SOP number	**59.011**	Version	**2.0**
Title	**Research Application Process**		

Prepared by	Alison Hamilton
Approved by	Chloë Cowan
Released by	Jesse Dawson

SOP category	West of Scotland Safe Haven

Staff category

Staff Category	**R**	**A**	**C**	**I**
West of Scotland Safe Haven Manager		X		
WoS Project Manager	X			
WoS Data Managers	X			
WoS Data Analyst	X			
WoS Innovation Hub Project Managers				X
DHVL Staff				X
Chief/Principal Investigators				X

1. Scope

This procedure applies to the West of Scotland Safe Haven (WoSSH) within the NHS Greater Glasgow and Clyde (NHSGGC).

2. Purpose

The purpose of this SOP is to outline the process by which project applications to the WoSSH are reviewed and either approved or declined.

3. Procedures

The WoSSH supports a diverse range of projects, including but not limited to feasibility, data-only projects, and assistance with clinical studies. For any project that relies on the WoSSH to provide data, early engagement with the WoSSH team is essential – regardless of the project type.

3.1. Initial Contact

When a Clinical Investigator (CI), Principal Investigator (PI), or other researcher first contacts the WoSSH, it is essential to establish a clear understanding of the research question, project scope, required datasets, and the number and/or frequency of data extracts. This process enables the WoSSH team to assess whether the researcher's requirements fall within its scope and capabilities as well as capture whether funding is available or being applied for. While initial discussions can take place via email, a meeting (preferably in person or via video call) should be arranged where possible. This meeting will include, at a minimum, the WoSSH Project Manager and/or Manager, along with a WoSSH Data Manager. Following these discussions, the project will be assigned a project number in accordance with SOP 59.007**.**

A member of the WoSSH team, typically the Project Manager, will complete Form 59.011A following the meeting and share it with the attending Data Manager. The completed form will be saved to the project folder. All correspondence related to the initial enquiry and discussions will also be stored in the appropriate section of the project folder.

3.2. Costing

3.2.1 Funding Type

Following the initial discussion with a researcher the project must be costed. How a project is costed can be impacted by the funder. There are 5 funding categories:

1. Eligible funding (see https://www.nhsresearchscotland.org.uk/uploads/tinymce/NRS%20CSO%20Eligible%20Funders%20List%2019%20February%202025.pdf)
2. Non Eligible funding
3. Investigator led commercially funded
4. Mixed model of charity/government funding and/or commercial funding
5. Commercially funded

Where a project is led by an NHS or Academic based researcher and funded by categories 1-4 these will be charged at NHS/Academic rates. Where a project is funded and led by a commercial entity regardless of NHS/Academic involvement, these projects will be costed at commercial rates.

3.2.2 Collating costs

Projects seeking retrospectively linked, electronic health record (EHR) data only or follow up of participants recruited to a clinical study this work will be costed at a flat rate in line with WoSSH schedule charges. Costs should be inclusive of project duration, number of datasets, complexity of cohort build, number of data refreshes, images and any dataset import requests. Additional cost considerations should be included for disclosure control checks and archiving. Costs for the TRE must also be included in the WoSSH quote. TRE costs should be obtained directly from the TRE service provider for projects which are not going to a pre-approved TRE additional scoping may be necessary including but not limited to DPIA and SSP, where these are involved additional costs may be incurred.

For projects seeking long term and repeated data linkages and/or ongoing clinical trial support (or similar) then these projects will be costed using labour costings (e.g. Band ‘x’ WoSSH Data Manager for 0.2 WTE (1 standard day) across three months). Time should be included for appropriate WoSSH data staff and the project manager.

Where WoSSH costs are the only NHSGGC costs and have utilised the WoSSH schedule charges model, these can be provided directly to the researcher or their delegate. Where a project is seeking WoSSH support as part of a bigger grant application with other NHSGGC costs included these costs will be shared with the relevant personnel within the Systems or West of Scotland Innovation Hub team for inclusion with all other NHSGGC costs. Where WoSSH staff time is being costed for but there is no Systems or West of Scotland Innovation Hub team involvement the WoSSH Project Manager or Manager will populate form 51.010A and submit to R&I finance in line with SOP 51.010.

3.3. Application Review

Once it has been confirmed that the project falls within the scope of WoSSH and appropriate funding has been secured, the project may proceed to the application stage. Under the Safe Haven's existing Research Ethics Committee (REC) approval, a delegated ethics pathway is available, allowing eligible projects to seek ethical approval through the Local Privacy Advisory Committee (LPAC). The eligibility criteria and scope of this approvals route are specifically defined in SOP 59.010.

Most projects requesting data from the WOSSH will require approval via the Local Privacy Advisory Committee (LPAC). In such cases, researchers must complete Form 59.011G. Upon submission, the application must be reviewed by, at a minimum, the Safe Haven Project Manager and a Safe Haven Data Manager.

