Public Benefit and Privacy Panel for Health and Social Care

Application Form

Application Control *Applicants should not fill out this section*			
Application Coordinator	Jackie Caldwell		
Application Number	eDRIS-0391	Submitted Date	16 March 16
Applicant Name	Dr Sarah Murray		
Proposal Name	Educational outcomes in offspring having undergone elective induction of labour compared with expectant management.		

Contents

Note to Applicants

Prior to completing your application form you should:

- Contact the eDRIS Team, who will assist you - Nss.edris@nhs.net or by phone on 0131 275 7333
- Read and understand the separate Guidance for Applicants

Your application should be typed, not handwritten. Your eDRIS application coordinator will inform you how to submit your application form and any supporting evidence. Before submitting your completed application, you should ensure that:

- All relevant sections of the application are complete
- Relevant supporting evidence is attached
- Individuals named on the form have read and approved its submission

Please note that submitted applications may be circulated to panel members, administrative colleagues, NHSScotland information governance and information security colleagues, Caldicott Guardians, the CHI Advisory Group and, where appropriate, non-NHS Scotland colleagues from a variety of participating partner bodies, in the course of processing. You must make your eDRIS application coordinator aware of any confidential or sensitive information contained in your application which you would consider inappropriate for circulation in such a manner. Your application could be subject to disclosure or partial disclosure under the Freedom of Information (Scotland) Act, and will be retained in line with NHSScotland information policy.

Section 1 – People

1.1	**Applicant** *Please read section 1.1 of the guidance*	
1.1.01	Full Name:	Sarah Murray
1.1.02	Title:	Dr
1.1.03	Position:	Clinical Research Fellow
1.1.04	Professional Registration No.:	GMC: 6166073
1.1.05	Organisation Name:	University of Edinburgh, Centre for Reproductive health
1.1.06	Address:	Centre for Reproductive Health, Queen's Medical Research Institute, 47 Little France Crescent, Edinburgh
1.1.07	Postcode:	EH16 4TJ
1.1.08	Telephone Number:	0131 242 2691
1.1.09	Email:	Smurray8@staffmail.ed.ac.uk
1.1.10	Do you have an NHS contract/honorary contract?	Yes
1.1.11	Provide details of the most recent information governance training undertaken - a list of training courses is included at Appendix A, and you should particularly indicate if you have undertaken any of those listed	
	Name of course:	MRC Research Data and Confidentiality e-learning course
	Link to course content:	http://www.byglearning.co.uk/mrcrsc-lms/login/index/php
	Institution:	MRC
	Date completed:	17/06/15

1.2	**Clinical Sponsor/Lead** *Please read section 1.2 of the guidance*	
1.2.01	Full Name:	Jane Norman
1.2.02	Title:	Professor
1.2.03	Position:	Professor of Maternal and Fetal Health
1.2.04	Professional Registration No.:	GMC: 3181175
1.2.05	Organisation Name:	Tommy's Centre for Maternal and Fetal Health, Centre for Reproductive Health, University of Edinburgh
1.2.06	Address:	Centre for Reproductive Health, Queen's Medical Research Institute, 47 Little France Crescent, Edinburgh
1.2.07	Postcode:	EH16 4TJ

1.2.08	Telephone Number:	0131 242 2694
1.2.09	Email:	Jane.norman@ed.ac.uk
1.2.10	Does this person have an NHS contract/honorary contract?	Yes
1.2.11	Provide details of the most recent information governance training undertaken - a list of training courses is included at Appendix A, and you should particularly indicate if this person has undertaken any of those listed	
	Name of course:	MRC Research Data and confidentiality e-learning course
	Link to course content:	http://www.byglearning.co.uk/mrcrsc-lms/login/index/php
	Institution:	MRC
	Date completed:	8/2/15

1.3	**Information/Data Custodian** *Please read section 1.3 of the guidance*	
1.3.01	Full Name:	As 1.1
1.3.02	Title:	
1.3.03	Position:	
1.3.04	Professional Registration No.:	*If applicable*
1.3.05	Organisation Name:	
1.3.06	Address:	
1.3.07	Postcode:	
1.3.08	Telephone Number:	
1.3.09	Email:	
1.3.10	Does this person have an NHS contract/honorary contract?	Choose an item.
1.3.11	Provide details of the most recent information governance training undertaken - a list of training courses is included at Appendix A, and you should particularly indicate if this person has undertaken any of those listed	
	Name of course:	
	Link to course content:	*If applicable*
	Institution:	
	Date completed:	

1.4 Others with access to identifiable or potentially identifiable data *Please read section 1.4 of the guidance*			
Complete this section if applicable – for each additional person			
Full Name:	Jill Pell	Telephone or Email:	Jill.pell@glasgow.ac.uk
Organisation:	University of Glasgow	Position:	Henry Mechan Professor of Public Health Deputy Director of Farr Scotland
Professional Registration No:	3259687	NHS contract/ honorary contract?	Yes

IG Training - Name of course:	MRC Research Data and Confidentiality e-learning Course		
IG Training - Link to course:	*http://www.byglearning.co.uk/mrcrsc-lms/login/index/php*		
IG Training - Institution:	MRC	Date completed:	15/05/15

