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# NHS Scotland Public Benefit and Privacy Panel for Health and Social Care

## Annual Report 2017/18



# Executive Summary

## Background

This Annual Report reviews the operation of the NHS Scotland Public Benefit and Privacy Panel for Health and Social Care (PBPP) for the period 2017/2018. Created in May 2015, PBPP is an information governance (IG) structure of NHS Scotland that provides a central national IG scrutiny process focussed on requests for access to NHS Scotland-originated data for purposes other than direct care. Such purposes may include research or service planning.

## Structure

Support is provided to all applicants seeking access to data with applications scrutinised and determined either at fortnightly panels of NHS IG leads (Tier 1 decisions which carry lower levels of risk) or a regularly-convened subgroup of the Committee, where applications are of greater risk and require a higher level of consideration.

## Performance

Through this second full year of operation the performance of PBPP has continued to be good across a range of performance metrics. PBPP has built on the processes established in 2015/16 and 2016/17 giving an increasing and valuable consistency in the scrutiny procedures. Over 20 IG leads from the 14 territorial boards and 7 national boards within NHS Scotland, have been engaged in the process, thus embedding IG in the general operational approach of the NHS across Scotland.

During 2017-18, 136 applications were submitted to the PBPP, similar numbers to those submitted in 2016-17. These applications came mainly from academia (53%) and the NHS (38%) with the remainder from Scottish Government and commercial companies (less than 4%). The majority of these applications were initiated from within Scotland (79% in 2017/18 compared with 81% in 2016/17), with the others from the rest of the UK.

The median time to approval decreased in 2017/18, compared with 2016/17, by 3 days for clocked time and by 6.5 days for total time. The PBPP continues to work to improve the efficiency of the service in the interests of its stakeholders while maintaining its responsibility to preserve the security of the data it oversees.

## Development

During the year a revision of the PBPP scope was published aiming to improve understanding by potential applicants and other stakeholders of the process. This quickly indicates whether an application is necessary and will remain relevant over time.

A new "End of Project" reporting system was introduced in this year, as part of NHS Scotland Governance and monitoring. This requires the applicant to demonstrate that they have complied with the obligations outlined in their approval, including data archiving/destruction and submission of manuscripts for publication of results.

**“PBPP is a valuable single point of contact for IG issues in the NHS in Scotland, offers an efficient and improving process and is increasingly seen across the UK as a centre of excellence in the scrutiny of the requests of health data, safeguarding data while promoting its appropriate use to the benefit of all patients and carers.”**



# Future developments in 2019

Looking to 2018/19 PBPP must ensure that the right balance is struck between safeguarding the privacy of all people in Scotland and the benefit to all from improved treatment and care informed by high quality research. A communications strategy is planned for 2018/19, to make information about the PBPP more accessible to the public. This will include an update of the PBPP website, wider distribution of the PBPP Annual Report, and the development of an external PBPP training workshop, for potential applicants.

With an increasing public and professional awareness of IG and concerns about the importance of the protection of personal data, PBPP has developed an ambitious set of aims and priorities for 2018/19. In the coming year it will build on the success of the initial two years of operation while developing important new work streams around the awareness of its work. PBPP is a valuable single point of contact for IG issues in the NHS in Scotland, offers an efficient and improving process and is increasingly seen across the UK as a centre of excellence in the scrutiny of the requests of health data, safeguarding data while promoting its appropriate use to the benefit of all patients and carers.



# Chair's introduction

**NHS Scotland is a world leader in capturing, storing and maximising data on the health of millions of people, providing an exceptional opportunity for large scale research projects, quality improvement and patient-care audits to be undertaken. Through the development of world-leading proportionate governance criteria, the Public Benefit and Privacy Panel for Health and Social Care (PBPP) supports a transformational information governance structure. This enables NHS Scotland to conduct and contribute to the investigation and understanding of the health of its population, through the safe and trusted use of patient data.**

In its second full year, the PBPP has built on and consolidated the processes that were established in 2016/17. This has led to consistency in the scrutiny procedures, which are the mainstay of the panel's work. PBPP has continued to involve the Information Governance Leads across the different NHS Scotland Health Boards, thus ensuring that the PBPP process is a truly national endeavour and not limited to select individuals within specific Health Boards. Up to the end of March 2018, the PBPP has approved over 300 applications, showing that the demand remains high for using health data. The change in sources of applications during 2017/18, with an increase in number of applications from the NHS and Scottish Government, shows that the use of health data is not only important for academic research, but also for audit and service-improvement purposes and supports the ongoing commitment of the NHS in Scotland to develop and expand its services as required.

This annual report demonstrates some of the activities in which PBPP members have been engaged over the past year. This work showcases the PBPP as a centre of excellence for privacy, confidentiality, and information governance expertise in relation to health data in Scotland. It highlights the PBPP's objective to connect the many strands of relevant governance activity, and the need to react quickly to the changing landscape regarding public interest and benefit. While the PBPP continues in its role, there is always room for improvement and the priorities for 2018/19 show that the PBPP will continue to develop its procedures to improve efficiency, while maintaining integrity.

