A Health and Biomedical Informatics Research Strategy for Scotland

Enhancing research capability in health informatics for patient and public benefit 2015-2020

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The Scottish Government
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A HEALTH AND BIOMEDICAL INFORMATICS RESEARCH STRATEGY FOR SCOTLAND

ENHANCING RESEARCH CAPABILITY IN HEALTH INFORMATICS FOR PATIENT AND PUBLIC BENEFIT 2015 – 2020

Health Informatics Research Advisory Group

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Executive Summary and Recommendations

Scotland is fortunate to have some of the best health service data in the world. Few other countries have systems that combine high quality data, consistency, and national coverage with the ability to link data to allow patient-based analysis and follow up. Scotland has a long tradition of using linked health service data for research and methods have recently been developed for combining health service datasets with other data sources such as the Census and population surveys. Data linkage is a highly efficient way to evaluate the capacity of interventions to deliver patient benefit. It allows us to measure long term outcomes in clinical trials, assess the safety of new medical interventions and to understand patterns of health and illness across the whole population. It is a key contributor to our aim, set out in the NHS Scotland Quality Strategy[1] of providing the highest quality of healthcare services to people in Scotland and through this, to be counted among the best in the world.

However, we cannot afford to remain complacent. The pace of scientific discovery has quickened, including:

- a revolution in genomics
- advances in information technology
- increasing complexity of the molecular understanding and treatment of disease
- the need to integrate services across health and social care

In addition, citizens' expectations, of both efficiency and effectiveness in health research and in the way data are handled, are continually evolving. In consequence there is a need to review our collective approach to health informatics research, in order to ensure that it is fit for purpose. Any recommendations for change must be in harmony with our enduring commitment to the highest standards of information governance and active public participation.

In December 2012, the eHealth Strategy Board of the Scottish Government, in collaboration with the Chief Scientist Office, convened a group under the leadership of Sir Lewis Ritchie to consider how Scotland should respond to the opportunities and challenges in health informatics research. This strategy reflects that group's findings. It aims to build upon Scotland's widely-recognised strengths in health informatics research and to ensure we continue to set an international standard for the secure use of routinely collected patient data for research. The strategy is aligned with the Data Vision for Scotland which sets out an objective to champion and unleash across Scotland trustworthy uses of data for public benefit[2]. The strategy also seeks to align the investment by the Medical Research Council and others in a UK wide Institute for Health Informatics Research, with existing infrastructure to enhance Scottish capability in health informatics research for

[1] The Healthcare Quality Strategy for NHSScotland. The Scottish Government, May 2010 (http://www.scotland.gov.uk/Resource/Doc/311667/0098354.pdf)
[2] Data Vision for Scotland. Data Management Board. The Scottish government. April 2014. (http://www.scotland.gov.uk/Resource/0044/00448438.pdf)

patient, public and economic benefit. This is primarily a research strategy, but we recognise that optimum use of high quality data is a cornerstone of the best health systems, and that our proposals can help to drive service improvement as well as research productivity.

We conclude that to realise this vision, we need strong working relationships between the emerging and existing infrastructure. Researchers must have better access to high quality sources of data and be able to work in settings where they can share expertise and new ideas. This in turn requires information governance to be proportionate and the processes of approval and assurance streamlined. Data controllers need to be assured that the new arrangements are secure. The NHS and Industry partners must be engaged to accelerate the translation and impact of health informatics research. Throughout, public confidence and trust need to be maintained through a two-way dialogue about uses of data.

We identify six key areas for action:

1. Embedding the Farr Institute Scotland within a federal network of safe havens to create a national focus for innovation

2. Clear points of access to the new data linkage infrastructure for researchers in the NHS, Universities and, working in partnership with academic researchers and the NHS, industry

3. Proportionate and efficient governance, with close monitoring of performance

4. Improved quality and accessibility of clinical, laboratory, imaging, molecular and primary care datasets for research

5. Engagement with patients, the public and industry, demonstrating how the benefits of health informatics research can be shared, and:

6. Developing capacity in health informatics research expertise in Universities and the NHS.

We propose that these actions would be achieved within the 5 year span of this strategy. Furthermore, we suggest that the progress of the strategy be reviewed within 3 years.

Our specific recommendations are to:

Recommendation 1: Establish a Charter to set out the principles, and address at a high level the practical, technical and governance challenges that need to be overcome to establish a strong and efficient federal network of safe havens, and to provide a basis for the development of an accreditation framework for NHS safe havens in Scotland. Future funding of NHS partners including National Services Scotland (NSS) and the NHS Research Scotland (NRS) nodal safe havens in Aberdeen, Dundee, Edinburgh and Glasgow should be conditional on their agreement to the Charter, and ability to fulfil the standards it specifies. Safe havens may be established within NHS Boards other than the NRS nodes, or to support specific projects, and consideration should be given to whether they should also be able to join the network.

Recommendation 2: Remove duplication in the research governance process, and improve the speed and consistency of decision-making. This should be facilitated by the Safe Haven and accreditation framework. The success of any new structures in terms of streamlining decision-making should be closely monitored and national benchmarks and performance metrics established; further changes should be implemented if necessary to bring performance into line with other approvals processes.

Recommendation 3: Improve the provisioning of national primary care, prescribing and clinical datasets for research and in support of NHS healthcare activity by ensuring that provision for both system query and data extraction is built into the specification of new systems. At the same time, this should promote more efficient integration of data across NHS Boards through specification of common data standards, and/or initiatives to map local data standards to consistent data definitions.

Recommendation 4: The Farr Institute Scotland, the Safe Haven Network, the Chief Scientist Office and eHealth Strategy Board should consider the ways in which health informatics research capability can generate economic benefit, and work with partners in industry to develop early exemplars of the benefits of engagement for both economic, health and social benefit.

Recommendation 5: The eHealth Strategy Board should work with the Scottish Informatics and Linkage Collaboration and Data Management Board to develop a programme of public engagement activities to widen understanding of how data is used in research to improve population health and the quality and effectiveness of healthcare.

Recommendation 6: Research funders and the NHS should be encouraged to prioritise investment in health informatics research expertise through doctoral and postdoctoral training schemes, and by increasing the capacity of the NHS to use patient data to inform service improvement.

Foreword

The power and efficiency of research using electronic health records is widely recognised. The opportunity to use technology to transform the quality, efficacy and delivery of healthcare has never been greater. Research can be a driver of this transformation by generating and reinvesting new knowledge into a "learning" healthcare system in a continuous, iterative process of enquiry and implementation to benefit patient care. Realising this potential is currently challenging, due to the need to commit significant resources to extract, quality check, and integrate data from disparate clinical information systems whilst at the same time, meeting the requirements of information governance to ensure that data are used and shared securely and in ways which are acceptable to data owners and data subjects.

Scotland now has both the opportunity and the obligation to capitalise further on its well established tradition of health informatics research and to attract a substantial share of the significant new investments now being made in health research capacity.

This Strategy sets out how that ambition should be achieved.

As the UK Data Forum[3] has emphasised, *'a thriving research community is one that is engaged with major new developments in data resources, ensuring that they meet current research needs and provide the opportunities for future research. The challenge is to ensure that these needs are met and that research opportunities are grasped.'* This strategy seeks to address the challenge identified by the Forum, of effectively combining the essential elements of a physical research infrastructure, the technology and processes to facilitate access and to empower researchers with the appropriate skills and knowledge to use the data infrastructure.

I have been supported in developing this strategy by the Health Informatics Research Advisory Group, convened on behalf of the Scottish Government by the Chief Scientist Office. The Group's membership is listed in Annex A, and we thank them for their expert and generous contribution. We should also like to thank the many colleagues in the NHS, public representatives, Scottish Government and wider research community who have kindly supplied information or responded to our many queries.

I believe that if this Strategy is accepted and actioned, Scotland will not only maintain and enhance its international reputation in health informatics research, but also will aspire to be world leading in this field. Equally important, we will see the benefits of this technology flow through to better and safer patient care and additional health improvement dividends for the people of Scotland.

Sir Lewis Ritchie

[3] UK Data Forum (2012) UK Strategy for Data Resources for Social and Economic Research. A five-year plan to inform and guide the development and utilisation of data and related resources for social and economic research (http://www.esrc.ac.uk/_images/UKDF-strategy-data-resources_tcm8-26806.pdf)

1 Introduction

Information from electronic health records (EHR) has been extensively used in health and biomedical research in Scotland. It has enabled the development of novel approaches to life course epidemiology, cost-effective evaluations of large-scale health service and public health interventions, efficient long term follow-up of clinical trials, and important work in pharmaco-epidemiology and a wide range of clinical research areas. In brief, it has helped to transform the safety, effectiveness and efficiency of the health services that we provide. Important examples include:

- *Revitalisation of historic cohorts:* linkage of information collected in childhood on a series of Scottish birth cohorts with the Scottish Morbidity Record (SMR: see Box 1) and other sources has enabled researchers to establish a number of valuable life course studies, with very high levels of ascertainment of mortality, cancer incidence and hospital admission[4,5]. A particularly valuable feature of these cohorts is the data they contain on cognitive ability in childhood, and work based on them has been instrumental in establishing the discipline of cognitive epidemiology[6,7].

- *The impact of the 2006 ban on smoking in public places*: information on hospital admissions, again from the SMR system, has been used to assess the impact of the ban on acute coronary syndrome[8] and childhood asthma admissions[9], and on pregnancy complications[10]. The marked reductions observed in these outcomes strengthen the case for public smoking bans, by showing that its positive impact extends to a wider range of outcomes than anticipated. The research has also shown that some of adverse consequences postulated as a result of more smoking within the home have not occurred.

