

Obtaining data from NHS Digital for health research – a guide for researchers

The guidance below is intended to complement that which is available on the NHS Digital web site at content.digital.nhs.uk/dars. NHS Digital have implemented an online applications system, the DARS online portal, together with additional guidance on the [DARS process](#).

What data do NHS Digital hold?

NHS Digital hold data from a variety of national registries in England and Wales. Access to this data is via the [Data Access Request Service \(DARS\)](#). The DARS web pages provide access to a list of NHS Digital information, products and services. These include Hospital Episode Statistics (HES), Mortality Data from the Office of National Statistics (ONS), Mental Health Minimum Data Set, patient status and tracking, bespoke data linkage services and many more.

To discuss your requirements contact NHS Digital on:

0300 303 5678 or email: enquiries@nhsdigital.nhs.uk

To access these datasets or services, an application to the **Data Access Request Service** is required.

NHS Digital charge for providing access to data and linking data. For further details please see: [NHS Digital](#). These charges are reviewed annually.

NHS Digital have Service Level Agreements (SLAs) outlining what they promise to deliver to their customers including the timelines. These are NHS Digital in-office timelines and don't represent the total time that an application will take, as they don't consider all the time taken by the applicant.

There are three different timelines depending upon the complexity of an application:

- 'Standard' – typically this would be for an extension to an existing agreement which allows you to hold data for longer – the process should take 14 days
- 'Medium' – typically this would be for a new request for pseudonymised and non-sensitive data – 30 days
- 'Complex' – typically this would be a request for identifiable data involving a linkage across a series of datasets - 60 days

You can measure NHS Digital performance against these targets on the [DARS Dashboard](#) (currently under review). You should anticipate NHS Digital working within these SLAs for any new application.

NHS Digital breaks the process up in to 5 stages - **Application, Approval, Access, Audit and Deletion of Data**. The first three are concerned with obtaining the data.

In practice there are aspects of the process that will take much longer as they involve liaison with others in your organisation and have proved problematic for many. Approval from other bodies may also be required. Specific issues for your study/circumstances can be identified from your answers to the following questions.

Questions to ask yourself before you apply to DARS

The significance of these questions is further explained throughout this short guidance document. NHS Digital is committed to updating its guidance at regular intervals, so do read through the latest version at content.digital.nhs.uk/dars in conjunction with this guide.

- Has your organisation signed the NHS Digital Data Framework Contract? Is your Department included / covered by this? If not, please liaise with your organisational / departmental contract managers. A Higher Education version of the contract is available, which means that the whole organisation may not be covered by the contract. Note that NHS Digital requirements may exceed your organisation's around data ownership (IP, publication rights and data deletion). Many organisations have taken a risk-based approach to this as data may not be held without a live contract, and have deemed the risk of not signing too great.
- Has your organisation completed the IG Toolkit? Would the arrangements for your study be covered in their Toolkit return? If not, it can take 6-9 months to complete the Toolkit as this will require liaison with others in your organisation, e.g. IT security experts.
- Is access to identifiable information absolutely essential? Will you need to share identifiable information with NHS Digital, for example in order for them to perform linkage? If so, you need consent or an alternative legal basis such as section 251 approval for these data flows. Section 251 approval is managed via the [Confidentiality Advisory Group \(CAG\)](#) at the [Health Research Authority \(HRA\)](#).
- Do you have explicit consent from participants to access data from NHS Digital? It is obviously the preferred option to have consent, but if it can't be obtained you will need to justify this in an evidenced-based way. You will need to identify an alternative legal basis to access NHS Digital data, such as section 251 approval.
- Do you require mortality data? If so you may also need to obtain approved researcher status for accessing ONS data.
- As you will read below interpretation of consent can vary, you may consider you have consent, yet NHS Digital may require additional assurance (see page 4).
- Do you require Research Ethics Committee (REC) approval? This depends on the requirements of the Health Departments Research Governance Frameworks (as outlined in the HRA/MRC decision tool [Do I need NHS REC approval?](#)) whether you are accessing identifiable or non-identifiable information, with or without consent. Further explanation is given below.

