**RSU030 – Project Modification Policy**

This document describes the steps involved in processing various types of project modifications within the NILS/NIMS/ADR.

The exclusion of health bodies in the Digital Economy Act resulted in ADRNI health research using primary healthcare data being permitted through the NILS environment. These projects have been given the naming convention ADRn. The Research Approvals Group (RAG) review both NILS/NIMS and ADRn project applications and modifications. Within this Modification Policy ADRn modifications should be treated in the same way as NILS Distinct Linkage Projects (DLP’s).

Note: Applications and modification requests for ADRNI projects (those ADR projects that do not use health data, including the themed datasets) should not be submitted to the RAG. These should be approved by all specified data providers on the project and by the UK Statistics Authority, Research Accreditation Panel (RAP). Further details of the specific data providers can be found within each individual DSA and for themed datasets this information can also be found within the Summary Information for themed datasets document (FI1/23/512970).

All modification requests from researchers should be submitted to RSU via the RSU031 NILS Project Modification Form for NILS/NIMS/ADRn projects. RAP require a completed project change request form for all ADR project modifications. Approval from data providers via the RSU081 Project Modification Approval form is also required for non-themed dataset ADR projects.

**Modification Types**

Permitted types of modifications are:

1. Adding researchers to a project
2. Changing the Chief Researcher on a project
3. Removing researchers from a project
4. Extension to project end date
5. Addition of variables
6. Addition of data
7. Creation of project-level univariate synthetic data (NILS/ADRn only)

**Approval of Modifications**

As outlined above, project modification requests for ADRNI projects should be reviewed for approval by the specified data providers on the project and RAP; they should not be submitted to the RAG.

The remainder of the document regarding specific project modification approval routes applies only to NILS/NIMS/ADRn projects. While RAG will review most project modifications, they have delegated the responsibility for approving some project modifications to NILS-RSU. This section details these types of modifications but will not cover all scenarios.  There may be exceptional circumstances that are not covered in this document which necessitate consideration as to whether NILS-RSU can approve the project modification.  If NILS-RSU feels that it should be able to approve such a modification, this should be discussed and agreed with the Chair of the Research Approvals Group (RAG) who may decide that the matter needs the approval of the RAG.

1. **Adding Researchers to a Project**

Researchers can be added onto a project at any time and these can be approved by NILS-RSU. All additional researcher(s) should read RSU070 RSU Policies (includes Security Policy, Disclosure Control Policy, Licence Agreement and Census Confidentiality Undertaking) and complete RSU071 RSU Project Agreement to confirm their adherence to these policies. They are also required to have Approved Researcher status and to complete Safe Researcher Training. If researchers wish to access data in the secure environment they are also required to have a Baseline Personal Security Standard (BPSS) check completed.

Distinct Linkage Projects (DLP’s)/ADRn Projects

If additional researchers wish to be added to the research team of a DLP/ADRn project, they must follow the standard NILS project procedures. Data Custodians should agree to the addition of any researchers by means of a supporting email. This email should be requested by the Chief Researcher and submitted to NILS-RSU. No notification to the Research Ethics Committee is required as this is considered a minor amendment.

1. **Changing the Chief Researcher on a Project**

A change to the Chief Researcher on a project can be approved by NILS-RSU. However, if the new Chief Researcher is not an existing researcher on the project they should follow the steps for adding researchers to a project described above. The Chief Researcher cannot be an undergraduate student.

Distinct Linkage Projects/ADRn Projects

The Chief Researcher on a DLP/ADRn project cannot be an undergraduate student. Data custodians should agree to a change in Chief Researcher by means of a supporting email. This should be submitted by a member of the project team to NILS-RSU. The Research Ethics Committee should also be notified as this constitutes a major amendment to the project.

1. **Removing Researchers from a Project**

A Project Modification form must be submitted to NILS-RSU in order for a researcher to be removed from a project. The researcher should be informed that they are no longer able to access intermediate outputs from the specified project and written verification of compliance with this stipulation is required by NILS-RSU. If the project is being carried out by a PhD, Masters or Undergraduate student, then their supervisor cannot be removed from the project unless a replacement supervisor is added to the project. Should NILS-RSU be concerned about a request to remove a researcher, they can submit this to the RAG for approval.

1. **Extension to Project End Date**

At the outset of a project, a reasonable end date should be stated on the application form for completion of the project. This is used by RAG to assess whether the project is feasible within the time period. The form states ‘Please ensure that you propose a realistic end date. This can only be amended at a later stage in exceptional circumstances.’

NILS-RSU should email the research team two months prior to the project end date to notify them that the end date is approaching. If further time is required for continued analysis, a Project Modification form should be completed by the researcher and submitted to the NILS-RSU.