1.4 Others with access to identifiable or potentially identifiable data *Please read section 1.4 of the guidance*			
Complete this section if applicable – for each additional person			
Full Name:	Sarah Stock	Telephone or Email:	Sarah.stock@ed.ac.uk
Organisation:	University of Edinburgh	Position:	Senior Lecturer/Honorary Consultant
Professional Registration No:	4544806	NHS contract/ honorary contract?	Yes

IG Training - Name of course:	MRC Research Data and Confidentiality e-learning Course		
IG Training - Link to course:	*http://www.byglearning.co.uk/mrcrsc-lms/login/index/php*		
IG Training - Institution:	MRC	Date completed:	13/03/15

1.5 Others *Please read section 1.5 of the guidance*			
Complete this section if applicable – for each additional person			
Full Name:		Involvement in Proposal:	
Organisation:		Position:	

Section 2 – Organisations & Bodies

2.1	**Organisation or Body Leading Proposal** *Please read section 2.1 of the guidance*	
2.1.01	Organisation or Body Name:	Centre for Reproductive Health, University of Edinburgh
2.1.02	Is this organisation or body a registered data controller? If 'Yes', provide Data Protection Registration Number:	Yes – University of Edinburgh: Z6426984
2.1.03	Is this a commercial organisation or body?	No
2.1.03a	If 'Yes', please provide a full explanation of the organisation or body's activity and industry sector, including any previous experience of using NHSScotland data - append supporting documentation as appropriate	*If applicable*
2.1.04	Is this organisation or body wholly funding or paying for the costs of conducting the proposal?	No

2.2	**Organisation or Body Funding Proposal** *Please read section 2.2 of the guidance*	
Complete the following section if you answered 'No' to question 2.1.4		
2.2.01	Organisation or Body Name:	Wellcome trust
2.2.02	Is this organisation or body a registered data controller? If 'Yes', provide Data Protection Registration Number:	Yes Z6599948
2.2.03	Is this organisation or body a commercial organisation?	No
2.2.03a	If 'Yes', please provide a full explanation of the organisation or body's activity and industry sector, including any previous experience of using NHSScotland data - append supporting documentation as appropriate	

2.3 Other Relevant Organisations or Bodies *Please read section 2.3 of the guidance*		
Complete this section if applicable		
Organisation Name	Nature of Business/Sector	Nature of interest in proposal

Section 3 – Overview

3.1	**Proposal Essentials** *Please read section 3.1 of the guidance*	
3.1.01	Proposal title/name:	Educational outcomes in offspring having undergone elective induction of labour compared with expectant management
3.1.02	Is this proposal an extension or renewal of an existing approval (for example to conduct a study over a wider geographic area or for a longer period of time)? Please provide details, include the reference number of the original approval, and summarise the changes requested	No
3.1.03	Is this new proposal related to a previous application (approved or not)? Please give details, indicate if this is a resubmission, including the reference number of the original submission	This is a new proposal but is similar to the previously approved eDRIS project on twins and educational outcomes ref 1516-0252
3.1.04	What is(are) the substantive purpose(s) of the proposal? (tick all that apply) ☒ Patient Care ☐ Audit ☐ Service Planning/Improvement ☐ Systems Implementation/Testing ☐ Quality (Clinical, Educational, etc) ☒ Research ☐ Performance Monitoring/Management ☐ Health/Social Care Administration ☐ Training/Education	
	If other clearly defined purpose, please give details:	
3.1.05	Does the proposal require the use of information which can identify or potentially identify individuals?	Some potentially identifiable information is requested in the proposal, please see details in the attached variable list and justification in section 4.3
3.1.06	Access is being requested to data from which sources? (tick as many as are relevant)	

	☐ A single NHS Scotland Board (excluding NSS) ☒ NHS National Services Scotland ☐ More than one NHS Scotland Board ☐ A national NHS Scotland system/database ☐ More than one NHS Scotland system/database ☐ Community Health Index (CHI) database ☐ NHS Central Registry
	If other, please give details: Scot Xed School Census and examination database
3.1.07	Provide a full, clear concise outline of the proposal background – describe why it is needed, aims and objectives and envisaged benefits to the public and/or patients: The purpose of this work is to guide clinicians on the optimum timing of the elective delivery of singleton pregnancies. Data from singletons illustrates the need to consider the effects of timing of delivery on short and long-term complications. In singletons appropriate timing of delivery is best determined using the perinatal risk index. This is defined as the risk of death in pregnancies continuing beyond a certain gestation (compared to the risk of death in pregnancies delivered at that gestation). In singletons perinatal risk index is lowest at 38 weeks. In other words, in terms of perinatal death it is safer for the baby to be delivered at 38 weeks compared to continuing the pregnancy. Consistent with this, data from our group suggests that elective induction of labour from 37 weeks in uncomplicated pregnancy reduces the risk of perinatal death. These data have resulted in a Scientific Impact Paper from the Royal College of Obstetricians and Gynaecologists suggesting that early elective delivery should be offered to women with a singleton pregnancy in whom the background risk of stillbirth is high. This study, published in the BMJ, looked at the immediate outcomes of induction of labour in terms of perinatal morbidity and mortality but did not look at any longer term childhood outcomes. In singleton pregnancies it is important to note that gestation at delivery also has a strong, dose-dependent relationship with special educational need, with a progressive decrease in special educational needs requirement with increasing gestational age. Hence although perinatal death could be reduced by early delivery in singletons, such a strategy