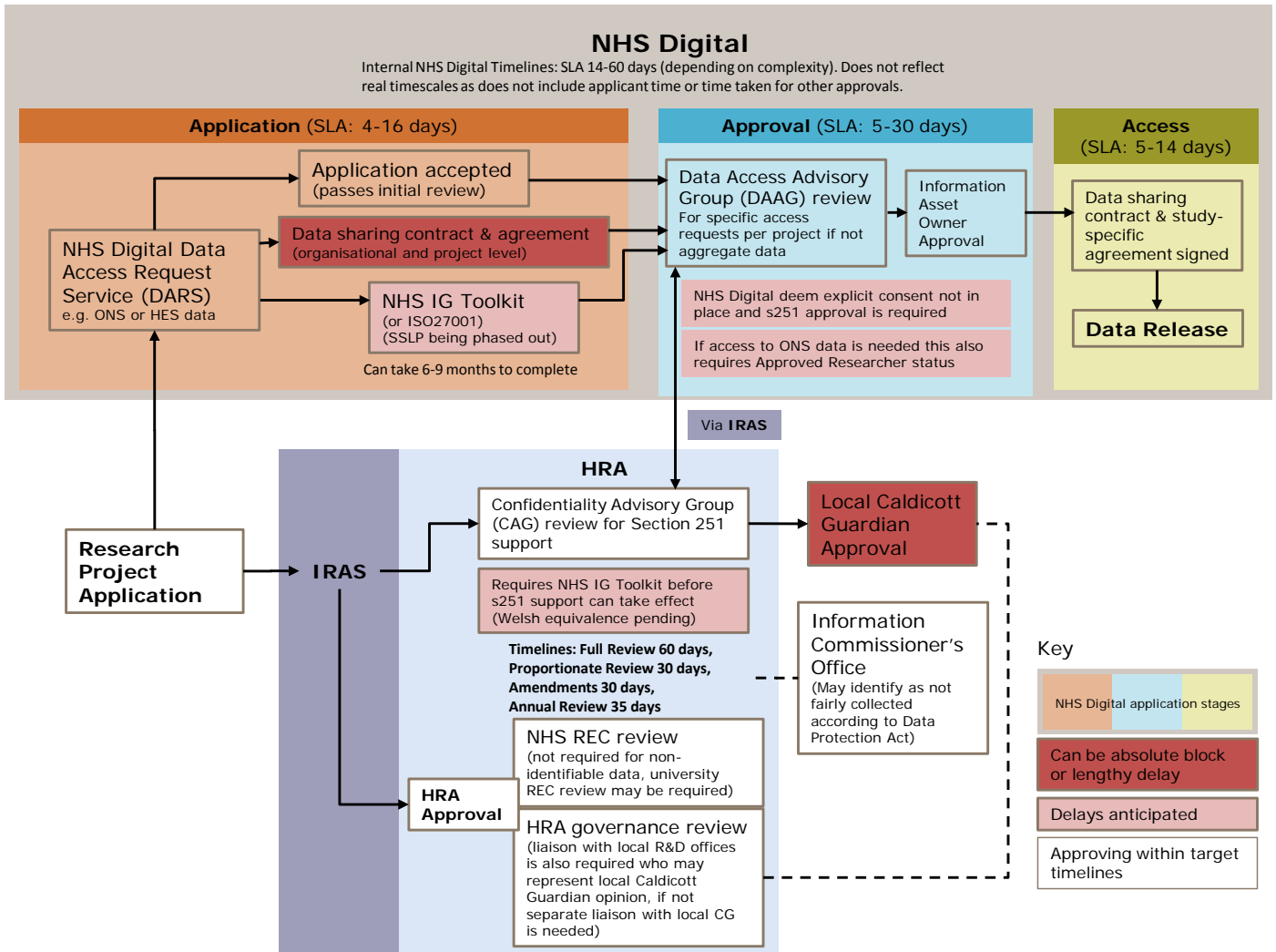
Research Ethics Committee Approval

If accessing **non-identifiable information** from NHS Digital, HRA Research Ethics Committee (REC) review is not required (an explanation is given in page 10 of HRA guidance [Does my project require review by a Research Ethics Committee?](#)). University Research Ethics Committee review can be sought for this research if required, e.g. Journal mandate for publication.

