA

HRA Approval brings together the assessment of governance and legal compliance, undertaken by dedicated HRA staff, with the independent ethical opinion by Research Ethics Committee (REC) so that you only need to submit one application. HRA HCRW approval is required for all project-based research, which involves NHS, and Health and Social Care. It applies where the NHS organisation has a duty of care to participants, as either patients/service users or NHS staff/volunteers. References to participants include people whose data or tissue is involved in a research project. The submission process is via the Integrated Research Application System (IRAS), this portal enables review by HRA, REC, and applications for CAG (confidentiality Advisory Group). IRAS enables the researcher to submit information relating to their project once, instead of having to duplicate information in separate application forms.

Guidance can be found on the www.hra.nhs.uk website. https://www.hra.nhs.uk/about-us/committees-and-services/integrated-research-application-system/ https://www.myresearchproject.org.uk/Help/HelpPage.aspx

Once the Health Board has been selected to participate in a Research Study, through either a feasibility process undertaken for most multi-site studies, a staff member has come forward with an in-house study, or an independent research group have approached the HB, the R&D team works with the local investigators and research teams to Assess, Arrange and Confirm Capacity and Capability for the study.

3. Definitions/Abbreviations

CI	**Chief Investigator**
PI	**Principal Investigator**
LC	**Local Collaborator**
LIP	**Local Information Pack**
CTIMP	**Clinical Trial of an Investigational Medicinal Product**
LPMS	**The research database used by SBU LHB for managing set up and delivery of studies and to record monthly recruitment**
HRA HCRW Approval	**Health Research Authority Health and Care Research Wales** **HRA HCRW approval is required for all project-based research-taking place within England and Wales. Application is submitted through the IRAS website.**
REC	**Research Ethics Committee**
ICH GCP	**International Conference on Harmonisation Guidelines for Good Clinical Practice**
IRAS	**Integrated Research Application System**
Swansea Bay University Local Health Board	**SBU LHB**
R&D	**Research and Development**
OID	**Organisation Information Document**
HTA	**Human Tissue Act**
Sponsor	**An 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. The sponsor can be an individual, an academic institution, a pharmaceutical company, a private organization or other organisation.
C&C	**Capacity and Capability**
CPMS	**Central Portfolio Management System**
LPMS	**Local Portfolio Management System**
JSRC	**Joint Study Review Committee**
SLA	**Service Level Agreement**
PHW	**Public Health Wales**
MTA	**Material Transfer Agreement**
JCRF	**Joint Clinical Research Facility**
PIS	**Patient Information Sheet**
mNCA	**Model Non Commercial Agreement**
mCTA	**Model Clinical Trial Agreement**

4. Who should use this SOP and when?

This SOP should be used by anybody who wishes to conduct research within SBU LHB, and when confirmation of Capacity and Capability from R&D is required in order to set up research studies in the Health Board.

In the majority of instances, R&D confirmation will be required from SBU LHB and any other sites involved in the study, if it is multi site. However, in some cases, the HRA HCRW letter will state that the study does not require formal confirmation of Capacity and Capability. The R&D department will still need to be notified, so that they can issue a non-formal no objection to the study taking place within the Health Board. This SOP provides guidance for researchers and investigators about the process, and what needs to be considered when setting up a study. The Research Facilitator (or the Research Officer / Research Assistant if available to support set up) * works with the research team and investigators from the start of the study set up, by confirming C&C, to process applications for Letters of access/Honorary contracts (if appropriate) for the researchers (see SOP Application Process for an Honorary Contract Letter of Access or Research Passport), through to monitoring/ auditing (where appropriate) and finally, through to archiving - (see SOP – RD-01-Archiving for Hosted Studies-)

*It is possible set up of a study is being facilitated by a Research Assistant or Research Officer

5. Procedure prior to submission of study and Local Information Pack (LIP) to R&D

5.1 Before requesting confirmation of Capacity and Capability (C&C) at SBU LHB R&D Department

Any queries should be addressed to SBU LHB R&D via email: - SBU.RandD@wales.nhs.uk

(a) Sponsor

A sponsor needs to be identified prior to requesting SBU LHB R&D to confirm Capacity and Capability. This is sometimes a university in the event of student research, a Pharmaceutical Company for Commercial Studies and sometimes our local R&D at SBU LHB for in house studies. If you are unsure as to who the sponsor should be, then please feel free to email us on SBU.RandD@wales.nhs.uk

(b) The proposed project needs to be a research project. If you are unsure as to whether your project is research or not, then please refer to the HRA website, your sponsor or your local R&D office.
http://www.hra-decisiontools.org.uk/research/
http://www.hra-decisiontools.org.uk/ethics/
https://www.hra.nhs.uk/approvals-amendments/

(c) What if my project is deemed non research/service evaluation?