The review should assess whether the proposed work aligns with the initial understanding captured in Form 59.011A. Any discrepancies or changes must be clarified with the researcher. The application must clearly articulate the project's aims and scope, and demonstrate both feasibility and potential benefit. Researchers should avoid excessive use of technical jargon to ensure the application is accessible and understandable to LPAC reviewers.

Applications must also include:-

- Clear and detailed inclusion and exclusion criteria for the cohort(s), where cohort construction is to be undertaken by the Safe Haven
- A fully completed data section, clearly defining the data extract requirements
- Relevant codes and filters, where applicable, to support data specification
- A justification for large or whole dataset requests, explaining the necessity in relation to the research question(s)
- Evidence that data minimisation principles have been applied, ensuring that only the minimum necessary data is requested.

If the application includes a request for access to a Tier 2 dataset (a dataset that is available through WoSSH but with additional approvals), it must also be shared with the relevant data owner for review. Inclusion of such datasets is contingent upon receiving the appropriate additional approvals.

When the Safe Haven team reviewing the application and the researcher are happy with the application it may be submitted to the LPAC for review.

3.4. LPAC Review

Completed applications will be submitted to the LPAC by the Safe Haven Project Manager via email. The LPAC typically has up to two weeks to review each application. If no response is received within this initial review period, a follow-up email will be issued by the Project Manager.

Alongside the application form (Form 59.011G), the LPAC will also receive Form 59.011F to record their assessment. Completed forms should be returned to the Safe Haven Project Manager for collation.

A project will be considered approved when:-

- No concerns are raised by the LPAC, and
- A minimum of three LPAC members provide formal approval

In such cases, an approval letter (Form 59.011B) will be issued to the researcher via email by a member of the WoSSH team. The approved project will then be added to the workload for the WoSSH in accordance with SOP 59.013.

If the LPAC raises concerns, the Project Manager will compile the feedback and issue a provisional response (Form 59.011C). The researcher will be given the opportunity to respond, and their responses will be shared with the LPAC for further consideration, researchers should aim to respond in a timely manner, ideally as soon as is practicable. If the LPAC is satisfied with the clarifications provided, the project will be approved and an approval letter (Form 59.011B) will be issued.

In cases where the LPAC determines that a project is not suitable for WoSSH support, a letter of non-approval (Form 59.011D) will be issued inclusive of feedback from the LPAC with respect to their issues or concerns. While appeals are typically not standard, researchers are permitted to revise their application and resubmit.

3.5. REC

Depending on the nature of the project, Research Ethics Committee (REC) approval may be required in addition to Safe Haven approval.

- If the Safe Haven is being used to inform a future prospective study, Safe Haven approval alone may be sufficient to begin preliminary work prior to obtaining REC approval
- If the Safe Haven is contributing data to a broader research project, REC approval must be in place before any data can be released.

For projects with REC approval that require Safe Haven support, the following documentation must be submitted to the Safe Haven team:-

- A copy of the REC favourable opinion
- The study protocol
- The IRAS form

These documents must be stored in the relevant project folder in accordance with data governance procedures.

3.6. Caldicott Approval

Where the Safe Haven is providing support to a clinical trial or a project where the researcher needs identifiable to patient identifiable data, e.g. screening for potential participants then Safe Haven approval may not be necessary, however Caldicott approval is. Where Caldicott approval is required a copy of the Caldicott request and associated approval must be provided to the Safe Haven. These documents must also be stored in the relevant project folder.

3.7. DPIA/SSP

Where a non Scottish Safe Haven Network affiliated TRE is being used a DPIA and/or SSP may be needed. In these instances it is important to follow the eHealth risk triage process which, which starts by completing the eHealth Risk Register form: https://scottish.sharepoint.com/sites/ITSecurityTeam/_layouts/15/listforms.aspx?cid=MDlhZTM1YmYtMjI4Mi00NGIyLTkwZjMtMzIzNmI3ZDgwNjEx&nav=YmI4OTAyNjctZjNmNS00NGI0LWE0YTYtOGY1NDQ4NGZjYTY3&LOF=1.
The eHealth team will score the submission and forward the relevant documentation. DPIAs and SSPs must be stored in the relevant project folder.

4. Referenced documents

- SOP 59.007 -Assigning Local Study Numbers and Subject IDs
- SOP 59.010 - Local Privacy Advisory Committee: Purpose
- SOP 59.013 - Administration of Research Projects
- Form 59.011A - Application Assessment for Project Application
- Form 59.011B - West of Scotland Safe Haven Feedback Letter - Approved
- Form 59.011C - West of Scotland Safe Haven Feedback Letter – Provisional
- Form 59.011D - West of Scotland Safe Haven Application Feedback Form – Not Approved
- Form 59.011G - West of Scotland Safe Haven Project Application Form
- GUI 59.011A - West of Scotland Safe Haven Notes for Applicants

5. Related documents

- N/A

6. Document history

Version	Date	Description	Retrospective Implementation
1.0	03/05/2024	Migration to Glasgow Clinical Trials Unit QMS	No
2.0	06/11/2025	Update to procedures	No