NHS Scotland Public Benefit and Privacy Panel for Health and Social Care (HSC-PBPP)

Annual Report
2024/25

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1. Abbreviations and Glossary

AI / ML	Artificial Intelligence is computer software that mimics the ways that humans think in order to perform complex tasks, such as analysing, reasoning, and learning. Machine Learning is a subset of AI that uses algorithms trained on data to produce models that can perform such complex tasks.
CG	Caldicott Guardian**:** A senior person within an NHS board responsible for protecting the confidentiality of patients' health and care information.
CHI	Community Health Index number is the NHS number used as a patient identifier across NHSS.
CHIMB	CHI Management Board (previously the CHI Advisory Group [CHIAG]) manages the use of CHI for NHSS business and operational uses in the delivery of health and social care. HSC-PBPP has a complementary role for the use of CHI for research and non-NHS-operational uses.
DPO	Data Protection Officer. Each NHSS board as has a DPO.
eDRIS	electronic Data and Research Innovation Service within PHS. Applicants to HSC-PBPP are assigned an eDRIS coordinator to advise on data availability and provide support for the application processes.
HSC-PBPP	Public Benefit and Privacy Panel for Health and Social Care.
HSC-PBPP Only	An application that does not require input from eDRIS prior to submission, as the application will not require data to be extracted from national datasets and the data will not be accessed via the National Safe Haven (NSH).
IG	Information Governance.
IG Lead	Person in an NHS board responsible for Information Governance in that board, under the Caldicott Guardian.
MS Teams	Microsoft Teams is the platform used for online meetings of HSC-PBPP
NES	NHS Education for Scotland, a special (national) NHS board and a data asset holder.
NHSCR	NHS Central Register: contains basic demographic details of everyone born, registered with a GP or died in Scotland. NHSCR data can be requested for medical research to flag deaths or cancer diagnosis in the long-term follow-up of a research cohort. https://www.nrscotland.gov.uk/statistics-and-data/nhs-central-register
NHSS	NHSScotland.
NRS	National Records of Scotland, a data asset holder.
NSS	NHS National Services Scotland (the common name for the Common Services Agency for the Scottish health service) and data asset holder.

NSH	National Safe Haven: a secure environment where access to NHSS data is controlled by eDRIS and the recommended space for researchers to access NHSS national data.
PHS	Public Health Scotland, a special (national) NHS Board and data asset holder, established in April 2020. The HSC-PBPP management team sits within PHS, as part of the PHS Data Protection Team and feed into some of its governance processes.
RDS	Research Data Scotland, a Scottish Government initiative, formally established in 2021, and set up to bring together public sector data for use for research.
SG	Scottish Government.
SMR	Scottish Morbidity Records: a group of datasets which include the main contacts of patients with secondary (hospital) care.
Tier 1	Operational level at which all applications to HSC-PBPP undergo their first review.
Tier 2	Higher / strategic level of HSC-PBPP, which has oversight of HSC-PBPP, and at which higher risk applications are reviewed.
Tier 2 OOC	The Caldicott Guardians and Public Representatives who sit on the full committee who review applications “out of Committee”.

2. Executive Summary

Background

This Annual Report covers the operation of the NHSScotland Public Benefit and Privacy Panel for Health and Social Care (HSC-PBPP) for the year April 2024 to March 2025.

Created in May 2015 by Scottish Government (SG), the HSC-PBPP is an information governance (IG) structure of NHSScotland (NHSS). It provides a central national IG scrutiny process focussed on requests for access to NHSS-originated data, which are held in the NHSS boards, for purposes other than direct care. Such purposes include research or service planning.

Support is provided to all applicants seeking access to data, via the electronic Data Research and Innovation Service (eDRIS). The HSC-PBPP works on a two-tier basis: the operational Tier 1 panel or the more strategic Tier 2 committee. Applications are scrutinised at fortnightly panels of NHS IG leads (Tier 1 panel), who attend on a rotational basis. The majority of applications are decided (usually approved) at this level. Where the applications are of greater privacy risk and require a higher level of consideration, applications will be referred to a convened-as-required subgroup of the Tier 2 Committee for scrutiny, known as Tier 2 Out of Committee (T2 OOC), and if deemed necessary, by the full Tier 2 committee.

Performance

Through this year of operation, HSC-PBPP has continued to show good performance across a range of metrics. IG leads from the territorial and national NHS Boards within NHSS have been engaged in the process, thus embedding IG in the general operational approach of the NHS across Scotland.

The number of submitted applications in 2024/25 was similar to that in 2023/24, but lower than that in previous years. This may be due to changes in data sharing across NHSS boards, reducing the requirement for HSC-PBPP approval for some activities. While the number of applications has fallen, the complexity of them has increased, with more datasets requested and the use of more complex analysis. Similarly to preceding years, these applications came mainly from academia (~80%), with the proportion of NHS applications markedly reduced from over 30% in previous years to ~20% in the last 2 years; the remainder of the submissions came from SG and commercial companies. As seen in previous years, the majority of applications were from organisations within Scotland, with about a third of applications from the rest of the UK.

Development work

HSC-PBPP endeavours to keep abreast of current and future developments, particularly in this rapidly moving research landscape. The requirement for regular updates from HSC-PBPP to the NHSS boards has continued during this year, through some of the different governance forums that regularly meet within NHSS.

An HSC-PBPP Development Day was held in March 2025, using a similar format to that of the annual workshops that previously took place. This is seen as an important opportunity to bring together HSC-PBPP members from Tier 1, Tier2 and eDRIS. In addition, any researchers or others who contributed to the day were able to join the other discussions. The day allowed networking and gave an opportunity to discuss some challenging situations that have arisen from recent applications.

Looking at the IG landscape more widely, the Development Day included a session on a Federated Governance model that is being developed for the four Regional Safe Havens with the proposal to explore further how HSC-PBPP fits with other governance or approval processes, including that of Research Data Scotland (RDS). The role of HSC-PBPP will continue and adapt to changes in the landscape, while ensuring consistency and maintenance of the public confidence in the scrutiny process.

Future developments in 2025/26

Looking forward to 2025/26, HSC-PBPP must continue to ensure that the right balance is struck between safeguarding the privacy of people in Scotland and the benefit to all from improved treatment and care informed by high quality research. Ongoing development to improve processes will continue, to help and support the needs of researchers.

Preliminary discussions regarding access to GP data are ongoing. It is hoped that in 2025/26 a process aligned with HSC-PBPP will be developed, to make these data available to researchers, subject to resources and agreements with the GPs.

3. Chair's introduction

This report covers the work undertaken by HSC-PBPP during 2024/25. The outcomes achieved during this past year are a testament to the hard work of all those involved, sometimes in complicated circumstances. Once more, it is a chance to be able to express appreciation to everyone who has contributed to these processes in such a conscientious and professional manner. I should especially like to thank the Panel Manager for all she has done in helping us negotiate this period of very significant change which has not by any measure been straightforward and also acting as a valuable resource to inform decisions.

NHSS has a tremendous amount of health data for its population, providing an exceptional opportunity for large scale research projects, quality improvement and patient-care audits to be undertaken. Applications have become more complex since the time when HSC-PBPP was originally implemented and often includes the use of highly sensitive data from extremely vulnerable people. Because of the need to use innovative technology for analysis, this has raised new questions with research reflecting societal and technological changes.

