Public Benefit and Privacy Panel for Health and Social Care

Application Form

Application Control *Applicants should not fill out this section*			
Application Coordinator	Dionysis Vragkos		
Application Number	1516-0370	Submitted Date	07/09/2016
Applicant Name	Richard Peter Gerardus ten Broek		
Proposal Name	Adhesion-related hospital readmissions after abdominal and pelvic surgery: An update of the SCAR studies		

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:	Richard Peter Gerardus ten Broek
1.1.02	Title:	MD, PhD
1.1.03	Position:	Post-doctoral researcher, Project coordinator
1.1.04	Professional Registration No.:	*If applicable*
1.1.05	Organisation Name:	Radboud University Medical Center, Nijmegen, the Netherlands - department of Surgery
1.1.06	Address:	PO box 9101
1.1.07	Postcode:	6500 HB, Nijmegen, the Netherlands
1.1.08	Telephone Number:	+31636304310
1.1.09	Email:	Richard.tenBroek@radboudumc.nl
1.1.10	Do you have an NHS contract/honorary contract?	No
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 online module
	Link to course content:	MRC Research Data and Confidentiality online module
	Institution:	Medical research Council
	Date completed:	May 12 2016

1.2	**Clinical Sponsor/Lead** *Please read section 1.2 of the guidance*	
1.2.01	Full Name:	Ewen A Griffiths MD, FRCS
1.2.02	Title:	Consultant Upper GI and General Surgeon,
1.2.03	Position:	Clinical sponsor
1.2.04	Professional Registration No.:	GMC 4732039
1.2.05	Organisation Name:	Queen Elizabeth Hospital, Birmingham
1.2.06	Address:	University Hospitals NHS Foundation Trust Edgbaston, Birmingham, UK
1.2.07	Postcode:	B15 2TH
1.2.08	Telephone Number:	0121 3715883

1.2.09	Email:	Ewen.griffiths@uhb.nhs.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 online module
	Link to course content:	MRC Research Data and Confidentiality online module
	Institution:	Medical research Council
	Date completed:	1st Aug 2016

1.3	**Information/Data Custodian** *Please read section 1.3 of the guidance*	
1.3.01	Full Name:	Same as applicant
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:	Pepijn Krielen	Telephone or Email:	+31613218398
Organisation:	Radboud University Medical Center	Position:	PhD Student
Professional Registration No:	Z478129	NHS contract/ honorary contract?	No

IG Training - Name of course:	MRC Research Data and Confidentiality online module		
IG Training - Link to course:	MRC Research Data and Confidentiality online module		
IG Training - Institution:	Medical research Council	Date completed:	8th AUG 2017

Full Name:	Janienke van Lier	Telephone or Email:	+31613218398
Organisation:	Radboud University Medical Center	Position:	PhD Student
Professional Registration No:	Z516230	NHS contract/ honorary contract?	No

IG Training - Name of course:	MRC Research Data and Confidentiality online module		
IG Training - Link to course:	MRC Research Data and Confidentiality online module		
IG Training - Institution:	Medical research Council	Date completed:	

1.5 Others *Please read section 1.5 of the guidance*			
Complete this section if applicable – for each additional person			
Full Name:	Michael Parker	Involvement in Proposal:	Principal investigator, Study design
Organisation:	Royal College of Surgeons	Position:	Emeritus Professor in Surgery, study steering group

Complete this section if applicable – for each additional person			
Full Name:	Harold Ellis	Involvement in Proposal:	Study design
Organisation:	Kings college London	Position:	Emeritus professor, study steering group
Complete this section if applicable – for each additional person			

Full Name:	Harold Ellis	Involvement in Proposal:	Study design
Organisation:	Kings college London	Position:	Emeritus professor, study steering group

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: Dutch Adhesion Group (Research workgroup linked to the Dutch college of gastro-intestinal surgeons and Dutch college of gynaecologists and obstetricians)	*If the organisation here is an NHSScotland board, note this and go directly to question 2.1.4*
2.1.02	Is this organisation or body a registered data controller? If 'Yes', provide Data Protection Registration Number:	No
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?	Yes

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:	*If the organisation here is an NHSScotland board note this and, go directly to section 2.3*
2.2.02	Is this organisation or body a registered data controller? If 'Yes', provide Data Protection Registration Number:	No
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
Radboud University Medical Center, Nijmegen, the Netherlands	University Medical Center	University supporting proposal and facilitating the applicant