The PBPP will continue to work to effectively to maximise the value of Scotland's health data, while managing emerging information risks, addressing public concern around privacy, and promoting the protection of privacy as in the public interest. The PBPP supports the development of innovative information governance streams and look forward to being able to contribute to the development of the new Digital Health & Care Strategy. 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.

**Brian Houston**  
Chair of PBPP Committee





# Purpose of the Public Benefit and Privacy Panel for Health and Social Care

**The Public Benefit and Privacy Panel for Health and Social Care (PBPP) is an information governance structure of NHS Scotland that exercises delegated decision-making on behalf of NHS Scotland Chief Executive Officers and the Registrar General.**

The PBPP operates as a centre of excellence for privacy, confidentiality and information governance (IG) in relation to Health and Social Care in Scotland, providing strategic leadership and direction in this area to NHS Scotland Boards, the research community, and wider stakeholder groups.

## The panel:

- Streamlines the previous governance processes for the scrutiny of requests for access to NHS Scotland originated data for purposes other than direct care, e.g. audit, service-improvement, research, or health and social care planning;
- Provides robust, transparent, consistent, appropriate and proportionate information governance scrutiny of such requests;
- Further strengthens the direct involvement of members of the public in the scrutiny process and decision making regarding access to NHS Scotland-originated data.

Since its inception in May 2015, the PBPP has provided a centralised, simplified and national Information Governance scrutiny process. It has successfully harnessed expertise across NHS Scotland health boards implementing a collaborative approach which contributes to consistency and continued capacity development across the sector. This is the report of our second full year of operation.

## Structure of the PBPP

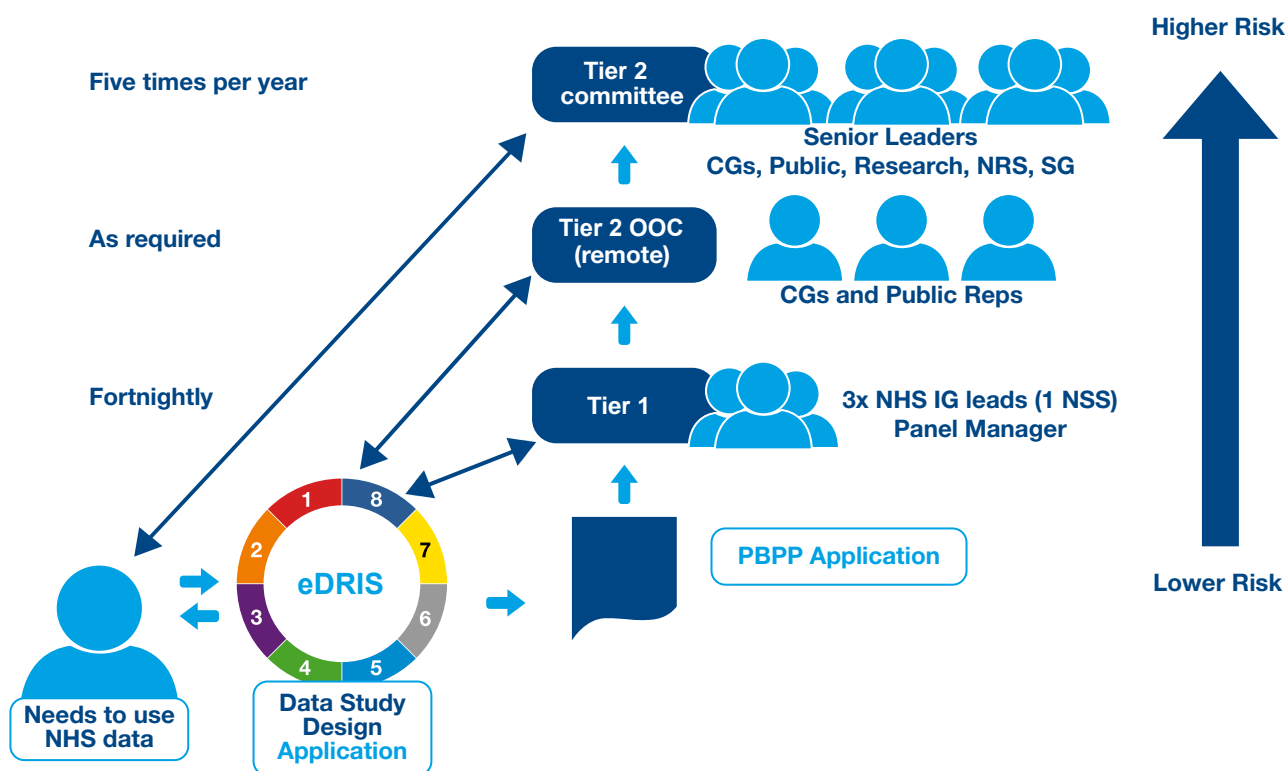
The PBPP structure and process is summarised in the flow diagram shown in Figure 1. There is a single entry point for all applications to PBPP, via the eData Research and Innovation Service Team (eDRIS). This helps to maintain consistency of advice for all applicants, including those from NHS services or Scottish Government for core business, as well as those wishing to use NHS data for research.