The HSC-PBPP has continued to involve the IG Leads across the different NHSS Boards, thus ensuring that the HSC-PBPP scrutiny is a truly national process and not limited to select individuals within specific Health Boards. From its inception in 2015 up to the end of March 2025, in total, the HSC-PBPP has made decisions for over 900 applications, showing that the demand for using NHSS health data remains high. The prospect of a Federated Governance model for access to health data across Scotland is an interesting development and needs to be developed with due diligence. The panel is well aware of the need for transparency and meaningful public engagement when considering applications.

Some personnel changes to the HSC-PBPP Tier 2 committee have taken place, with the addition of new Caldicott Guardian representatives, representatives for the CHI Management Board (CHIMB) and the National Records of Scotland (NRS), all of whom will bring different perspectives and skills to the HSC-PBPP Committee. For those who have moved on for different reasons, HSC-PBPP is very grateful for their contribution over the time they sat on the HSC-PBPP Committee.

HSC-PBPP recognises the need to react quickly to the rapidly changing landscape of governance in an increasingly technological age. HSC-PBPP will continue to engage with those who are also working in this space to continue to develop its procedures to improve efficiency, while maintaining integrity. Ultimately the aim is that this will all work together so that the people of Scotland will gain the benefits of better health and social care.

Dr George Fernie
Interim Chair of Public Benefit and Privacy Panel for Health and Social Care

4. Purpose and Structure of the Public Benefit and Privacy Panel for Health and Social Care (HSC-PBPP)

NHSScotland (NHSS) is the healthcare service in Scotland, with 14 territorial NHSS Boards, which are responsible for the protection and the improvement of their population's health and for the delivery of frontline healthcare services. There are also 8 national NHSS Boards, which provide a range of support, specialist and national level services. The responsibilities of NHSS also include population health, health protection, education and training.

HSC-PBPP is an IG structure of NHSS that exercises delegated decision-making on behalf of NHSS Chief Executive Officers acting on behalf of their boards and the Registrar General of the National Records of Scotland (NRS) for NHS Central Register (NHSCR) data.

The HSC-PBPP endeavours to operate as a centre of excellence for privacy, confidentiality and IG in relation to Health and Social Care in Scotland, providing strategic leadership and direction to NHSS Boards, the research community, and wider stakeholder groups.

The panel aims to:

- Streamline the governance processes for the scrutiny of requests for access to NHSS-originated data for purposes other than direct care, e.g. audit, service-improvement, research, or health and social care planning;
- Provide robust, transparent, consistent, appropriate and proportionate IG scrutiny of such requests;
- Strengthen the direct involvement of members of the NHS and public in the scrutiny process and decision-making regarding access to NHSS-originated data.

Since its inception in May 2015, the HSC-PBPP has provided a national IG scrutiny process for the secondary use of patient health data held within NHSS Boards. It has successfully harnessed expertise across the NHSS Boards implementing a collaborative approach which contributes to a uniform approach and continued capacity development across the sector.

4.1. Structure of the HSC-PBPP

The HSC-PBPP structure and process is summarised in the flow diagram shown in Figure 1. Currently, eDRIS provides a single entry point for all applications to HSC-PBPP. This helps to maintain reliability of advice for all applicants, including those from NHS services or SG for core business, as well as those wishing to use NHSS data for research.

The eDRIS team provides support to all applicants applying to HSC-PBPP. They do this by providing an eDRIS Coordinator to facilitate applicants to refine their projects and the data requested, as well as review and assist applicants to finalise their applications for submission. The eDRIS team works closely with the HSC-PBPP. Through shared learning between the two teams, this aims to ensure that applications are fit for submission, thus making the HSC-PBPP review process as efficient as possible for both applicant and reviewer.

The HSC-PBPP operates on a two-tier structure (see figure 1). Tier 2 is the level of strategic oversight and consideration of policy, whereas Tier 1 is the more operational level at which most applications are approved. The HSC-PBPP management team sits within Public Health Scotland (PHS). The HSC-PBPP Panel Manager is a permanent member of Tier 1 and Chairs the Tier 1 panel meetings.

Tier 1

Tier 1 is the first level of scrutiny of applications, acting at an operational level, with panels meeting approximately every two weeks. Facilitated by the Panel Manager, each panel comprises of IG practitioners from across the NHSS Boards, who attend on a voluntary basis as representatives of the NHSS boards as data controllers. Applications are reviewed according to agreed proportionate governance criteria. The Tier 1 scrutiny examines the technical and IG aspects of an application at a Tier 1 panel meeting. Each application is scrutinised against a set of proportionate governance questions and criteria. Up to four applications and two amendments were considered at each meeting. If the Tier 1 panel were satisfied that the public benefit of the proposal was clear and that all privacy risks will be managed appropriately and securely, the application was approved. There may have been questions to the applicant seeking clarification or reassurance before the approval or another outcome was agreed. For more complex, novel or potentially contentious applications, the Tier 1 panel may refer the application on to Tier 2. This would be assessed by a subgroup of the full committee, the Tier 2 Out of committee (T2OOC).

Tier 2

Tier 2 comprises a regularly convened strategic Full Committee, and a smaller subgroup of committee members working 'Out of Committee' (T2OOC). The latter comprises of the Caldicott Guardians (CGs) and public representatives of the Full Committee. All Committee members attend on a voluntary basis because they have an interest in the governance and use of data. Applications referred from Tier 1 are reviewed first by the T2OOC. Most applications referred to Tier 2 are approved at this level, with only a minority referred on to the full committee. When applications are referred to the full committee, the applicant is invited to attend the meeting to answer questions and inform the discussion.

