Quick Guide to NHS Scotland Data for Research and Innovation

CANCER INNOVATION CHALLENGE

What data sets are available?	National whole population administrative data e.g. Cancer registry, prescription data	Clinical data (diagnostic/treatment)	Primary care data
Where are they held?	NHS National Services Scotland	Territorial health boards	Individual GP practices
Who gives permission for access?	Public Benefit and Privacy Panel (PBPP)	•Single Health Board - the relevant Board's Caldicott Guardian •Mulitple health boards - PBPP	Individual GPpractices
How can the data be accessed?	Approved Safe Havens - Remote access via secure VPN - Terminal in Safe Haven	Approved Safe Havens - Remote access via secure VPN - Terminal in Safe Haven	Approved Safe Haven or other method determined by GP

Who can access NHS Scotland data for research and innovation?

The PBPP will only grant direct access to patient level data (including de-identified patient data) to Approved Researchers.

Approved Researchers need to be employed by an Approved Institution (i.e. Universities, NHS, Local Authorities, Scottish Government)

Private sector organisations MUST partner with an Approved Institution

Open Source Data

Open source data sets are also available from the NHS National Services Scotland (NSS) for research and innovation. These include:

Prescribing data - Available from ISD (Information Services Division of NSS)
Various ISD statistics - Available from Statistics.gov.scot
Various sets (lacking meta-data) - Available from the USmart platform

Further information

Where are the data held?

NHS Scotland holds data in three key locations:

- National Services Scotland (NSS) curate whole population national datasets – primarily Scottish Morbidity Recording data (SMR), prescribing, and birth/death information (held in agreement with National Records Scotland);
- Territorial health boards hold patient level clinical data (diagnostic and treatment);
- General Practice primary care data are held by individual practitioners.

Who gives permission to access data?

The Public Benefit and Privacy Panel (PBPP) has devolved authority from NHS Scotland Chief Executives to grant access to data held by National Services Scotland and territorial health boards. In practice the PBPP considers applications for access to national level datasets and/or data from multiple health boards. Please note that it is still important that discussions are held with data providers to determine if the data required can be physically provisioned.

Permission to access data from a single health board is via the approval of the board's Caldicott Guardian (further information about the role of the Caldicott Guardian in Scotland can be found http://www.gov.scot/Publications/2011/01/31115153/0) .

General practices grant permission to access primary care data on a practice-by-practice basis.

Further information about the Information governance process for NHS Scotland data and the application form for the PBPP is available at the following link:
http://www.informationgovernance.scot.nhs.uk/pbpphsc/

The PBPP will only accept applications that have been reviewed by the eDRIS team http://www.isdscotland.org/Products-and-Services/EDRIS/. This team have a great deal of experience in submitting applications and seek to help researchers avoid common information governance pitfalls. This process aims to ensure that applications have a high chance of success and are processed by the panel as quickly and efficiently as possible.

Who can access data?

The PBPP will only grant direct access to patient level data to Approved Researchers. The criteria for becoming an approved researcher can be found at http://www.isdscotland.org/Products-and-Services/EDRIS/FAQ-eDRIS/. Further information about eDRIS is detailed at the end of the document.

It is important to note that one of the criteria involves being employed by an Approved Institution and these are currently public sector organisations (ie Universities, NHS, Local Authorities and Scottish Government).

Private sector organisations who wish to work with NHS Scotland data are asked to partner with a public sector organisation (ie an Approved Institution). Normal practice involves agreeing the project objectives and creating project governance mechanisms that include input from the NHS or a university or local authority or Scottish Government. In terms of undertaking data analysis there are two options:

a) the private sector organisation may be able to agree a partnership with a public sector organisation that involves securing an honorary contract for their employee with the public sector organisation. Thereafter the private sector employee would be able to achieve direct access to de-identified data via their honorary contract with the public sector organisation.
b) a private sector company can ask an Approved Researcher (ie a public sector employee to run analysis on their behalf) to undertake analysis/run algorithms on their behalf.

Private sector partners are free to review analytic outputs after statistical disclosure control – this process seeks to protect the privacy of NHS Scotland patients http://www.isdscotland.org/About-ISD/About-Our-Statistics/.

How are data accessed?

The Scottish Government eHealth Division have introduced a system of Accredited Safe Havens and it is normal practice for data to be held within these secure computing environments. There is a National Safe Haven located in Edinburgh and regional safe havens located in Aberdeen, Dundee and Glasgow. For the majority of projects data access is achieved remotely via a secure VPN. However, when data are particularly sensitive the PBPP or data controller may decide that access can only take place from a terminal within a Safe Haven. As standard the Safe Havens provide multiple statistical packages ie R, STATA, SAS and SPSS. However, other packages may also be approved and installed following discussions with the Safe Haven IT team. Machine learning approaches are supported by the National Safe Haven.

It is possible to apply to the PBPP for data to be held outwith the Scottish Approved Safe Haven network. However, this will involve providing proof that the proposed environment is secure and that access to the data is securely managed.

What data are available?

The following links provide catalogues of national datasets that exist within Scotland

http://www.ndc.scot.nhs.uk/Data-Dictionary/SMR-Datasets/

http://www.adls.ac.uk/find-administrative-data/

Key Scottish Government policy documents

Safe Haven charter for Scotland http://www.gov.scot/Publications/2015/11/4783/4

Open Source Data

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Various sets (lacking meta-data) - Available from the USmart platform (made available for Future Health Product Forge in January 2017)

ELECTRONIC DATA RESEARCH AND INNOVATION SERVICE (eDRIS)

A SHORT GUIDE

BACKGROUND

The eDRIS service is designed to provide a single point of contact to assist researchers in study design, approvals and data access in a secure environment. eDRIS operate a triage system where you will be asked to complete an initial enquiry form and be sent this guide.