The eDRIS team provides support to all applicants applying to PBPP. They do this by providing a Research Coordinator to facilitate researchers to refine their data linkage projects and/or review and assist applicants to finalise applications for submission. The eDRIS team works closely alongside the PBPP. Through shared learning between the two teams, this helps to ensure that applications are fit for submission, thus making the PBPP review process as efficient as possible for both applicant and reviewer.

The PBPP operates on a two-tier structure (see figure 1).

### Tier 1

**Tier 1 is the first level of scrutiny of applications, acting at an operational level, meeting every 2 weeks. Facilitated by the Panel Manager, each panel comprises of specialist Information Governance (IG) practitioners from across the NHS Boards. Applications are reviewed according to agreed proportionate governance criteria. The Tier 1 scrutiny examines the technical and IG aspects of an application and takes place at a Tier 1 panel meeting. If the Tier 1 panel is satisfied that the public benefit of the proposal is clear and that all privacy risks will be managed appropriately and securely, the application is approved. There may be an exchange of questions seeking clarification before the approval or another outcome is 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 at Tier 2 Out Of Committee (OOC) by a subgroup of the full committee.**



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

**CG:** Caldicott Guardian

**NRS:** National Records of Scotland

**SG:** Scottish Government

**OOC:** Out of Committee

**IG** Information Governance

**NSS:** NHS National Services Scotland

## Tier 2

Tier 2 comprises a regularly convened strategic Full Committee, and a smaller subgroup of this working as 'Out Of Committee'. The latter comprises of the Caldicott Guardians and public representatives from the Full Committee. Applications referred from Tier 1 are reviewed by the Tier 2 Out of Committee. Most applications referred to Tier 2 are approved at this level, with only a minority referred on to Full Committee. When applications are referred to the Full Committee, the applicant is invited to attend to answer questions and inform the discussion.

The Full Committee provides the intellectual space for senior leaders, Caldicott Guardians, researchers and public representatives to consider the wider privacy issues in regard to particularly contentious or novel cases and applications that would set precedence or proposed policies in the Scottish Government and/or NHS Scotland 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.

# PBPP Committee Membership 2017–18

**Brian Houston (Chair)**

**Dr Emilia Crichton (NHS Caldicott Guardian)**

**Dr George Fernie (NHS Caldicott Guardian)**

**Professor Alison McCallum (NHS Caldicott Guardian)**

**Dr Janet Murray (NHS Caldicott Guardian)**

**Professor Abbe Brown (Public Representative)**

**Dr Angus Ferguson (Public Representative)**

**Kenneth McLean (Public Representative)**

**Professor Daniel McQueen (Public Representative)**

**Dr Corri Black (Research Community Representative)**

**Professor Helen Colhoun (Research Community Representative)**

**David Knowles (CHI Advisory Group representative)**

**Dr Steve Pavis (NSS IG/Informatics Data Linkage Lead Specialist)**

**Stuart Law (NRS Representative)**

The following members of the committee resigned during 2017–18:

**Mr Gerry Donnelly (NRS Representative)**

**Dr Hugo van Woerden (NHS Caldicott Guardian)**

During the year 2017/18, the Scottish Government representative role remained vacant.

# Application review processes and meetings of the PBPP

## Tier 1

The Tier 1 Panel met fortnightly at central locations in Edinburgh and Glasgow during 2017/18. Each panel comprised of three IG Leads/Managers from different NHS Boards, on rotation, and the PBPP Panel Manager. The IG leads were drawn from the regional health boards around Scotland, as well from the national NHS boards. The panel members considered each application against a set of proportionate governance questions and criteria. Up to five applications and two amendments were considered at any one meeting. In 2017/18 over 20 IG practitioners from across NHS Scotland participated in the Tier 1 PBPP scrutiny process.

The PBPP would like to acknowledge and thank the Tier 1 panellists for all their hard work in making the scrutiny process possible.

## Tier 2 Out of Committee

The Tier 2 Out of Committee (OOC) group convened as required to consider applications referred up from Tier 1. A committee subgroup of NHS Caldicott Guardians and Public Representatives undertook these reviews. During 2017/18, 18 applications were scrutinised and approved by the Tier 2 OOC and a further 4 applications were referred on to the Full Committee.