	could be associated with an increase in developmental compromise for the baby. The following specific research aim will be in investigated in this study: 1. To determine the long term educational outcomes in singletons who have undergone elective induction of labour compared with expectant management including record of additional educational support need, type of need, examination attainment level and school leaver destination The answer to this question will add more information to what is already known about induction of labour in singleton pregnancies and help guide clinicians on the optimum timing of elective delivery of singletons.
3.1.08	Provide a full, clear and concise outline of the proposal design, listing: data sources; sample size ; inclusion/exclusion criteria (eg involvement in trial/survey; health event, etc); relevant date range; need for identifiable or potentially identifiable data; requirement for a matched control cohort etc. <u>Study Design</u> I propose to carry out a population based retrospective cohort study of all singleton deliveries from 1988-2014. In order to determine the longer term educational outcomes following induction of labour by gestational age the SMRO2 records will be linked to the ScotXed school census and SVQ databases at an individual level. The personal identifiers (names, addresses, postcodes, dates of birth and community health index – CHI) will be removed before the datasets are placed in the safe haven and therefore are not accessible to me as a researcher. I will use binary and ordinal logistic regression models to explore the relationship between gestation of delivery and each outcome, adjusting for potential confounders including infant sex, maternal age and height, marital status, parity, birth-weight centile, induction of labour, mode of delivery, year of delivery, previous spontaneous and therapeutic deliveries and the 5-min apgar score. I will then be able to present the data in a residual and influence plots to show the trend in special educational need in induced singletons versus those expectantly managed. <u>Data sources</u> Maternity Inpatient and Day case dataset (SMR02): for pregnancy and maternity records.

	NRS Births (information on all registered births), stillbirths (information on all registered stillbirths) and deaths (information on all registered deaths). Child health and surveillance programme for early childhood outcomes prior to school. ScotXed annual census which collates and holds the data on behalf of the Learning Directorate of the Scottish Government. The Scottish Qualifications Authority (SQA) which maintains a database of all children who have been entered for a qualification and the results obtained – the data are already transferred to ScotXed and linked to the school census. SMR11 and Scottish Birth Record <u>Inclusion/Exclusion criteria</u> Inclusion criteria are all women who have had a singleton pregnancy at 37 weeks' gestation or greater from 1988 onwards as the educational outcomes data is only available from 2006. Exclusion criteria are women who have recognised contraindications to induction of labour, including malpresentation, abdominal pregnancy, placenta praevia, previous caesarean section and prelabour rupture of membranes. Women with an antepartum intrauterine death will be excluded from both the induction of labour and the expectant management group. <u>Sample size</u> There are approximately 500,000 children in the school census the majority of which will deliver at or greater than 37 weeks.
3.1.09	Does the proposal have implications for, or target, sensitive groups or vulnerable populations? Please give details
	Yes, this study contains sensitive information as it involves possible pregnancy in those under 16 and stillbirths. Knowledge regarding previous stillbirths and abortion is important and necessary as it may influence induction of labour in a future pregnancy which I would then need to consider as a medical induction of labour. I am not requesting all the abortion fields from SMR02/SBR just absolute numbers. Ethnicity information is important as ethnicity can be associated with increased rates of gestational diabetes and factors which may influence induction of labour. I will only be

	requesting white and other. Drug/alcohol misuse information – necessary as can be a confounder for preterm delivery, abruption and growth restriction and also admission to the neonatal unit and therefore should be noted in the analysis.
3.1.10	Does the proposal seek to use information exclusively about deceased persons? Please give details
	No
3.1.11	Have any members of the public/lay representatives been involved in the proposal design? Please give details
	No
3.1.12	Has any peer review of the proposal been undertaken? Please give details (for example formal review by a peer organisation or funding body, informal internal review, review by a third party)
	Yes - this is a Wellcome Trust funded Clinical Research training fellowship.
3.1.13	Is there *any* commercial aspect or dimension to the proposal or its outcomes? Please give details
	No

3.2 Proposal Geography *Please read section 3.2 of the guidance*
☐ Local/Regional (relating to one or more specific areas within Scotland)

☒ National (relating to the whole of Scotland)

☐ UK-wide (relating to the whole of the UK, or to UK regions outside Scotland)

☐ International (relating to areas within the EEA)

☐ International (relating to areas beyond the EEA)

3.3	**Proposal Duration and Frequency** *Please read section 3.3 of the guidance*	
3.3.01	What is the proposed duration of the proposal?	**2 years**
3.3.02	Does the proposal require updates of information at regular intervals? Please give details	**No**
3.3.03	Are you seeking approval to iterate the proposal (ie the *whole* project, audit or study) at regular intervals? Please give details	**No**

3.4	**Statutory and Regulatory Context** *Please read section 3.4 of the guidance*	
3.4.01	Does your proposal have a statutory or regulatory justification - is the proposal responding to a statutory or regulatory instruction, duty or order? Please give details	*No*
3.4.02	Which Data Protection Act schedule 2 and schedule 3 conditions are relevant? (a list of conditions can be found at Appendix B)	We believe the following conditions cover the process and make the data-linkage lawful: • Schedule 2 – condition 6(1): the processing is necessary in order to pursue the legitimate interests of the data controller or certain third parties (unless prejudicial to the interests of the individual) • Schedule 3 – condition 8(1): The processing is necessary for medical research purposes and is undertaken by a health

		professional Dr Sarah Murray.
3.4.03	Are there any relevant information sharing agreements, protocols or contracts in place which support your proposal? Please give details and attach as supporting documentation if available	Once access to the education data has been agreed, a data sharing agreement will be produced, signed by both the SG and the requestor.
3.4.04	Has a Privacy Impact Assessment been carried out which supports your proposal? Please give details and attach as supporting documentation if available	*No*
3.4.05	Has local Caldicott approval been given for your proposal at a local level? Please give details	*No*
3.4.06	Are approvals from Caldicott Guardians outside Scotland pending or received? Please give details	*No*