The NILS-RSU should assess the extension taking account of the following information:

* Number of overall project modifications – this may indicate a project changing direction/scope and therefore the need to become a new project rather than extending the current project. Alternatively, the researcher may now be struggling with too much information and a new more focussed project would be recommended.
* Activity on the project - this can be assessed by the frequency of visits to the secure environment and numbers of intermediate and final outputs submitted. If there has been little or no activity to date, this may indicate an unrealistic start date, or that data issues, staffing issues, etc. have prevented the project from starting. A significant number of intermediate outputs with no recent or limited final outputs may indicate that the research is not sufficiently focussed or the project may be changing direction/scope. In these cases, it may be better for the researcher to submit a new more focussed project rather than extending the current project.
* Level of support - can the current level of NILS-RSU support for the project be sustained over the period of the extension? Some projects may require intensive support that cannot be sustained. Granting an extension may either put too much burden on the NILS-RSU or leave the researcher(s) unable to complete their project.
* Consider the actual start date of the project (i.e., was there a significant delay to researchers receiving access to the project data?). RAG have agreed that the actual start date should be used to avoid unnecessary project extension requests being presented to RAG.
* Consider if the project has been on hold (i.e., researcher on maternity leave). RAG have agreed that the project timeline can be put on hold if this is the case and then restarted to avoid unnecessary project extension requests being presented to RAG.

NILS-RSU should monitor the number of project modifications, the activity on the project and the level of support required. This information helps to inform the RSU/RAG project extension decision.

RSOs can approve extensions of up to 6 months. The maximum number of times this can be done is 3. If a further extension is requested this must be approved by RAG. Extensions longer than 6 months can be approved by DP and above in RSU. The longest extension which can be approved by DP and above is up to 18 months. Only one extension of up to 18 months can be approved provided sufficient justification to explain the need for the extra time has been provided by the research team. All further extension requests must be approved by RAG. In exceptional circumstances RSU must use judgment to assess the extension as detailed in the bullet points above. RSU will monitor project extensions and report to RAG once a year.

Researchers should not keep a project open in order to wait on any possible feedback on papers submitted if no further research is planned. In these circumstances, projects should be archived and the NILS Archiving Policy applied. If the researcher receives feedback from referees requiring further work, then the project can be de-archived to facilitate the additional analyses. For further information see RSU027 NILS Archiving Policy.

Distinct Linkage Projects/ADRn Projects

All DLPs/ADRn projects have a start date and an end date agreed with all Data Custodians who signed the project’s Data Access Agreement (DAA).  Any proposed change to the end date requires a Project Modification form to be completed by the research team (including a full explanation of why the project needs to be extended) and agreement from all Data Custodians (in written form). This should be sent to the RAG for final approval.

Approval for extending the end date should be granted before the end date is reached. Otherwise, no extension can be granted as NILS-RSU cannot hold onto project data once the project end date has passed. However, approval from data providers can be sought at a later date if the data has been archived in accordance with the data retention period for the project data as specified in the DAA.  If the original DAA suggests so, an amendment to accompany the original DAA needs to be written and signed by all Data Custodians if agreement to extend the end date is reached.

1. **Addition of Variables**

If a project team requires additional variables added to a project, they should complete and submit a Project Modification form to NILS-RSU. NILS-RSU should assess the request to ensure the direction and scope of the project does not change with the addition of further variables. If NILS-RSU decides that the request is in line with the original aims of the project, a new data extract containing the requested extra variable(s) will be prepared using the same date stamped version of the NILS database to ensure the extract is as close to the original extract as possible. However, if any requested variable is marked as Restricted, or if the NILS-RSU is unsure whether the requested variables are in line with the original aims of the project, then the request must be submitted to the RAG for approval.

Distinct Linkage Projects/ADRn Projects

Any proposed change to the variable list requires a Project Modification form to be completed and agreement from all Data Custodians (in written form). This should be sent to RAG for final approval.

If the addition of variables does not alter the scope of the project approved by the Research Ethics Committee (REC) then this should be considered a minor amendment and the REC does not need to be notified. Note the NILS Data Controller is responsible for the decision on whether further ethical approval for the additional variables is required.

In the case of a request to add an anonymised GP Practice identifier, details of the project should be submitted to the GPIT subcommittee who will assess whether approval can be granted.

If the original DAA suggests so, an amendment to accompany the original DAA should be written and signed by all Data Custodians affected by the change. An amended data extract should be created and all previous data files should be destroyed.

1. **Addition of Data**

**Linking Data**

This refers to an instance where external data is linked to a project. As a general rule, if the external data is to be linked on an individual level, the project will become a Distinct Linkage Project and a new application should be submitted and approval from the Research Ethics Committee should be sought.

