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**Secure Anonymised Information Linkage (SAIL)**

**Information Governance Review Panel (IGRP) Application Form**

**SAIL IGRP Application Form**

The following form has been designed to collect the information needed for the information governance approval process for work involving the SAIL databank. The information you provide will facilitate consideration of your enquiry. Guidance notes on completing this form can be found at: <http://www.saildatabank.com/media/25300/Guidance_Notes_for_SAIL_IGRP_Application.docx>

***SAIL Feasibility Agreement***

*All projects require a SAIL Feasibility Agreement to be completed and signed before proceeding to IGRP. This agreement will have been developed as part of the initial project scoping process with a SAIL analyst. Do not continue with this form until you have had your project scoping discussion.*

*Please provide the agreement number: 0744*

**1a. Provide contact details of project lead:**

Name: Dr Arron Lacey

Job title: Research Officer

Organisation: Swansea University Medical School (SUMS), SAIL Databank

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Fax:

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**1b. Provide contact details of the lead contact from any other organisation who will be accessing the data:**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Name** | **Job title** | **Organisation** |
| 1 | Dr Owen Pickrell | Clinical Lecturer | AMBUHB / SUMS |
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**2. Provide full title of the project:**

Educational attainment of children with epilepsy in Wales

**3. Provide details on who is commissioning the project:**

Swansea Neuroscience Research Group and the Health Data Research group at the SAIL Databank.

**4. Provide the aim of the project, including anticipated outcomes:**

*Please include a copy of the protocol/plan for the proposed work with SAIL, including the contact details of any co-applicants when you return your completed form.*

We aim to obtain investigate educational attainment using the Department for Children Education, Lifelong Learning and Skills dataset for children with epilepsy, and compare their Key Stage 1-4 results during school to a matched control group (sex, school year, social deprivation, birth weight and gestational age). The steps taken to conduct this study are:

1. Obtain Key Stage 1-4 data between 2003 and 2016 for all-Wales using the Department for Children Education, Lifelong Learning and Skills dataset (SAIL schema EDUCV).
2. Identify which children have been diagnosed with epilepsy from GP records (SAIL schema WLGPV) before their year of study in each Key Stage. This will be done by using an existing algorithm developed and validated on SAIL data [10.1016/j.seizure.2017.10.008](https://dx.doi.org/10.1016%2Fj.seizure.2017.10.008)
3. For each child with epilepsy, and for each Key Stage, define a matched control cohort where control variables would aim to include sex, school year, social deprivation, birth weight and gestational age, ideally with a minimum of a 1:3 match.
4. Stratify the epilepsy cohort by what anti-epileptic drug prescriptions they are taking
5. Compare attainment between the epilepsy cohort (and subgroups) to the matched control using the Core Subject Indicator (CSI), maths, science and language (English or Welsh), where each child is classed as either achieving a pass (Level 2 or above) or not. A proportions test such as chi-square or logistic regression will be used to indicate statistical significance of the comparisons.

**5. Provide a lay summary of the project:**

Epilepsy is a condition associated with a range of co-morbid conditions. Around 40% of adolescents with epilepsy also have an additional neurological condition and 1 in 4 persons with epilepsy of any age has a learning disability. Behavioural issues are prevalent in children with epilepsy exhibited both in school and at home. Children with epilepsy are a stigmatized group and are twice as likely to be bullied at school than their peers, and a qualitative study of children with refractory epilepsy viewed seizures as a barrier to a normal life. It is inevitable that children with epilepsy do not achieve as highly in school when compared to their peers.

Additional support for children in school is provisioned according to evidence based guidelines. The aim of this study is to determine if children with epilepsy perform worse than their peers, and if so by how much. Given that treatment of epilepsy differs between each person, different anti-epileptic drugs may have any effect on how well a child with epilepsy performs. As such factors within children that have epilepsy will be explored.

**6. Provide an outline of the public engagement strategy for the study, or a brief explanation why there is not public engagement:**

The results of this study would likely be published in an academic journal, and given that the results would come from routinely collected data rather than a prospective observational study, there would not be any public engagement strategy required.

**7. Provide information on the relevant permissions you have obtained or that are being sought:**  *Obtained Being sought Not required*

***Research ethics***[  ] [  ] [  ]

*Please state the name of the committee that is being applied to/ has given approval, as applicable:*

*Research ethics committee:*

*If you have ticked ‘not required’ please specify the reasons:*

The project will use onlyanonymised data, and therefore research ethics review is not required.

*Obtained Being sought Not required*

***Independent peer review***[ ] [ ] [ X ]

*Please state the name of the peer reviewing organisation that is being applied to/ has given approval, as applicable:*

*Peer reviewing organisation:*

*If you have ticked ‘not required’ please specify the reasons:*

This project uses only routinely collected data that has been pseudoanonymised and already made available for research via the SAIL Databank.