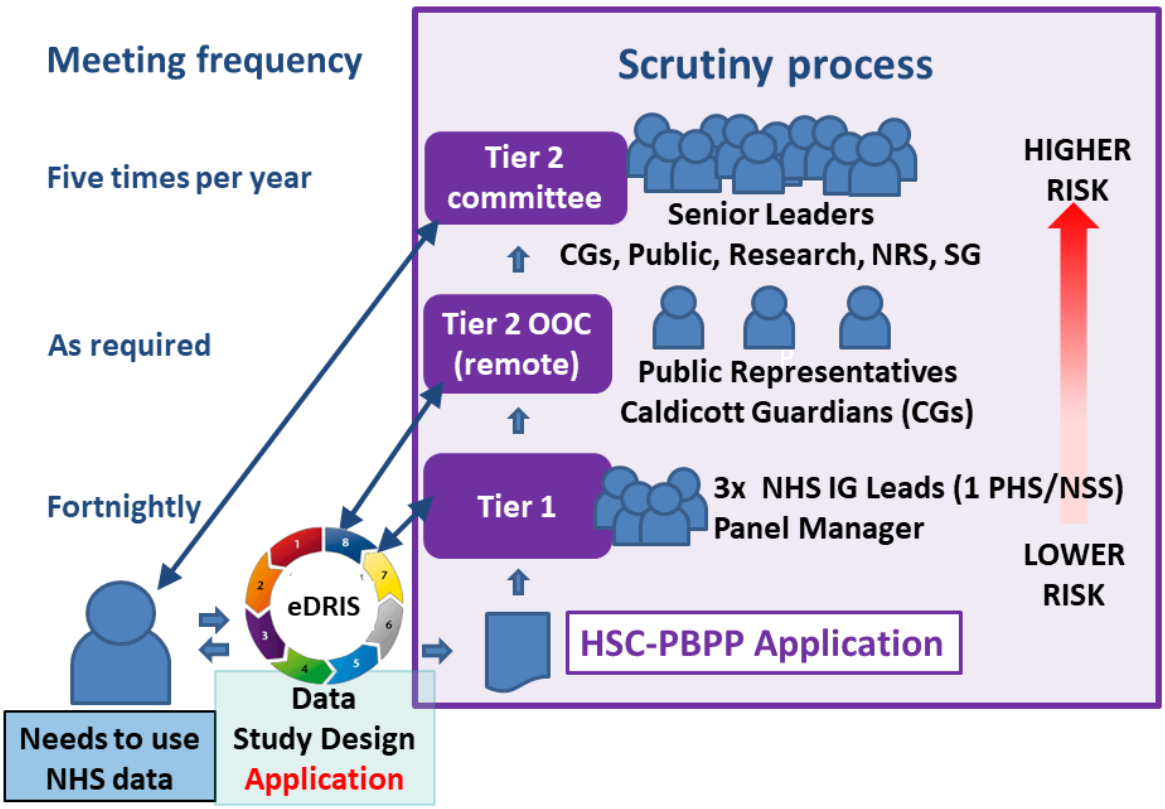

Figure 1 **Flow-diagram of the HSC-PBPP scrutiny process**

CG: Caldicott Guardian
SG: Scottish Government
IG Information Governance
NRS: National Records of Scotland
OOC: Out of Committee

The full committee consists of senior leaders from the different stakeholders involved in HSC-PBPP. This includes:

- Representatives of the major data asset holders relevant to HSC-PBPP: Public Health Scotland (PHS), NHS National Services Scotland (NSS), NHS Education for Scotland (NES, which hosts the National Clinical Data platform) and National Records of Scotland (NRS)
- Representative of Caldicott Guardians from NHSS boards
- Representative from the CHI Management Board (CHIMB)
- Representatives from the research community
- Representatives from the public (lay representatives)
- Representative from Scottish Government.

The full committee provides the intellectual space to consider the wider privacy issues in regard to:

- Particularly contentious, sensitive or novel applications;

- Applications that would set precedence;
- Proposed policies in the SG and/or NHSS relating to the use of health and social care data.

The use of the two tiers also ensures that scrutiny is proportionate, and that available resources are effectively used. Each of the two tiers focuses on the assessment of privacy risks as well as the balancing of privacy risk with likely public benefit.

5. HSC-PBPP Tier 2 Committee Members 2024/25

Dr George Fernie (Interim Chair)
Dr Tara Shivaji (PHS Caldicott Guardian representative)
Dr Mark McGregor (NHSS Caldicott Guardian representative) until November 2024
Dr Arun Chopra (NHSS Caldicott Guardian representative) until November 2024
Dr Seshadri Vasan, (NHSS Caldicott Guardian representative) from April 2024
Kenneth McLean (Lay Representative)
Martin Walsh (Lay Representative)
Chioma Dibia (Lay Representative)
Dr Stacey Noble (Lay Representative)
Professor Alison McCallum (Research Representative)
Professor Colin McCowan (Research Representative)
Dr Lindsey Ross (CHIMB representative) from April 2024
Dr David Felix (NES Representative) until January 2025
Julie Ramsay (NRS Representative) until June 2024
Esther Roughsedge (NRS Representative) from June 2024
Lisa Hill (SG representative)

Committee membership vacancies and changes during 2024/25

During the year 2024/25, the following changes occurred:

- One Caldicott Guardian retired at the end of March 2024 and was replaced in 2024/25. Two other Caldicott Guardians resigned during the year and will be replaced in 2025/26.
- A new CHIMB representative was appointed from April 2024.
- The NRS Representative changed, due to the promotion of the representative and was replaced by their successor.
- The NES Representative retired in January 2025 and will be replaced in 2025/26.
- The Social Care representative role on the committee remained unfilled during 2024/25.

It was with sadness that HSC-PBPP marked the passing of the first HSC-PBPP Chair, Brian Houston, in January 2025.

The HSC-PBPP is grateful and thanks all current members as well as those who have left the Tier 2 committee for their contribution over the years and in particular in the early years as HSC-PBPP has grown and developed.

6. Meetings of the HSC-PBPP

Tier 1

During 2024/25 the Tier 1 Panels continued to meet regularly on MS Teams, approximately every fortnight. Each panel comprised of three IG Leads/Practitioners from NHSS Boards, on rotation, and the HSC-PBPP Panel Manager. The IG leads were drawn from the territorial (local) and national NHSS Health boards around Scotland. Each IG Lead brings their experience and viewpoint from their specific NHSS Board. Tier 1 panels often have questions and clarifications for the applicant regarding specific points within the applications. With the continued use of MS Teams, the convening of an *ad hoc* meeting to review these clarifications, has improved the Tier 1 review process. In 2024/25 IG Leads from 18 of the 22 NHSS Boards were involved in the Tier 1 panels. A number of observers joined the panels as a training opportunity as well as for those with a view to join the Tier 1 rota.

The HSC-PBPP wishes to acknowledge and express thanks to those who sat on Tier 1 panels during 2024/25 and who contributed their time and considerable IG expertise to the scrutiny process, in addition to their day jobs, often under busy and trying circumstances. The HSC-PBPP wishes to thank particularly the NHS Boards for releasing their IG leads for HSC-PBPP work, to help the HSC-PBPP function well, due to the work of these highly qualified people.

Tier 2 OOC and Full Committee

The Tier 2 OOC was convened as required to consider applications referred from Tier 1, with reviews being done by email. This group consists of the NHS CGs and Lay Representatives, who sit on the full committee, and who also undertake these reviews. In 2024/25, seven applications were reviewed by Tier 2 OOC, five of which were referred to the full committee. These were discussed and subsequently approved with conditions.

In 2024/25 the Full Committee met on the following occasions, with the meetings held using MS Teams.

Full Committee Meeting Wednesday 24th April 2024
Full Committee Meeting Tuesday 20th June 2024 was cancelled due to illness
Full Committee Meeting Tuesday 17th September 2024
Full committee meeting Wednesday 27th November 2024
Full Committee Meeting Wednesday 22nd January 2025 (as a hybrid meeting).

Minutes of these meetings are available on the HSC-PBPP website:
http://www.informationgovernance.scot.nhs.uk/pbpphsc/application-outcomes/

The HSC-PBPP wishes to acknowledge and express thanks to those who sat on the Tier 2 Committee during 2024/25, who contributed their time and considerable expertise to the scrutiny process and wider strategic work, again in addition to their day jobs. The HSC-PBPP wishes particularly to thank the NHS Boards and other organisations for releasing their senior staff for HSC-PBPP work, as the HSC-PBPP only functions well due to the contribution and generosity of these experienced people.

With both tiers, there is a considerable amount of documentation to read and consider before a meeting, which is then discussed to reach specific conclusions. It is very much appreciated by the HSC-PBPP that this is done by Tier 1 and Tier 2 members in such a timely manner given the complexity of the subject manner.

