



**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: 0696

1a. Provide contact details of project lead:

Name: Dr Owen Pickrell
Job title: Clinical Lecturer
Organisation: Swansea University Medical School
Address: Room 329, Institute of Life Sciences, Swansea University
Tel: 01792 295134
Fax:
Email: w.o.pickrell@swansea.ac.uk

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

	Name	Job title	Organisation
1	Dr Alex Wojtowicz	Academic F2 doctor and honorary clinical research fellow	Swansea University Medical School
3	Beata Fonferko-Shadrach	Research Assistant	Swansea University Medical School

2. Provide full title of the project:

Mortality and sudden unexpected death in epilepsy

3. Provide details on who is commissioning the project:

Swansea University Neuroscience group.

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.

This project has two main aims:

- (1) To validate a method for identifying Sudden Unexpected Death in Epilepsy (SUDEP) cases from SAIL.
- (2) To use this method to study the epidemiology of SUDEP and other epilepsy related mortality in Wales.

The first aim has emerged from previous studies of SUDEP using SAIL data (projects 0196 and 0208). There are many variables thought to correlate with SUDEP and these include factors, such as social deprivation and treatment resistant epilepsy, which are ideal for analysis using the SAIL model. However, because SUDEP has historically been under-recognised - both clinically and in official documentation related to death - there is significant potential for studies of SUDEP to fail to identify a representative sample of relevant cases. To address this issue, we would first identify cases of known, probable, or possible SUDEP in Wales which have occurred in the past 10 years, collecting this information from clinicians and the SUDEP action register (a charity-run register of SUDEP cases). These would be uploaded using the standard SAIL split file approach. We would then be able to validate the accuracy of various algorithms to identify SUDEP cases

The second aim, involves building on projects 0196 and 0208 to further examine factors associated with SUDEP and epilepsy related mortality in Wales. This is particularly relevant to the Welsh population, as issues such as social deprivation and isolation from specialist care centres are more pronounced here relative to the UK overall. We would seek to examine risk factors including the type of epilepsy diagnosed, the frequency of seizures, the duration of chronic epilepsy preceding death, whether the epilepsy was 'treatment resistant', the sex of patients, age of onset for epilepsy, the presence of nocturnal seizures, and treatment compliance. All of these have been linked to some extent with SUDEP, and understanding associated factors is key for developing future research into prevention strategies and improving patient education about the risk of SUDEP as part of an individual person's epilepsy.

5. Provide a lay summary of the project:

The aim of this project is to see whether we can identify when people have died of epilepsy related causes, including sudden death in epilepsy (SUDEP), by looking at routinely collected health data. For example, if we know that a patient's death was linked with SUDEP, is this recorded as cause of death in GP records? If not, is there another cause of death commonly reported instead? This is important because it tells us whether we can accurately do research into SUDEP using this type of data. If we want to research, for example, risk factors linked with SUDEP, which is much more difficult if you cannot reliably identify cases.

The project would also aim to learn more about things which may be linked with SUDEP and epilepsy related mortality in Welsh patients. Understanding the factors linked with SUDEP is important because this supports further research into possible prevention strategies to reduce risk, and helps people with epilepsy better understand the risk of SUDEP as part of their own lives. Looking at this issue in the Welsh population specifically would help us understand the link

between issues such as social deprivation and SUDEP, which may be a bigger issue in Wales than in studies of other countries.

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

We have had discussions with the charity SUDEP action (a leading epilepsy mortality charity) about this project who have very kindly agreed to help by providing data from their extensive SUDEP register. We will keep SUDEP action informed of the results and ask their advice on communicating potentially sensitive results.

7. Provide information on the relevant permissions you have obtained or that are being sought:

	<i>Obtained</i>	<i>Being sought</i>	<i>Not required</i>
Research ethics	[<input type="checkbox"/>]	[<input type="checkbox"/>]	[<input checked="" type="checkbox"/>]

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 only anonymised data, and therefore research ethics review is not required.

☐ Other:

	<i>Obtained</i>	<i>Being sought</i>	<i>Not required</i>
Independent peer review	[<input type="checkbox"/>]	[<input type="checkbox"/>]	[<input checked="" type="checkbox"/>]

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:

The method used for this project has already been used for a previous SAIL project (0387)

	<i>Obtained</i>	<i>Being sought</i>	<i>Not required</i>
Permission from data-holding organisation to use their datasets	[<input checked="" type="checkbox"/>]	[<input type="checkbox"/>]	[<input type="checkbox"/>]

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

Data organisation:

SUDEP action have agreed to share relevant data from their epilepsy deaths register. The relevant clinicians (South Wales neurologists and epilepsy specialists) have also given their permission for us to use their data on SUDEP deaths in Wales

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.