- *Evaluation of routine screening for bowel cancer:* Bowel cancer screening has been found to be effective in reducing mortality in randomised controlled trials, but such trials are an imperfect guide to the benefits that would be found if the treatment were carried out routinely. To see whether the benefits could be replicated when bowel screening was implemented on a larger scale, researchers used the Community Health Index (CHI) number to link information on participation in screening in three Scottish NHS Boards to Cancer Registry, Scottish Morbidity Records and mortality data. They found a 10% overall

[4] Leon DA, Lawlor, D, Macintyre S eta l. Cohort Profile: The Aberdeen Children of the 1950s Study. International Journal of Epidemiology 2006; 35:549–552.
[5] Deary IJ, Gow AJ, Pattie A et al. Cohort Profile: The Lothian Birth Cohorts of 1921 and 1936. *International Journal of Epidemiology* 2012;41:1576–1584
[6] Deary IJ. Intelligence, health and death: the new field of cognitive epidemiology. *Psychologist 2005*;*18:610*-13
[7] Batty GD, Deary IJ. Early life intelligence and adult health: emerging associations, plausible mechanisms, and public health significance. *BMJ 2004*;*329:585*–86.
[8] Pell JP, Haw S, Cobbe SM, et al. Smoke-free legislation and hospitalizations for acute coronary syndrome. N Engl J Med 2008;359:482e91
[9] Mackay DF, Haw S, Fischbacher C, et al. Smoke-free Legislation and Hospitalizations for Childhood Asthma. N Engl J Med 2010;363:1139-45.
[10] Mackay DF, Nelson SM, Haw SJ, et al. (2012) Impact of Scotland's Smoke-Free Legislation on Pregnancy Complications: Retrospective Cohort Study. PLoS Med 9(3): e1001175. doi:10.1371/journal.pmed.1001175

reduction in bowel cancer deaths, and a 27% reduction in those who took up the offer of screening. The research also identified ways in which the programme could be improved to increase uptake and maximise the benefits from screening[11,12].

- *Long-term follow-up of the WOSCOPS trial:* The West of Scotland Coronary Prevention Trial was a path-breaking trial of the use of statins for primary prevention of coronary events, which found reductions in acute myocardial infarction and coronary deaths after five years of treatment. Participants in the trial were followed up for a further five years via their primary care records and (by electronic data linkage) their SMR records. At ten years' follow-up, patients in the active arm of the trial had a lower risk of non-fatal myocardial infarction, fewer cardiac deaths and lower overall mortality[13].

- *Understanding drug safety and effectiveness:* Linkage of Tayside prescribing data with information on traffic accidents obtained from police records has shown a link between use of benzodiazepines, but not tricyclic or selective serotonin re-uptake inhibitor (SSRI) antidepressants and risk of road accident[14]. Again in Tayside, linkage of prescribing and cancer registry data in an observational cohort of Type 2 diabetes patients showed that patients prescribed metformin, as opposed to an alternative course of therapy, had a lower incidence and a longer median time to a diagnosis of cancer. The results provide a strong rationale for conducting randomised trials of metformin in subjects with a high risk of developing cancer[15].

Studies like these have positioned Scotland as a leader in research using routinely collected health data. The large-scale investment now being made in health informatics research in Scotland and elsewhere in the UK, coupled with novel ways of capturing biomedical and clinical data, creates huge new opportunities. To the research areas listed above we can add:

- The impact of new cost-effective genomic technologies, not only as a research tool to elucidate mechanisms and susceptibility to disease in populations but also for the tailored treatment of people living with cancer and other chronic diseases (precision medicine)

- The diagnosis of rare diseases and subsequently for the clinical evaluation of individual risk of disease, and:

- The targeting of prevention, diagnosis and treatment

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[11] McClements PL, Madurasinghe V, Thomson C, et al. Impact of the UK colorectal cancer screening pilot on incidence, stage distribution and mortality trends. Cancer Epidemiology 2012; 36(4): e232-42

[12] Libby G, Brewster DH, McClements PL, et al. The impact of population based faecal occult blood test screening on colorectal cancer mortality: a matched cohort study. Br J Cancer 2012; 197(2): 255-9

[13] Ford I, Murray H Packard C et al. Long-Term Follow-up of the West of Scotland Coronary Prevention Study, N Engl J Med 2007;357:1477-86

[14] Barbone F, McMahon AD, Davey PG, et al. Association of road-traffic accidents with benzodiazepine use. The Lancet, 352 (1998) 1331-1336.

[15] Libby G, Donnelly LA, Donnan PT, et al. New users of metformin are at low risk of incident cancer: a cohort study among people with type 2 diabetes. Diabetes Care 32 (2009) 1620-1625

But to realise the full potential of these opportunities, there are challenges in creating the optimum configuration of infrastructure, governance principles on access to data, the quality and consistency of that data and engaging the public, and customers. Much work is already in train to address these issues.

However we believe it is necessary to co-ordinate the activities to deliver these opportunities by promoting a vision of where Scotland aims to be, and what needs to be done to achieve those aims.

The Vision

Our vision is for Scotland to set an international standard for the safe and secure use of EHRs and other routinely collected population-based data for research purposes. We will achieve this by:

- Creating the national focus for high-quality research using EHRs within a federal network of accredited safe havens, trusted environments where research can take place, across Scotland

- Contributing to the development of a streamlined, efficient, proportionate governance system for health informatics research that has public engagement and public involvement at its heart

- Playing a leading role in the new UK Farr Institute of Health Informatics Research, and collaborating in international initiatives such as the Global Alliance for Genomic & Health that is looking at sharing genomic and clinical data internationally

- Developing innovative training programmes to build research capacity and capability within the NHS and beyond

- Advancing methodological development in data linkage, manipulation, and analysis

- Creating opportunities to link datasets that are not yet linked routinely for research, such as Scottish general practice (GP) records, the Scottish nationwide prescribing dataset, disease registers, and non-health datasets

- Collaborating through the UK-wide network, to promote the establishment of *'deeply phenotyped'* cohorts using EHRs linked to biologic datasets to advance the field of stratified medicine

- Developing partnerships with research organisations, policy makers and industry, in order to accelerate the translation and impact of health informatics research

- Supporting the development of the Scottish Government's policy *Joined Up Data for Better Decisions*[24] through delivery of a National Data Linkage Framework

- Promoting greater convergence of research and eHealth strategies to ensure the ability to efficiently use and share routinely collected NHS data for research and other purposes is built into the specification of new clinical information systems

In Chapter 2 we have described the features of the health informatics research landscape in Scotland; Chapter 3 sets out how that landscape needs to develop to deliver our Vision.

2 The Health Informatics Research Landscape in Scotland

2.1 The Unique Patient Identifier

The foundation of Scotland's success in the use of health data for research was the adoption of the Community Health Index (CHI) in the 1970s. Every person registered with a GP in Scotland is allocated a 10 digit CHI number from a centrally maintained register. The register contains data on address, postcode, GP, date of birth, region of registration and, where relevant, date of death. The CHI number is the unique patient identifier used in all primary health care activities and hospital-based clinical information systems, throughout NHS Scotland, including the emergency care summary (ECS). The ECS links the CHI register with prescribing and other information documenting known adverse reactions. Data in Scotland are currently coded in GP and secondary care systems according to Read 2 and International Classification of Diseases (ICD-10) respectively. Where the CHI number is unavailable (e.g. historical or non-health datasets), probabilistic matching can be used to link records.

2.2 Clinical Information

The Scottish Government's eHealth Directorate works with NHS Boards to promote convergence across NHS Scotland in the use of clinical systems and how data are stored and managed. PACS (Picture Archiving and Communications System) is a national repository of clinical images and radiological reports in which all the contributing Health Board PACS use Data Imaging and Communications in Medicine (DICOM) standards. The use of these common data standards in PACS should facilitate the development of a national clinical images dataset. However, many existing clinical systems have evolved independently as local initiatives. Differences in data structures and terminologies need to be resolved to link these rich datasets across (and sometimes within) Boards. Health Board Scottish Care Information stores (SCI store) are repositories which receive data from multiple laboratory systems. There is no standardisation in Health Board SCI stores, resulting in systems with different data standards and laboratory reference ranges. This constitutes a significant challenge to making laboratory data from Health Boards readily and securely available to researchers in the form of a national dataset.

Ownership and control of NHS data are shared between the NHS Boards and the Information Services Division (ISD) of NHS National Services Scotland (NHS NSS). NHS Boards are the data controllers, under the Data Protection Act (1998) for their patients' clinical information, whether held on local systems or held centrally. NHS NSS is the data controller of the national datasets. ISD holds information centrally that is updated on a monthly basis on hospital admissions across Scotland (See Box 1) and community prescribing (Prescribing Information System for Scotland - PRISMS dataset) and provides NHS Boards with local extracts. ISD also uses the datasets to provide health information, health intelligence, statistical services and for advice to support the NHS in planning, decision-making and quality improvement.

Box 1: The Scottish Morbidity Record (SMR)

SMR are a set of national datasets compiled by Information Services Division of NHS NSS that are derived from information collected about patients treated in Scottish Hospitals.

Outpatient Attendance dataset (**SMR00**) comprises of data from 1997 for patients on new and follow up appointments at outpatient clinics in all specialities (except A&E and Genito urinary Medicine). General Acute / Inpatient dataset (**SMR01**) comprises episode level data from 1981 on hospital inpatient and day case charges from acute specialities. Maternity Inpatient and Day Cases dataset (**SMR02**) comprises episode level data from 1975 every time a mother goes in for an obstetric event and includes information on mother and baby characteristics, birth weight, gestational age, mode of delivery, induction and outcome of pregnancy and where a baby is delivered. Mental Health Inpatient and Day Case dataset (**SMR04**) comprises episode level data since 1981 on patients that are receiving care at psychiatric hospitals at the point of both admission and discharge. Scottish Cancer Registry (**SMR06**) comprises information from 1958 on Scottish residents when they are diagnosed with malignant (and some benign) tumours. Scottish Birth Record (**SBR**) introduced in 2002 is a universal record for all babies born in Scotland. SBR replaced the Neonatal Inpatient dataset (**SMR11**) which provided episode level data on babies discharged from hospital from 1975 to 2002 and supplemented the mother's delivery information as recorded in the Mother's Maternity and Inpatient Day Cases dataset (**SMR02**).