7. Performance Metrics for HSC-PBPP applications for 2024/25

7.1. Summary Tables of HSC-PBPP metrics for 2024/25

The applications and amendments submitted to HSC-PBPP for the year 2023/24 to 31st March 2024 for all applications and amendment requests are summarised in table 1 below.

Applications	Number submitted	Number of decisions		Level of decision	n	%
Applications received for 2024/25 at 31/03/2025	**71**	Approved	49	T1 panel meeting	29	44.0
		Not approved	6	T1 review	33	50.0
		Withdrawn	3	T2 OOC	2	3.0
		In progress	13	T2 full committee	2	3.0
Carried forward from 2023/24	**12**	Approved	11	**Total with decisions**	**66**	
		Not approved	0	**Total withdrawn**	**4**	
		Withdrawn	1	**Carried forward**	**13**	
Total	**83**	In progress	0	**Total**	**83**	

Amendment requests	Number submitted	Number of decisions		Level of decision	n	%
Amendment requests for 2024/25 at 31/03/	**203**	Approved:	199	eDRIS	101	50.8
		Not approved:	0	Panel Manager	87	43.7
		Withdrawn:	6	Tier 1	11	5.5
		In progress	8	Tier 2	0	0
Carried forward from 2023/24	**10**			**Total decisions**	**199**	
Total	**213**	**Total**	**213**			

Table 1: *Summary of the applications and amendments processed by HSC-PBPP in 2024/25.*

For applications, the information from Table 1 is broken down into by application type and for each quarter of the year in Table 2. The application 'type' is classed as:

- NSH: applications for which NHSS data will be provided by eDRIS for analysis within the National Safe Haven (NSH);
- Data Only: applications that request data to be provided directly to the researchers and will be analysed in an environment outside the NSH;
- HSC-PBPP Only: applications that require HSC-PBPP approval but do not require support from eDRIS, either for provision of data or use of the NSH. The data for

these applications will be provided by another NHSS body e.g. direct from the NHSS boards or NHSCR.

Application Submissions	Annual	Q1	Q2	Q3	Q4
ALL applications received	**71**	18	12	23	18
Analysis in NSH	25	9	4	7	5
Data Only	25	7	3	9	6
HSC-PBPP Only	21	2	5	7	7
Carried over from previous quarter	**12**	12	15	11	14
Total applications in progress†	**83**	30	27	34	32

Application Decisions	Annual	Q1	Q2	Q3	Q4
Approved	**60**	14	14	15	17
Not approved	**6**	1	1	3	1
Tier 1 decisions	62	14	14	16	18
Tier 2 decisions	4	1	1	2	0
Withdrawals	**4**	0	1	2	4
Ongoing	13*	15	11	14	13*
Total applications progressed†	**83**	30	27	34	32

Table 2: *Numbers of application submissions and decisions for each quarter of 2024/25*
*These applications will be carried forward to 2025/26
†The quarterly totals do not add up to the total as some applications are processed in more than one quarter.

For amendment requests the information from Table 1 is further broken down for amendment requests in Table 3. The levels at which decisions were made for amendments to an approved application are shown as:

- eDRIS: approval by the eDRIS coordinator for very low risk changes to the applications.
- Panel Manager: approval by the Panel manager or Depute manager, for low-risk changes within clear IG guidelines.
- Tier 1: changes to an application with a potential IG risk are reviewed at Tier 1
- Tier 2: change to an application with higher IG risks are reviewed at Tier 2.

From Tables 2 and 3, it can be seen that for both applications and amendments, numbers of submissions and decisions vary across the year.

Amendment Submissions	Annual	Q1	Q2	Q3	Q4
New amendment requests	**203**	48	50	55	50
Carried over from previous quarter	**10**	10	14	8	9
Total amendments in progress	**213**	58	64	63	59
Amendment Decisions	**Annual**	**Q1**	**Q2**	**Q3**	**Q4**
Approved	**199**	44	52	53	50
Not approved	**0**	0	0	0	0
Level of decision					
eDRIS	101	27	25	28	21
Panel Manager	87	14	26	22	25
Tier 1 decisions	11	3	1	3	4
Tier 2 decisions	0	0	0	0	0
Withdrawals	**6**	0	4	1	1
Ongoing (at end of quarter)	**8***	14	8	9	8*
Total no. amendments progressed†	**213**	58	64	63	59

Table 3: *Numbers of amendment request submissions and decisions in each quarter of 2024/25.*
*These applications will be carried forward to 2025/26
†The quarterly totals do not add up to the total as some applications are processed in more than one quarter.

Subjects of Applications

Applications for different types of studies were submitted and reviewed, reflecting the variety of research, audit and service assessment that used NHSS data for the benefit of the public. Some of the different types of study are:

- UK-wide audits assessed the outcomes and needs of different conditions or procedures.
- NHSS data were used to investigate the long-term outcomes of Clinical Trials.
- Epidemiological studies investigated the risk of different factors on the patterns of disease incidence or health outcomes.
- Longitudinal studies of specific cohorts used NHSS data to look for patterns in disease onset, processes and responses to interventions.
- Use of NHSS data for NHS service planning and improvement, for assessing the cost-effectiveness of specific interventions, or the interactions of social and environmental factors on specific health outcomes.
- Use of NHSS data for technological advances such as machine learning / artificial intelligence to help develop algorithms for detection of specific conditions.
- Applications for flagging of patients from the NHS Central Register.

- There were applications which stated that there was some commercial involvement (n=16, of which two were withdrawn and two were rejected, but not necessarily because of the commercial aspect). The commercial activity included: an active commercial partner, use of a commercial trusted research environment (TRE); a commercial contractor for a specific task (e.g. mailing, survey contractor), provision of an AI algorithm to be tested by academics, provision of a specific treatment for a clinical study.

Lists of the approved applications for each year with their lay summaries, where available, is available on the HSC-PBPP website:
https://www.informationgovernance.scot.nhs.uk/pbpphsc/application-outcomes/

7.2. Comparisons with previous years

Comparisons with previous years indicates the demand for NHSS data and HSC-PBPP scrutiny over time.

Submissions

During 2024/25, a total of 64 applications were submitted to the HSC-PBPP. These are compared with the numbers of application submissions in previous years (figure 2).

As can be seen from figure 2, the number of submitted applications has fluctuated but has decreased, but most markedly post-pandemic from 2022/23 onwards. Various factors may have influenced this:

- Previous new applications for 'pilot' studies for new processes that were reviewed and approved by HSC-PBPP, then became 'business as usual' and so were not renewed.
- The increased emphasis on using the Intra-NHSS Information Sharing Accord across NHSS and therefore applications to HSC-PBPP are no longer necessary for some NHSS projects.
- The creation of PHS as a national NHS board with well-defined core functions, means that some projects that would have previously requested approval from HSC-PBPP are now covered by PHS governance processes.