3.5	**Research and Ethics Governance** *Please read section 3.5 of the guidance*	
3.5.01	Has your proposal sought research/ethics approval?	No
3.5.01a	If yes, please provide committee details and status of approval (ie pending, approved, etc). Please attach as supporting documentation if available	*N/A*
3.5.01b	If no, please explain why research/ethics approval is not sought:	There is no new information to be collected from the participants in the study and no contact will be made with them.

3.6	**Safe Havens** *Please read section 3.6 of the guidance*	
3.6.01	Do you intend to access the data requested exclusively through a safe haven listed at Appendix A? Please provide details of which safe haven/s	*Yes* NHS NSS ISD Electronic Data Research Innovation Service (@Farr Institute) Farr Institute, Edinburgh Bioquarter

3.6.02	If you applying to use NHS NSS data and you do not intend to do this through the National Safe Haven, please explain why	*N/A*

Section 4 – Data & Data Subjects

4.1 Data yet to be collected *Please read section 4.1 of the guidance*		
Dataset/source Name	Collection by (whom)?	Explicit consent sought? If Yes, describe how explicit consent being sought – provide copies of participant consent/registration forms, etc. If No, explain why consent is not being sought (eg impractical, risk associated with seeking consent, etc)

4.2 All Other Datasets / sources *Please read section 4.2 of the guidance*		
Dataset/source Name	Data Controller (Organisation)	Original purpose compatible with proposal?
ScotXed (School census and SQA attainments)	Scottish government – Educational analytical services	Yes - The database was set up to provide data to analysts within the Scottish Government for national and international statistical publications
NRS Birth, stillbirth and Death records	National Records of Scotland	Yes - registrations of births, and deaths in the first year of life
SMR02	NHS National Service Scotland	Yes - The Maternity Inpatient and Day Case dataset (SMR02) collects episode level data every time a mother goes in for an obstetric event (this can be an antenatal, delivery or postnatal episode).
SMR11/SBR	NHS National Service Scotland	Yes
Scottish stillbirth and Infant Death Survey (SSBID)	NHS National Service Scotland	Yes
CHSP (Child health	NHS National Service Scotland	Yes

and surveillance survey)		

How were individuals originally informed of the use of their data? (if known)

NHS data

NHS Scotland has produced a leaflet: “Confidentiality – It’s your right”. Within the section on Confidentiality there is a clause which states “sometimes the NHS also uses relevant information about your health to help to improve NHS services and public health in Scotland – for example to find out how many people have a particular illness or disease”.

Education data

Information about pupils’ education is collected through our statistical surveys in partnership between the Scottish Government and Local Authorities through the ScotXed Programme which aims to help schools and Local Authorities by supporting efficient collection, processing and dissemination of statistical information. The Scottish Government then provides analysis of the data to support research, planning, management and monitoring of education services as well as to produce National Statistics publications.

Education data within Scottish Government is managed effectively by secure systems and is exploited as a valuable corporate resource, subject to confidentiality restraints. As part of its data policy, Scottish Government will not publish or make publicly available any information that allows individual pupils to be identified, nor will data be used by Scottish Government to take any actions in respect of individuals. Data is held securely and no information on individual pupils can or would be made publicly available by Scottish Government.

Why do we need your data?

In order to make the best decisions about how to improve our education service, Scottish Government, education authorities and other partners such as the SQA and Skills Development Scotland need accurate, up-to-date data about our pupils. We are keen to help all our pupils do well in all aspects of school life and achieve better examination results. Accurate and up-to-date data allows us to:

- plan and deliver better policies for the benefit of all pupils
- plan and deliver better policies for the benefit of specific groups of pupils
- better understand some of the factors which influence pupil attainment and achievement
- share good practice
- target resources better

enhance the quality of research to improve the lives of young people in Scotland *(taken from http://www.gov.scot/Topics/Statistics/Browse/School-Education/datausage)*
For existing dataset/sources for which the data controller is not an NHSScotland board, please append evidence of the data controllers permission to use the data I have applied to the Scottish government educational analytical services to access the education data

4.3 Data Variables *Please read section 4.3 of the guidance*			
Dataset/source Name	Variable	Time Period/Range	Processing only?
See excel sheet			Choose an item.
			Choose an item.
			Choose an item.
Please justify your need for identifiable or potentially identifiable variables:			
Month/Year of delivery – necessary as obstetric practice changes greatly between years and is a potential confounding factor determining gestation of delivery			

4.4	**NRS/NHSCR Data Sources** *Please read section 4.4 of the guidance*	
Complete this section if access to NHSCR is required, or if there is any National Records of Scotland involvement		
4.4.01	Does the proposal require access to NHS Central Registry as a sampling frame for cohorts?	No
4.4.02	Does the proposal involve flagging of individuals on the NHSCR for long term follow up?	No
4.4.03	If yes, is flagging necessary: ☐ To trace and contact individuals throughout the UK? ☐ To be informed of fact and cause of death? ☐ To be informed of the incidence of on-going cancers? ☐ To be informed of emigrations prospectively and retrospectively?	