If accessing **identifiable confidential patient information with consent**, HRA REC review is required, (this would be sought anyway in order to review the consent process). The REC may be satisfied with the arrangements for consent, yet NHS Digital may not.

If accessing **identifiable confidential patient information without consent**, section 251 approval via CAG and HRA REC approval are both required (as specified on the [relevant HRA web pages](#)). You can apply for REC approval and section 251 approval in parallel, but there must be a favourable ethical opinion before any s251 approval can come into effect.

NHS Digital data request process



The following sections apply to the corresponding coloured NHS Digital stages in the above flowchart.

Application

If you haven't already, discuss your application with NHS Digital (contact details on page 1). NHS Digital structure their case-worker teams according to university to ensure retention and sharing of knowledge.

Please also see the [DARS Process](#) webpage and the [DARS Pre-Application Checklist](#).

With one exception (outlined in the above checklist), your organisation or department is required to sign the [Data Sharing Contract](#) (organisation/department level), and [Data Sharing Agreement](#) (study level). A specific Data Sharing Agreement for your study will be issued once you have approval. NHS Digital recognises that due to the federated nature of universities it might be more appropriate for the Framework Contract to represent a defined number of named projects or a particular department, rather than that of the whole organisation.

Guidance on the [Data Sharing Framework Contract](#) and [Data Sharing Agreement](#) is available, as are some [Data Sharing Framework Contract FAQs](#).

Complete the [DARS online application](#), [guidance](#) is available, including some useful tips. Clearly demonstrate that the request is being made to support the provision of health and social care and the promotion of health.

The following is required:

1. A legal basis for accessing the data – in practice for research this is likely to mean evidence of patient consent to access registry data, or [section 251 approval](#) via the [Confidentiality Advisory Group](#)¹ (Section 251 approval sets aside the common law duty of confidentiality but does not override the Data Protection Act. It will only be granted for certain medical purposes (including medical research) where it is not possible to use anonymous information and there is no other practical alternative to the disclosure of patient confidential information, [further guidance](#) has been produced by HRA/MRC in this area).

When **seeking consent** from research participants to access data from NHS Digital, either prior to recruitment or reconsenting for further access, NHS Digital requires such consent to be explicit for access to data held by them. **NHS Digital can consider and will give advice on your consent material. Applying for such advice is recommended as it may save considerable time later.**

Previously, explicit consent was **not** deemed to be in place by NHS Digital, when the following wording was used:

"I agree that information about any serious illnesses (such as heart attacks, strokes, cancer etc.) may be supplied to the study coordinators by my own doctors and by [central registries](#)."

Further advice for applicants on Consent, Fair processing and PhD and other research applications has been produced by the Data Access and Advisory Group and can be downloaded from their [approval page](#).

2. Details of the security arrangements your organisation has in place (please speak to your IT security and information governance professionals), one of the following is required:

- IG Tool Kit score (a demonstration that you meet NHS Information Governance standards, there's more about the IG Toolkit on page 6) – RECOMMENDED,
- ISO 27001 certification (The new ISO 27001:2013 standard is required, ISO 27001:2005 is now invalid), or
- System Level Security Policy (this is being phased out).

NHS Digital look specifically for evidence of:

- physical security
- antivirus and anti-malware
- intrusion defence
- access controls
- employee awareness and training
- segmentation
- policies
- device hardening

More information is available from their [security arrangements](#) publication.

Additionally you will need to provide evidence of your organisation's Data Protection Act registration (which must state Research), please see your local Data Protection Officer.