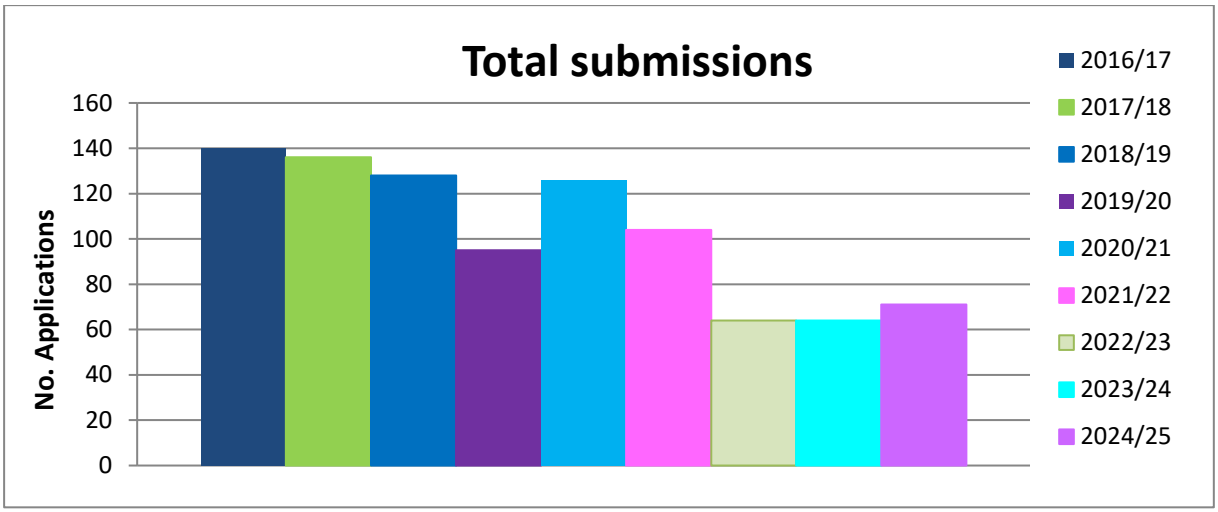

Figure 2: *Numbers of applications submitted to the HSC-PBPP from 2016/17 to 2024/25.*

Sources of applications

The organisation category and countries from which applications were received are shown in figures 3a and 3b, respectively, for the years 2016/17 to 2024/25.

Figure 3a shows that the majority of applications were received from academia and NHS with only a small percentage from commercial companies or Scottish Government. The proportions of submissions between 2016/17 and 2021/22 from NHS and academia were fairly constant (~30-40% and 50-60% respectively). Since then, the requests from the NHS have gradually decreased which is seen again in 2024/25, with now over 80% of applications coming from academia. The requests from Scottish Government or commercial companies has remained constant over the years.

Figure 3b shows that the majority of the applications were initiated from within Scotland with the other applications from the rest of the UK. However, the proportion of applications from the rest of the UK is gradually increasing: in 2016/17 80% of applications were from Scotland whereas in 2021/22 this had dropped to 54% of applications. In 2024/25, the proportion of requests from Scotland vs. rest of the UK was similar to that in 2020/21 and is within the overall variation.

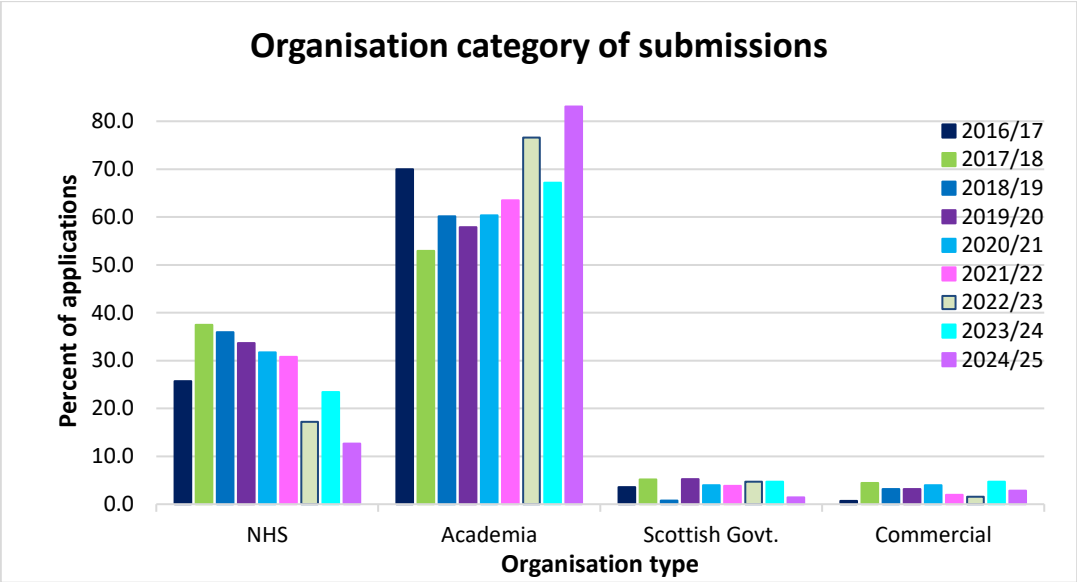

Figure 3a: *Sources of applications to the HSC-PBPP in 2016/17 to 2024/25*

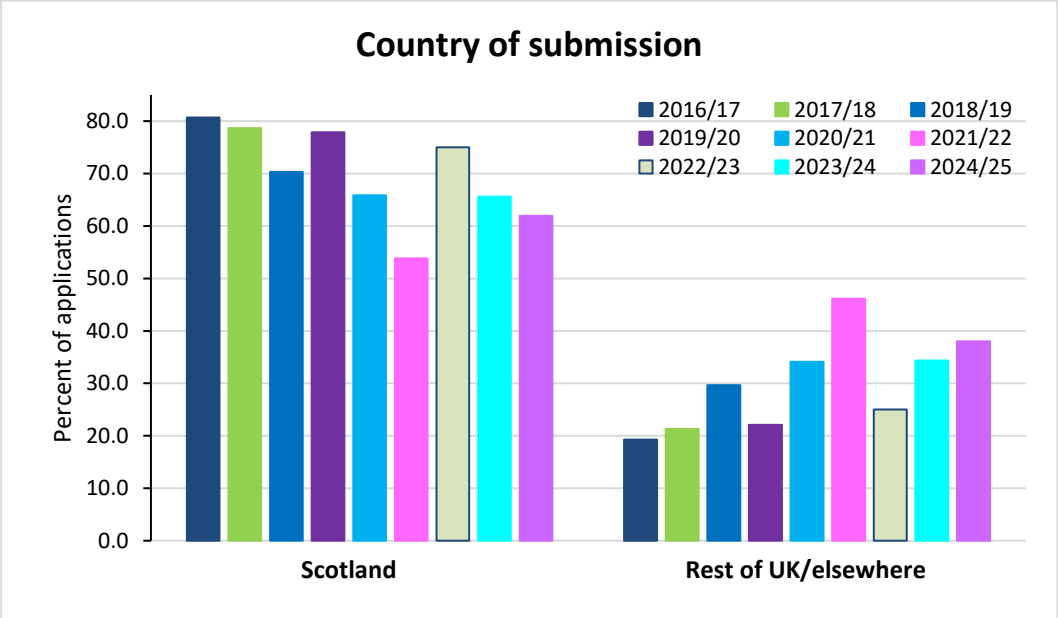

Figure 3b: *Sources of applications to the HSC-PBPP from 2016/17 to 2024/25*

Requests for data and/or flagging from the NHS Central Register (NHSCR)

The NHSCR contains demographic details of everyone born, registered with a GP or died in Scotland. The register exists to allow the smooth transfer of patients who move between health board areas, across borders within the UK or in and out of the Armed Forces. The NHSCR can 'flag' patients (for cancer or death) as part of a medical research project, so that researchers can keep track of their progress and be notified if their patients develop cancer or die. In 2024/25, 12 applications (16.9 %) requested information from NHSCR, either as

part of a study requiring other NHSS data or as the only data requested. This is within the range of those requested in previous years (range 8.4-18.8).