4.4.04	Is any other NRS involvement required? Please provide details	

4.5	**Making Contact with Individuals** *Please read section 4.5 of the guidance*				
4.5.01	Is any direct contact with any group of individuals required? If Yes, please provide details below				No
	Contact Group and Method of contact				Contact by (whom)
	☐ Hospital Consultants	☐ Letter	☐ Phone	☐ Other (specify) :	
	☐ Other NHSS Staff	☐ Letter	☐ Phone	☐ Other (specify) :	
	☐ General Practitioners	☐ Letter	☐ Phone	☐ Other (specify) :	
	☐ Patients/Public	☐ Letter	☐ Phone	☐ Other (specify) :	
	☐ Relatives of participants	☐ Letter	☐ Phone	☐ Other (specify):	
	☐ Others (please specify):	☐ Letter	☐ Phone	☐ Other (specify) :	
4.5.02	Please explain why contact is being made – append copies of relevant correspondence as supporting evidence				
	If applicable				

4.6	**Community Health Index (CHI) Database** *Please read section 4.6 of the guidance*
Complete this section if access to CHI Database is required	

4.6.01	What monitoring and audit of the use of CHI is planned? Please provide details	
4.6.02	What technical method will be used to access CHI (online read-only, download, other extract, anonymised extract, etc)? Please provide details	
4.6.03	Have any risks been identified in the proposal which relate specifically to CHI?	

Section 5 – Methodology & Data Processing

5.1	**Methodology** *Please read section 5.1 of the guidance*	
5.1.01	Does the proposal require any of the following: ☒ Data matching/linking ☐ Single anonymised data extract ☐ Use of matched controls Other (please specify):	
5.1.02	Who is carrying out any indexing/ linkage/anonymisation, and where?	NRS indexing team
5.1.03	Which data sources listed at section 4.1 and 4.2 will NSS/NRS receive identifiers for linkage purposes?	*All those listed in 4.1 and 4.2*
5.1.04	What variables will be provided for linkage? ☐ CHI Number ☐ Forename ☐ Surname ☐ Date of Birth ☐ Address or Postcode ☒ NHS Number Other Please Specify: *For indexing of the educational data the SG will provide the following variables to the NRS indexing team: date of birth, gender and postcode*	

5.2	**Access** *Please read section 5.2 of the guidance*	
Complete the following section if you answered 'No' to question 3.6.1		
5.2.01	At what location is identifiable or potentially identifiable data being accessed?	
5.2.02	Please provide details of security policy/procedure governing access to this physical and technical environment – append supporting documentation	
5.2.03	Does this policy/procedure cover password policy in detail? Please provide details/ append supporting documentation	
5.2.04	Does this policy/procedure cover user account	

	management, including review or removal of access to sensitive/personal data, in detail? Please provide details/ append supporting documentation	
5.2.05	Will individuals with access to data have individual or shared accounts?	
5.2.06	Will the data be accessed by staff working off site eg staff working from home at any time during the duration of the proposal?	Choose an item.
5.2.06b	If yes, are policies/procedures in place to facilitate, monitor and audit this access? Please provide details/ append supporting documentation	*If applicable*
5.2.07	Provide any additional detail of how data is protected from unauthorised access	*If applicable*

5.3	**Store & Use** *Please read section 5.3 of the guidance*	
Complete the following section if you answered 'No' to question 3.6.1		
5.3.01	Where is data being stored and used? (location, organisation, address – refer to addresses in previous sections if appropriate)	
5.3.02	Data Protection Registration Number	*If applicable*
5.3.03	ISO 27001 Cert. No.	*If applicable*
5.3.04	Please provide details of security policy/procedure governing storage and use of data within this physical and technical environment – append supporting documentation	
5.3.05	Does this policy/procedure cover the implementation of up-to-date controls for the detection and prevention of malware? Please provide details/ append supporting documentation	
5.3.06	Does this policy/procedure cover access control and auditing of system administrator activity? Please provide details/ append supporting documentation	
5.3.07	Does this policy/procedure cover the production of backups and the controls in place around these? Please provide	

	details/ append supporting documentation	
5.3.08	Does this policy/procedure describe the controls in place to prohibit unauthorised copying of data? Please provide details/ append supporting documentation	
5.3.09	Does this policy/procedure describe physical and site controls? Please provide details/ append supporting documentation	
5.3.10	Does this policy/procedure cover hardware repair, replacement or disposal and protection of data from inappropriate access during such procedures? Please provide details/ append supporting documentation	
5.3.11	Describe the systems, software and security used to store and use data - please provide details/ append supporting documentation	
5.3.12	Is outsourced IT in use? Please give details	
Please repeat section 5.3 above for each relevant location in the proposal – see guidance		

