STU-SOP-TS-012 – Standard Operating Procedure on Applying for Confirmation of Capacity and Capability, Health Research Authority and Health and Care Research Wales Approval

1. Purpose

This Standard Operating Procedure (SOP) describes the procedure of obtaining Health Research Authority (HRA) and Health and Care Research Wales (HCRW) and NHS confirmation of Capacity and Capability (C&C) 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 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. 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 (2004). 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.

The **Trial Manager (TM)** is responsible for coordinating the application and documents required for submission.

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

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. Student research - Health Research Authority (hra.nhs.uk)

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) – requires review by an AcoRD Specialist at a Lead Local Clinical Research Network/Devolved Administration. Can be completed before submission.

Schedule of Events Cost Attribution Tool (SoECAT) – identifies resources and provides clarity fro NHS.HSC organisations on how costs associated with the research project are attributed.

Current requirements for a LIP can be found on the IRAS portal www.myresearchproject.org.uk.

Medicines and Healthcare products Regulatory Agency (MHRA) approval (required for Clinical Trials of Investigational Medicinal Products (CTIMPs) or medical devices) is now combined with Research Ethics Committee (REC) and HRA/HCRW approvals.

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.

4.4 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.

4.5 Applications for NHS R&D Permission in Wales

The Health and Care Research Wales Permissions Service usually coordinates the process of applying for NHS R&D permission on behalf of NHS Wales. For instances where NHS ethics has not been required, contact with local R&D offices should be initiated before completion of the application form.

Applications for NHS R&D permission must be made on standard forms available from the Integrated Research Applications System (IRAS) at www.myresearchproject.org.uk. For help and guidance using IRAS for NHS R&D Permission please consult https://www.myresearchproject.org.uk/help/hlpnhshscr.aspx#wales

4.6 Applications for NHS C&C with Wales or England as Lead Nation

Applications for NHS C&C are made on forms available from the Integrated Research Applications System (IRAS) at www.myresearchproject.org.uk.

For help and guidance using IRAS for NHS applications please consult https://www.myresearchproject.org.uk/help/hlpnhshscr.aspx#wales

The submission must include an IRAS form, study documents and for NHS/HSC organisations a UK Local Information Pack (LIP) as indicated in section 5.2.

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.

4.7 Scotland as the lead nation

The submission must include documents as indicated in section 5.2. Compatibility arrangements are in place for England, Wales and Northern Ireland, there is no requirement to send a separate application to obtain HRA and HCRW approval.

Where the research is led from Scotland and involves one site, the application should be submitted via email directly to the local R&D office. Where the project involves multiple sites, NHS Research Scotland Permissions Coordinating Centre (NRS PCC) provides a coordinated and streamlined process for obtaining NHS permission from Health Boards. Your application should be submitted via email to gram.nrspcc@nhs.scot

For more information visit http://www.nhsresearchscotland.org.uk/services/permissions-co-ordinating-centre/permissions

4.8 Northern Ireland as the lead nation

The submission must include documents as indicated in section 5.2. Compatibility arrangements are in place for England, Wales and Scotland, there is no requirement to send a separate application to obtain HRA and HCRW approval.

Where the research is led from Northern Ireland, single or multisite applications should be submitted via email directly to the local R&D office. Contact details are available on the

Northern Ireland Health and Social Care Trust website HSC website or the Gateway via email: research.gateway@hscni.net).

For more information visit Research in the HSC | Public Health Agency - Research & Development in Northern Ireland (hscni.net)

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 2004 - http://www.legislation.gov.uk/uksi/2004/1031/contents/made
- HRA application guidance - http://www.hra.nhs.uk/research-community/applying-for-approvals/hra-approval/#2.
- NHS Research Scotland Permissions Coordinating Centre - http://www.nhsresearchscotland.org.uk/services/permissions-co-ordinating-centre/permissions
- Integrated Research Application Service (IRAS) - www.myresearchproject.org.uk

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

7. Abbreviations

List of Abbreviations	
ARSAC	Administration of Radioactive Substances Advisory Committee
C&C	Capacity and capability
CAG	Confidentiality Advisory Group
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
NRES	National Research Ethics Service
PCU	Permissions Coordinating Unit
REC	Research Ethics Committee
SoA	Statement of Activities
SoE	Schedule of Events
SOP	Standard Operating Procedure
SSI	Site Specific Information
STU	Swansea Trials Unit
SU	Swansea University
TM	Trial Manager

8. Appendices

Appendix 1: Document History

Version No:	2	**Effective Date:**	22-Apr-2024
Description of changes:	Updated to SOP Template v5		

Appendix 2: Application flowchart