We have a process at SBU LHB, whereby all in-house projects seeking to be deemed as non research/ service evaluation and not requiring NHS ethics/R&D application, are ratified at our Joint Study Review Committee (JSRC). The committee will require the project protocol, or summary, which should include the project tile, background, aims, objectives, data collection and data protection issues, analysis, references, what you will do with the information and details of the staff/patients and at which site in SBU LHB. The JSRC meets monthly and the information would need to be submitted to Anne-Claire Owen (Assistant R&D Manager) one week in advance of the meeting. If you have any queries, please email anne-claire.owen@wales.nhs.uk

(d) What if my project is a student project?

The same process would apply as per the submission of the LIP, but, in the first instance, you would liaise with your local Governance Officer at your place of study, and they will guide you through the process, and may then submit the LIP on your behalf.

(e) What if my project is an audit?

In the event that your project is an audit, the project would need to be registered with the Clinical Audit & Effectiveness Department, and contact would need to be made with Information Governance, to ensure that they approve how the information is gathered, and register the study.
Information Governance – SBU.confidentialityissues@wales.nhs.uk
Clinical Audit – Sharon Ragbetli Sharon.E.Ragbetli@wales.nhs.uk

6. Local Information Pack (LIP) submission to R&D

The Sponsor (or their representative) are responsible for submitting the relevant paperwork, in the form of a Local Information Pack (LIP) this is in order for the Research Facilitator* to being the "arrange" stage of the C&C process, (further detail below)

The LIP must be submitted to R&D using the email template as per the IRAS website https://www.myresearchproject.org.uk/help/hlpsitespecific.aspx#UK-Local-Information-Pack

7. Study set up

The process of Confirmation of Capacity and Capability, (C&C) consists of three main steps, which are **Assess, Arrange and Confirm.** To begin the initial "assess" stage of the C&C review, all that is required is a copy of the finalized protocol, the Patient Information Sheet (PIS)/ Informed Consent Form (ICF) and the relevant study agreement (OID, mNCA, mCTA). Once the initial assessment has taken place, the Research Facilitator* and the Principal Investigator will be able to confirm if hosting the study is feasible. If it is agreed between all parties to move forward with the "arrange" process, the Sponsor (or their representative) are responsible for submitting the relevant paperwork, in the form of a full Local Information Pack (LIP) to start the process, and to continue towards confirmation of C&C

7.1 **Assess** – Initial assessment to see if it is feasible for the study to be conducted within the Health Board. – Liaise with researchers and other key stakeholders. Usually a protocol is submitted. This is usually in its final version, to be submitted to HRA for approval

Assessment consists of the following :-

1. Participant population
2. Staff requirements and input
3. Equipment required, supporting departments i.e. pharmacy, radiology, etc. required to deliver the study

In the event that it is not possible for the study to take place within the Health Board, and we do not have the Capacity and Capability to take this study forward, then this will be communicated to the Sponsor, and SBU LHB will not proceed to be set up as a site.

If everything is in place and the Health Board has the Capacity to deliver the study, then the next stage is **Arrange**.

7.2 **Arrange**

To initiate the Arrange process, the LIP must be submitted to R&D using the email template as per the IRAS website https://www.myresearchproject.org.uk/help/hlpsitespecific.aspx#UK-Local-Information-Pack

All the relevant documents, which are listed on the HRA/HCRW approval letter, will need to be submitted at this point. These consist of:-

- Copy of IRAS form, as submitted to HRA (signed, not draft)
- Protocol
- Any amendments
- All relevant documentation which are listed in the HRA/HCRW letter, such as the Participant information sheet, consent forms, Statement of Activities, Relevant template contract/Model agreement/ Organisation Information Document (OID) (fully localised)
- HRA Initial Assessment letter and HRA approval letter, which lists the authorised documents and their versions
- Costing template (if the study is commercial) or Schedule of Events (for non-commercial studies) – the HB accepts the NIHR Tariffs and will accept the costs of the online costing template as agreed by the Lead site however local costs can be agreed with the Sponsor where local variance can be justified, such as overhead costs for JCRF etc.