SMR datasets are commonly linked to research datasets (e.g. clinical trial cohorts) and population based studies such as the Scottish Longitudinal Study (see Box 3) and the Scottish Health Survey.

2.3 Primary Care Data

Scottish GP information systems are a rich repository of consistently recorded patient level clinical information in electronic form, with great potential for research. However, the data are distributed across nearly one thousand practices and accessibility for research is very limited. Each practice controls its own patients' information, which requires researchers to approach large numbers of data controllers for all but the most local studies.

For 26 years until 2013, when the GPASS system (General Practice Administration System for Scotland) on which it was based was superseded by commercial systems, the Primary Care Clinical Informatics Unit (PCCIU) at the University of Aberdeen extracted details of patient encounters, diagnoses, test results and issued prescriptions from some 20-30% of Scottish volunteer general practices. Better use could be made of the information held within the primary care system for both primary care services and research through establishing a national system to simplify and standardise the process for data extraction and analysis. Currently, GP practices in Scotland are subject to multiple electronic data extractions for the purposes of audit and making performance payments linked to GP general medical services and local enhanced services contracts. Quality and Outcomes Framework (QoF) payments are currently managed on behalf of Health Boards by Practitioner Services Division (PSD) of NHS NSS, using a UK-wide data extraction mechanism.

ISD manages a limited data extraction involving 6% of practices in Scotland where the focus is to record consultations with practice clinical staff. Health Boards directly manage the additional payments to practices linked to local enhanced services contracts via data extraction mechanisms conducted by Board information service departments or via private sector partners. These data are used by Health Boards to manage these contracts and for the provision and improvement of local services.

Following a recommendation by the Delivering Quality in Primary Care Steering Group, ISD are implementing a National GP Information service to manage regular data extraction from GP practices in Scotland (see Box 2)[16].

Box 2: Scottish Primary Care Information Resource (SPIRE)

SPIRE, a collaboration between the Scottish Government and NHS National Services Scotland (NHS NSS), will provide a national information resource to inform on the provision of primary care across Scotland, and facilitate payments to GP practices against the Quality and Outcomes Framework. SPIRE will create and maintain a new National Primary Care dataset with NHS NSS as the data controller. Information Services Division (ISD) will manage an automated extraction of a defined dataset, designed to be of broad utility, at regular intervals from participating GP Practices in Scotland. The data will be stored securely in the National Safe Haven at NHS NSS. Additionally, SPIRE will be able to perform approved ad hoc data extractions where the national dataset does not meet requirements. SPIRE will also be available for research purposes. Participating GP Practices can elect to opt-out of any particular data extraction. Patients will also be able to decline the use of data from their health records for research. An Independent Advisory Body including GP and patient representation will manage requests for data and approve linkages to other datasets. Extensive engagement with a range of stakeholders, including the British Medical Association (BMA) and Royal College of General Practitioners (RCGP), is expected to act as impetus to encourage wide participation of GP practices to make their patients' data available to SPIRE.

SPIRE has been primarily conceived as an information resource for the management and planning of primary care services, but is also configured to facilitate secure access to primary care data in the National Safe Haven for research purposes.

2.4 Safe havens

Safe havens are now widely accepted as the preferred method of providing access to de-identified data for research and other secondary uses. The Thomas-Walport Data Sharing review, published in July 2008[17], recommended the establishment of safe havens to ensure that de-identified data could be used for research and analysis in the public interest. The use of accredited safe havens has since been

[16] A National GP Information Service. Proposal by the Primary Care Data Extraction Short Life Working Group. National Services Scotland. October 2012. See also: Delivering Quality in Primary Care: Progress Report, SGHD, 2012. (http://www.scotland.gov.uk/Resource/0039/00395413.pdf)
[17] Thomas, R and Walport M, Data Sharing Review Report, 2008. http://systems.hscic.gov.uk/infogov/links/datasharingreview.pdf/view

endorsed by the Administrative Data Taskforce[18], and by the recent Caldicott 2 Information Governance Review[19] on behalf of the Department of Health, England.

For several years, the Scottish Longitudinal study (Box 3), which combines Census, Scottish Morbidity Record, Mortality and other routinely-collected data has been accessible via a safe setting within National Records of Scotland[20].

Box 3: The Scottish Longitudinal Study (SLS)

The Scottish Longitudinal Study (SLS) is a large-scale record linkage study which pulls together Census, Vital Events (births, deaths, and marriages), National Health Service Central Register (NHSCR), and NHS data on 274,000 members (5.3%) of the Scottish population. The study is a replica of the England and Wales Longitudinal Study (LS) which has been running successfully for the past 30 years, but with the added advantage of a wider range of non-Census data. The linkage of individual social, demographic and health records through time on such a large sample creates a unique and powerful resource for health and social research in Scotland, which is designed to be used widely. But because the sample, and much of the valuable information, is derived from the Census, special procedures have been put in place to ensure confidentiality.

The SLS data are held within National Records of Scotland (NRS), and can be accessed only from a secure room using NRS stand-alone computers. Researchers who need to work with individual-level data may visit the SLS safe setting in Edinburgh where support officers are available to help users extract and use the data in the correct way. Alternatively, the researcher may obtain a version of the database, from which all the data except variable names and labels, has been removed. The researcher specifies the analyses required and returns the code to the SLS team to be run on the original dataset. The only aggregated data outputs that can be released to users are tabulations and model outcomes (such as regression coefficients). Users are instructed thoroughly about the confidentiality rules, and must sign an SLS Undertaking Form describing how they must hold and use any data received from the SLS before they can begin analysis.

Use of SLS data are covered by the National Statistics Code of Practice and the Protocol on Data Access and Confidentiality. Specific legislation also covers the release of information held in the SLS: for example, the 1920 Census Act, the 1938 Population (Statistics) Act, the Data Protection Acts and Freedom of Information Legislation.

Strengths of the SLS include its comprehensive coverage of the Scottish population, low levels of attrition, incorporation of health as well as demographic information, and its configuration from the outset as a freely accessible (subject to the constraints of good governance) resource for all bona fide researchers.

[18] The UK Administrative Data Research Network: Improving Access for Research and Policy. Report from the Administrative Data Taskforce. Economic and Social Research Council. December 2012. (http://www.esrc.ac.uk/_images/ADT-Improving-Access-for-Research-and-Policy_tcm8-24462.pdf)

[19] The Information Governance Review. The Department of Health. April 2013. (https://www.gov.uk/government/news/health-secretary-to-strengthen-patient-privacy-on-confidential-data-use)

[20] Boyle, P., Feijten, P., Feng, F., Hattersley, L., Huang, Z., Nolan, J. & Raab, G. (2009) Cohort Profile: The Scottish Longitudinal Study (SLS), *International Journal of Epidemiology* 38(2):385-392.

Full information of the use of the SLS can be obtained from the Longitudinal Studies Centre Scotland

A national safe haven, hosted by NHS NSS and funded through SHIP became operational in 2013 (Box 4).

Box 4 ScottisH Informatics Programme (SHIP – formally the Scottish Health Informatics Programme)

SHIP, a collaboration between the Universities of Dundee, Edinburgh, Glasgow and St Andrews, and NHS National Services Scotland (NSS), was funded by a £3.7 million grant from the Wellcome Trust, the Medical Research Council and the Economic and Social Research Council between 2009-13. SHIP has been instrumental in creating an infrastructure and governance framework (SHIP Blueprint, Box 6) to promote secure data sharing across institutional boundaries and enhancing the capability in Scotland to conduct research using data in electronic patient records.

The National Safe Haven and eDRIS research portal (Box 5), hosted by NHS NSS and central elements of this infrastructure, became operational in January 2013 and provides a state of the art technical facility with high end performance computing. Infrastructure investments have been supported by a programme of work centred on a core set of four generic activities: provisioning of datasets for research; governance; engaging researchers; and engaging the public. The core programmes have supported a related series of research projects; supporting clinical trials; national epidemiology; pharmacovigilance; and the linkage of electronic patient records to socioeconomic, geospatial and environmental data.

The success of SHIP has paved the path for subsequent investment by the Medical Research Council (MRC) and others, first in a Scottish Health Informatics Research Centre and then in the Farr Institute Scotland. SHIP has now come to an end and the programme has moved onto the Farr Institute Scotland.

Through Chief Scientist Office (CSO) infrastructure investments NHS Research Scotland (NRS) safe havens have now been established in the four lead NHS Boards, the nodes of NHS Research Scotland (Greater Glasgow & Clyde, Lothian, Grampian and Tayside), in addition to the National Safe Haven in NHS NSS which from April 2014 is also funded by CSO as an NRS safe haven. These safe havens are in varying stages of development and so far have evolved with little central co-ordination or standardisation. Each will have individual responsibility to operate at all times in full compliance with all relevant codes of practice, legislation, statutory order and in accordance with current good professional practice. There is an opportunity however to collaborate to share best practice; this will be co-ordinated by the Scottish Informatics and Linkage Collaboration (SILC; see Box 7).

The National Safe Haven is supplemented by a research advisory service, eDRIS (Electronic Data Research and Innovation Service - Box 5)[21].