☐ Other:

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):

01/10/17 (or as soon as the project is approved)

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

30/09/18 (or 12 months after project start date).

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

Please list:

The SAIL datasets you require information from:

ADDE (Annual District Death Extract)

EDDS (Emergency Department Data Set)

OPDW (Out Patient Dataset for Wales)

PEDW (Patient Episode Database for Wales)

WDSO (Welsh Demographic Service Dataset)

WLGP (Welsh Longitudinal General Practice dataset)

The information needed from each dataset:

The ADDE (Annual District Death Extract) will be used specifically to check if someone has died, and was alive during the intervention and follow-up period, as well as the cause of death. The EDDS will be used to identify emergency department attendances prior to and after inpatient episodes. The OPDW (Out Patient Dataset for Wales) will be required to track the care people receive pre and post inpatient care. Furthermore, it may flag up relevant patients who did not receive their care in the PEDW dataset. The PEDW (Patient Episode Database for Wales) will be required to track services received as part of inpatient care, including details such as attendance type, method, reason including discharges and other available specialty information. LSOA 2001 (however we would like to also receive

2011 once this is available). The WDS (Welsh Demographic Service Dataset) to define dates of resident and registration in Wales, including practice history and any changes in location, including at LSOA 2001 level (however we would like to also receive 2011 once this is available), dates of movement out of Wales or death (to know when to stop follow up). The WLGP (Welsh Longitudinal General Practice dataset) will be required to build the patient pathway including primary care data to track and see pre- and post-diagnosis care and treatment prescribed.

In all datasets, where available data will be required to enhance details about the patient history, epidemiology and interactions with services and details around epilepsy diagnosis codes and prescription data including but not limited to age, gender, diagnosis and treatment codes and dates, LSOA 2001 (however we would like to also receive 2011 once this is available) in order to track access and distances travelled to received care, dates of movement out of Wales or death.

Please indicate the time period for which data is requested:

January 1st 2005 onwards.

Please indicate the geographic area for which data is requested:

All residents of Wales and all admissions/attendances from non-Welsh residents to Welsh facilities.

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

All ages and genders, of people with a diagnosis of epilepsy.

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

Yes [☒] No [☐]

If yes:

Provide the name of the dataset(s): Clinical registry of SUDEP cases from South Wales and register of deaths of people with epilepsy.

Provide details of the contents of the dataset(s): Identity of patients with deaths from SUDEP together with certainty level of diagnosis of SUDEP (e.g. definite, probable)

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

The project proposes a retrospective cohort study using the SAIL Databank data for the period between 2005 and 2016. Initially prevalent epilepsy cases would be identified at the beginning of this study window, with the addition of any incident cases. A note of any deaths among patients with epilepsy, and whether the death is a known, probable, or possible case of SUDEP. Validation of the projects search strategy which identifies the cases of known, probable, or possible SUDEP between 2005 and 2016 would be completed, which have been highlighted to the project by epilepsy specialists in Wales and from the epilepsy deaths register (SUDEP action). Data relevant to these cases would be uploaded using the standard SAIL split file approach. If the strategy identifies all such cases, we would consider this to support the efforts to identify cases of epilepsy-related death as valid and the first aim would be accomplished.

With this data set of epilepsy cases and epilepsy-related deaths derived from a validated search strategy of SAIL data, a comparison to overall group mortality with a matched non-epilepsy cohort would be completed. In addition to calculating the incidence of SUDEP and mortality rates, factors which are known to be associated with SUDEP will be investigated to see whether similar associations can be observed in SUDEP cases. Comparisons between people with epilepsy who died of SUDEP and those who died of other conditions would also be made, including comparing measures of social deprivation. We will attempt to estimate the annual risk of SUDEP in different epilepsy risk groups as a useful guide for clinicians.

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

Yes [☒] No [☐]

If yes, please specify: It is likely that there will be further projects looking at SUDEP in Wales given its significance.

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

We intend to present the results of this project at neurological conferences (e.g. the association of British neurologist's annual conference) and publish the results in a peer-reviewed neurological journal e.g. Neurology or JNNP (journal of Neurology, Neurosurgery and Psychiatry).

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:

We do not anticipate any sensitive issues. 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 Thank you.