Before you can be given access to data, you need appropriate permissions from data controllers. The Public Benefit and Privacy Panel for Health and Social Care (PBPP) gives permission for use of the national NHS Scotland Datasets, access to locally held NHS Scotland data from more than one board and by agreement with National Records Scotland (NRS) Births, Deaths and Marriages.

eDRIS offer assistance with applications to PBPP and other permissions, advice on coding, liaise with data suppliers, support Safe Haven access and can carry out bespoke analyses on your behalf.

There is a charge for applications which require eDRIS to provision data. Initial quotes e.g. for use in funding applications can be generated based on your responses to the initial enquiry form. The quote will be revisited when your PBPP application is approved and adjusted to reflect any changes in scope.

eDRIS aim to identify as soon as possible whether they will be able to support your enquiry or not. If eDRIS can assist, a Research Co-ordinator will be allocated to work with you. This may take some time depending on how busy the service is. More information on the eDRIS service is available.

OTHER PERMISSIONS

Ethical approval

Is required for all research studies unless the following conditions are met. The research:

- is only using de-identified data provided and controlled by NHS National Services Scotland;
- does not involve any contact with research participants/subjects;
- has undergone scientific peer review;
- data are held in and accessed via the National Safe Haven

NHS Research &Development (R&D) approval

If your research involves the use of any resources from a territorial health board then R&D approvals may be required and you should approach local R&D for confirmation. If your study only requires data held at national level by NHS National Services Scotland then R&D approval from your local health board is not required.

SAFE HAVENS

Researchers are encouraged to use an approved Safe Haven for analysis of linked data. You can access the national Safe Haven remotely from within the UK and the European Economic Activity Area. The following software is provided R, R Studio, Stat and 7Zip. For any other software, the national Safe Haven operates a "Bring Your Own Licence" policy. There is no charge for your time in the national Safe Haven beyond set up and support.

Generally speaking only high level aggregate results can be taken out of the Safe Haven; they will be subject to our Disclosure Control Policy - details are contained in the eDRIS User Agreement which you and your organisation will be asked to sign.

APPLICATIONS TO PBPP – A QUICK GUIDE TO COMPLETION

Section 1.1 – 1.4 Everyone named in these sections **must** have undertaken approved training in Information Governance within the past 3 years **prior** to the PBPP being submitted and belong to an Approved Organisation

Section 2 Enter an organisation's name to find its Data Protection Registration Number.

Section 3.1.07 and 3.1.08 Focus on clearly and concisely explaining the proposal background (3.1.07) and proposal design (3.1.08). Please structure using the headings indicated on the form in language that is understandable to a lay person. This is your opportunity to sell your study and its benefits! Completion of our initial enquiry form should help you answer these sections.

Section 3.4.02 Demonstrate that you understand why you are citing the particular conditions of Schedule 2 and 3 of the DPA.

Section 3.4.04 Consider the PIA screening questions on Page 33 of the "Conducting PIAs code of practice" available on this link https://ico.org.uk/for-organisations/guide-to-data-protection/privacy-by-design/ Complete a PIA if you answer yes to any question.

Section 4 Use these data resources to understand more about the national NHS datasets and fields that are available.

Section 5 If you are using an approved Safe Haven some sub sections do not need to be completed. If you wish data to be returned to you then you will need to complete all of Section 5. Please engage with your IT department for assistance with supplying relevant policies and cite appropriate sections of each as supporting documents.

Section 7 Ensure all supporting documents are clearly named, supplied in .pdf format and referenced in your application e.g.

1617-0001 - Brown – 1 – Study Protocol
1617-0001 – Brown – 2 – Patient Information Leaflet

Using the above will help reduce the timescales to create an application of a good standard which will minimise the number of queries from the Panel and need for potential amendments to your submission.

PBPP APPLICATION DEADLINES

The PBPP website gives details of deadlines for submissions to a particular Panel meeting. However, it is **currently not realistic** to assume that meeting the deadline will guarantee that the relevant Panel meeting will have sufficient capacity to consider your application. Once your application has been submitted your research co-ordinator will be able to confirm the Panel meeting at which it will be considered.

AFTER YOUR PBPP IS SUBMITTED

You should expect to hear within three working days of the Panel meeting one of the following outcomes:

Outcome	Actions
Approved	Your study can commence. If eDRIS are provisioning data we will schedule the work and contact you.
Approved with conditions	You need to provide suitable evidence to show that you have met the conditions prior to work commencing.
Queries	You will need to respond to these queries and comments within two weeks. Your responses will be reviewed by the original Panel and you should hear the outcome within 15 working days. An outcome may be that the application is referred to Tier 2 Out of Committee
Referred to Tier 2 Out of Committee	Tier 2 Committee will review your application and consider by email. You should hear the outcome within 15 working days.
Referred to Tier 2 Sitting Committee	The Tier 2 Committee meets quarterly and you will be asked to attend in person or by teleconference to discuss the Committee's concerns.

Note that the Panel may require amendments to e.g. Patient Information Leaflets previously approved outwith Scotland to ensure consent from Scottish patients is fully informed and freely given.

DATA LINKAGE

Look here for an explanation of our data linkage process

SANCTIONS FOR THOSE WHO MISUSE DATA

NHS Scotland believes that penalties will only be an effective deterrent if they are fully understood. It should also be clear that NHS Scotland is more focused on prevention than punishment. The eDRIS User Agreement must be signed by each Approved User before access to the system is provided. The Agreement also outlines sanctions and penalties which may be applied as a result of non-compliance. An example offence is transferring log-in details to any other user. In this case, a first offence would result in 1 year access suspension, while a second offence would result in permanent suspension.