It would also, at this point, be helpful to send through an up to date **Research CV,** template attached, and a valid Good Clinical Practice (GCP) certificate (if the study is a CTIMP). (See links below for training).

Once your Sponsor representative submits your study to R&D for set up, you will then be allocated a Research Facilitator*. They will work closely with you to set up your study in the Health Board. They will liaise with the relevant support departments on your behalf. As soon as your study is submitted to R&D, it is important for you to inform all the relevant parties that the study will be commencing in the Health Board as soon as confirmation of C&C is received and the sponsor has given the green light.

(a) **The LIP**

The LIP will be sent to your Research Facilitator* either by the Sponsor, the Investigator, or the Research Team. Upon receipt of the LIP, the Research Facilitator* will commence the arrange stage of the C&C process, and will work closely with the Research Team, the Investigator and any relevant support departments, to ensure that they all have the capacity and capability to support the study. This is undertaken in a timely manner in order for confirmation of C&C to be issued, thus ensuring that research can be commenced as soon as the Sponsor gives the green light.

As part of the LIP submission, there will be an OID or a Contract. The sponsor will be responsible for deciding which is used. The rule of thumb is that the OID is used for all non-interventional studies and a model contract is used for interventional studies.

Once the LIP is received, the Contract/OID will be sent to the R&D Manager, Assistant R&D Manager, Finance Manager and the Human Tissue Act Officer for internal review. If the contract has already been reviewed and accepted by another Welsh HB, as part of the One Wales Contracts and Costings process, this review will be accepted.

The OID must be mainly completed by the Sponsor, as it is their responsibility to ensure that the information is accurate, and all the relevant sections are completed and the yellow highlighted sections are appropriately finalised and removed, if relevant, before sending through with the LIP. The OID should be localised to the relevant Health Board/Trust. Sections for completion by the HB will be completed by the Research Facilitator*

It is the expectation of the R&D department that the relevant UK agreed model template agreement would be used. However, there are exceptions and in these cases, non-model template agreements will be reviewed by the R&D department, and in turn they may need to be referred for external legal review. In addition to the model agreement, depending on support required, an Service Level Agreement (SLA) may be required between Swansea

University or Public Health Wales (PHW) for example or other parties as necessary. In the event that a Material Transfer Agreement (MTA) is required, this would normally be included within the Commercial agreement or via the relevant section being ticked in the OID in the event of a non-commercial study.

We will always ensure that PHW are informed of studies being set up, in the event that they will be required to process standard of care bloods. An SLA will be put in place for this service.

(b) **SBU LHB as sponsor**
The process is slightly different if SBU LHB are Sponsor, as we would not issue a LIP to ourselves, but, if the study is multi-site then we would issue a LIP to the other sites. You will be allocated a Research Facilitator* who would still work with the support departments, obtaining Clinical Director approval, and ensuring that the various support departments have the capacity and capability to deliver the study as well as agreeing process for data upload and management on LPMS.

(c) **SBU LHB as Host**
If a study is Hosted by SBU LHB, then the Research Facilitator* will also have the discussion with the researcher as to how the recruitment information will be uploaded to either CPMS (Central Portfolio Management System) or LPMS (Local Portfolio Management System). If the recruitment information is to be uploaded via LPMS, then the Research Facilitator* will contact you monthly, to ensure that they have the recruitment information in a timely manner in order to be able to upload to LPMS. Sometimes, this information is uploaded via the Research Nurse who may be supporting the research.

(d) **JCRF – Study set up**

The process for submitting a study for C&C is slightly different for the Joint Clinical Research Facility (JCRF).

The LIP will be submitted to the Business Manager for their initial assessment, along with the various costing templates, commercial agreement and OID.

The Business manager will forward the Contracts to the R&D Department for review, and any relevant SLA's, such as with the University or PHW. The SLA's and Contracts will be reviewed by the R&D Manager, Assistant R&D Manager, Finance Manager and HTA Officer.

Once the Business Manager is happy for the study to be set up within the Health Board, they will forward the LIP to R&D along with the confirmations from the support departments and the Clinical Director, together with the research CV's and GCP certificates of the staff involved in in the study (new HRA guidance states that not all staff will require GCP). The Research Facilitator* will verify the capacity/capability statements with each support department before issuing final C&C.

Once the SLA's and contracts have been reviewed by the various departments, such as the University, or PHW, and R&D, they will be returned to the Business Manager to arrange final sign off, and a copy of the signed version is sent back to R&D.