## Tier 2 Full Committee

**In 2017-18 the Full Committee met on five occasions:**

Full Committee Meeting	<b>Tuesday 18th April 2017</b>
Full Committee Meeting	<b>Tuesday 27th June 2017</b>
Full Committee Meeting	<b>Wednesday 13th September 2017</b>
Full Committee Meeting	<b>Thursday 5th October 2017</b>
Full Committee Meeting	<b>Wednesday 24th January 2018</b>

Minutes of these meetings are available on the PBPP website:

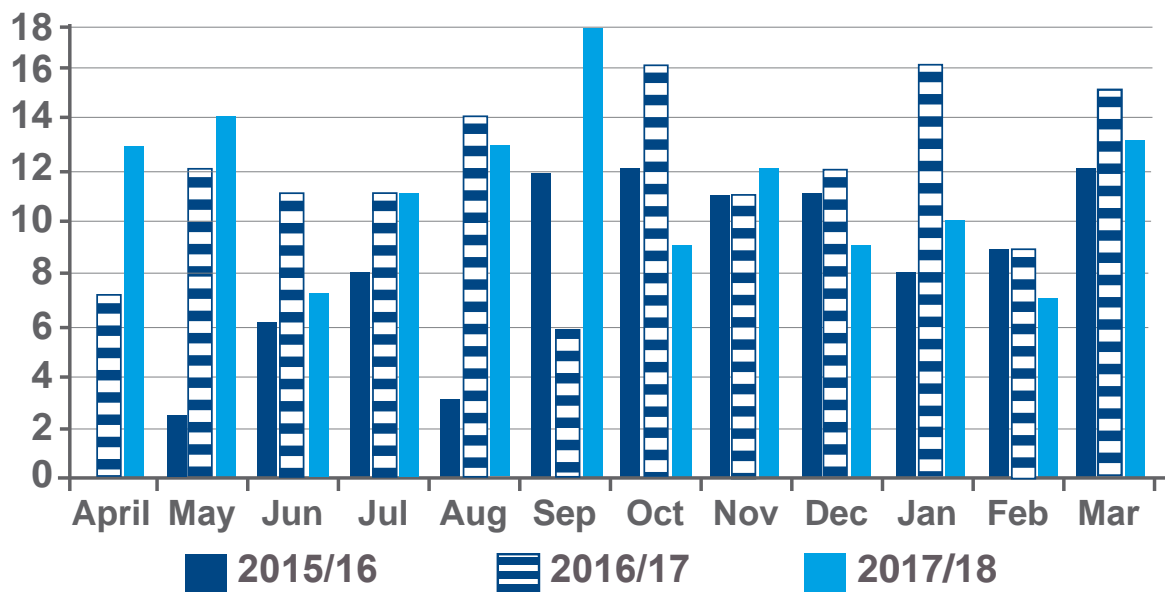
<http://www.informationgovernance.scot.nhs.uk/pbphsc/application-outcomes/>

## Application Submissions

During 2017-18, 136 applications were submitted to the PBPP. This is similar to that submitted in 2016-17 (n=140). From Figure 2, it is clear the timing of submissions fluctuates throughout the year, but with no specific pattern. The PBPP monitors these peaks in submissions and arranges Tier 1 panel meetings to accommodate these where possible.

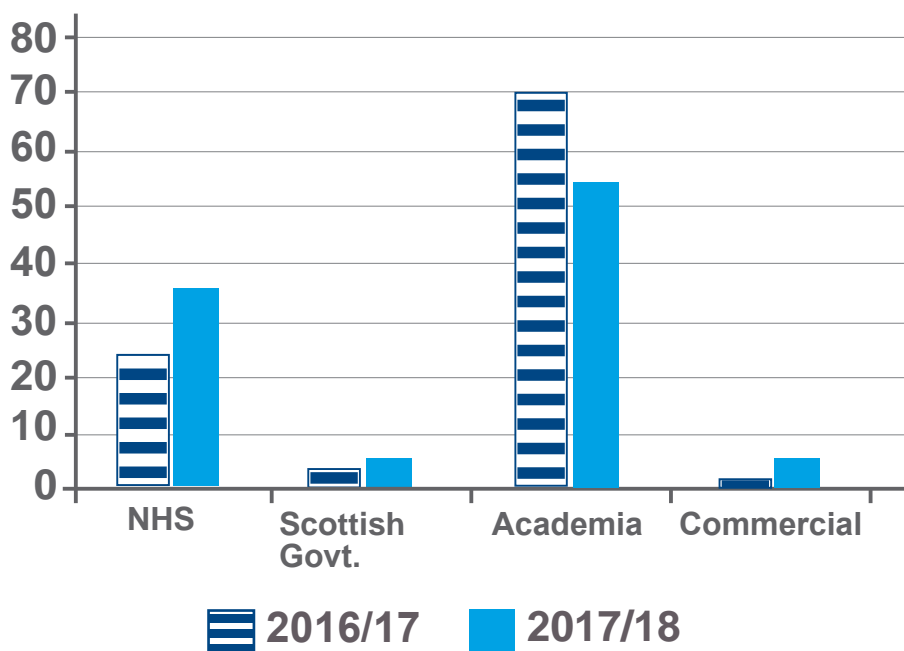


## Application Submissions



**Figure 2:** Numbers of applications submitted to the PBPP during 2017-18 (light blue) compared with 2016/17 (blue and white stripes) and 2015/16 (dark blue)

## Sources of PBPP applications



**Figure 3:** Sources of applications to the PBPP in 2016/17 compared with 2017/18.

The sources of applications are shown in figure 3 for 2017/18 (light blue) compared with 2016/17 (blue and white stripes). Figure 3, shows that in 2016/17 the majority (70%) of applications came from academia, 26% from NHS, 3.5% from Scottish Government and less than 1% from commercial companies. In 2017/18 the proportion of applications from the NHS increased to 38%, with 5% from Scottish Government, while 53% came from academia and 4% from commercial companies.

