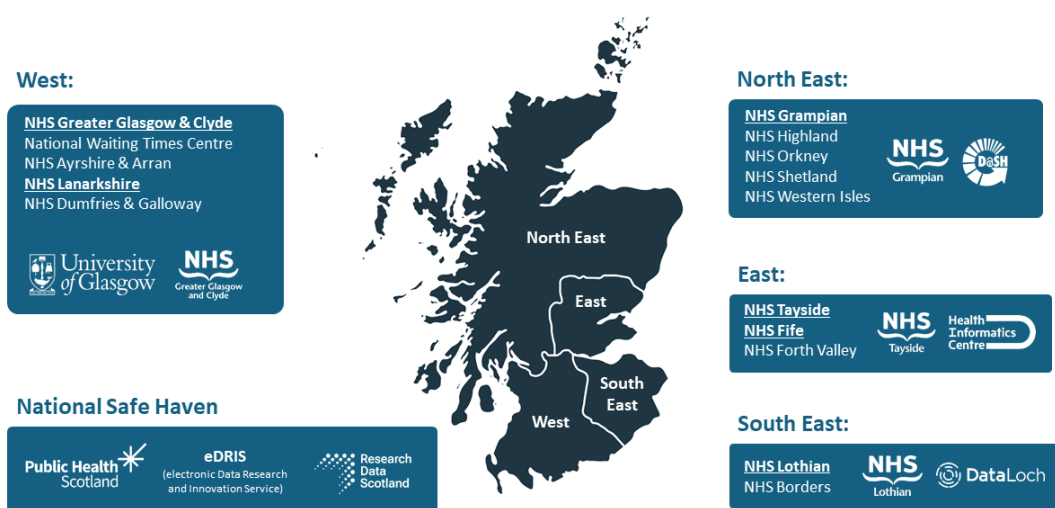


# Federated Governance for Safe Haven data access

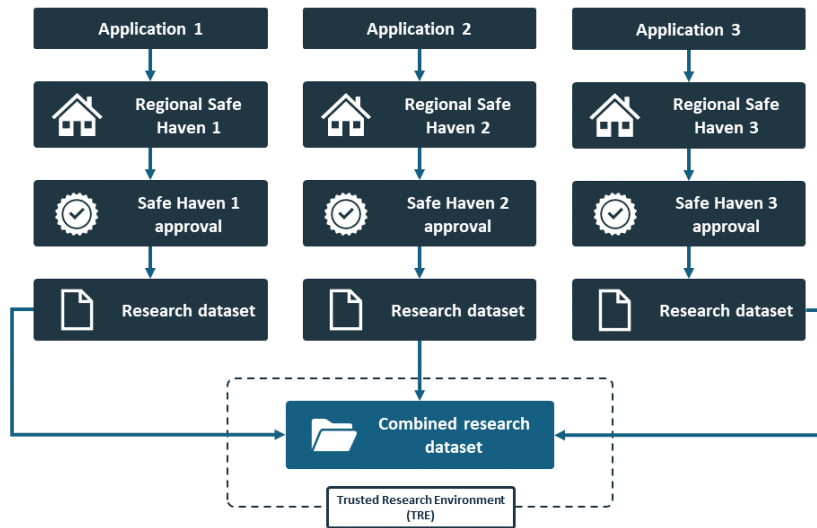
## A summary

Since 2015, a network of Research Safe Havens in Scotland has securely enabled access to extracts of de-identified health data for research in the public interest. This network is made up of the National Safe Haven and four Regional Safe Havens. The National Safe Haven provides access to high-level datasets covering the whole of Scotland. The four Regional Safe Havens enable access to more detailed (and still de-identified) data within specific regions.



## The challenge

There has been a growth in demand for research involving access to detailed data from across several Regional Safe Havens. Unfortunately, researchers have had to submit separate applications to each region in question. Each of these regions have their own distinct processes for researchers to go through to access data. These differences have led to delays in starting projects, duplication of effort, increased costs, different risk assessments, and a poor experience for researchers overall.