***Permission from data-holding*** *Obtained Being sought Not required* ***organisation to use their datasets***[ ] [ ] [ X ]

*Please state the name of the data provider that is being applied to/ has given approval, as applicable:*

*Data organisation:*

*If you have ticked ‘not required’ please specify the reasons.*

The project uses only SAIL unrestricted core datasets and/or data held by the project.

**Please note that it is the responsibility of the project lead to ensure that the relevant permissions are obtained.**

**8a. Provide a prospective start date for the work involving SAIL (dd/mm/yy):**

01/04/2019

**8b. Provide anticipated end date of the project: (**End date OR time duration after approval):

01/18/2020

**9a. Provide details of data you require access to for the proposed work with SAIL?**

The SAIL datasets you require information from:

NCCHD (Child Health Dataset)

EDUCV (Wales Education Dataset)

WDSD (Welsh Demographic Service Dataset)

WLGP (Welsh Longitudinal General Practice dataset)

**NCCHD (Child Health Dataset)**

* Maternal age
* Gestational age
* Birth Weight

**EDUCV (Wales Education Dataset)**

* Key stage 1-4 CSI, Maths, Science English Welsh results
* School year
* Learning difficulties (LEN)
* Days of absense

**WDSD (Welsh Demographic Service Dataset)**

* LSOA to obtain WIMD Quintile at birth and school year

**WLGP (Welsh Longitudinal General Practice dataset)**

* Event\_cd (Epilepsy status and anti-epileptic drugs)
* Event\_dt

Please indicate the time period for which data is requested:

Between January 1st, 2003 and December 31st, 2018.

Please indicate the geographic area for which data is requested:

All -Wales

Please indicate demographic criteria for the data requested (age, gender, etc.):

All ages and genders (includes mothers and children)

**9b. Will you be providing any other dataset(s) to be incorporated into the SAIL databank?**

Yes [ ] No [X]

If yes:

Provide the name of the dataset(s):

**9c. Provide an outline of your analysis plan including the anticipated outputs:**

We will establish three separate datasets containing MPS stress testing and imaging data that will be linked to the SAIL databank to evaluate the ability of MPS diagnose coronary artery disease and predict:

• Major clinical outcomes (All cause and cardiac mortality, myocardial infarction, coronary revascularisation and other major cardiovascular events).

• Healthcare resource utilization (Hospital admissions, A+E visits, clinical (cardiac) procedures, clinic visits, medication use).

We will use multivariable regression analyses to determine the risk of major outcomes as composite event rate and individual major adverse outcomes according to:

• Presence and extent of ischaemia.

• Left ventricular ejection fraction and resting/inducible regional wall motion abnormalities.

• Major CVD risk factors.

• Other major co-morbidity and deprivation indices.

• Medication use.

Analyses will be undertaken for each individual approach to MPS quantification and comparisons of diagnostic and prognostic performance of each evaluation strategy will be undertaken.

Our dataset comprises approximately 8,000 patients dating back to October 2008. Estimating an annual major CV event rate of 1.5 -2% in the population referred for MPS and considerably higher rate of hospital admissions and invasive cardiac procedures, we anticipate sufficient power to satisfactorily address the main questions outlined above.

**9d. Are the results/methods developed likely to have other potential applications?**

Yes [ X ] No [ X ]

If yes, please specify: Other Cardiac and Radiological Imaging strategies.

**10a. Please indicate your plans for publishing the results of your project, e.g. target journal or intended recipients of report:**

Intended to be presented at nationally and international specialist conferences and published in major, peer-reviewed neurology/epilepsy journals.

**10b. What are the potentially sensitive issues that need to be taken into account when publicising the findings of the project?**

Please outline the issues and your proposed solutions:

The project make use of data from the NHS which will be in identifiable form, but we will follow data safe handling and use procedures as well as ensure all data follows standardised anonymization and privacy protecting processes to ensure the data coming into SAIL is protected. To this end the data held in the NHS will mitigate issues by some of the following measures: Clinical records will remain behind NHS firewall; prudent disclosure of results will be considered; Individual hospitals and clinicians will not be identified;

The project will also look at strategic optimization of resources and could potentially be misinterpreted by healthcare providers. As such, all results and outputs will make sure to ensure results can be interpreted correctly.

We will follow all standard data masking protocols to make sure no small numbers (<5) are allowed to be communicated via our results, as well as making sure no potentially identifiable subgroups or cohorts are communicated via our results. Hence, we do not anticipate that small numbers disclosure issues will arise. We will follow all SAIL policies on such issues when reviewing outputs for data out and publication in project findings.

**What to do next**

Please return your completed form and supporting documents by email to Cynthia McNerney, Information Governance Coordinator [c.l.mcnerney@swansea.ac.uk](mailto:c.l.mcnerney@swansea.ac.uk) Thank you.