The majority of these applications were initiated from within Scotland (79% in 2017/18 compared with 81% in 2016/17), with the others from the rest of the UK.

# Types of Applications

Applications for different types of studies were submitted and reviewed in 2017/18, reflecting the variety of research and service assessment that used NHS Scotland data for the benefit of the public. The different types of study are:

- Local and national audits assessed the outcomes and needs of different conditions or procedures.
- NHS Scotland data were used to investigate the long-term outcomes of a number of Clinical Trials.
- Various epidemiological studies investigated the risk or environmental factors on the patterns of disease incidence or health outcomes.
- Longitudinal studies of specific cohorts used NHS Scotland data to look for patterns in disease onset, processes and responses to interventions; in particular there were a few studies that were following up radiation workers exposed to radiation and their long-term health outcomes.
- Scottish Government surveys used NHS Scotland information to understand how patients used and felt during their use of cancer, maternity or emergency services, so this information can be used to improve service planning and improve the patient experience.
- Other studies used NHS Scotland data for NHS service planning and improvement, for assessing the cost-effectiveness of specific interventions, or the interactions of social and environmental factors on health outcomes.

A list of the approved application titles is available on the PBPP website:

<https://www.informationgovernance.scot.nhs.uk/pbpphsc/application-outcomes/>

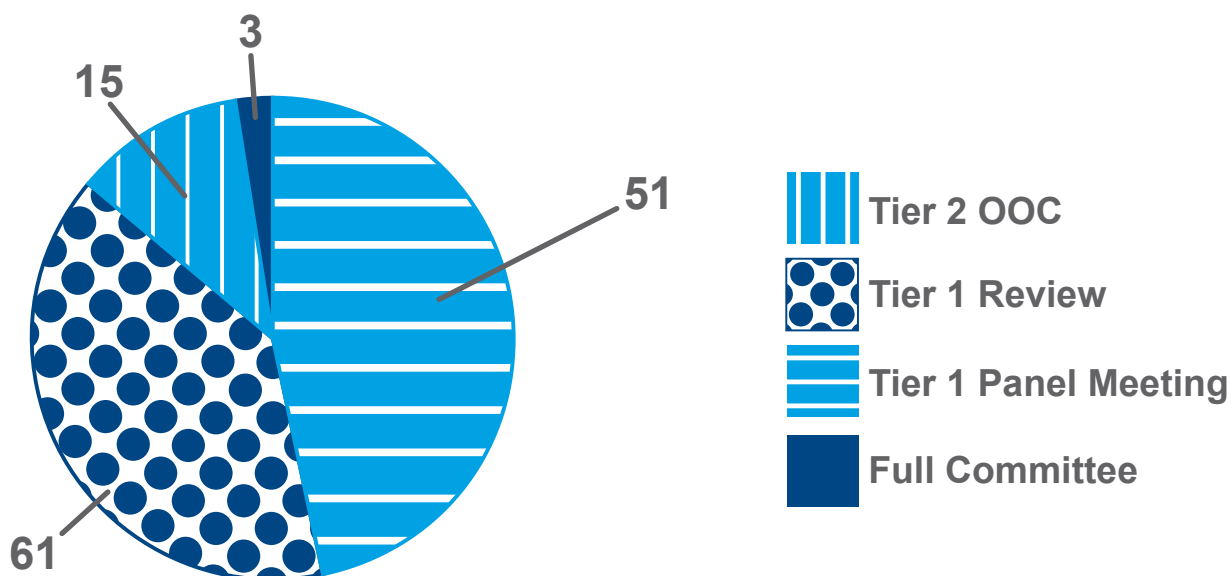


# Application outcomes

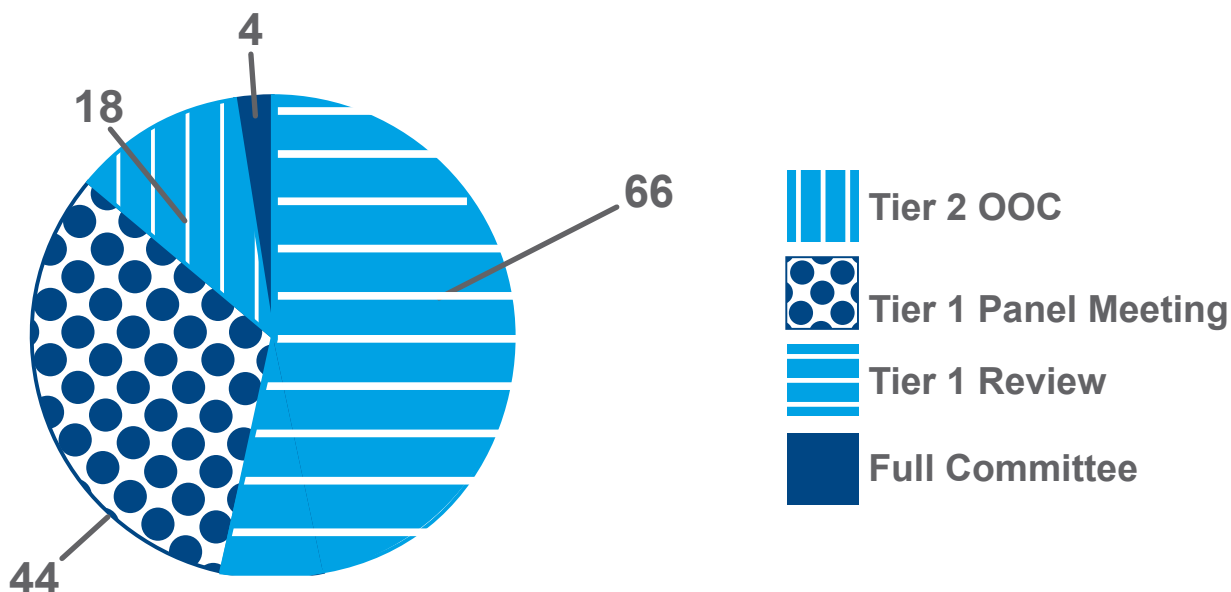
