STU-SOP-TS-012 – Standard Operating Procedure on National Approvals and Confirmation of Capacity and Capability

Version No:	3	**Effective Date:**	10-Apr-2026
Description of changes:	SOP reviewed in light of clinical trial regulations 2025 and GCP updates.		

List of Abbreviations	
C&C	Capacity and capability
CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
HCRW	Health and Care Research Wales
HRA	Health Research Authority
HSC	Health and Social Care
IRAS	Integrated Research Application System
LIP	Local Information Pack
MHRA	Medicines and Healthcare products Regulatory Agency
NHS	National Health Service
REC	Research Ethics Committee
SoE	Schedule of Events
SOP	Standard Operating Procedure
SSI	Site Specific Information
STU	Swansea Trials Unit
SU	Swansea University
TM	Trial Manager
TMF	Trial Management File

1. Purpose

This Standard Operating Procedure (SOP) describes the procedure of obtaining Health Research Authority (HRA) and Health and Care Research Wales (HCRW) for research projects in England or Wales respectively and NHS confirmation of Capacity and Capability (C&C) at each project location which replaced NHS research permission to conduct a research project.

2. Background

HRA and HCRW approval is required for all research projects involving the NHS or Health and Social Care (HSC) organisations in England or Wales. This approval assesses the ethical, governance and legal compliance of research and is undertaken by HRA staff at a project level. Approval also includes an independent ethics review. There are equivalent arrangements if the project involves Scotland or Northern Ireland.

A review will be initiated once a valid submission/document pack has been received on IRAS or the combined review area for CTIMPs. This includes studies not requiring NHS REC

approval but still need HRA/HCRW approval. The HRA web pages give current advice on how to navigate and manage your application.

R&D permission in the form of C&C is still required at a local level before any research activities can commence and is based on the assessment of a Local Information Pack (LIP). Obtaining this permission is an essential requirement to conduct any project and is required by the UK Policy Framework for Health and Social Care Research (2017) and the UK clinical trial regulations (2025). Once granted, C&C ensures the R&D activity is covered by the relevant NHS Indemnity Scheme

3. Roles and Responsibilities

The **Sponsor** is responsible for reviewing and agreeing the documents for submission.

The **Chief Investigator (CI)** is responsible for overseeing a research project submitted for HRA/HCRW approval and NHS R&D C&C at each project location.

The **Trial Manager (TM)** is responsible for coordinating the application and documents required for submission and filing them in the Trial Master File (TMF).

External use of SOP: This SOP and Associated Documents (AD) may be used for research projects not adopted by STU where Swansea University (SU) staff and associated NHS organisations require guidance. In such instances, oversight responsibility for any associated tasks will not be the responsibility of STU.

4. Procedure

For research projects requiring NHS REC approval, STU-SOP-TS-009 should be followed to secure REC and any other approvals before moving directly to Section 4.2 of this SOP. Where NHS REC is not required, please refer to section 4.1 below.

4.1 Agreeing the Research Sponsor

Before applying for approvals there needs to be agreement for an organisation to act as the research sponsor. For non-commercial research it is usual for the substantive employer of the CI to be approached or for doctorate projects the registered University.

Sponsor arrangements must be confirmed before a project can be submitted for review as a signature on behalf of the Sponsor is required.

4.2 Health Research Authority / Health and Care Research Wales

HRA and HCRW approval only applies to projects that meet specific criteria:

- Lead NHS office in in England or Wales
- It is a project-based study type
- NHS premises, patients, staff or involves HSC organisations.

Doctorate level applications are eligible to complete health and social care research. Undergraduate level applications are not accepted under any circumstance. Masters' students are required to complete the Student Research Toolkit to check eligibility. https://www.hra.nhs.uk/planning-and-improving-research/research-planning/student-research/.

Confirmation of C&C can be sought concurrently with the HRA/REC approval process and will require a LIP to be submitted and validated for non-commercial research. The contents for a LIP must include:

- *Organisation Information Document (OID)* – Commercial and non-commercial templates are available. There should be an OID for each project location type. https://www.myresearchproject.org.uk/help/hlpsitespecific.aspx#UK-Local-Information-Pack-OID

- *Schedule of Events Cost Attribution Tool (SoECAT)* – For non-commercial projects only. It identifies resources and provides clarity for NHS. HSC organisations on how costs associated with the research project are attributed. It requires review by an AcoRD Specialist at a Lead Local Clinical Research Network/Devolved Administration. https://www.myresearchproject.org.uk/help/hlpsitespecific.aspx#UK-Local-Information-Pack-SoE-SoECAT, https://healthandcareresearchwales.org/researchers-support-and-guidance-researchers-finances-and-funding/identify-study-costs-nhs-and

Current requirements for a LIP can be found at www.myresearchproject.org.uk.

The HRA approval team will facilitate the completion of any additional information requirements in order to review the research project and confirm with the sponsor that the information is correct.

The processes for obtaining approvals are subject to regular review by the HRA. Research teams should always check the HRA website to ensure the most up to date process is followed.

While HRA/HCRW covers the central review, local NHS organisations must still confirm they have the capacity and capability to take part (C&C approval).

4.3 Local NHS R&D office

Should be contacted as early as possible in the application process for advice on local requirements of the project and authorisations needed. The local NHS R&D office may also be able to advise on feasibility, sponsorship, funding, scientific review and agreements/contracts required.

Local R&D offices will also provide information on whether they can be involved in setting up primary care research as this differs within geographical areas and UK nations.

C&C will be issued by each project location to be involved in the project before they can be activated to begin recruitment.

4.4 Modifications to HRA approvals

Where a modification is needed to a project, STU-SOP-TM-015 should be followed. Once the modification is approved, the project location should be sent the relevant documents including the locked Amendment Tool for them to review.

The IRAS website has templates for use to help advise R&D departments of Category A and B modifications to help their review process. https://www.myresearchproject.org.uk/help/hlpamendmentsresearch.aspx#Understanding-amendment-categories

They have 35 days to review category A and B modifications and issue C&C acknowledging their approval of the modification before it can be implemented.

4.5 NIHR Clinical Research Network (CRN) Portfolio

A Portfolio Application Form is no longer required to apply for NIHR CRN support. The IRAS project filter now contains a question to indicate CRN support is required. Key information from an application will be shared with the CRN and used to assess eligibility.

5. References

- Health Research Authority website (HRA) - http://www.hra.nhs.uk/
- Medicine and Healthcare products Regulatory Agency website (MHRA) - https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/services-information
- UK policy framework for health and social care research (2017) - https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/
- UK Medicine for Human Use (Clinical Trials) Regulations 2025 - https://www.legislation.gov.uk/uksi/2025/538/contents
- HRA application guidance - https://www.hra.nhs.uk/planning-and-improving-research/research-planning/prepare-study-documentation/
- Integrated Research Application Service (IRAS) - www.myresearchproject.org.uk
- Health and Care Research Wales (HCRW) https://healthandcareresearchwales.org/researchers-support-and-guidance-researchers-finances-and-funding/identify-study-costs-nhs-and

It is assumed that by referencing the principal regulations that all subsequent amendments are included in this citation.

6. Associated Documents

Number	Title	Location
N/A	N/A	N/A