Box 5: Electronic Data Research and Innovation Service (eDRIS)

eDRIS was established by NHS NSS in January 2013 as a service to support the use of health data and electronic medical records held across NHS Scotland institutions for the purpose of research, service and quality improvement, planning, public health, health surveillance and epidemiology. A key remit is to support the NHS making better use of its own data to develop and improve service delivery. eDRIS is a portal to national data and the National Safe Haven, and also works in conjunction and collaboration with the local safe havens established in partnership with the main academic institutions in Scotland. An important role of eDRIS will be to facilitate access to datasets held by other bodies in the NHS or other area of the public sector.

The service is part of NHS NSS's contribution to SHIP and seeks to support researchers from project conception to completion. Each study receives a dedicated research coordinator to ensure that the project runs smoothly by providing support with; study design and feasibility, advice on metadata, coding and terminology, liaison between data suppliers, approvals to procure and link datasets, and when required data analyses and interpretation.

2.5 Governance Framework

The SHIP Blueprint[22] (Box 6) and associated governance framework[23] define standards and processes for the use of non-consented linked data for health-related research purposes in Scotland. They seek to provide data controllers and Privacy Advisory Committees (PACs) with a common framework of reference for deciding which linkages should be approved and which checks and balances should be in place.

[21] Electronic Data Research and Innovation Service (eDRIS). NHS National Services Scotland http://www.isdscotland.org/Products-and-Services/eDRIS/)
[22] A Blueprint for Health Records Research in Scotland 2012 (http://www.scot-ship.ac.uk/sites/default/files/Reports/SHIP_BLUEPRINT_DOCUMENT_final_100712.pdf)
[23] SHIP Guiding Principles and Best Practices. A document of the SHIP Information Governance Working Group (http://www.scot-ship.ac.uk/sites/default/files/Reports/Guiding_Principles_and_Best_Practices_221010.pdf.)

Box 6: Promoting efficient and secure data sharing: the SHIP Blueprint

The Walport/Thomas Data Sharing Review Report[17] recommended specific actions to reduce the regulatory burden to secure access to health service data. These included simplifying the legal framework governing data sharing and providing authoritative guidance to its interpretation, and the establishment of safe havens, which would provide a technical and administrative solution to the proportionate and safe sharing of data for research.

The SHIP Blueprint[22], addressing challenges raised in the Walport/Thomas report, delineates data sharing and linkage governance standards to serve as a benchmark for data controllers and researchers, and an infrastructure that supports a network firmly embedded within NHS Scotland comprising a national and local safe haven(s) that operate in conjunction with a research portal to facilitate efficient secure access to electronic health data.

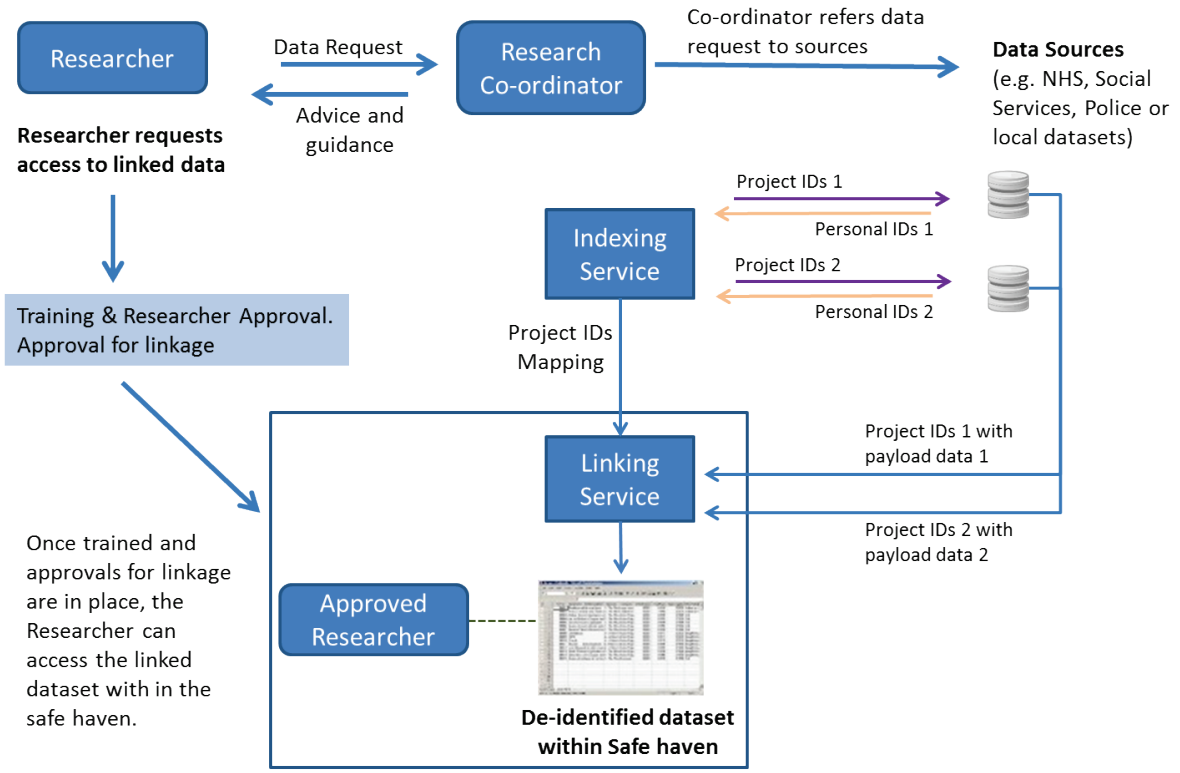

Figure 1: Overview of the SHIP Infrastructure showing the interactions between individuals and organisations.

The network of NHS safe havens are expected to conform to a charter of agreed principles to provide a secure environment for the linkage, storage and analysis of non-consented patient data. These principles are based on the framework of principles and good practice set out in the Scottish Government's Guiding Principles for Data Linkage[23] and the SHIP Blueprint[22]. This Charter will underpin the establishments and operation of the network of Safe Havens (see 3.1).

The technical infrastructure outlined in the SHIP Blueprint is designed to provide confidence to data controllers that only authorised researchers will have access to anonymised patient-level data and only summary data can be removed from the facility following statistical disclosure control. Furthermore, safe havens will not per se maintain 'data warehouse' functions, but may do so to efficiently manage their own data. Linked data sets created for the purposes of particular projects will be held in an accredited safe haven for a specific duration. They will be subject to a plan of analysis and curation as specified in the project's data sharing agreement between contributing data controllers.

A different approach was taken in England, in accordance with the UK Government's Open Data Policy, to support the use of anonymised NHS data for both academic and commercial research. The Clinical Practice Research Datalink (CPRD: www.cprd.com/home/), established by the Department of Health and the Medicines and Healthcare Regulatory Authority to facilitate access to English NHS data, with its partner the Health and Social Care Information Centre (HSCIC) are able to authorise the release of appropriately anonymised patient level datasets to enable researchers to conduct their own in-house analysis of the data. This may promote the emergence of private sector service providers enabling access to, and analysis of, NHS data. The implications of diverging governance models for research collaboration need to be kept under review.

2.6 National Data Linkage Framework

The Scottish Government has signalled its commitment to using data linkage for statistics and research through the development of a National Data Linkage Framework[24,25,26] that aims to promote the linkage of health with non-health administrative data. This initiative, jointly led by the Scottish Government's Chief Statistician, National Records of Scotland's Registrar General, and the Director of NHS NSS's Information Services Division will contribute to the Scottish Informatics and Linkage Collaboration (Box 7). The administrative and research centre for this initiative, will be co-located with the Farr Institute Scotland.

[24] Joined-up Data for Better Decisions: A strategy for improving data access and analysis. Scottish Government. November 2012. (http://www.scotland.gov.uk/Resource/0040/00408151.pdf)
[25] Joined-up data for better decisions: Guiding Principles for Data Linkage. The Scottish Government. November 2012. (http://www.scotland.gov.uk/Resource/0040/00407739.pdf)
[26] Technical Consultation Paper on the Design of the Data Sharing and Linking Service (http://www.isdscotland.org/Products-and-Services/eDRIS/DSLS-consultation/DSLS-consultation-final-gd-060313.pdf)

Box 7: Scottish Informatics and Linkage Collaboration

Published in November 2012, *Joined Up Data for Better Decisions* (the Data Linkage Framework)[24] sets out an ambitious pathway to realise the benefits from linking cross-sectoral administrative and survey data at a population level. The key benefits include: accelerating cycles of improvement based on evidence to inform public policy and strategic planning, spending and delivery decisions. The framework seeks to overcome barriers to data linkage by acting as a focus to first improve the quality and consistency of existing administrative data systems. This should deliver data that are capable of being linked, and to expand access to facilities to enable secure data sharing, linkage and analysis. This should also aid data controllers and other decision makers to take a more proportionate approach to managing risks associated with data-linkage. It aims to build on existing successful programmes, such as SHIP, to create a culture where legal, ethical and secure data-linkage is widely understood and accepted by the public.

The foundation stone of the Data Linkage Framework is a set of Guiding Principles which are intended to promote the public interest in scientifically sound, ethically robust research while appropriately protecting privacy[25]. Building on these Principles, a Scottish Informatics and Linkage Collaboration (SILC) has been established, incorporating Farr Institute Scotland and the Scottish Administrative Data Research Centre (ADRC). SILC is an overarching structure responsible for the provision of an integrated national data service to support health and non-health statistical and research activity and includes eDRIS (Box 5), the National Safe Haven, an Indexing Service provided by National Records of Scotland (NRS) that handles all personally identifying data (and have no access to "payload" or characteristic data), and a Linking Service, provided by NHS NSS (which will have no access to personally identifying data). The Index Service matches data provided by data controllers to a linking population spine to allow personal identifiers to be replaced using anonymous keys. SILC will also act as a forum to co-ordinate sharing of best practice within the network of accredited safe havens across Scotland.