During 2017-18, following the scrutiny process, 132 applications were approved by the PBPP. Of these, 22 approvals were for applications that had been submitted during late 2016/17 and had not completed the scrutiny process before the end of the year and 110 were those submitted during 2017/18.

Of the 136 submitted during 2017/18, 110 were approved in 2017/18, while 17 were carried over to 2018/19, six were withdrawn and three were not approved. The number of approved applications is similar to the number approved in 2016-17 (n=130). The levels at which these applications were approved (tier 1 or tier 2) are shown in figure 4. Of the approved applications, 74 were “Approved with conditions”, whereby the application was approved subject to specific conditions which the applicant had to fulfil, usually before the project could start.

## PBPP Approvals 2016/17



## PBPP Approvals 2017/18



**Figure 4:** Level of approval by PBPP of applications during 2017/18 (A) compared with that in 2016/17 (B).



From figure 4 it can be seen that:

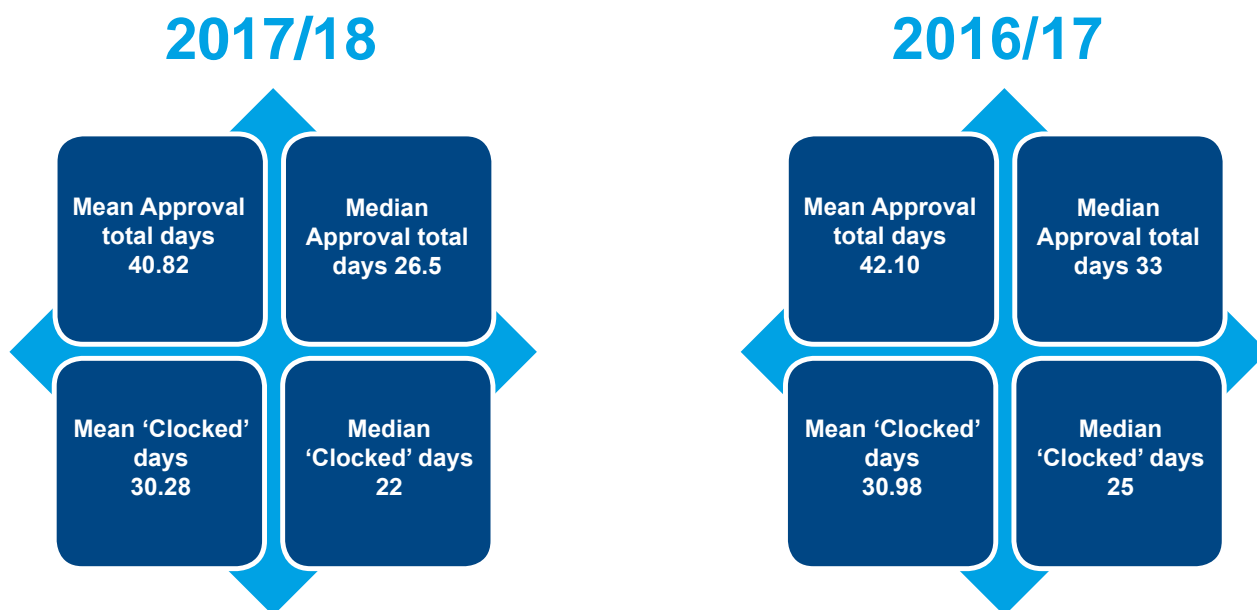
- The majority of applications were approved either at a Tier 1 Panel Meeting or shortly afterwards, following clarification sought from the applicant (Tier 1 Review). During 2017/18, 110 applications (83%) were approved at Tier 1, similar to that in 2016/17 (n=112, 86% applications).
- For 2017/18, 22 applications (17%) were approved at Tier 2 level; again this is similar to that in 2016/17 (n=18, 14% applications). These were applications assessed by Tier 1, and referred to the Tier 2 Out of Committee for further scrutiny as they were deemed to be of higher risk under the proportionate governance criteria.
- Only a small number of applications were further escalated to the Full Committee (n=4 in 2017/18 compared with n=3 in 2016/17); these were usually highly complex or novel proposals.