3. The data being requested e.g. Hospital Episode Statistics (HES), Mental Health Minimum Data Set; and the amount e.g. a single year, monthly extracts over three years. There are a [suite of forms](#) available, some of which may need to be completed, depending on the data you are requesting.

NHS Digital Initial review – if there isn't sufficient information provided on:

- the purpose,
- the legal basis for access,
- assurance of your data handling and security systems;

the application is rejected and resubmission with the additional information is required.

If NHS Digital has questions over the scope of any section 251 approval, you should work closely with NHS Digital to understand and address the issues. You should expect to provide NHS Digital with a copy of your CAG application and any supporting documentation. The CAG or its Advice Team can't advise until you have had this comprehensive discussion with NHS Digital.

¹ Other legal bases apply e.g. public interest but only in exceptional circumstances like to assist with the investigation of serious crime; or for public health reasons such as communicable disease surveillance.

If there isn't the technical feasibility within NHS Digital to provide what is being asked for, the application will also be rejected. If this is the case please contact NHS Digital (contact details on page 1 of this guidance) to explore your options.

Once the application passes this initial review it is accepted and NHS Digital timelines can take effect. The clock stops ticking when information is requested from you or you are seeking approval from another organisation e.g. s251 support.

Finally, do ensure that your application is absolutely transparent on who is holding the data, how, and for what purpose. You may not use the data for any purpose other than that outlined within the application, and any breach of the eventual agreement is likely to have consequences for your organisation. Do ensure therefore that the final application is correct and complete before you submit it to DARS. Please also see the section below on common reasons for delay.

Approval

All applications, other than requests for aggregate data, are reviewed by the [Data Access Advisory Group](#)², an independent group that will check that there is an appropriate legal basis for accessing the data. The DAAG will advise NHS Digital on whether approval should be granted. See the [DAAG approval process](#) webpage for information on DAAG considerations when reviewing applications.

Before submitting to DAAG the Information Asset Owner (IAO) at NHS Digital will assess the application and any necessary actions are discussed or completed with you.

Potential outcomes following DAAG review include:

- Recommendation (i.e. approval) A Data Sharing Agreement is produced for your organisation's signature and your application moves to the Access phase
- Recommend with caveats – IAO will discuss actions and timescales to represent to DAAG
- Deferred } IAO will discuss with you
- Withdrawn } IAO will discuss with you
- Rejection }

If ONS registry data are required (e.g. mortality data) this can only be accessed via one of [3 legal gateways](#). If consent is not being sought then the most likely gateway is Approved Researcher status, which determines that the researcher is 'fit and proper' and the research project is suitable. Please see the [Approved Researcher scheme](#) webpage, an application is required, assessment of which should take 3 weeks.

Access

Once the [Data Sharing Agreement](#) (DSA, which is based on your application) and the [Data Sharing Contract](#) have been signed, you will be provided with access to the data. Data may only be used in accordance with the DSA and DSC.

Data deletion – NHS Digital stipulate that all data must be deleted when a Data Sharing Contract or Agreement expires. Both can be renewed (for agreements presently annually), but subject to reapproval at that time. When the agreements expire and are not renewed, a [certificate of destruction](#) needs to be completed and returned to NHS Digital.

A **renewals process** is being established, which will be a more streamlined application system where circumstances have not changed. We'll update this guidance when this process is established, in the meantime contact NHS Digital (contact details on page 1) to discuss further.

² The [Independent Group Advising on the Release of Data \(IGARD\)](#) will replace DAAG in due course. The transition from DAAG to IGARD will be smooth and there will be some continuity of membership.

