Project Amendment Policy

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Owners	Charlotte Arkley & Rachel Carpenter
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1.   SAIL PROGRAMME PROJECT AMENDMENT – OVERVIEW.

1.1   Background

The Secure Anonymised Information Linkage (SAIL) Databank is a Wales-wide trusted research environment (TRE), focused on improving health, well-being, and services. It contains anonymised data about the population of Wales and is world recognised. SAIL receives core funding from the Welsh Government's Health and Care Research Wales (HCRW) and the Economic and Social Research Council (ESRC). A range of anonymised, individual-level data sources are held in SAIL, and subject to safeguards and approvals, these can be anonymously linked together to address important research questions.

1.2   Purpose

This document sets out the process for considering and managing requests for amendments to projects. Amendments are defined as any change required by a project following the original approval of the project, which differs from the scope and services described in the original signed scoping form and approved Information Governance Review Panel (IGRP) application. As a result, extensions and amendments have been combined in to one policy the amendment policy, in which extensions are a subtype of an amendment and all covered by one application form, (the amendment application form).

All amendments should be requested using the process described within this document.

1.3   Scope (Types of amendments)

Projects should make every effort to reduce the numbers of amendments required by ensuring that all known project requirements are included within their original scoping form, and that a reasonable time-period is agreed for the completion of the project and SAIL services required. The duration of the project should take into account possible time needed for publication, even if it is beyond the period for which the project is funded.

In the event that researchers realise following completing the scoping process but prior to submission of their IGRP that they need to make changes then they should contact the team that completed the original scoping to arrange for an update to the SAIL scoping form.

Once an IGRP approval is received and a project is active if additional data requirements or services are required which were not previously included in the signed scoping form and approved IGRP application, they will need to complete an amendment form request.

Examples of additional services which may be required include:

- **Add or change of organisation(s) accessing SAIL data for the project.**
- **Additional user/researcher.**
- **Acquisition of a new data source(s) into SAIL.**
- **Provision of a new data source to the project from the SAIL catalogue.**
- **Additional data refresh(es) in addition to agreed provisions** *(where a refresh is not to correct a technical error or provisioning error)* **or additional variables to an existing provisioned data source.**
- **Technical requirements such as change of desktop specification.**
- **Additional analytical support and involvement with a project, including additional data preparation.**
- **Change of project scope.**
- **Extension to the project end date.**
- **Putting a project on hold for up to 12 months (due to unforeseen circumstances e.g. researcher sickness).**

This is not an exhaustive list of possible amendments, please see amendment form for fuller description of options

2.   SAIL PROGRAMME PROJECT AMENDMENT – POLICY.

2.1   Process for applying for amendments

2.1.1   To apply for an amendment, fill in the amendment form. https://jira.hiru.swan.ac.uk/servicedesk/customer/portal/6/create/206

2.2   Management of amendments

2.2.1   Requests for amendments to projects will be internally reviewed by the SAIL team, with input from the Information Governance Review Panel (IGRP) in some applications.

2.2.2   The following types of amendment require IGRP external review:

Amendment	IGRP External Approval Required
Extension over 12-months from original project end date	Yes
Add or change of organisation(s) accessing SAIL data	Yes
Additional data set/additional variables	Yes
Change of project purpose	Yes
Additional users or read only users if in a different organisation	Yes

2.2.3   SAIL will take the following into account when considering amendment requests:
- Reasons for needing an amendment and reasonableness of the request.
- Audit of project activities to confirm that analyses to be performed still fall within the original approved scope.
- Consideration of whether the amendment makes the focus or goals of the project substantially different.

2.2.4   If the requested amendment requires additional support services such as data refreshes, these will be chargeable at standard SAIL rates. In the unusual event that a Researcher could not use what they had paid for during the project lifecycle due to a delay by SAIL (for example if a user account did not work for a month, or wrong data was provided and data had to be re-provisioned), then a short cost-free extension reflecting the delay suffered would be granted. Other exceptional circumstances requiring cost free amendments would be at the discretion of SAIL Cost Waiver Committee.

2.2.5   If a project once active requires a temporary hold on the project which will not affect the overall active duration of the project, then the project can apply for this via the amendment application form prior to requirement. E.g., if a project was approved for 12 months and after 3 months the PI asked for a hold for a month, once the project resumed it would have 9 months remaining. The application will require anticipated length of hold time and justification, and this will be considered on a case-by-case basis. If agreed access to the project will be suspended for all users for the period that the hold is in place.