Note: A Trusted Research Environment is a secure technical platform allowing safe access to sensitive data to undertake analysis while maintaining strict security controls to protect individual privacy.

In 2024, the Scottish Safe Haven Network explored the establishment of a federated system of governance across Scotland’s Regional Safe Havens, based on data security good practice. This exploration involved engagement with NHS Caldicott Guardians (senior clinicians responsible for ensuring data are used appropriately), members of the public, and representatives of the Regional Safe Havens. The main objective is to enable a researcher to go to any of the Regional Safe Havens for access to regional data from multiple health boards. The resultant data extracts would be transferred to the ‘lead’ Regional Safe Haven that received the original application. With the approval of the NHS Caldicott Guardians in each NHS Board involved, the approach to establishing federated governance will be implemented in two phases:

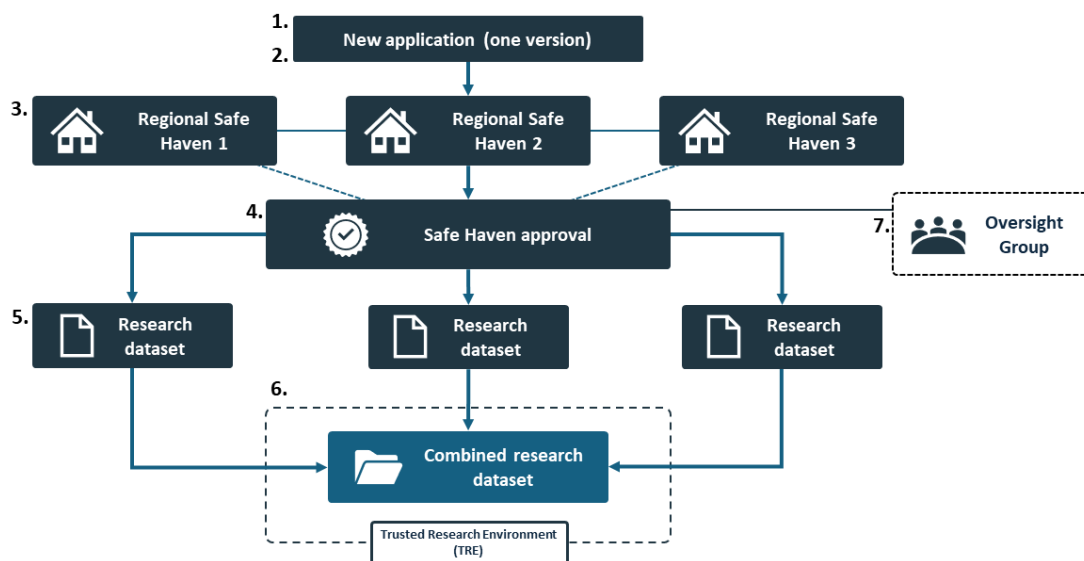
- Phase 1: in 2025, each Safe Haven will take every federated data access application they receive to the other involved Safe Havens and an Oversight Group for per-project review, in order to build confidence in each other and establish an evidence base for phase 2.
- Phase 2: in 2026 (pending review of phase 1 outcomes), federated data access applications will be processed by the lead Safe Haven according to the data access pathway described below, with retrospective review by the Oversight Group to ensure continuous improvement over time.

Not all research projects will be suitable for the federated approach. Projects that are within scope of this federated governance will involve:

- Academic research using a Scottish Safe Haven to access NHS data.
- UK-based researchers.
- Five of the NHS health boards currently supported by Scottish Safe Havens – Fife, Grampian, Greater Glasgow and Clyde, Lothian, Tayside – though new health boards may be included in the future.
- Any regional datasets available to the Regional Safe Havens under existing agreements.
- Secure transfers of identifiable data to allow cross-region data to be linked and permit the removal of duplicate patients within the data extract (i.e. where

patients have been treated in more than one health board region), but with all project-specific data de-identified before access by researchers.