Once all the checks are complete, the Research Facilitator* will confirm C&C by sending the Sponsor, the JCRF Manager and the Researchers an email, attaching a copy of the fully executed contract.

7.3 Confirm – the final C&C email is issued, once all of the Assess, Arrange and Confirm steps have been completed.

ASSESS	Upon receipt of study protocol, a brief check will be conducted of the study to see if it is possible to run the study within the Health Board; consider a potential Principal Investigator (PI) (if one hasn't already been identified) and whether there are the facilities/support departments/patient/participant types available.
	Email the Sponsor to acknowledge receipt of protocol.
	Record 'Participating Site Invited' date on LPMS
ARRANGE	Upon receipt of the local information pack from the Sponsor, record 'Participating site Selected' date on LPMS
	R&D to carry out site checks for capacity and capability by email. Ensuring that Clinical Director approval has been sought and that PI and supporting departments are happy to carry out the study, and have the capacity to be able to do so
	R&D review costings, OID etc. – Contract to be reviewed by R&D Manager - negotiate terms of contract where required.
	Upload study documents to LPMS
	Upon receipt of HRA Approval letter from Sponsor, record date on LPMS and upload document to LPMS
	Record 'Date participating organisation confirmed by Sponsor' date on LPMS (this is either the date of the first signature on the agreement/contract or Sponsor emails)

CONFIRM	Record 'Date participating organisation confirmed' on LPMS when in receipt of either a fully executed study agreement/mNCA or email confirming acceptance of the Confirmation of Capacity and Capability email.
	Once Sponsor confirms that recruitment can begin at site, and has given the Green Light, record date in 'Open to Recruitment' field on LPMS
	If Sponsor declines site or site confirms they do not have the capacity and capability, to carry out the study, then record the study as withdrawn on LPMS

8. Role of Research Facilitator Beyond Set up.

The Research Facilitator* will be your main source of contact in the R&D department. Once you have gained C&C for your study, the Facilitator will be in contact monthly to ensure that they have your recruitment information for upload, if appropriate. They will also be the contact for any amendments to your study. The Research Facilitator* will work with the research teams to review the amendment paperwork, and contact the relevant support departments, to ensure that they are able to support any changes required due to the amendment. Providing all relevant departments are able to implement the amendment, the Research Facilitator* will process the no objection to the study amendment, and will send through the no objection email to the Sponsor.

Throughout the course of the study, the Research Facilitator* will be in close contact with the researcher, and from time to time may undertake a site file check, this will be booked at a mutually convenient time, once completed, the Research Facilitator* will send the Researcher a report with any findings.

Once the study comes to an end, the study will need to be archived. The process for this can be found in the SBU LHB Archiving SOP. (see below). The researcher's official relationship with R&D ends when the study has been archived. The sponsor will be required to inform the R&D team of the destruction of the archived documents. A formal final email will be sent to the sponsor and the research team, to confirm destruction date.

*It is possible set up of a study may also be facilitated by a Research Assistant or Officer

Related SOPS and documents:

Health Research Authority
www.hra.nhs.uk

Health Research Authority, Decision tool for Research
http://www.hra-decisiontools.org.uk/research/

UK Policy Framework for Health and Social Care Research
https://www.healthandcareresearch.gov.wales/research-governance-framework/
https://www.healthandcareresearch.gov.wales/uploads/Policy%20%26%20Strategy/Research%20Governance/uk-policy-framework-health-social-care-research.pdf

SBU LHB R&D SOPS
Honorary Contracts and Letters of Access

Archiving
Sponsorship SOP

Appendices:-

1. **Template for Researcher**


Submission process email for researcher

2. **Template for sharing LIP**


Email_Template_to_share_the_Local_Inf

Non commercial

Email_Template_to_
share_the_Local_Infc

Commercial

3. **Template for requesting more info JSRC**

JCRF MDS
collection email.doc

4. **Template for research CV**

CV_Template.doc

5. **Links to GCP training**
   https://www.nihr.ac.uk/health-and-care-professionals/learning-and-support/good-clinical-practice.htm

   https://www.healthandcareresearch.gov.wales/introduction-to-good-clinical-practice-gcp/

   https://www.hra.nhs.uk/about-us/what-we-do/

6. **NIHR agreement Templates**
   https://www.nihr.ac.uk/documents/model-site-agreements-model-contracts-standard-research-agreements/11612