Common reasons for delay

Staff at NHS Digital have identified the following reasons for delays in the application process for research:

- 1. Lack of clarity in the application** – it's not clear who is performing certain processing functions or where data is flowing, e.g. there's a surprise University mentioned late in the application. For this a Data flow diagram is useful to clarify which organisations are involved. See the [DARS Pre-Application Checklist](#) for more information on these.
- 2. Inconsistency within or between applications** – either within the DARS application which means that the true intentions are unclear; or between applications to different review bodies, e.g. the application for section 251 differs to the DARS application. If the two applications are deliberately different it's useful to explain why.
- 3. Patient consent** – This doesn't always cover the research, or any flow of data that is going to NHS Digital, or include mortality data from ONS. DAAG will advise on consent material before the application review.
- 4. Longstanding consent** – In cohort studies if consent that was taken many years ago, does it still represent the current research, which may have evolved. If the research has remained the same, DAAG will advise that consent was legal and appropriate at the time and there has been no change to the research and so identifiable data are being fairly processed (hypothetically, if you asked a cohort member they understand what is happening to their data), and DAAG will approve the application. If the research has evolved into something different then another legal basis for access may be needed e.g. s251 support.
- 5. Limited purposes** – NHS Digital data can be used for research that promotes health and/or social care. Some methodology research or student research would benefit from linking back to why it is important, stating the bigger picture as to how it promotes health and/or social care.
- 6. Fair processing statements** – Meeting the requirements of the Data Protection Act, making sure fair processing information outlines how identifiable data are being handled and how participants know what is being done with such data. These are either inconsistent with the research or don't tell the full story. In these cases the DAAG may approve the application and advise that the fair processing information needs to be improved.

Information Governance Toolkit

The [Information Governance Toolkit](#) is an online system which allows organisations to be self-assessed against NHS Information Governance standards, i.e. that the organisation can be trusted to maintain confidentiality and security of personal information. NHS Digital has been commissioned to develop and maintain this Toolkit.

Your organisation may have already completed the IG Toolkit, talk to your local Information Governance or IT security experts to find out. It is possible for your organisation to have more than one toolkit return recognising that arrangements may differ between departments /faculties /studies.

All organisations have to assess themselves against requirements for:

- Management structures and responsibilities e.g. assigning responsibility for carrying out the IG assessment, providing staff training
- Confidentiality and data protection
- Information security

The exact list of requirements will depend on the Type of Organisation, e.g. an HEI will probably be classed as either a [Hosted Secondary Use Team/Project](#) (for individuals, teams and their projects that process NHS patient information for the purposes of non-direct care e.g. clinical research activities and other related patient data analysis (public health planning)); or a [Secondary Use Organisation](#) (an organisation that processes patient information for secondary purposes, and not direct patient care).

If Secondary Use Organisation your organisation will need to provide additional assurances on Clinical Information and Corporate Information. The majority of HEIs that have completed IG Toolkit returns are classified as Hosted Secondary Use Teams/Projects.

Completion of the IG Toolkit should be carried out by those with sufficient relevant knowledge of your organisation's systems for managing the requirements bulleted on page 5 and above. Different sections will probably require completion by different departments, e.g. information security by IT professionals.

First completion of the IG Toolkit needs to be carried out within the timelines specified by NHS Digital and/or HRA CAG. Second and subsequent assessments are needed annually by March 31st.

The terminology within the IG Toolkit may not be familiar to the non-NHS-initiated within the research sector, e.g. your organisation may not have a Caldicott Guardian. To aid mutual sector understanding, an **NHS-Higher Education Information Governance Working Group** has been liaising with the relevant department of NHS Digital. A list of members of the group and those HEIs that have achieved the IG Toolkit standards (listed by Type of Organisation) can be found on the working group's [web pages](#).

Further Help

For more information about consent and confidentiality in research please see the following:

- [MRC Data and Tissues Tool Kit](#)
- [MRC e-Learning on Research Data and Confidentiality](#)
- [HRA/MRC Consent and patient information sheet preparation guidance](#)
- [HRA/MRC Reducing the disclosure of confidential patient information - Guidance for CAG applicants and potential applicants](#)
- [HRA/MRC decision tool Do I need NHS REC approval?](#)

Please contact the MRC Regulatory Support Centre for help or to comment on this guidance: info@rsc.mrc.ac.uk