Full permissions (local) pathway

The full local permissions pathway is for researchers and clinicians from any institution who want to conduct a research project using only NHS Grampian data, including those with the support of a non-commercial or commercial/industry sponsor.

Early in your project planning you should contact the following teams to discuss your project and governance requirements:

- **Contact DaSH** to discuss your data, data management requirements and governance arrangements.

- **Contact your Sponsor:**

➢ If you are a University of Aberdeen **or** NHS Grampian employee or student, contact the Research Governance Team, who will act as your Sponsor, as soon as possible to begin the sponsorship process.

➢ If you are an employee of an external university, NHS Health Board or commercial company, your employer is likely to act as the research Sponsor. You should contact your institution's Sponsor Representative in this instance.

➢ Your Sponsor will determine the permissions that you will need to arrange for the project; therefore, you should liaise with your Sponsor at the earliest opportunity. The Sponsor is usually the institution and/or company that employs the Chief Investigator. Your Sponsor will determine whether your project is classified as research, audit or service evaluation. The Health Research Authority (HRA) has developed an online tool to help you determine the category your project fits into, but ultimately the final decision rests with your Sponsor. DaSH should be copied into this correspondence so that we can support your applications to the various permission providers if required.

➢ If your project is considered to be Service Evaluation or Audit, you will need to follow the relevant Permission Pathway here.

➢ If your project is considered to be Research, then continue to follow the step-by-step process below.

Step-by-step process

1. Contact the DaSH team to discuss your requirements, who will confirm the correct pathway for your project and consider your data management protocol. To kick things off, please 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, we'll schedule an initial meeting. This is a chance to discuss project feasibility, permissions, and the

next steps. The DaSH team will then be happy to guide you through creating the three key documents you'll need for your application:

- Data Linkage Plan
- Data Specification File (cohort criteria, datasets and variables required for your project)
- Specific Data Management Plan

3. If you haven't already, confirm you have completed Information Governance Training.

4. **Arrange Sponsorship.** All DaSH research projects require a Sponsor to be in place. Your Sponsor should be your university or another entity, depending on your affiliation.

- **University of Aberdeen/NHS Grampian Researchers:** If you are affiliated with the University of Aberdeen or NHS Grampian, your sponsor will likely be the UoA or NHSG.
- **External Researchers:** Your University, NHS Health Board, or commercial company will likely be your research Sponsor; however, we recommend contacting your organisation's Research Governance or Sponsor Representative team. DaSH can help you navigate this process.

4.1 **Sponsorship submission**: the documents you must send to Sponsor for their review usually include, but may not be limited to:

- Protocol – *for UoA and NHSG employees a protocol template is available here (non-CTIMP template).*
- Completed IRAS Form *(see 4.2 - submitted as full dataset PDF document)*
- Organisation Information Document (OID) - *a guidance document is available here. For UoA and NHSG sponsored studies, templates are available here.*
- Data Linkage Plan
- Data Specification File
- Specific Data Management Plan
- Evidence of Information Governance Training
- Signed and Dated CVs of researchers
- Evidence of Funding
- Evidence of Independent Peer review:
    - *If your research is externally funded, evidence of peer review along with proof of funding will suffice.*
    - *If your research is internally funded, you'll need two separate peer reviews. This should be done by professionals who are independent of the project but have the relevant expertise in the field of study.*
- If you will seek consent from participants for access to their data, you will also need to provide a Participant Information Sheet (PIS) and an Informed Consent form. For UoA and NHSG sponsored studies, templates can be found here.

4.2 For NHS Ethics and/or NHS R&D permission, you must complete the Integrated Research Application System (IRAS) form on the IRAS website before you apply for Sponsorship. Sponsor is a signatory on the IRAS form, and this must be reviewed by them before you submit for approvals. If your study requires both, these will be completed as one combined form and submitted to NHS Ethics and NHSG R&D simultaneously. Sponsor will liaise directly with the

research team on the completion of the form, what documents will be required and how to upload these to the application.

4.3 The DaSH team can review your application prior to submission.

4.4 The DaSH team must be cc'd into all correspondence with Sponsor.

5. Complete the NHS Grampian Caldicott Guardian (NHSG CG) application form. To obtain the application form, simply email NHSG CG. Once completed, return it via email to the NHSG CG, copying DaSH. This can be done simultaneously with your Sponsorship application.

6. Once Sponsorship is confirmed, submit your application and supporting documentation for NHS R&D and NHS Ethics review via IRAS, and via email for NHSG CG, copying in the DaSH team.

7. All applications will be reviewed by NHS Ethics first, with R&D undertaking their checks in the background.

8. You may receive conditional ethical approval based on changes needing to be made to the application. If so, you will need to revise and resubmit your documentation.

9. Once you have received a favourable ethical opinion and approval from the NHSG CG, evidence of these must be supplied to the NHSG R&D by the researcher. These will not be provided by Ethics/CG on the researcher's behalf. NHSG R&D will not give local permission until they receive evidence of a favourable ethical opinion. The NHSG R&D office can be contacted via gram.randdpermissions@nhs.scot.

10. You may receive conditional R&D approval based on changes needing to be made to the application. If so, you will need to revise and resubmit your documentation.

11. Ensure the DaSH is copied into all correspondence regarding permissions. DaSH must receive evidence of all the required permissions before data can be released.

Please note that certain projects may also need:

a) **Agreements (e.g. Data Sharing or Processing Agreements)**
Data agreements (e.g. data sharing, data access or data processing agreements) may be required for some projects (e.g. for commercial partners), however Sponsor will advise on this and DaSH will discuss with the relevant teams if required.

b) **Data Protection Impact Assessment (DPIA)**

This is required when projects are deemed to be 'high-risk'. The Information Commissioners Office has guidance on what constitutes 'high risk'. The Data Protection Team at your institution must be involved in drafting the DPIA.

For projects sponsored by the University of Aberdeen (UoA), researchers that may require a Data Protection Impact (DPIA) should contact the UoA Data Protection Officer, copying in DaSH. For projects sponsored by NHSG, researchers requiring a DPIA should contact the NHSG Data Protection Officer, copying in DaSH. Please also note that permission providers (e.g. ethics) may ask you to confirm that you have considered whether a DPIA is required.

Post-approval

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

13. Once DaSH has received your documents, we will assign an Analyst to your project and arrange a pre-linkage meeting with the 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), or 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 Sponsor before any changes can be implemented by DaSH. Sponsor will categorise the amendment (e.g. 'minor' or 'major' amendments) and inform the research team who they need to inform and/or seek permission from. 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. DaSH should be cc'd into all amendment correspondence and must receive evidence of the amendment permissions and approved documents. Please not 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

A progress report must be submitted to the Sponsor, NHS Ethics committee and NHSG R&D 12 months after the date on which the study was approved and annually thereafter. Please use the annual progress report template available on the Health Research Authority's website. Please cc' DaSH into the submission of the report.

End of Study

Once the study is complete an End of Study form must be completed and sent to Sponsor, the NHS ethics committee and NHSG R&D. The declaration of end of study form can be found on the Health Research Authority website. Please cc' DaSH into the submission of the end of study declaration.

Final Report

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 this to DaSH once available.