## Time to approvals

The PBPP measures two time-periods for approvals to review its efficiency and processing times:

- The number of 'clocked' days: this is the time the application is being processed by the PBPP. The time for the applicant to respond to any queries regarding the application is not included.
- The total number of 'calendar' days from submission until the final decision is made, which includes any time spent back with the applicant.

The mean and median days to approval for both clocked days and total days are shown in figure 5 for 2017/18 (left) compared with 2016/17 (right).



**Figure 5:** Numbers of days to approval for 2017/18 compared with 2016/17. The mean and median times for clocked and total times are presented.

From figure 5 it can be seen that the median time to approval decreased in 2017/18 compared with 2016/17 by 3 days for clocked time and by 6.5 days for total time, although the mean time did not change. Both the mean and median are shown, as the mean may be affected by any outliers in the length of time to approval. The median provides an idea of the middle point in the entire time range of all applications reviewed by the PBPP. The PBPP continues to endeavour to improve the efficiency of the service.

# Audit of Tier 1 review processes

The PBPP has a duty to the public to identify and support public benefit in the use of NHS Scotland data. In 2016/17 an auditing process was introduced with the purpose of reviewing the decisions made regarding applications to the PBPP. For this process, a set of applications were chosen at random to be reviewed by the Tier 2 Out of Committee to consider whether these were reviewed and approved appropriately using the proportionate governance criteria by Tier 1, or whether they should have been referred to Tier 2 for further scrutiny. The process from 2016/17 raised a number of recommendations to strengthen the application process. A copy of the report on the audit process, findings and recommendations is available on the PBPP website.

<http://www.informationgovernance.scot.nhs.uk/pbpphsc/application-outcomes/>

Due to the success of this audit process, it was repeated in 2017/18. The results and feedback was considered as part of the Annual PBPP training day in September 2018.

## Performance Monitoring

The PBPP has a duty to be accountable to the public and stakeholders and strives to improve its processes continuously, so that applications are processed as efficiently and quickly as possible, whilst maintaining standards of governance. In addition to regular monitoring of processing times of applications the PBPP also takes on board lessons learned from novel, complex or commonly sighted applications often recording Policy Decisions and Case Law Principles to enable consistent decision making at both Tiers.

## Annual PBPP Workshop 2017

After the successful training workshop in 2016, this was repeated on 3rd October 2017, again at Strathclyde University. The workshop has become an annual event, where delegates from Tier 1 and 2 panels and the eDRIS team come together to review processes, exchange ideas and listen to invited guests talk about future developments in the NHS.

This 2017 workshop programme included presentations on Scotland's Safe Havens (secure data repositories and analytical platforms run as a partnership between the NHS and Universities), and the PBPP from an applicant's perspective. Future developments included the possibilities of using Genomic Biobanks, eHealth Data and Synthetic Data, with respect to the opportunities and challenges these present, both to the data and research communities and to PBPP when such applications are received in the future.



## Resourcing the PBPP

The Panel is managed centrally from NHS NSS by the Panel Manager (fully funded by Scottish Government) and a Panel Administrator (part-funded by NHS NSS). The Tier 1 Panels are resourced by NHS IG Practitioner staff whose time is provided by the NHS Health Boards at the request of the Scottish Government. The Tier 2 Panel members contribute their time voluntarily, which is not formally committed by any organisation. All members are entitled to reimbursement of expenses for travel to and from meetings or PBPP events, reimbursed by the Scottish Government.

## Operational Group

The Operational Group was established in 2016 and has continued its work during 2017/18. The Operational Group focuses on the development of PBPP processes, public engagement and support for the PBPP management team. Members of this group include the Panel Manager, an eDRIS representative, a Privacy Advisor, two Information Governance leads, a Caldicott Guardian and a representative from NHSCR. Some key areas that the group worked on throughout the year were:

- To publish a clearly defined scope which can be easily understood by potential applicants and other stakeholders, which quickly and easily indicates whether an application is necessary or otherwise, and which remains relevant over time;
- Processes for recruiting panel members;
- Becoming GDPR-ready. In May 2018 the new General Data Protection Regulation (GDPR) and its related Data Protection Act 2018 came into force across the UK. In preparation for this, all the PBPP paperwork, including the application form, guidance notes and all paperwork involved in the approval process, had to be reviewed and updated, to ensure compliance with the new legislation.