Section 3 – Overview

3.1	**Proposal Essentials** *Please read section 3.1 of the guidance*	
3.1.01	Proposal title/name:	Adhesion-related hospital readmissions after abdominal and pelvic surgery: An update of the SCAR studies
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	No
3.1.04	What is(are) the substantive purpose(s) of the proposal? (tick all that apply) ☒ Patient Care ☒ Research ☐ Audit ☐ Performance Monitoring/Management ☐ Service Planning/Improvement ☐ Health/Social Care Administration ☐ Systems Implementation/Testing ☐ Training/Education ☐ Quality (Clinical, Educational, etc)	
	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?	No
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:
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:* Adhesion formation is the most common cause for long – term complications in abdominal surgery. Abdominal surgery is performed by a multitude of specialist, including general surgeons, gynaecologists, vascular surgeons and urologists. In Scotland, like many other developed countries, adhesion- related complications cause a huge burden of morbidity. Adhesion-related complications comprise various clinical entities such as small bowel obstruction, chronic pain and female infertility. In 1999 Prof. Ellis demonstrated in the SCAR studies, using data from the Scottish National Health Service record linkage database, that as many as 34.6% of patients undergoing abdominal surgery are readmitted for complications directly or possibly related to adhesion formation in 10 years after surgery. Since this landmark study a number of strategies were introduced to reduce adhesion formation. First are the so-called 'anti-adhesion' barriers. Almost simultaneously there has been the rise of minimal invasive surgery. Minimal invasive surgery is associated with less extensive peritoneal injury and adhesion formation. While minimal invasive surgery became adopted quickly, the use of anti-adhesion barriers remains marginal. Many surgeons therefore feel that with laparoscopy further adhesion prevention is not necessary, despite some evidence that incidence of adhesion- related complications is still considerable.

	To evaluate the impact of laparoscopic surgery on adhesion- related formation, we are planning to perform an update of the SCAR studies to recent years in which a large number of laparoscopic surgeries have been performed. Comparison of readmissions for adhesion- related complications after open and laparoscopic surgery will be made. The study will provide an estimate of the current burden of adhesion-related morbidity in Scotland, which could also serve as a model for the current burden in other European countries. Further such estimate can be used to model the impact of further implementation of anti-adhesion barriers on adhesion-related morbidity and healthcare costs in both Scotland and abroad.
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.* We intend to use the Scottish National Health Service record linkage capabilities. Inclusion criteria are all patients undergoing initial abdominal or pelvic surgery between June 2009 and June 2011. Selection will be made by OPCS-4 codes related to the admission. A list of relevant codes can be found in the appendix. We choose for these years to allow inclusion of an incident population in a time that laparoscopic surgery had already been implemented and that allows for 4 to 5-years of follow-up. We will exclude patient who had had abdominal or pelvic operation in the 5 years before 2009, as pre-existing adhesions from this prior surgery might influence results. There are no further exclusion criteria. For analyses patients will be grossly divided in three groups of anatomical location of the surgery: hindgut, female reproductive tract, and foregut or other. Within each group subgroups of laparoscopic and open procedures will be made. We expect approximately 70,000- 100,000 patients to have had abdominal or pelvic surgery in the period June 2009- June 2011. Approximately 25,000 are expected to have had prior abdominal surgery in the previous 5 years. Thus, we expect an incident population of 45,000 to 75,000 to be included in the study.

	For the study we will analyse re-admission in the years following surgery that are directly related to adhesions, possibly related to adhesions, and readmission with surgery that might be complicated by adhesions. For this purpose we will need a patient identifier that allows to link readmissions to the initial surgery. The data can be anonymized so that the identifier represent just a random number. As baseline characteristics we will only require age and sex. No further potentially identifiable data such as birth date, postal code or NHS number is required. From the initial admission with abdominal or pelvic surgery we need ICD- 10 codes and OPCS- 4 codes describing the type of surgery performed as well as information whether the operation was performed laparoscopic ally or open. This same set of information is needed for any readmission in follow-up. Further we need the time interval (in months) between the index operation and the readmission. Only readmissions coded by one or more relevant ICD-10 or OPCS-4 code need to be included. For a readmission to be classified as directly related to adhesions, an explicit adhesion reference was required in the operative OPCS-4 or diagnostic ICD-10 coding. Adhesions might however not always be coded, especially not if readmission goes without surgery. For example, a conservative treated small bowel obstruction might only be coded as abdominal pain, nausea, and vomiting. Therefore we will define a broader set of operative codes and diagnostic codes that might indicate a possibly adhesion- related complication. Data from follow-up is requested to the latest date from which a complete record can be extracted.
3.1.09	Does the proposal have implications for, or target, sensitive groups or vulnerable populations? Please give details
	No
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)
	Informal internal review has been performed within the Radboud University Medical Center, department of Surgery. The research proposal and internal funding for performing the study were approved.
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?	We now requested for access to the data until 2019-12-31, for the purpose of answering a few questions of the editorial team of Lancet on the presentation of the data (e.g. adding standard deviations to data presented)
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)	Schedule 2: Condition 3; the use of patient identifying data is not necessary to carry out the research. The linking code can be anonymized using a random number. The researcher therefore do not need identifying data for carrying our analyses. Also the use of data which is not directly identifiable is minimized, by requesting a minimum in baseline characteristics and only data from readmissions with a relevant code. Schedule 3, Condition 8:

		The processing is necessary for medical researcher, and analyses is undertaking by health professional who completed information governance training.
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	*No*
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	*Yes, see attachment. Privacy risk can be adequately eliminated.*
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?	Yes
3.5.01a	If yes, please provide committee details and status of approval (ie pending, approved, etc). Please attach as supporting documentation if available	Radboud University medical Center-Institutional review board PO box 9101 6500 HB, Nijmegen, the Netherlands T +3124 361 31 54 E:commissiemensgebondenonderzoek@RadboudUMC.nl - approved -
3.5.01b	If no, please explain why research/ethics approval is not sought:	