Application Outcomes

The number of application decisions per year are shown in figure 4, with 66 decisions made in 2024/25, as the total number of applications that were approved and not approved.

Previously, the number of applications that have been withdrawn had gradually increased over the past years. Sometimes withdrawal of an application has been requested by the applicant for various reasons; in addition, applications are withdrawn by HSC-PBPP if there has been no response from the applicant to the clarifications requested by Tier 1 within three months of the date of the Tier 1 panel review. The reasons for the applicants' failure to respond are unclear. In 2020/21 the number of withdrawn applications peaked at 16 applications, but has fallen again to 4 withdrawn applications in 2024/25. There were 13 still ongoing from 2024/25 so it is still possible that some of these may yet be withdrawn.

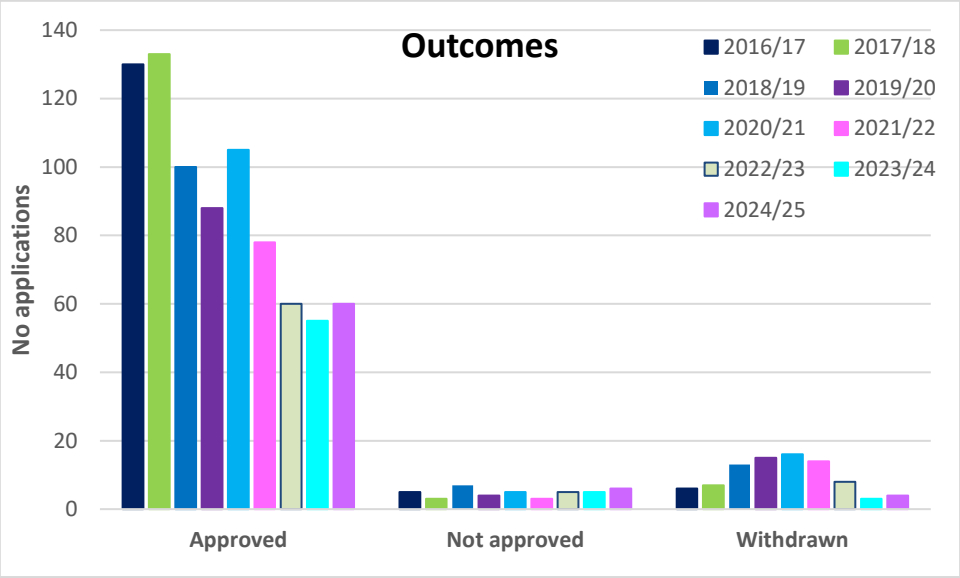

Figure 4: *Application outcomes from 2016/17 to 2024/25*

The level of HSC-PBPP at which decisions were made are shown in figure 5. As can be seen the majority of applications were approved by Tier 1, either at a panel meeting or after the questions and clarifications from the initial review have been reviewed by Tier 1 panel members. In 2024/25 four (6.0%) applications were decided at Tier 2, which were the most complex with the highest privacy risks. This is indicative of the amount of work done by Tier 1 as approximately 90% or more of applications are approved at that level. The COVID-19 rapid response panel (COVID-19 RRP) was stopped in 2021/22.

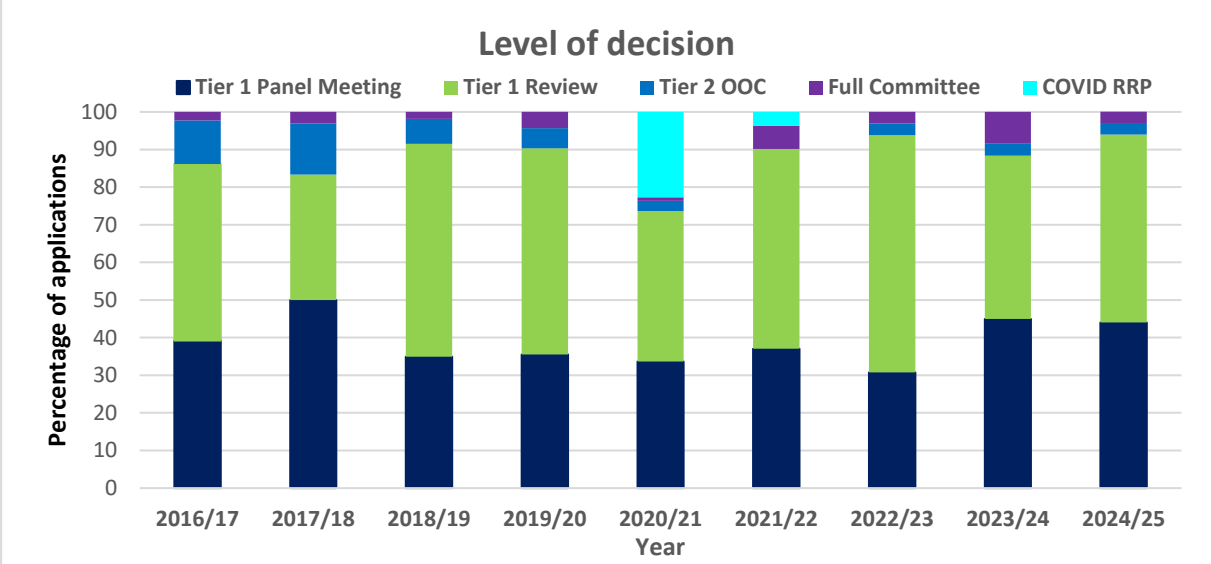

Figure 5: *Level of decisions for applications from 2016/17 to 2024/25*

7.3. Times to decisions

The HSC-PBPP measures two time-periods for decisions to review its processing times between an application being submitted to the HSC-PBPP and the decision by the panel:

- 'Clocked' time: this is the number of working days for which the application is being processed by the HSC-PBPP, from submission to decision. The time taken by the applicant to respond to any queries from the HSC-PBPP regarding the application is not included.
- Total time: this is the total number of working days from submission until the final decision is made, which includes any time the application spent back with the applicant. The difference between the clocked and total times indicates the number of days an application spent with the applicant during the approvals process.

Neither of these measures includes the time that any application spends with an eDRIS coordinator before submission to HSC-PBPP, nor the time taken between HSC-PBPP approval and provision of the data requested.

Time to decisions (days) for applications 2024/25

The time taken for decisions to be made by HSC-PBPP to 31st March 2024 are summarised in table 4. The times are given for all decisions (ALL) and separately for those decided at Tier 1 and those applications decided at Tier 2. The mean, median and interquartile range (IQR) are given below.