## Achievements for 2017-18

### PBPP Resourcing

The PBPP strives to provide leadership across a range of complex privacy and information governance issues. This has to be achieved while managing emerging information risks, addressing public concern around privacy, and promoting the protection of privacy as being in the public interest. During 2017/18 we achieved a better balance of public representatives, information governance experts and senior academics for the Tier1 and Tier 2 panels. In addition, the Scottish Government agreed to increase the resources for the administration and support management of the PBPP and nominated a Scottish Government Information Governance Lead for the Full Committee.

### Scope /Jurisdiction

The PBPP published a revision of their scope for ease and understanding by potential applicants and other stakeholders, which quickly and easily indicates whether an application is necessary or otherwise, and which remains relevant over time.

### End of Project reporting

The PBPP introduced a new End of Project Reporting system. As part of NHS Scotland Governance and monitoring we require the applicant to complete an End of Project Reporting form to demonstrate that the applicant has complied with the obligations outlined in their approval, including data archiving/destruction and submission of manuscripts for publication of results.



# Priorities for 2018/2019

## Training and Communications

**The PBPP acknowledges that transparency in decisions made to access NHS Scotland data is vital in order to protect the rights of participants and patients. The PBPP must ensure that the right balance is struck between safeguarding the privacy of all people in Scotland and the benefit to patients from improved outcomes and care informed by high quality research.**

To help achieve this aim, the development of a communications strategy is planned for 2018/19, to make information about the PBPP more accessible to the public. This will include:

- Review and redesign of the PBPP website;
- Wider distribution of the PBPP Annual Report;
- Development of an external PBPP training workshop, for potential applicants, with the investigation of the practicality of whether it could be combined with information sessions covering the processes for obtaining ethical opinion.

## Partnership with other UK Governance bodies

**The PBPP is committed to working with governance partners across the UK in order to streamline the approvals process for those seeking access to health and social care data and to make the whole process across the UK as smooth as possible.**

To achieve this aim, the PBPP will seek to strengthen collaborative relationships across the UK to sustain and develop information-sharing and to promote the UK as a centre of excellence for research. This will include strengthening our contacts with other approval bodies:

- Acting in an advisory capacity to the Human Fertility and Embryology Authority (HFEA) to scrutinise applications from Scottish applicants using HFEA and/or NHS Scotland data;
- Collaboration with NHS Digital (England) to streamline information governance processes for applications that require access to data from the whole of the UK;
- Exploring the possibility, and practicalities, of incorporating the PBPP application process into the Integrated Research Application System (IRAS), provided by the Health Research Authority. This is currently used for the approval processes for all research projects involving patients and seeking both NHS Ethics and NHS R&D permissions. Addition of the PBPP process for research applications would reduce a layer of complexity currently seen for the approvals processes required for research, requiring data from across the UK.



# Scottish Government Digital Health and Care Strategy

**In 2017, the Scottish Government launched its Digital Health and Care Strategy for Scotland. This will focus on person-centred health and social care is at the heart of the strategic agenda in Scotland. A new, integrated Digital Health and Social Care Strategy is being developed that will build on achievements to date and set out future development and priorities.**

As part of this strategy, the Information Governance processes across NHS Scotland and use of data will be reviewed, including those of the Public Benefits and Privacy Panel for Health and Social Care. The aim of this review is to ensure that health and social care information is available to patients and their health and social carers when it is required. At the same time, it is imperative that such personal information is handled appropriately, safely, securely and in an approved and controlled way.

The aim is that by 2020, clear arrangements will be in place to deliver a simplified and consistent national approach for information governance, that will take into account the different needs of users and citizens and provide clarity around information sharing across health and social care,

Further details are available on the Scottish Government website: <https://www.digihealthcare.scot/home/news-and-events/scotlands-new-digital-health-and-care-strategy-published/>

## Conclusion

From this report it can be seen that 2017/18 has been a year where the PBPP has consolidated and built on the processes established in the previous 18 months, since its inception. Such processes will be further developed and refined, with the potential for addition of new procedures as the PBPP continues to progress in the fast-changing world of Information Governance and the increased use of NHS Scotland data for the benefit of the public in Scotland.

## Quotes

**Tier 1 member: I think the standard of information governance within NHS Scotland has improved because of PBPP. IG Leads from different boards meet at panel meetings and have the opportunity to compare notes and address issues from different applications. I always go away having learned something new.**

**Applicant: One of the most critical steps in this application process was ensuring open communication with the eDRIS Research Coordinator to ensure that we were able to provide the appropriate information in our responses to the panel's queries.**