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)
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	*Not applicable*

Section 4 – Data & Data Subjects

4.1 Data yet to be collected *Please read section 4.1 of the guidance*		
Not applicable		
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?
Scottish Morbidity Record (SMR01)	National Services Scotland	Yes
NRS Deaths	**NRS**	**Yes**
CHI Database	**NHS Boards**	**Yes**
How were individuals originally informed of the use of their data? (if known)		
Project specific consent was impractical for this study because of large size of the survey group and patients are not contacted. However: a) no identifiable patient data will be disclosed b) the necessary linkage will be performed by data controllers from the NHS Scotland board, that already hold the data. After linkage the data will be anonymised. c) the medical research serves public interest as outlined under 3.1.07. The final dataset for analysis will not hold data that could result in indirect identification.		
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		

4.3 Data Variables *Please read section 4.3 of the guidance*

Dataset/source Name	Variable	Time Period/Range	Processing only?
Anonymised ID			
Scottish Morbidity Record (SMR 01)	CHI	2004- Dec 2016	Yes
Scottish Morbidity Record (SMR 01)	Date of admission	2004- Dec 2016	No
Scottish Morbidity Record (SMR 01)	Sex	2009- Dec 2016	No
Scottish Morbidity Record (SMR 01)	Age (Date of admission-birth date)	2009- Dec 2016	No
Scottish Morbidity Record (SMR 01)	ICD-10 codes	2009- Dec 2016	No
Scottish Morbidity Record (SMR 01)	OPCS-4 codes	2009- Dec 2016	No
Scottish Morbidity Record (SMR 01)	Duration since index operation (date of admission from readmission - date of admission from index operation)	2009- Dec 2016	No
Scottish Morbidity Record (SMR 01)	Details of operation - laparoscopic/ open	2009- Dec 2016	No
Scottish Morbidity Record (SMR 01)	End of follow-up (month) (Date of end of follow-up, typically June 2016; however some patient might not complete follow-up because of mortality or migration)	2004- Dec 2016	No
Scottish Morbidity Record (SMR 01)	Continuous Inpatient Stay	2009- Dec 2016	No
CHI Database	Migration Month / year	2004- Dec 2016	No

NRS Deaths	Patient alive or death by end of follow-up	2004- Dec 2016 (measured in months, no date provided)	No

Please justify your need for identifiable or potentially identifiable variables:

Identifiable data is only needed during the processing of data. Data will be collected during a range of 5 years from index surgery. Patients with a relevant OPCS-4 code as listed in the appendix are selected, if no prior such operation was found in the five years previous to the index operation. Identifiable information, NHS number and birth date are needed during processing to select reoperations that are definitely or potentially related to adhesion in patients following their index surgery. After processing these data can be removed. Age is potential risk factor for adhesions and will therefore be calculated.

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?	Choose an item.
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		Not applicable
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?	Data controler - national Services Scotland (@Farr Institute)
5.1.03	Which data sources listed at section 4.1 and 4.2 will NSS/NRS receive identifiers for linkage purposes?	Scottish Morbidity Record (SMR 01)
5.1.04	What variables will be provided for linkage? X CHI Number ☐ Forename ☐ Surname ☐ Date of Birth ☐ Address or Postcode ☐ NHS Number Other Please Specify:	

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	Identifiable data will not be transported. Only results from statistical analyses will be downloaded through secure file transfer protocols while connecting to the safe haven. Downloaded data will be stored solely on computer at the Radboud University Medical Center, complying

		to its electronic safety protocols.
5.4.02	At what intervals/ trigger points will data transfer take place?	Analysed data will be transferred regularly, during a period of 4 months.
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	*If applicable*
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	Results will be published as a paper in a peer-reviewed medical journal. Results will further be presented a surgical conferences and congresses using powerpoint format.
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	Graphs and tables in publications will provide only large nationwide number that is not identifiable.
5.5.01c	If yes, are there any circumstances where a living or dead individual would be cited? (eg where a person	*No*

	consented to their data being used as a case study)? Please give details	
5.5.01d	If yes, were any permissions to publish data required or sought (for example from data controllers)? Please provide details	*No*

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)?	
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)?	
5.6.03	Who will retain the data and where?	
5.6.04	What is the purpose for retaining the data for the specified time?	
5.6.05	What method of disposal or destruction will be used when this period has expired (including archive/backup copies)?	
5.6.06	What evidence will be obtained that destruction has occurred (eg IT supplier certificate of destruction, etc)?	

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	
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)	
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	

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): RICHARD TEN BROEK	Date: 22-04-2018

- 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):	Date:

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
- Appendix with list of OPCS 4.7 and ICD10 codes relevant for selection of data - Certificates of Research data and confidentiality training - Protocol as send for IRB approval - IRB approval - Privacy Impact assessment

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