ACONF and/or AMND permission pathway

This pathway is for researchers and clinicians from any institution who want to conduct projects using data only from Aberdeen Children of the 1950s (ACONF) and/or data from the Aberdeen Maternity and Neonatal Databank (AMND). For projects requiring ACONF or AMND data, work is conducted within the secure Grampian Data Safe Haven (DaSH) environment.

Please note the following step-by-step guides for ACONF and AMND datasets are designed for projects that use only these datasets and do not require any linkage to other datasets. If you need to link other datasets with ACONF and/or AMND, contact DaSH for guidance as you will need to seek permissions from the ACONF and/or AMND Steering Committees, as well as NNPAC or full (local) permissions. You will need to follow the step-by-step process(es) included below as well as the step-by-step processes for either NNPAC or Full (local) permissions, or Full (national) permissions[1].

ACONF Step-by-step process

1. Contact the DaSH team to discuss your requirements, confirm this is the correct pathway for your project and consider your data management protocol. To kick things off, submit a Project Initiation Document (PID). This helps us understand your project and assess its feasibility with DaSH.

2. Once we have reviewed your PID and confirmed DaSH can support your project, contact ACONFs Steering Committee (SC). Approval to use anonymised sub-sets of the data requires approval by the ACONF Study Steering Group. Please contact ACONF to discuss your variable requirements and any other enquires you might have.

3. Submit your application form and any supporting documentation (as requested by ACONF SC) to the ACONFs administrator copying in DaSH.

4. If you haven't already, confirm you have completed Information Governance training.

5. Before proceeding with your work, DaSH requires the following documentation:

- ACONF Application
- ACONF Approval letter/email

6. You may receive conditional approval based on changes needing to be made to the application. If so, you will need to revise and resubmit your documentation. In this case, the ACONF administrator can guide you through this process.

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[1] The Full permission (national) pathway is currently under development and will be available on our DaSH website shortly.

7. Upon receiving the documentation, DaSH will create the following documents for your reference:

- Data Linkage Plan (DLP)
- Specific Data Management Plan (Data spec)

8. DaSH will liaise with the researchers for any additional requirements before accessing the data (i.e. external University of Aberdeen accounts if applicable).

Post-approval

9. Once you have received approval, please contact DaSH with final approval documents.

10. For projects that involve linking ACONF and/or AMND with other NHS Grampian datasets, DaSH will assign a Data Analyst to your project after receiving your documents. We will then arrange a pre-linkage meeting with the Data Analyst to review your datasets and software needs.

AMND Step-by-step process

1. Contact the DaSH team to discuss your requirements, confirm this is the correct pathway for your project and consider your data management protocol. To kick things off, submit a Project Initiation Document (PID). This helps us understand your project and assess its feasibility with DaSH.

2. Once we have reviewed your PID and confirmed DaSH can support your project contact AMNDs Steering Committee (SC). Approval to use anonymised sub-sets of the data requires approval by the AMND Steering Group. Please contact AMND to discuss your variable requirements and any other enquires you might have.

3. Submit your application form and any supporting documentation (as requested by AMND SC) to the AMNDs administrator copying in DaSH.

4. If you haven't already, confirm you have completed Information Governance training.

5. Before proceeding with your work, DaSH requires the following documentation:

- AMND Application
- AMND Approval letter/email

6. You may receive conditional approval based on changes needing to be made to the application. If so, you will need to revise and resubmit your documentation. In this case, the AMND administrator can guide you through this process.

7. Upon receiving the documentation, DaSH will create the following documents for your reference:

- Data Linkage Plan (DLP)
- Specific Data Management Plan (Data spec)

8. DaSH will liaise with the researchers for any additional requirements before accessing the data (i.e. external University of Aberdeen accounts if applicable).

Post-approval

9. Once you have received approval, please contact DaSH with final approval documents.

10. For projects that involve linking ACONF and/or AMND with other NHS Grampian datasets, DaSH will assign a Data Analyst to your project after receiving your documents. We will then arrange a pre-linkage meeting with the Data Analyst to review your datasets and software needs.

International access approval

Researchers needing access to DaSH from outside the UK will require to complete the "Application for Researcher Access from Outside the UK" form. Contact DaSH to provide you the form and guidance. The application is reviewed internally, then forwarded to the appropriate data controller and data protection team(s). This process applies to researchers from outside the UK, collaborating with international colleagues, or accessing any existing DaSH projects from abroad. We recommend starting this process as early as possible. Approval from all relevant data controllers and data protection teams may take significant time.

Amendments

If **any** changes are to be made to the data required (e.g., changes to cohort, including inclusion or exclusion criteria, date range of datasets, or changes to datasets/additional variables required), to the research staff working on the project, or to the length of time you require access to the project data in DaSH, an amendment must be submitted, reviewed and approved by the ACONF and/or AMND Steering Committee before any changes can be implemented by DaSH. You should contact DaSH in the first instance to determine feasibility of the amendment and to discuss any extra data requirements that may be needed. An amendment form must then be completed and submitted to the relevant Steering Committee(s) for review. (Note: If your project also requires NNPAC, Full (local) permissions, or Full (national) permissions, these may also require amendments depending on which aspects of your project are being amended; please liaise with DaSH, who will guide you through this process).

Please note that changes may result in a re-costing of the project due to additional data processing time or an extension to the length of access.

Annual Progress Report

The ACONF and AMND committees do not have any annual reporting requirements.

However, if your project requires NNPAC, full (local) permissions or full (national) permissions, a progress report must be submitted every 12-months after the date on which the study was approved and annually thereafter.

For NNPAC studies, please use the template available here. The report should be submitted to the NNPAC committee via nnpac@abdn.ac.uk.

For full (local) and full (national) permission projects please use the annual progress report template available on the Health Research Authority's (HRA) website and send this to your Sponsor, the NHS ethics committee that provided your favourable ethical opinion and to the relevant R&D office(s).

Please cc' DaSH into the submission of the report.

End of Study

Prior to your study period coming to a close, DaSH will contact you so we can initiate the relevant close down procedures.

The ACONF and AMND committees do not have any formal end of study reporting requirements. You should inform the committee via email when the study completes.

If your project also requires NNPAC, full (local) or full (national) permissions, an end of study declaration must be submitted once the project is complete.

For NNPAC projects, you should complete the form here and submit this to NNPAC.

Please copy in DaSH on the submission of the declaration.

For projects requiring full (local) or full (national) permissions, an End of Study Declaration form should be submitted once the project is complete. The form for this is available on the HRA's website and should be submitted to Sponsor, the NHS ethics committee that provided a favourable ethical opinion, the relevant R&D office(s) and any other permissions bodies (Caldicott Guardian, PBPP etc) as required.

Please copy in DaSH on the submission of the declaration.

Final Report

The ACONF, AMND and NNPAC committees do not have any formal end of study reporting requirements.

However, if your project also requires full (local) or full (national) permissions, a final report (summarising the projects findings) will be due one year after the end of study declaration has been submitted. This should be completed via the HRA's website. The researcher will be provided with a copy of the report from the NHS Ethics Committee once is has been reviewed.

Please send a copy of the final report to DaSH once available.