No. of days		ALL		Tier 1		Tier 2	
		Total	Clocked	Total	Clocked	Total	Clocked
ALL applications for 2024/25 to 31/03/2025	N	66	66	62	62	4	4
	Mean	47.1	22.0	45.2	19.8	77.0	55.5
	Median	47	18	43.5	15.5	78.5	55.5
	IQR	25–67	13–29.5	23.5-66	12–25	6–89	42–69

Table 4: *Time to decision for applications 2024/25*

Comparison of times to decisions across years

The median times to decisions at the different levels of HSC-PBPP from 2016/17 to 2024/25 are shown in figure 6. The figures for 2020/21 and 2021/22 are for non-COVID-19 applications. The times for all applications shows that these have remained fairly constant over the years, with some minor variation . By the nature of their referral to Tier 2, the few applications that are referred to Tier 2 will take longer for a decision. The most notable increases in recent years were seen in the total times, which suggests that applicants are taking longer to respond to clarification requests, but perhaps not so long that the applications are withdrawn.

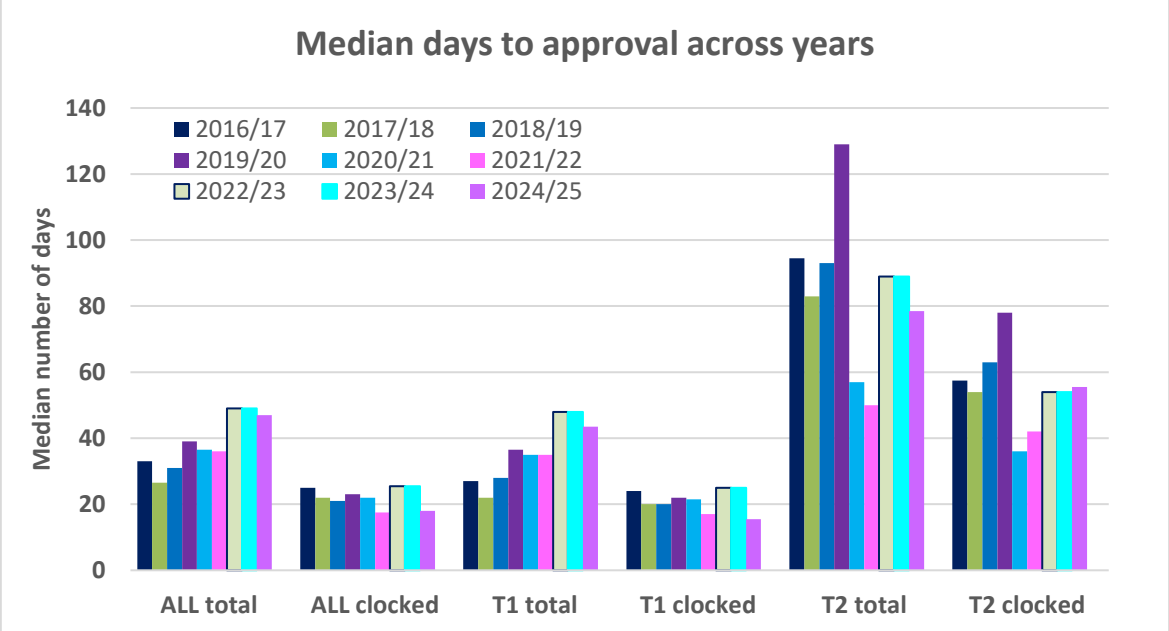

Figure 6: *Median times (days) to decisions at different levels of HSC-PBPP*

8. Dataset Requests

In 2024/25 due to a query from one of the NHSS board IG leads as to which datasets were requested for each application, this was included in the monthly reports from HSC-PBPP. For 2024/25 the requested datasets are grouped and summarised in table 5 with an explanation of the dataset groups below. The Scottish Morbidity Records (SMR) datasets are the most frequently requested datasets, followed by the NRS datasets (particularly deaths).

Dataset Groups	Total No. requests	Q1 (Apr-Jun)	Q2 Jul-Sept	Q3 Oct-Dec	Q4 Jan-Mar
Scottish Morbidity Records (SMRs)	**124**	41	25	29	29
Prescribing	**24**	7	6	6	5
Unscheduled Care	**35**	13	2	7	13
Scottish National Audit Programme	**30**	9	0	5	16
Screening Programmes	**6**	3	0	0	3
Cancer Datasets	**13**	11	2	0	0
Other PHS	**34**	10	9	7	8
Territorial Boards	**37**	7	8	9	13
NRS datasets	**54**	23	10	8	13

Table 5: *Datasets requested by quarter and totals.*

- ***SMRs***: records of patient contacts with secondary (hospital) care, including outpatients attendances, hospital admissions, maternity admissions, mental health admissions and the Cancer Registry.
- ***Prescribing***: primarily community prescribing through GPs.
- ***Unscheduled Care***: records of unexpected NHS contact by patients, including attendances at Accident & Emergency, attendance by the Scottish Ambulance Service, contact with NHS24, contacts with GP Out of Hours service.
- ***Scottish National Audit Programme***: these are datasets that are regularly audited and includes datasets such as Intensive Care records, Scottish Renal Registry, Scottish Stoke Care.
- ***Scottish Screening Programme***: datasets for Breast, Bowel and Cervical screening
- ***Cancer Datasets***: cancer datasets in addition to the Cancer Registry
- ***Other PHS***: PHS holds a lot of datasets to fulfil its specific purposes. These might be requested for specific research projects.
- ***NHS Territorial Boards***: Some applications request clinical data that can be obtained from the NHSS territorial boards, rather than the national datasets, as well as some national datasets for which the data controllers are the NHS territorial Boards.
- ***NRS Datasets***: PHS holds copies of a few datasets from NRS that are specifically health related (e.g. deaths, births, stillbirths). NRS is the data controller for the NHS Central Register.

9. Research Resources

9.1. Unconsented studies

Recently, various researchers have requested large amounts of NHSS data to set up a separate research resource that they can then use for a number of projects. As part of this, the researchers also requested the delegated approval to scrutinise other applications for the provision of the NHSS data for further research. Often these requests do not contain any clear or well-described processes as to who would do that scrutiny and how, and limited information governance considerations. From the researchers, the main argument for this was to request the same data for different but linked studies under an overall programme of work is repetitive and time- and labour-consuming.

HSC-PBPP is a governance structure but it is not a legal entity. It has delegated authority from the Chief Executives of NHSS Boards to scrutinise and approve/recommend approval for data to be disclosed. It also has delegated authority from the Registrar General of NRS for access to be made available to the NHSCR. If an application is approved by HSC-PBPP, individual NHSS Boards can still refuse to provide the relevant data to the applicant. This rarely happens as the NHSS boards are part and trust the HSC-PBPP process. Therefore, a decision of HSC-PBPP is *advisory* rather than binding on NHSS Boards. Therefore HSC-PBPP cannot delegate that authority any further to others outside NHS Scotland.

For programmes of work that request a large amount of unconsented data from the national datasets (primarily those held by PHS), HSC-PBPP has developed a process to set up a specific Research Resource in the National Safe Haven (NSH) for a specific programme of work, with an overarching application to set up the resource. This main application would cover most or all the legal and IG aspects of the study, under the responsibility of the main resource holder. Because much of the processing will be done in the same way, researchers wishing to use the data from such a resource, with the knowledge and support of the main resource holder, would be able to complete a partially completed 'call-off' application form and only be required to complete the aspects that are specific to the people and the particular research project covered in that application. The call-off applications should only need to be reviewed by Tier 1 and questions would be limited to the specifics of the project because the overall Research Resource had already been approved. This process was approved by the HSC-PBPP Committee and by March 2025 there were three Research Resources held in the NSH that had obtained approval from HSC-PBPP.