The oversight and terms of reference of SILC will be published in Spring 2015

2.7 Connectivity with UK-wide health informatics research and administrative data linkage initiatives

In Sections 2.1 to 2.6 we have described key aspects of the development of health informatics research in Scotland. The potential benefits and challenges of electronic health records (EHR) research have also been recognised by the major UK health and social research funders and there have been a number of important recent developments at UK level. In 2012, the Medical Research Council (MRC), in collaboration with a range of other funders (including the CSO), invested £19 million in four research centres through the Health Informatics Research Centres initiative. Scotland was awarded £4 million, and was also invited to lead the UK Network, for which a further £1.5 million has been allocated. In February 2013, the MRC invited the Health Informatics Research Centres to bid for a further £20 million to create a UK Institute of Health Informatics. This award, plus the identification of an additional

£2.5 million by the Scottish Government and NHS NSS, provides an opportunity to drive a step-change in the scale of health informatics research in Scotland and participate fully in the development of a UK wide Institute. This was named as the Farr Institute after William Farr, the 19th century epidemiologist, regarded as one of the founders of medical statistics.

The Scottish hub, Farr Institute Scotland, encompasses four areas of investment: (1) a building in the Edinburgh Bioquarter and refurbishment of accommodation at Ninewells Hospital, Dundee, to provide a multidisciplinary environment for health informatics research; (2) high performance statistical computing facilities; (3) investment in enabling datasets; and (4) linkage to the safe havens located at the NHS Research Scotland nodes, in order to create a single networked Institute.

The Institute will focus on the following areas of priority:

- Providing strong leadership and governance in health and biomedical informatics
- Providing a cohesive, high quality research and data infrastructure for transformational health informatics research based in Scotland
- Promoting close integration with health service infrastructure, with opportunities for capacity building in key skills
- Anticipating new models of research encompassing genetic data, imaging data, integration of unstructured and heterogeneous data, and non-health data
- Creating a multidisciplinary environment that brings together NHS Scotland, academia and industry to deliver novel approaches to discovery from data
- Developing strong links to other centres of excellence across the UK and internationally, through initiatives such as the Global Alliance[27], to promote standards for secure sharing of clinical and genetic data

Having a physical focus for the Institute is essential for scientific leadership, delivery-focused management, capacity building and world-class facilities for collaborative research, but NHS-academic-industry collaboration will be the core of all its activities.

The Farr Institute Scotland will be closely integrated with NHS infrastructure and will be managed as a joint academic/NHS collaboration. It will be configured as one hub of a Scottish network of safe havens, with regional hubs in the NRS regional nodes in Aberdeen, Dundee, Edinburgh and Glasgow. A senior management team has been created to ensure good governance and delivery of the vision of the Institute. Leadership has been strengthened by co-opting experienced NHS and University leaders, who can bring a distinctive set of skills, including lay representation, informatics, clinical medicine, general practice, the law, ethics, NHS, epidemiology, social science and the pharmaceutical industry. An International Advisory Board has

[27] Creating a Global Alliance to Enable Responsible Sharing of Genomic and Clinical Data http://www.ebi.ac.uk/sites/ebi.ac.uk/files/shared/images/News/Global_Alliance_White_Paper_3_June_2013.pdf

been established to provide independent oversight of the Institute, and ensure the highest standards of research excellence are combined with clear strategic direction.

A final important development to note is that the UK Administrative Data Taskforce (ADT), led by the Economic and Social Research Council (ESRC), MRC and the Wellcome Trust, called for the establishment of Administrative Data Research Centres (ADRC) in each of the four UK countries[18] (Box 8). In 2013, Scotland was awarded £7.9 million to establish the Scottish ADRC.

Box 8: Administrative Data Taskforce (ADT)

ADT was established by ESRC in collaboration with the MRC and the Wellcome Trust, with the purpose of improving access to public sector administrative data (social security, tax and education records, for example) for research and policy purposes. The report, published in December 2012, noted that the UK has an opportunity to be a world leader in research using de-identified administrative data routinely collected by government departments, agencies and statutory bodies, but accepts that access to such data has been difficult, due mainly to the concerns that data controllers have over the identification of individuals, and legal restrictions on data sharing between government departments. It concludes that improvements in procedures for access to and linking between such data are urgently required, supported by new legislation to permit sharing and linkage of data.

ADT proposed the establishment of an Administrative Data Research Centre (ADRC) in each of the four countries of the UK. The ADRCs will be responsible for undertaking secure linkage of de-identified data. Access to data will be managed through an Information Gateway. A UK Governing Board has been established to provide the governance structure for the ADRCs.

ADT recommends that government administrative data should be made available at no cost to publicly-funded researchers. Initially, ADRCs will not engage with the private sector, though the Governing Board will, at an early stage, investigate guidelines for such engagement.

ADT proposed that the ADRCs collaborate to produce plans for public engagement and debate about the academic and wider social and economic benefits of research using administrative data.

2.8 Connectivity between Universities, the NHS and Industry in Scotland

Scotland has a strong international profile in life sciences and medicine, with significant MRC and EU grant portfolios and national pooling initiatives. It is also home to leading international institutions in informatics and bioinformatics. The Scottish Government has long recognised the importance of the life science sector to national economic development. Universities in Scotland have built strong long standing partnerships with the NHS, both at the level of local NHS Boards and nationally. SHIP itself is a good example of collaboration between leading universities and NHS NSS. Interaction between the universities and NHS and other centres of excellence in Scotland and the UK will be essential to facilitate the

development of new clinical information systems to record and analyse the new genetic datasets and other biologic data as they emerge. Scotland has also recently committed substantial funds to innovation centres in digital healthcare and stratified medicine (led by informatics and medical scientists).

The potential for Scotland to be world-leading in health and biomedical informatics was acknowledged by the Council of Economic Advisers First Annual Chair's Report to the First Minister published on 28th March 2013[28]: This supported the development of a Health and Biomedical Informatics Research Strategy for Scotland and the creation of a Scottish Health and Biomedical Informatics Research Institute, which would focus on addressing the challenges of handling the linking of medical and genetic information and other heterogeneous data types in order to maximise the value of these unique sources of information across Scotland. It emphasised that in order to strengthen Scotland's international position in this area there should be a clear link between the ambitions and milestones set out in the Strategy and its funding.

[28] Council of Economic Advisers First Annual Chair's Report to the First Minister. Published 28th March 2013 (http://www.scotland.gov.uk/Resource/0041/00417465.pdf)

3 Moving Forward: What is needed now?

3.1 Optimising the infrastructure for health informatics research

A flexible federated network of accredited safe havens

Safe havens are being established within NHS NSS (the National Safe Haven) and within the four lead regional NHS Research Scotland nodes, using similar data and security architectures and operating according to SHIP information governance and data sharing principles. This should allow them to function as a federated network in which each node develops particular resources, datasets, skills or analytical methods, with the potential to provide site-specific services across the Safe Haven Network or to approved external researchers. The governance standards applied to the network of safe havens must reassure data controllers that data can be safely shared between nodes of the federated network, in order to facilitate access to data for researchers from external organisations. Safe havens are therefore distinct from the data repositories used by Health Boards to manage and analyse their own data (although they may be involved in that activity on behalf of their Health Board). Work is already in hand to develop a Safe Haven Charter that will underpin the establishment and operation of such a network. Independent accreditation of safe havens would provide additional confidence about the operation of safe havens to data controllers, the patients and the wider public. The Scottish Government, through the eHealth Directorate and CSO, should play a lead role in establishing independent accreditation standards for safe havens, and establishing systems for monitoring compliance. In addition to the accreditation of safe havens (safe places), national safe researcher (safe people) training is being established providing further standardisation and controls.

The National Safe Haven is best-placed to take the lead when the research requires the linkage of national datasets with supplementary data from multiple Health Boards or other public bodies. The node safe havens may be better placed to handle datasets where the majority of the data are derived from a local source. Specific projects could be led from any node in the network with the direction of data flows reflecting volume requirements, specialised expertise and capability, and available capacity to take on new projects but the handling/processing of the data will require the express agreement of the Data Controller for the source data. Appropriate data and income sharing arrangements, and transparent mechanisms to ensure data security, will be needed to underpin relationships within the network. The key is to find a balance between centralisation and standardisation on the one hand, and the potential for each safe haven to develop and innovate on the other hand.

The services provided by safe havens encompass a range of activities such as creating research datasets abstracted from clinical databases, adding capability to enhance the visualisation and analysis of data, or promoting interoperability between analogous and heterologous data sources. Due to the incremental way in which hospital clinical information systems have developed, work will be needed to make analogous data held in different node safe havens interoperable. This will require an understanding of the underlying data structures and how the data relate to real world clinical information and current knowledge. It will also require close interaction

between data analysts and domain experts (clinical specialists, medical physicists, and other colleagues).

Health data within NHS Scotland range from data held within national datasets (e.g. on hospital admissions, discharges, cancer registration, prescriptions) to the much more detailed biomedical and clinical data recorded in various formats in distributed hospital clinical information systems and bespoke research datasets. Appreciating the range of data that may be available for research and how to access it can be challenging for researchers, the Electronic Data Research and Innovation Service (eDRIS) (Box 5) aims to provide a single-point of entry to the wide range of national datasets that may be accessible for research, and to assist researchers in study design, obtaining approvals and performing linkages. As well as increasing overall capacity, the node safe havens can potentially add specific analytical, programming or clinical expertise and access to specialist regional datasets.