5.4	**Transfer** *Please read section 5.4 of the guidance*	
5.4.01	Please provide details of security policy/procedure to ensure that data will be transferred in such a way that it is protected from inappropriate or unauthorised access (mention email encryption, secure file transfer protocols SFTP, device encryption, physical controls, etc, as appropriate) - append supporting documentation	The NRS indexing service will be using the secure transfer protocol 'Thru' to receive personal identifiers from the Scottish Government. ISD will use the secure transfer protocol 'U-serv' to pass the NHS numbers for the cohorts to the NRS indexing team. Both data providers, ISD and the Scottish Government, will be using 'U-serv' SFTP to transfer

		indexed content data to the National Safe Haven.
5.4.02	At what intervals/ trigger points will data transfer take place?	Other than the initial data transfers for indexing/linkage and moving content data to the NSS safe haven as detailed in 5.4.01, no further data transfer is planned
5.4.03	Will any identifiable or potentially identifiable data be transferred outside of the UK?	No
5.4.03b	If yes, please provide details of the country of destination, the method of transfer, the proposed location and method of storage outside of the UK, and details of any further onward transfer	
5.4.04	Other than initial transfers from source systems, is there any copying of data required within the proposal? Please give details	No

5.5	**Dissemination** *Please read section 5.5 of the guidance*	
5.5.01	Will proposal findings be published or disseminated beyond the proposal team?	Yes
5.5.01a	If yes, how will proposal findings be published or disseminated, to what audience and in what format? Please give details	Research findings from anonymised data will be written up and submitted to a peer-reviewed journal or at relevant conferences
5.5.01b	If yes, what steps will be taken to ensure that persons cannot be identified in published findings (eg disclosure control procedures (safe haven), use of aliases, numbers, avoidance of small geographical areas, avoidance of small numbers , etc)? Please give details	Data will be anonymised for analysis; I presume the data will be derived from all over Scotland but I do not plan for any geographical analysis. The analysis will

		be described in group terms for publication. Should a sub-group become very small, it will be hard to draw any statistically valid conclusions due to its small size
5.5.01c	If yes, are there any circumstances where a living or dead individual would be cited? (eg where a person consented to their data being used as a case study)? Please give details	*No*
5.5.01d	If yes, were any permissions to publish data required or sought (for example from data controllers)? Please provide details	N/A

5.6	**Retain/Dispose** *Please read section 5.6 of the guidance*	
5.6.01	Which information/data/records retention policy will you be applying to the proposal data (details of the policy and the organisation to which it belongs)?	This is an MRC centre, so I will follow the recommendation of the MRC, which states that research records relating to clinical or public health studies should be retained for 20 years to provide scope for longer follow-up if necessary (MRC guidelines on personal information in Medical Research, Medical Research Council, 2000). This does not apply to individual level data but analysed information taken

		out from the safe haven after appropriate statistical disclosure control by eDRIS.
5.6.02	How long do you intend to retain identifiable or potentially identifiable data after the conclusion of the proposal (including archive/backup copies)?	The linked data will be kept in the Safe Haven for 2 years, after which it will be destroyed.
5.6.03	Who will retain the data and where?	The data will be retained in the safe haven.
5.6.04	What is the purpose for retaining the data for the specified time?	As 5.6.01
5.6.05	What method of disposal or destruction will be used when this period has expired (including archive/backup copies)?	The linked data will be destroyed according to the requirements of the safe haven. The researchers will have no access to the linked-data containing patient identifiable information.
5.6.06	What evidence will be obtained that destruction has occurred (eg IT supplier certificate of destruction, etc)?	Confirmation received from host

5.7	**Review** *Please read section 5.7 of the guidance*	
5.7.01	Describe how the mechanisms which safeguard data security will be audited and reviewed at regular intervals to ensure their continued efficacy	The anonymised record-linked data will be stored in a safe haven. Analysed data will be processed on a computer within the Queen's Medical Research Institute, University of Edinburgh at Little France. This is a secure building with ID card-activated access, only available to workers based in the building. Data will be stored on remote secure servers run by the

		University of Edinburgh which are password protected. The drive which will be used is only accessible by the person to whom it was given and computer administrators. The following security measures are in place at NHS National Services Scotland where the required data can be accessed: 1. Manned reception area 2. Swipe card access to building 3. No internet access allowed within the safe haven 4. USB ports, Cd drives and internet connections are disabled within the safe haven **5.** All users of the safe haven are required to accept the citrix user agreement before each access to the safe haven.
5.7.02	Describe any resource implications to any of the proposed measures for the protection of physical or technical security of information which are unresolved at the time of this application? (for example encryption of devices is an intention not yet fulfilled, training is not yet undertaken, etc)	Not applicable
5.7.03	Describe the breach reporting mechanisms to be invoked in the event of any inappropriate access to data or other information security incident	Should there be a security breach, we will inform the eDRIS Research Coordinator or Information Consultant as soon as we are aware.

Section 6 – Declaration

- I DECLARE THAT this application is accurate, and that, should it be successful, any health data made accessible will be used for no other purpose, and in no other way, than as described above.
- I UNDERTAKE TO notify the Public Benefit and Privacy Panel of any future changes to the purpose or manner in which data is processed in accordance with this application.
- I UNDERSTAND THAT any future applications by me, or my employing or sponsoring organisation, may be refused should any health data made accessible be used for any other purpose or in any other way than that described above.
- I CERTIFY THAT all those who have access to health data in this proposal are aware of the requirements of confidentiality and understand that any breach (eg disclosure of confidential information to a person not authorised to receive it) will be reported to the data controller, and in the case of NHS Scotland originated data to Scottish Government eHealth division.
- I GUARANTEE THAT no publication will appear in any form in which an individual may be identified without the written permission of that individual, and that I will apply appropriate disclosure control when planning publications involving the data requested.
- I UNDERSTAND THAT the Data Controller, and agents acting on its behalf, reserves the right to inspect the data on the sites where it is being processed.