9.2. Consented studies

Over the years applications have been received from consented longitudinal cohorts, often limited to a specific geographical area and/or a specific time period (e.g. Aberdeen Children

of the Nineteen Fifties, Generation Scotland, UK Biobank), but are not population-wide studies. For such longitudinal consented studies, a group of people were specifically recruited to take part in a longitudinal research cohort. With full consent, the participants may have provided specific information to these studies in the form of questionnaires and possibly body measurements or samples (e.g. blood, saliva etc.), with the knowledge that the data and samples provided would be provided to researchers for use in research, through well-defined and clear processes. The data for these longitudinal consented studies are usually held within the applicant's organisation. As part of this process the participants provide consent for linkage of these data to their own medical records. For such studies the NHSS data was provided. The participants may also have given permission for their data to be provided to commercial or international organisations, which would apply to access to the data via the same process as those from academia.

UK Longitudinal Linkage Collaboration

In a further development to this process, an application was received by HSC-PBPP from the UK Longitudinal Linkage Collaboration. This comprises of several such consented longitudinal cohort studies, originally set up to follow participants over time, which have decided that they no longer wish to follow-up such participants as separate and independent studies but have been combined as the UK Longitudinal Linkage Collaboration UK LLC. The data from each of the cohorts sit on a trusted research environment platform at the University of Bristol, at the request of the longitudinal cohort owners and with the knowledge and consent of the individual participants. The request was that these data would then be linked with data from the NHSS national datasets with regular data updates and then be used in research. Data controllership remains with each of the longitudinal cohort studies. In 2024/25, this application was approved for those studies that already had HSC-PBPP approval and a mechanism put in place for adding those who did not already have HSC-PBPP approval. The NHSS Board IG Leads will be kept updated with the uses of the NHSS-linked cohort data from the UK LLC website.

10. Quality Improvement and Development

The HSC-PBPP has a duty to be accountable to the public and stakeholders and strives to continually improve its processes, so that applications are processed as efficiently and quickly as possible, whilst maintaining standards of governance. In addition to regular monitoring of processing times for applications, the HSC-PBPP also takes on board feedback and lessons learned from novel and complex applications; these are usually those that were reviewed by the Tier 2 full committee, especially if a precedent was set. Such information is recorded in a Policy Decisions and Case Law Principles document to enable consistent decision making.

10.1. Communication updates to NHSS Boards

The Adverse Event that took place in 2022/23 highlighted various aspects of HSC-PBPP, such as communication and risk-appetite between HSC-PBPP and the NHSS boards, which began to be addressed in 2023/24 and has continued into 2024/25.

To inform the IG leads that sit on Tier 1 panels of ongoing work and any new developments, the HSC-PBPPP manager has given regular updates at the NHS Scotland Information Governance or Data Protection Officer (DPO) Forums and the Caldicott Guardian Forums. These have been based on applications that had been reviewed by the panel and the challenges, implications and new ideas, or changes in procedure that had arisen from the review of a particular application. Not all IG leads that attend the IG / DPO Forums sit on HSC-PBPP panels and this has helped to widen the discussions with the NHSS boards.

10.2. Tier 1 Audit

Due to resignations from the HSC-PBPP Committee during the year, the Tier 1 Audit was postponed until 2025/26 when the Committee will be at full strength.

10.3. Access to data from GP practices

A number of preliminary discussions about access to data from GP practices for researchers have continued throughout 2024/25, particularly about the required governance process relating to access to these data. A separate GP Editorial Board was set up, consisting of GP representatives to review the use of patient health data from GP practices for all types of uses, including research. As some of these applications will also request data from the NHSS boards and will require HSC-PBPP scrutiny and approval, discussions have continued into 2024/25 as to how any new process will align with the HSC-PBPP approval processes. The HSC-PBPP Chair sits on the GP Editorial Board to promote reciprocal learning.

11. Annual HSC-PBPP Development Workshop 2024/25

In February 2025, a joint development day was held for Tier 1 and Tier 2 HSC-PBPP members and eDRIS at COSLA, in Edinburgh. As for the Development Day held in 2023/24, this was a hybrid meeting. Around 45 participants attended in person and approximately 30 attended online. The aim was to strengthen working relationships, to discuss issues that arise during the application reviews and try to find appropriate and pragmatic ways to address some of these challenges.

There were four sessions during the day:

- **Session 1** was a session to look back over the past year to look at some of the challenges that have been encountered over the past year or so. Some of the challenges include: applications which include artificial intelligence / machine learning (AI /ML); the increasing complexity of some applications; expectations of researchers; commercial aspects ; more non-standard applications.

- **Session 2** was a panel discussion looking at the different routes for access to NHS Scotland data: through eDRIS and HSC-PBPP, through the Regional Safe Haven Network and through the Researcher Access Service pathway provided by Research Data Scotland. With the setting up of the GP Editorial Board, there is a need to understand the different processes, where these overlap and how to prevent repetition.

- **Session 3** was a round-table discussion, with discussions at different tables in room and in breakout rooms for those online. There have been several applications for large datasets for complex studies, some using data for participants in consented cohorts and others requesting data for unconsented cohorts. Different Tables and breakout rooms were asked about permissions and review of such large data requests, the controls that should be in place and how international or commercial access changes the requests or should be taken into account in the review process.

- **Session 4** was a plenary from Professor Colin McCowan, from University of St. Andrews. He spoke about his work using NHS Scotland data for different studies, particularly concentrating on pregnancy, childbirth and family studies: (i) the use of data to identify the safest way for delivery of babies who are born early and with a breech (upside down) presentation; (ii) the use of data to look at the impact of mothers with several health conditions on the outcomes of their children at birth and as they grow; (iii) the linkage of mother/father/ child for projects where information about both parents around the time of conception is important for baby outcomes.

It was wonderful to see so many people attending and HSC-PBPP is grateful that so many gave up their time to attend and contribute to some very helpful discussions.

12. Priorities and Challenges for 2025/26

In a constantly changing data landscape with new demands and new technologies, there is always more things to develop. It is hoped that a number of tasks will be addressed in 2025/26:

i. Discussion raised at the Development Day regarding the Federated Governance model developed for the Regional Safe Havens for approvals of data provided for use in the Regional Safe Havens and how HSC-PBPP fits with that needs to be explored.

ii. There needs to be some conversations try to help develop guidance for applications that use or wish to develop models for AI / ML.

iii. At the end of March 2025, the idea of Data Licensing was raised as an alternative way for delegation of approval for the use of NHS Scotland Data. This would require a legally binding contract between the NHS Scotland boards (as data controllers) and the organisation that wishes to hold and allow data to be provided to others. The idea of data licensing and how this will be used within NHS Scotland needs to be explored.

13. Conclusion

From this report it can be seen that 2024/25 has built on and further developed some of the practices that were started in 2023/24. These processes will continue to be refined as the HSC-PBPP continues to operate to ensure the safe use of NHSS data for the benefit of the public in Scotland. This report reflects the volume and excellent quality of service and advice that was provided during what was a challenging period for the NHS.