A potential drawback of the safe haven approach is that by attempting to guarantee data security, it distances the researcher from the data themselves. Researchers are used to holding copies of linked datasets in restricted access areas of university servers. Systems such as the one used by the Scottish Longitudinal Study (SLS), where researchers specify analyses which are implemented within a safe haven but cannot remove data from the safe haven, are still the exception. Arrangements for permitting remote access, or for enabling researchers to use data within the safe haven, will have to be flexible, efficient and cost effective to win the confidence of researchers. Safe havens must be able to provide excellent metadata so that if researchers cannot see the raw data, they can at least understand how the data were processed, cleaned, how analytical variables were derived, and methods used.

A common complaint from both industry and university-based researchers is that there appears to be a multiplicity of entry points, and a confusing array of data providers, governance bodies and permissions processes.

eDRIS (Box 5), established to support researchers and facilitate access to national datasets, but also working in conjunction and collaboration with other safe havens within the federated network of accredited safe havens, can potentially offer a single point of entry for researchers wishing to access data. However, there are a number of technical challenges to be overcome to achieve interoperability between safe havens. A particular challenge is to define and agree the practical details of how a network of safe havens should operate. Some basic issues of principle must also be settled, such as whether there should be a single point of entry for each study (which could differ from study to study), or one point for all studies, and whether the network will include only the NHS NSS and NRS node safe havens. The advantages of a single point of entry need to be balanced against the need for local knowledge and expertise to maintain inventories of datasets, generate metadata, support local researchers and to liaise with data providers. It is important that sufficient incentives are in place for the node safe havens to drive up the quality of the data they manage and develop specialist expertise.

RECOMMENDATION 1: Establish a Charter to set out the principles, and address at a high level the practical, technical and governance challenges that need to be overcome to establish a strong and efficient federal network of safe havens, and to provide a basis for the development of an accreditation framework for NHS safe havens in Scotland. Future funding of NHS partners including National Services Scotland (NSS) and the NHS Research Scotland (NRS) nodal safe havens in Aberdeen, Dundee, Edinburgh and Glasgow should be conditional on their agreement to the Charter, and ability to fulfil the standards it specifies. Safe havens may be established within NHS Boards other than the NRS nodes, or to support specific projects, and consideration should be given to whether they should also be able to join the network.

Proportionate Governance

Robust, efficient and proportionate governance to mitigate risks to patient confidentiality and privacy is a key component in the promotion of public trust and maintaining public confidence in the use of their data by the NHS and researchers. Loss of public trust would undermine the use and reduce completeness and availability of health data for all purposes whether healthcare delivery, patient safety or research. Data controllers, processors and researchers each have a responsibility for Information Governance.

The Academy of Medical Sciences investigated the regulations and governance of health research. Although its report was primarily focussed on systems in England, it made observations that could be applied to Scotland, including duplication in ethics, Research and Development (R&D) and Information Governance approvals. It proposed that these systems be streamlined and simplified[29].

A more recent review of information governance, again on behalf of the Department of Health in England but with relevance to Scotland (Box 9), referred to 'a growing perception that information governance was being cited as an impediment to sharing information, even when sharing would have been in the patient's best interests', and acknowledged researchers' concerns about the 'complexity, confusion and lack of consistency in the interpretation of the requirements they have to satisfy before research projects can proceed'[19].

[29] Academy of Medical Sciences (2010). A new pathway for the regulation and governance of health research (http://www.acmedsci.ac.uk/viewFile/publicationDownloads/newpathw.pdf)

Box 9: The Caldicott 2 Review

In response to concerns that the legislative and regulatory environment was impeding appropriate sharing of information in the interest of the patient and the wider public, the Secretary of State for Health in England commissioned Dame Fiona Caldicott to review the balance between protecting and sharing information[19].

The review was conducted against the background of the UK Government's Information strategy, the Open Data White Paper, and the Health and Social Care Act 2012 which created a new legal basis for NHS bodies in England to share confidential information with the Health and Social Care Information Centre (HSCIC). The report, published in April 2013, endorsed the approach of the new NHS constitution in England to facilitate patients' access to their medical records, and give them the right to opt out of sharing personal information beyond their care pathway, including with HSCIC. It acknowledged that protecting confidentiality should be balanced with that of the benefits of exploiting electronic patient data for research and statistical purposes.

The report upheld the existing Caldicott principles and recommended that a seventh principle be added to the six set out in the original Caldicott Report, published in 1997[30]. The new principle states that *"the duty to share information can be as important as the duty to protect patient confidentiality".*

Outline Information Governance Principles from the Caldicott Reviews:

1. Justify the purpose(s)

2. Don't use personal confidential data unless it is absolutely necessary

3. Use the minimum necessary personal confidential data

4. Access to personal confidential data should be on a strict need-to-know basis

5. Everyone with access to personal confidential data should be aware of their responsibilities

6. Comply with the law

7. The duty to share information can be as important as the duty to protect patient confidentiality

Requests to use data held by NHS Boards in Scotland are reviewed by Caldicott Guardians appointed by each Board. Caldicott Guardians, who combine their information governance role with other significant responsibilities within their Boards, have had to cope with a sharply increasing volume of requests for national or cross-Board datasets in recent years. A National Caldicott Scrutiny Panel process was established in 2010 to streamline Caldicott review procedures through the use of a common application form, and the implementation of a system whereby applications to use data from multiple Boards or projects judged to have national implications are referred to the national panel. Any system of proportionate governance requires a commitment of time from, and complimentary skill of, information governance experts and Caldicott Guardians. Information governance leads within the Scottish Government (who currently provide the secretariat for the panel) have taken on some of the burden of risk assessments and administration.

[30] Report on the Review of Patient-Identifiable Information. The Department of Health. 1997. (http://www.wales.nhs.uk/sites3/Documents/950/DH_4068404.pdf)

The panel works to a target of dealing with requests within 20 working days. However, data suggests that obtaining permission from Caldicott Guardians still takes markedly longer than other NHS R&D decision-making processes, where performance is closely monitored with routine publication of performance statistics[31]. Despite the changes, obtaining permission from Caldicott Guardians and other approval bodies to use non-consented patient data for research can still be a lengthy and frustrating process for researchers (Boxes 10 and 11), and access to NHS data for commercially funded studies is a source of particular difficulty.

Box 10: The challenges of governance

For studies involving linkage of a number of datasets, for example to enable long term follow-up of a patient cohort to assess levels of service use, the regulatory burden can be substantial because of the number of separate approvals required. In a recent CSO-funded study to assess the feasibility of following a cohort of patients from a single GP practice, it took nine months to obtain the full range of approvals.

In the course of the study, for which prior R&D and ethical approval had been granted, the researchers were obliged to approach four separate Caldicott Guardians (two concerned with national, two with Board level datasets), the CHI Advisory Group, the Practitioner Services Division of NHS NSS and the Local Medical Committee, to obtain approval to approach patients to seek consent for the use of their primary care data in the study.

In some cases, approval was granted quickly, but in others decisions took several weeks, and were only obtained after considerable effort spent by the researchers on chasing responses. A number of promising avenues were abandoned altogether. In several cases approval was only granted to approach patients in ways that ruled out further attempts to contact non-respondents.

The overall picture is of a cumbersome process, tilted towards restricting rather than facilitating access to data for research purposes, even for ethically approved studies. The researchers concluded that conducting a study like theirs on a large scale would be too expensive and time-consuming, largely because of the requirement to obtain consent from cohort members to use their primary care data, and that the creation of a wholly anonymous cohort (via eDRIS) should, where possible, be the preferred route (Information Governance Principles 2 from the Caldicott Review[19]).

A recent review by the panel found that one of the key reasons for delays is insufficient information from the applicant in key areas required to scrutinise information governance (e.g. no clarity on how and where the data will be transferred, stored and deleted; absence of information on technical and personnel security; absence of information on local records management policy, deletion and back-up.) Thus, as well as Government and the NHS ensuring proportionate governance is in place, Researchers themselves can contribute to speedier processing by ensuring that applications are efficiently completed with clear and up-to-date information about their own institutions' information governance arrangements.

[31] NRS Permissions Coordination Centre, R&D Permissions times in Scotland www.nhsresearchscotland.org.uk/237_RDpermissiontimesinScotland.html

Box 11 Overlap and duplication in the governance process

Revitalisation of historic cohorts is one of the most exciting uses of linked health records for epidemiology, with potential to provide unique insights into early life influences on health over the whole life-course. In one such study, researchers planned to link information on intelligence tests conducted in the late 1940s to the Scottish Morbidity Record (and equivalent datasets in England and Wales) and to recontact a random subsample who had been selected to undergo more extensive testing during childhood and early adult life.

This is clearly an ambitious and highly sensitive study for which the highest standards of governance are required. It illustrates the challenges of addressing privacy concerns within such a complex, multi-stranded study and the close working with various bodies that feed into developing the study design to meet these concerns.

The researchers' experience illustrates a particular drawback with the current system of governance. In all the researchers had to make a total of 16 applications or resubmissions to nine separate bodies (across England, Wales and Scotland) and submit over 250 supporting documents. Within Scotland alone, the researchers had to apply in turn for ethical, NHS R&D and Privacy Advisory Committee approval, in addition to securing research passports for university based researchers to work within the NHS.

Up to 30 supporting documents had to be submitted with some of these applications, and as separate approvals were required for the same documents, amendments required by one body required resubmission of the documents that had already been approved by others.

The researchers found each individual body to be helpful and efficient. All their aims were eventually approved and the study is progressing well. But, in a process like this, with such a high degree of overlap between the responsibilities of the different bodies, delays are almost inevitable even if each body reaches decisions quickly.