To be signified by the APPLICANT

Name (in Capitals): SARAH MURRAY	Date: 15/03/16

- I DECLARE THAT (the applicant named above) is a *bona fide* worker engaged in a reputable project and that the data he/she asks for can be entrusted to him/her in the knowledge that he/she will conscientiously discharge his/her obligations, including in regard to confidentiality of the data, as stated in the declaration above.

To be signified by the INFORMATION CUSTODIAN named in Section 1.3 above (where the Information Custodian is not the applicant).

Name (in Capitals): SARAH MURRAY	Date: 15/03/16

Section 7 - Supporting Evidence

Supporting Evidence *Please read section 7 of the guidance*
Please list each piece of supporting evidence which you have included with your application in the box below – the name of each should clearly indicate what the document/file/reference is about
Study variables

Appendix A – Reference lists for applicants

1. Examples of Existing Datasets and Data Sources	
SMR 00 Outpatients	SMR 04 Mental Health
SMR 01 Inpatients and Day Cases	SMR 06 Cancer Registration
SMR 02 Maternity	SMR 11/SBR Neonatal/Scottish Birth Records
Scottish Drugs Misuse Database (SDMD)	Birth Registrations
A&E – Accident & Emergency	Stillbirth Registrations
PIS Prescribing Information	Death Registrations
CHSP-PS/CHSP-S/SIRS – Child Health Surveillance and Immunisation	SCI-DC
NHS National Service Scotland's Information Services Division (ISD) maintains a National Dataset Catalogue (NDC) containing details of all health and health related datasets that are held by ISD. The Administrative Data Liaison Service (ADLS) publishes further information on key NHSScotland datasets	

2. Common Identifiable Variables		
Forename	Middle Name	Surname
CHI Number	Date of Birth	UK NHS Birth Registration Number
Gender	Postcode	

3. Recognised Safe Havens
NHS NSS ISD Electronic Data Research Innovation Service (@Farr Institute)
NHS Research Scotland South East (ACCORD)
NHS Research Scotland East (TASC)
NHS Research Scotland North (DaSH)
NHS Research Scotland West
University of Dundee Health Informatics Centre (HIC)
National Records Scotland Scottish Longitudinal Study (SLS)
Robertson Centre @ Glasgow University

4. Research and Information Governance Training

MRC Research Data and Confidentiality online module
University of Edinburgh SHIP Information Governance training
NHS Health and Social Care Information Centre On-line Information Governance training
NHSScotland Information Governance eLearning: • Safe Information Handling (Foundation Level) • Information Handling in Practice (Intermediate Level)

5. Sensitive Data Categories		
Abortion	Mental health	Contraception
Pregnancy in age < 16 years	Drugs and alcohol misuse	Crime related statistics
Sexually transmitted disease	Suicide	Ethnicity
Assisted conception		

6. Vulnerable Populations	
Adults with Incapacity	Drugs users
Minority ethnic groups	Specific religious affiliation

Appendix B –The Caldicott Principles & the Data Protection Principles (& Schedules)

1. Caldicott Principles
1. **Justify the purpose(s)** Every single proposed use or transfer of patient identifiable information within or from an organization should be clearly defined and scrutinized, with continuing uses regularly reviewed, by an appropriate guardian.
2. **Don't use patient identifiable information unless it is necessary** Patient identifiable information items should not be included unless it is essential for the specified purpose(s) of that flow. The need for patients to be identified should be considered at each stage of satisfying the purpose(s).
3. **Use the minimum necessary patient-identifiable information** Where use of patient identifiable information is considered to be essential, the inclusion of each individual item of information should be considered and justified so that the minimum amount of identifiable information is transferred or accessible as is necessary for a given function to be carried out.
4. **Access to patient identifiable information should be on a strict need-to-know basis** Only those individuals who need access to patient identifiable information should have access to it, and they should only have access to the information items that they need to see. This may mean introducing access controls or splitting information flows where one information flow is used for several purposes.
5. **Everyone with access to patient identifiable information should be aware of their responsibilities** Action should be taken to ensure that those handling patient identifiable information - both clinical and non-clinical staff - are made fully aware of their responsibilities and obligations to respect patient confidentiality.
6. **Understand and comply with the law** Every use of patient identifiable information must be lawful. Someone in each organization handling patient information should be responsible for ensuring that the organization complies

with legal requirements.

7. **The duty to share information can be as important as the duty to protect patient confidentiality**
   Health and social care professionals should have the confidence to share information in the best interests of their patients within the framework set out by these principles. They should be supported by the policies of their employers, regulators and professional bodies.