## How Federated Governance will work



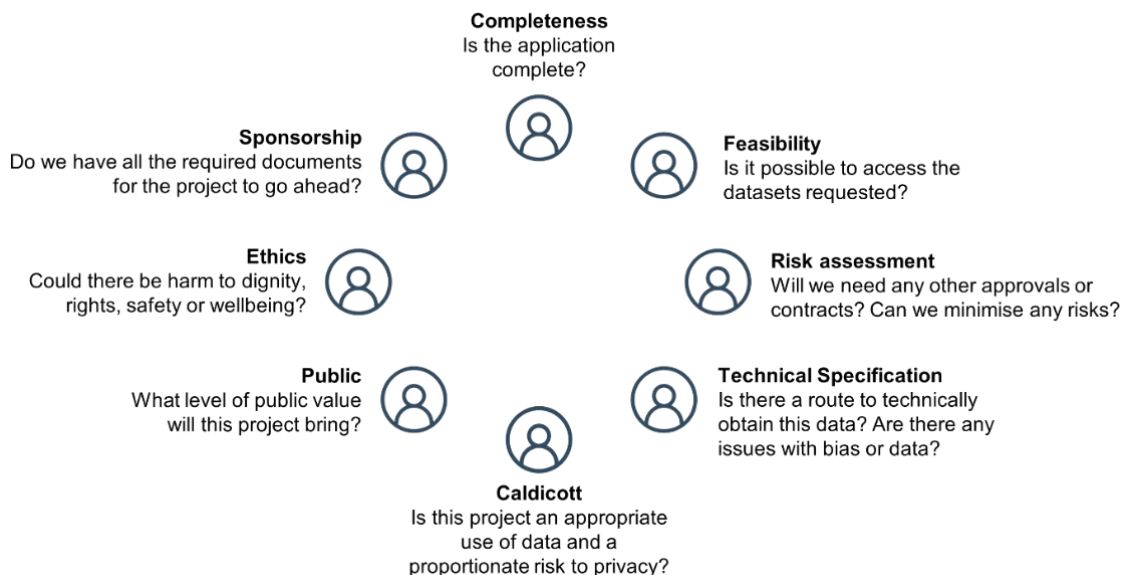
1. An application is received at a Regional Safe Haven (i.e. lead Safe Haven for that application and their Caldicott Authority).
2. An annex to the application describes a request for additional patient cohorts and linked data from another Regional Safe Haven/s.
3. The application is shared with the Regional Safe Havens for review of feasibility (whether they have the requested data) and to determine if the application is in scope for delegated approval.
4. The application is put through the established research governance pathway for the lead Safe Haven. As part of this approvals pathway, the Caldicott Authority at that site (i.e. lead Caldicott) can (a) approve; (b) request further information; (c) refer for additional approval from other project-relevant Caldicott(s); or (d) reject the application.
5. Once all approvals are in place, the project is initiated and patient cohorts and linked data are extracted at all relevant Regional Safe Havens.
6. De-identified data are transferred securely into a Trusted Research Environment in one Regional Safe Haven.
7. All relevant parties retain oversight and are informed of research outputs, project amendments, and project closure.

## The Oversight Group

Central to this approach is the role of the Oversight Group, members of which will be representatives from all the relevant NHS Health Boards that share data.

The Regional Safe Havens already have procedures that are founded on requirements set out in the [UK Policy Framework for Health and Social Care Research - Health Research Authority \(hra.nhs.uk\)](#) and the [Charter for Safe Havens in Scotland](#), but may have evolved over time given geographic and organisational differences that exist across regions. Nevertheless, these procedures align around the same core principles

(see image below). The initial phase of the revised Federated Governance process in 2025 will allow the Oversight Group to review the Federated Governance model and ensure practice across each Safe Haven is genuinely equivalent or whether amendments are needed. The goal will be to enable more robust and consistent decision-making over time.



## Additional information

The above information is a summary of a Memorandum of Understanding that has been signed by all Caldicott Guardians involved in establishing the approach to Federated Governance in quarter 1 of 2025.

For more about the Scottish Safe Haven Network, including details of the Federated Governance project, visit [the Scottish Safe Haven Network page](#).