Further work is underway to simplify the national governance structure and have a single information governance process with the creation of a Public Benefits and Privacy Panel for Health and Social Care (PBPP). This panel has the support of Chief Executives of NHSS, Health Board Caldicott Guardians and Chief Executives (who are the Data Controllers as defined by the Data Protection Act 1998). The panel will have delegated authority from Health Board Chief Executives to scrutinise how national data is used. Given the variety of requests, the panel will operate a two tier structure to triage projects to facilitate expedition of straightforward/non-contentious projects. There will be pooling of information governance resources so that personnel from each Health Board contributes to the new national governance structure and the inclusion of lay and research representatives in the panel reduces the risk of misunderstanding with the public as to how data is used beyond direct care. The merging of three district advisory groups (NHS NSS Privacy Advisory Committee (PAC), National Caldicott Scrutiny panel and CHI Advisory Group (CHIAG)), removes duplication in the information collected and scrutiny and adds consistency to decision making. This process is designed to cope with the growing workload and demand for cross-sector research or health/social care integration.

In support of streamlined information governance, the accreditation of safe havens should provide a means to demonstrate that robust controls and safeguards are in place[18,19] to minimise the risk to confidentiality and privacy, addressing key areas of interest to the PBPP. Their use will reduce the need for further scrutiny by the Information Governance leads or Caldicott Guardians in these specific aspects, building on the proportionate governance work already developed by NSS PAC where applications are filtered depending on sensitivity of data/risk. Combined with this, training will help users understanding the basic objectives of protecting privacy and confidentiality and help them design studies that meet these objectives[23]. There are a number of sources of training but work is underway to establish a standardised national training programme.

A major frustration and source of delay with the current system is the requirement to submit the same information in the course of several different approvals (Box 11). An obvious route to address this would be for a common application form for REC, NHS R&D and Caldicott approval. This could be implemented by incorporating the information required for Caldicott approval within IRAS, the Integrated Research Application System, which already captures the information needed for R&D, REC and a range of other approvals. However this would only be possible on a UK-wide basis. Before this is possible, or deemed feasible, the simplification and streamlining of the information governance application form in Scotland is required. This should be combined with the development of clear guidance and a source of advice.

A potentially efficient model for deciding applications to access data held by safe havens would be for accredited safe havens to handle requests through a bespoke access committee or governance board linked to the safe haven, rather than the researcher applying to the safe haven for the data and seeking permission separately from a Caldicott Guardian. The model could involve the Caldicott Guardian sitting on the access committee, or delegating decision making to the access committee. A similar approach is already used by Research Tissue Banks, such as the UK Biobank and by the Secure Anonymised Information Linkage (SAIL) service in Wales[32]. SAIL operates a streamlined review process with a single decision point covering research ethics, Caldicott Guardians and privacy advisory committees. Caldicott Guardians sign data access agreements that give permission for anonymised data held within SAIL to be used for research purposes approved by the Information Governance Review Panel. The creation of the PBPP provides the additional streamlining and simplification of information governance scrutiny and would be in a position to inform the decision making of the safe haven along the lines of the Information Governance Review Panel for SAIL.

The NHS Scotland Caldicott Guardian manual[33] allows for delegation of decisions involving research projects to others in the NHS Board (a senior colleague or a defined post in the R&D Office). Responsibilities could be further clarified by

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[32] Ford DV et al. The SAIL Databank: building a national architecture for e-health research and evaluation. BMC Health Services Research 2009, **9**:157. (http://www.biomedcentral.com/1472-6963/9/157).

[33] NHSScotland Caldicott Guardian's Principles into Practice – June 2012 v2 (http://www.knowledge.scot.nhs.uk/media/CLT/ResourceUploads/4014631/Caldicott%20Guardian%20Manual%20Scotland%20-%20June%202012.pdf)

considering whether the NHS Board should always remain the data controller after the data has been transferred to a data processor (e.g. a safe haven or a researcher) and therefore liable for breaches in security that occur. Legal advice is being sought by the NSS Caldicott Guardian on the roles of Data Controllers and Data Processes in relation to the National Safe Haven.

For this system to work, Caldicott Guardians must have confidence in the access procedures and information security arrangements implemented by the safe havens, and these should be key considerations in the accreditation of safe havens (see Recommendation 1).

A federated network of safe havens, operating with clearly defined information governance procedures, has the potential to deliver substantial efficiencies, in the context of a streamlined system of Caldicott approval for the use of national and cross-Board datasets. It is also worth considering whether legislative changes could be used to deliver further improvements. Unlike in England, there is no legislation defining the status of accredited safe havens, but the review of the Patients' Rights Act, due in 2016, may provide an opportunity to make clear in law the status of the safe havens.

RECOMMENDATION 2: Remove duplication in the research governance process, and improve the speed and consistency of decision-making. This should be facilitated by the Safe Haven and accreditation framework. The success of any new structures in terms of streamlining decision-making should be closely monitored and national benchmarks and performance metrics established; further changes should be implemented if necessary to bring performance into line with other approvals processes.

Improve Provisioning of National datasets

New national datasets: General Practice, laboratory and imaging datasets

NHS NSS is currently developing a National GP primary care dataset (Scottish Primary Care Information Resource (SPIRE)) (See Box 2) that aims to provide an efficient means of providing information to support policy, planning and evaluation at national and NHS Board levels, and that also meets the needs of researchers. SPIRE is conducting an engagement strategy with GP groups to ensure strong endorsement of the project with concomitant agreement to provide a rich minimum dataset, generic consent for bespoke extracts and a high rate of opt-in, all of which will be essential to create a valuable research resource. Local safe havens may also contain additional sources of GP data linked to local enhanced service contracts, which may be made available for research subject to the agreement by local GP management groups.

National Research Scotland (NRS) node safe havens are working to provide local datasets from Board PACS systems and SCI store laboratory data for linkage to other datasets (see Box 12). These clinical datasets from Health Boards across Scotland would create an extremely valuable national research resource. Possible uses include supporting novel ways of matching patients with clinical trial protocols

and more efficient surveillance of licensed medicines. Through the Farr Institute Scotland, there will be consultation with Health Boards on the creation of analysis-ready extracts of SCI store laboratory data and PACS images to enable linkage to existing national datasets for supporting NHS activity and research. The consultation will consider which organisation(s) should support and maintain these datasets. Health Board cooperation, leadership and collaboration will be essential as Health Boards' laboratory data in SCI store has been not been developed on common standards and will require local expertise to support migration and provide metadata. It is proposed that the dataset provider will supply node safe havens with local extracts of these data sources to maintain the capability to link these datasets to other locally-held datasets.

Box 12: Linking biochemistry, clinical care and demographic data to understand the epidemiology of chronic kidney disease

Not everyone with poor kidney function will go on to develop kidney disease requiring dialysis or transplantation. Understanding who will or will not progress is important for planning care for individual patients and their families, and for planning services for the population as a whole. Researchers at the University of Aberdeen and NHS Grampian created a cohort including all patients in Grampian on renal replacement therapy, all those with chronic kidney disease (i.e. impaired renal function for 3 months or more) and all those who had one test showing impaired function, plus samples of patients who had been tested but found to have adequate kidney function and people who had not undergone testing.

Following ethical, Caldicott Guardian and Privacy Advisory Committee approval, the biochemistry data was linked with hospitalisation and mortality data by ISD, and the dataset stored in the Grampian Safe Haven. The cohort, with a total size of ~70,000 participants, was followed for six years from 2003-2009, to ascertain incidence and progression of kidney disease, other major health events requiring hospitalisation, and deaths.

Using the linked data, the researchers were able to identify factors associated with risk of death, heart attack and progression to more severe kidney disease, and to develop accurate models of need for renal replacement therapy.

Maximising the potential for research to enhance the delivery of healthcare will require greater convergence with the eHealth strategy. This should ensure that in the implementation of new clinical and administrative information systems, the ability to efficiently use and share routinely collected NHS data for research and other purposes is built into the design. This will require the specification of in-built system queries, the mapping of diverse standards to equivalent data definitions and automated workflows to ensure that data can be accessed quickly and reliably for research. Investment in initiatives led by clinical groups committed to building effective electronic patient records to drive quality improvement should also be encouraged. Such initiatives should seek to make data available for research, based on internationally agreed standards.

RECOMMENDATION 3: Improve the provisioning of national primary care, prescribing and clinical datasets for research and in support of NHS healthcare activity by ensuring that provision for both system query and data extraction is built into the specification of new systems. At the same time, this should promote more efficient integration of data across NHS Boards through specification of common data standards, and/or initiatives to map local data standards to consistent data definitions.

3.2 Engagement with Industry

Active engagement of industry will be an important gauge of the success of the new investment in health informatics research. Developing a clear understanding of commercial partners' requirements is a priority. Work commissioned by Scottish Enterprise will identify the mechanisms by which health informatics research capability can generate economic benefit, and the opportunities to ensure that the earnings from such activity are recycled into further infrastructure developments or research activity. Models of engagement are required that balance commercial partners' requirements for the protection of intellectual property, with the delivery of public and patient benefit through placing the findings of research into the public domain. The Farr Institute Scotland and the Safe Haven Network should work with their partners in industry to develop exemplars of the benefits of engagement for both economic and social benefit.

RECOMMENDATION 4: The Farr Institute Scotland, the Safe Haven Network, the Chief Scientist Office and eHealth Strategy Board should consider the ways in which health informatics research capability can generate economic benefit, and work with partners in industry to develop early exemplars of the benefits of engagement for both economic, health and social benefit.