2. Data Protection Principles
1. Personal data shall be processed fairly and lawfully and, in particular, shall not be processed unless – (a) at least one of the conditions in Schedule 2 is met, and (b) in the case of sensitive personal data, at least one of the conditions in Schedule 3 is also met
2. Personal data shall be obtained only for one or more specified and lawful purposes, and shall not be further processed in any manner incompatible with that purpose or those purposes
3. Personal data shall be adequate, relevant and not excessive in relation to the purpose or purposes for which they are processed
4. Personal data shall be accurate and, where necessary, kept up to date
5. Personal data processed for any purpose or purposes shall not be kept for longer than is necessary for that purpose or those purposes
6. Personal data shall be processed in accordance with the rights of data subjects under this Act
7. Appropriate technical and organizational measures shall be taken against unauthorized or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data
8. Personal data shall not be transferred to a country or territory outside the European

Economic Area unless that country or territory ensures an adequate level of protection for the rights and freedoms of data subjects in relation to the processing of personal data

3. Data Protection Schedule 2 & 3 Conditions
Schedule 2 – Conditions for Processing any Personal Data
1. The data subject has given his **consent** to the processing
2. The processing is necessary— (a) for the **performance of a contract** to which the data subject is a party, or (b) for the taking of steps at the request of the data subject with a view to entering into a contract
3. The processing is necessary for compliance with any **legal obligation** to which the data controller is subject, other than an obligation imposed by contract
4. The processing is necessary in order to protect the **vital interests** of the data subject
5. The processing is necessary— (a) for the administration of **justice**, (aa) for the exercise of any functions of either **House of Parliament**, (b) for the exercise of any functions conferred on any person by or under any **enactment**, (c) for the exercise of any functions of the **Crown, a Minister of the Crown or a government department**, or (d) for the exercise of any other functions of a **public nature exercised in the public interest** by any person
6. (1) The processing is necessary for the purposes of **legitimate interests** pursued by the data controller or by the third party or parties to whom the data are disclosed, except where the processing is unwarranted in any particular case by reason of prejudice to the rights and freedoms or legitimate interests of the data subject. (2) The Secretary of State may by order specify particular circumstances in which this condition is, or is not, to be taken to be satisfied
Schedule 3 – Conditions for Processing any Sensitive Personal Data
1. The data subject has given his **explicit consent** to the processing of the personal data
2. (1) The processing is necessary for the purposes of exercising or performing any right or obligation which is conferred or imposed by law on the data controller in connection with **employment**

3. The processing is necessary— (a) in order to protect the **vital interests** of the data subject or another person, in a case where— (i) **consent cannot be given** by or on behalf of the data subject, or (ii) the data controller **cannot reasonably be expected to obtain the consent** of the data subject, or (b) in order to protect the **vital interests** of another person, in a case where **consent** by or on behalf of the data subject has been **unreasonably withheld**
4. The processing— (a) is carried out in the course of its **legitimate activities** by any body or association which— (i) is **not established or conducted for profit**, and (ii) exists for political, philosophical, religious or trade-union purposes, (b) is carried out with appropriate safeguards for the rights and freedoms of data subjects, (c) relates only to individuals who either are members of the body or association or have regular contact with it in connection with its purposes, and (d) does not involve disclosure of the personal data to a third party without the consent of the data subject
5. The information contained in the personal data has been **made public** as a result of steps deliberately taken **by the data subject**
6. The processing— (a) is necessary for the purpose of, or in connection with, any **legal proceedings** (including prospective legal proceedings), (b) is necessary for the purpose of obtaining **legal advice**, or (c) is otherwise necessary for the purposes of establishing, exercising or defending **legal rights**
7. (1) The processing is necessary— (a) for the **administration of justice**, (aa) for the exercise of any functions of either **House of Parliament**, (b) for the exercise of any functions conferred on any person by or under an **enactment**, or (c) for the exercise of any functions of the **Crown, a Minister of the Crown or a government department** (2)The Secretary of State may by order—

(a) exclude the application of sub-paragraph (1) in such cases as may be specified, or

(b) provide that, in such cases as may be specified, the condition in sub-paragraph (1) is not to be regarded as satisfied unless such further conditions as may be specified in the order are also satisfied

7A. (1) The processing—

(a) is either—

(i) the disclosure of sensitive personal data by a person as a member of an **anti-fraud** organisation or otherwise in accordance with any arrangements made by such an organisation; or

(ii) any other processing by that person or another person of sensitive personal data so disclosed; and

(b) is necessary for the purposes of preventing fraud or a particular kind of fraud

(2) In this paragraph "an anti-fraud organisation" means any unincorporated association, body corporate or other person which enables or facilitates any sharing of information to prevent fraud or a particular kind of fraud or which has any of these functions as its purpose or one of its purposes

8. (1) The processing is necessary for **medical purposes** and is undertaken by—

(a) a health professional, or

(b) a person who in the circumstances owes a duty of confidentiality which is equivalent to that which would arise if that person were a health professional

(2) In this paragraph "medical purposes" includes the purposes of preventative medicine, medical diagnosis, medical research, the provision of care and treatment and the management of healthcare services

9. (1) The processing—

(a) is of sensitive personal data consisting of information as to **racial or ethnic origin**,

(b) is necessary for the purpose of identifying or keeping under review the existence or absence of **equality of opportunity** or treatment between persons of different racial or ethnic origins, with a view to enabling such equality to be promoted or maintained, and

(c) is carried out with appropriate safeguards for the rights and freedoms of data subjects

(2) The Secretary of State may by order specify circumstances in which processing falling within sub-paragraph (1)(a) and (b) is, or is not, to be taken for the purposes of sub-paragraph (1)(c) to be carried out with appropriate safeguards for the rights and freedoms of data subjects

10. The personal data are processed in circumstances specified in an order made by the

Secretary of State for the purposes of this paragraph