If the external data is aggregated to SOA level or greater, then the data can be linked by the researcher themselves within the secure environment and does not require a Project Modification form request.

**Derived Variables**

Derived variables can also be added by NILS-RSU. Most requests for derived variables can be approved by NILS-RSU. However, if the derived variable makes use of a restricted variable, or NILS-RSU are concerned about the robustness of the derived variable, a Project Modification form must be submitted to RAG.

**Addition of data updates**

If a research team requests an update of their current data extract to include the latest data released, this must be approved by RAG. (NILS data updates are released on a bi-annual basis with the data release in June to include the April Health download from the same year and the January release to include the October Health download and GRO data from the latest Registrar General report).

A newly available additional Census year data (e.g., 1991 data) should be requested by submitting a Project Modification form to NILS-RSU under the following conditions:

* the variables requested are in line with the existing Census year‘s variables in the project; and
* the project must already have data from at least two Census years.

**Increased project cohort**

If a research team requires an expansion to the project cohort for specific variables NILS-RSU should assess the request. If the change to the cohort size is less than or equal to 10% of the original cohort size, a new data extract, containing the requested cohort, will be prepared using the same date stamped version of the NILS database to ensure the extract is as close to the original extract as possible. If the change to the cohort size is greater than 10% of the original cohort size or should NILS-RSU be concerned about the request, then this must be submitted to the RAG for approval.

Distinct Linkage Projects/ ADRn Projects

In the case of DLPs, the addition of data requires approval from RAG. RAG should assess the addition of data taking account of when the initial data for the project was created, the amount of additional data requested and whether or not the researcher has accessed the existing data to justify the need for additional data. It may be necessary to limit the number of data additions for DLPs to one, and that this re-linkage can only be approved when there is 12-18 months of additional data to add.

Any proposed change to the data requires a Project Modification form to be completed and agreement from all Data Custodians (in written form). This should be sent to RAG for final approval. If an additional dataset is requested, or the scope of the project changes, this should be considered a substantial amendment which requires approval from the Research Ethics Committee (REC). Note the NILS Data Controller is responsible for the decision on whether further ethical approval for the additional variables is required. If the original DAA suggests so, an amendment to accompany the original DAA should be written and signed by all Data Custodians affected by the change. An amended data extract should be created and all previous data files should be destroyed.

1. **Creation of project-level Synthetic Data**

Researchers can apply for a project-level univariate synthetic dataset for a NILS or NILS DLP project by completing and submitting a Project Modification form to NILS-RSU.

Requests for a synthetic dataset for a new project can be approved at RAG. RAG has stated that any requests for a synthetic dataset for a currently active project should be approved by all data providers on the project in accordance with the NILS Synthetic Data Criteria. Therefore, any modification requests for a synthetic dataset for an active project can be sent via NILS-RSU to the appropriate data provider/(s) for approval.

1. **Secondary Health Care Data**

For projects using secondary health care data (available through the HSC Regional Data Warehouse via the Honest Broker Service) additional input is required from the HSC Trusts. Modifications, once approved at RAG, should be shared with representatives from the trusts via the HSC Information Governance (IG) Network in order to agree final approval.

**Outcomes**

The information used to assess the project modification must be logged by NILS-RSU on the Project Modification Form/Project Administration Database (PAD) to ensure a full audit trail of the decision.

If NILS-RSU assess the modification request the outcomes can be:

* Approved
* Referred to RAG - the reasons why NILS-RSU was unable to make a decision should be included on the Project Modification form to allow the RAG to make an informed decision.
* Rejected – the reasons why it was rejected should be documented.

If a modification request is referred to RAG, RAG must assess it taking into account the overall number of project modifications already requested for the project and the activity of the project. The justification provided by the researcher and any comments from RSU on the Project Modification form should be carefully considered by RAG.

The outcomes that RAG may decide for a project modification are:

* Approved
* Partially Approved – the reasons why the full request was not approved should be documented and the extent to which it has been approved should be clearly defined e.g. only some variables approved or an extension period of less than that requested approved
* Rejected – the reasons why it was rejected should be documented.

If further information is required from the researcher to allow RAG to make a proper assessment of the modification request, then RAG must reject the modification. RAG cannot make a decision on any potential future modification requests; however, they are permitted to give an indication of what a future decision might be e.g. that they would be reluctant to grant any further extension requests and would prefer to see a project end date being met.

**Researcher Right of Appeal**

Researchers have the right to appeal to the RAG (if NILS-RSU made the initial decision) or to the NILS Steering Group (if RAG made the initial decision). Full reasons behind the decisions should be documented. The NILS Steering Group decision is final and no further appeals should be considered.

**NILS-RSU**

**January 2024**