3.3 Engaging patients and the public

Managing public concern about the risks to privacy and confidentiality associated with innovative uses of medical records for research is vital to continued progress. The available evidence suggests that the use of anonymised patient data for publicly funded research is accepted by the public, so long as confidentiality is protected and the research is intended to improve health[34]. Attitudes towards commercial use of patient data are much more ambivalent, and depend on factors such as the aims of the research and how the benefits will be shared[35,36]. The Administrative Data Taskforce found that data controllers in the public sector also had concerns about

[34] Mackenzie IS, Wei L, Paterson KR, Macdonald TM. Cluster randomised trials of prescription medicines or prescribing policy- public and general practitioner opinions in Scotland. Br J Clin Pharmacol. 2012;74:354-61

[35] Davidson S et al. Public acceptability of cross sectoral data linkage. Deliberative research findings. Edinburgh, Scottish Government, 2012. (www.scotland.gov.uk/socialresearch)

[36] Davidson S et al. Public Acceptability of Data Sharing Between the Public, Private and Third Sectors for Research Purposes. Edinburgh, Scottish Government, 2013. (http://www.scotland.gov.uk/Publications/2013/10/1304)

commercial access to data[18], and its potential impact on their continued ability to obtain information from members of the public. Research on public attitudes to the use of cross-sectoral data suggest that it is viewed in the same way as the use of health data, with recognition of the potential benefits and a confidence that public bodies will protect confidentiality[36].

Maintaining public confidence will be essential, as the use of health and cross-sectoral data increases. Public understanding of the uses that the NHS makes of patient data needs to be encouraged and developed in order to promote best patient care, quality assurance, research and development applications. The NHS and others who make use of data also need to listen and respond to citizens opinions about how data are managed and used. Continual effective two-way dialogue is essential in promoting the nation's health and economic transformation. Successful models of benefit sharing, especially with the private sector, also need to be identified. However, transparency in the sharing of public-sector data and independent oversight appear to be more important to the public than direct involvement in decision-making. A recent consultation exercise[33] has suggested that the Scottish Government's current approach to involving the public in decision-making primarily through consultation is broadly in line with expectations but should be maintained as an on-going process. Communicating the types of research that are being conducted and positive outcomes will form part of this dialogue. For example the role of the public and the importance of public trust is in-built into the proposed Public Benefits and Privacy Panel (PBPP). A communications and engagement strategy is currently being developed for the Scottish Informatics and Linkage Collaboration (SILC) (Box 7). This will address the issues associated with cross-sectoral data linkage, and it is important that developments within health are part of this wider strategy.

RECOMMENDATION 5: The eHealth Strategy Board should work with the Scottish Informatics and Linkage Collaboration and Data Management Board to develop a programme of public engagement activities to widen understanding of how data is used in research to improve population health and the quality and effectiveness of healthcare.

3.4 Building capacity

The new and emerging infrastructure is expected to generate a marked increase in the volume of health informatics research in Scotland. This will only materialise if there is an increase in the number of information specialists and researchers with the relevant training and expertise. SHIP has in the past provided a variety of training courses, as well as an online information governance toolkit (http://www.scot-ship.ac.uk/toolkit), and there is a range of Masters courses across Scotland relevant to health informatics research, including research ethics and data linkage.

Resources have been sought within the Scottish e-HIRC bid to fund a PhD programme plus a number of research positions intended to provide a broad range of career development opportunities for data managers, software engineers, informatics scientists and data analysts. These are important developments, which should, in time, provide the basis for further grant acquisition. There is also an

urgent need for the NHS to increase capacity and make investments in key expertise to enhance capability to use health informatics to promote the development of 'learning' healthcare systems that use data efficiently to manage services, monitor outcomes and improve policy.

RECOMMENDATION 6: Research funders and the NHS should be encouraged to prioritise investment in health informatics research expertise through doctoral and postdoctoral training schemes, and by increasing the capacity of the NHS to use patient data to inform service improvement.

4 Conclusions

The unprecedented investment by the MRC and its funding partners, coupled with strong Government support for both health and cross-sectoral data linkage, creates a unique opportunity for a step change in health and biomedical informatics research capability in Scotland.

For this potential to be realised, there are a number of challenges that must be overcome. Strong working relationships need to be built between the new and existing infrastructure and centres of expertise. Governance must be made more streamlined and efficient. Data custodians and industry partners must be effectively engaged. Public confidence and trust need to be maintained and promoted, throughout.

There is already action in hand in several of these areas, notably the work to establish the Farr Institute Scotland and to create a national primary care dataset. The view of the Group is that further progress in the short term will depend critically on effective action to create a functioning network of safe havens, and to streamline governance procedures. Looking further ahead, it will be vital to continue to maintain public trust and progress industry engagement, and to continue to build upon our existing research capacity. In this way the potential of the new capability will be realised for the benefit of Scotland, its economic development and, most importantly, for the optimal care of patients and health improvement of the Scottish public.

5 Glossary and List of Abbreviations

ADRC: Administrative Data Research Centre established to make routinely collected administrative data accessible for research in ways that prevent the identification of individuals, while providing a sound evidence base to inform research, and policy development, implementation and evaluation. http://adrn.ac.uk/about/

ADT: Administrative Data Taskforce (Box 8)
http://www.esrc.ac.uk/collaboration/collaborative-research/adt/

Anonymisation: the process of rendering data into a form which does not identify individuals and where identification is not likely to subsequently occur.

Caldicott Guardian: a senior person in a Health Board responsible for protecting the confidentiality of patient information and authorising appropriate information sharing.

CHI: Community Health Index, a centrally maintained register of all patients registered with a GP in Scotland. Frequently used for record linkage purposes.

CHIAG: Community Health Index Advisory Group, the group that provides advice to Directors of Public Health and the Chief Medical Officer on access to the Community Health Index (CHI). http://www.scot-ship-toolkit.org.uk/roles-and-responsibilities/chiag

CSO: Chief Scientist Office, part of the Scottish Government Health and Social Care Directorates. It supports and promotes high quality research aimed at improving the quality and cost-effectiveness of services offered by NHSScotland and securing lasting improvements to the health of the people of Scotland.

CPRD: Clinical Practice Research Datalink, a research service and database of English NHS clinical data designed to facilitate observational and interventional research. http://www.cprd.com/home/

Data Controller: an individual or organisation who determines the purposes for which and the manner in which any personal confidential data are or will be processed. Data controllers must ensure that any processing of personal data for which they are responsible complies with the Data Protection Act (1998).

Data Processor: a person who processes data on instruction from the Data Controller but who does not determine the purpose and manner in which the data are processed. In the context of safe havens, it is the safe haven and all the staff involved in providing this service.

De-identified data: personal confidential data, which has been anonymised in a manner conforming to the Information Commissioners Office anonymisation code of practice.

DICOM: Data Imaging and Communications in Medicine

eDRIS: Electronic Data Research and Innovation Service (Box 5).

EHR: Electronic Health Record, a computerised record of a patient's medical history. http://www.isdscotland.org/Products-and-Services/EDRIS/

ESRC: Economic and Social Research Council, a leading UK funder of research on economic and social issues. http://www.esrc.ac.uk/

Farr Institute: The Farr Institute of Health Informatics Research, a UK collaboration to harness health data for patient and public benefit by setting the international standard for the safe and secure use of electronic patient records and other population-based datasets for research purposes. There are four centres across the UK, of which the Farr Institute Scotland is one. http://www.farrinstitute.org/

Farr Institute Scotland: the Scottish hub of the UK wide Farr Institute and comprises six Universities and NHS National Services Scotland. http://www.farrinstitute.org/centre/Scotland/3_About.html

HSCIC: Health and Social Care Information Centre, a national provider of information, data and IT systems for health and social care in England. http://www.hscic.gov.uk/

Information governance: the management of information and data in accordance with legal requirements such as the duty of confidence and data protection, the legal basis for information sharing, key requirements in relation to information security, record management, and freedom of information.

IRAS: Integrated Research Application System is a system for applying for the permissions and approvals for health and social/community care research in the UK. https://www.myresearchproject.org.uk/Signin.aspx

ISD: Information Services Division of NHS National Services Scotland (NSS). http://www.isdscotland.org/

Linkage: the merging of data from two or more sources with the object of consolidating information concerning an individual or an event that are not available in any separate record.

MRC: Medical Research Council, a publicly funded government agency responsible for co-ordinating and funding medical research in the United Kingdom. http://www.mrc.ac.uk/

NHS National Services Scotland (NSS): provides advice and services to NHSScotland bodies. http://www.nhsnss.org/

National Records of Scotland (NRS): performs the registration and statistical functions for the Registrar General for Scotland, including responsibility for demographic statistics, the census and archival functions. **http://www.nrscotland.gov.uk/**

NHS Research Scotland (NRS): a partnership involving Scottish NHS Boards and the Chief Scientist Office (CSO) of the Scottish Government with the aim of ensuring that NHSScotland provides the best environment to support clinical research. http://www.nhsresearchscotland.org.uk/

PAC: NSS Privacy Advisory Committee, an advisory committee to the Board of NHS National Services Scotland and to the Registrar General. It provides advice on requests for the release of patient identifiable information. http://www.nhsnss.org/pages/corporate/privacy_advisory_committee.php

PACS: Picture Archiving and Communications System. http://www.nisg.scot.nhs.uk/currently-supporting/pacs-and-ris

Safe haven: term used to explain either a secure physical location or environment, supported by trained specialist staff working under agreed administrative arrangements within the organisation to ensure confidential personal information is processed and/or communicated safely and securely.

SAIL: Secure Anonymised Information Linkage system brings together an array of routinely-collected data from health and other public services in Wales for research, development and evaluation. http://www.saildatabank.com/

SCI store: Scottish Care Information Store, an information repository that provides clinicians with secure access to patient information at the point of care. http://www.sci.scot.nhs.uk/

SHIP: ScottisH Informatics Programme (formally the Scottish Health Informatics Programme) (Boxes 4 and 6). http://www.scot-ship.ac.uk/

SILC: Scottish Informatics and Linkage Collaboration (Box 7).

SLS: Scottish Longitudinal Study. (Box 3). http://sls.lscs.ac.uk/

SMR: Scottish Morbidity Record (Box 1).

SPIRE: Scottish Primary Care Information Resource (Box 2). http://www.spire.scot.nhs.uk/

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