2.2.6   A full audit trail of the decisions taken will be maintained by the SAIL team.

2.3   Extension amendment to the Project End Date

2.3.1   The SAIL team will notify projects 90-days and 35-days before they are due to expire, by automated email to the project lead and all project members who have SAIL gateway accounts. If an extension amendment to the project end date is required a member of the project team will be required to complete and submit an amendment form (see 2.1.1 above) as soon as possible. A project that applies for an extension amendment at least 35-days before the expiration date can expect to have a decision before the project ends and no interruption to SAIL access.

2.3.2   Extension to the project end date may be required for reasons like a delay in starting the project, the analysis was more complicated than anticipated, or more time was required for publication of

results or responding to peer review. Extension amendments are only appropriate for active projects or those in set up phase; if the project has already passed its end date, a new project must be scoped and agreed by the IGRP.

2.3.3 **Single extension amendment of up to 12-months** –A single extension amendment of up to 12-months after the original project end date can be granted by the SAIL team without involving the IGRP. Provided that there is no requirement for additional SAIL support, these extension amendments are usually provided at no additional cost, depending on your contract (some projects already have this 1-year extension built in at scoping). The project needs to indicate on application if any support is required from the SAIL team during the extension period (e.g., data refreshes etc). Any additional SAIL support required will be chargeable at standard SAIL rates.

2.3.4 **Extension amendment of more than 12-months** – Any request for an extension amendment of more than 12-months or a further extension on 2.3.3, will be checked to identify any additional support services required, and the extension and support services will be chargeable at standard SAIL rates. Once agreement on the additional costs has been reached, notification of the proposed extension amendment will be sent to the Chair of the IGRP. The extension amendment will be enacted 14-days after notification of the Chair, during which time they will have opportunity to comment and raise any concerns.

2.3.5 **Ad hoc short-term access after project expiration** – We are aware that there are some circumstances where project may need short term read only access to their data even after the project has expired e.g., to answer questions from reviewers about a publication. These requests would be considered on a case-by-case basis and a period of up to 1 month single full access user access may be granted in exceptional circumstances.

2.4   Archiving of Project Data

2.4.1 There is often a research governance requirement to keep project data and allow access to project members for a number of years after the project ends. The extension amendment process will not be used for this. Instead, it will be handled as follows: Project members who simply want to inspect the data will be given access at the discretion of SAIL and the project team.

3.   SAIL PROGRAMME PROJECT AMENDMENT – ROLES AND RESPONSIBILITIES.

ROLE	FUNCTIONAL RESPONSIBILITIES.
Document Owner	Responsible for the content of the policy and approving changes to content.
Document Reviewer	Responsible for: i). Keeping document up to date. ii). Raising issues within the document with the document owner. iii). Approving changes to formatting of the document.
SAIL Data Analysts/Information Governance Review Panel	Responsible for reviewing requests for amendment to projects.
SAIL Projects Co-Ordinator	Reviewing and redirecting requests for amendment to projects and where required costing.
Information Governance Co-Ordinator	Responsible for notifying projects of impending expiry and co-ordinating requests for amendment/extensions to projects.

4.   SAIL PROGRAMME PROJECT AMENDMENT – COMPLIANCE.

Any staff subject to this policy who fail to comply with the provisions as set out above shall be subject to appropriate management response. This may include disciplinary action in accordance with the Swansea University and Medical School Disciplinary Code and Procedures.

A.   DOCUMENT MANAGEMENT.

A.1   AUTHORISATION.

NAME	TITLE
Charlotte Arkley	Information Governance Co-Ordinator

A.2   REFERENCES.

DOCUMENT
SAIL Project Amendment Request Form
Cost Waiver Policy
SAIL Charging Model

A.3   DOCUMENT HISTORY.

VERSION	DATE	AUTHOR	DESCRIPTION	APPROVED BY
1.0	04/10/2021	Rachel Carpenter	New policy to replace extension policy and includes all amendments: i). Changed scope of policy to all amendments ii). Changed process and policy	Julie Kennedy
1.1	4/7/2022	Charlotte Arkley & Rachel Carpenter	Minor changes to document text to clarify meanings based on user feedback. i) IGRP approval process updated ii) Project on hold concept, included in amendment process. iii) Added owner (Rachel Carpenter)	Julie Kennedy
1.2	9/5/2023	Rachel Carpenter	Minor changes to document text to clarify i) 12-month free extension eligibility. ii) Ad hoc short-term access to project data after expiration. iii) Project holds	Julie Kennedy
2.0	19/9/2023	Rachel Carpenter	Minor changes to document i) Updated deadline for submitting amendment. ii) Updated definition of ad hoc access after project expiration.	Julie Kennedy