

Data Access Policy for the Nuffield Department of Population Health

Introduction

The aims of the Nuffield Department of Population Health (NDPH) ('the Department') are:

- to study the major causes of morbidity and mortality, both in adults and in early life, by conducting high quality research that generates reliable results about the causes of, and treatments for, such diseases; and
- to provide high quality training in the methods of population health research, in particular by encouraging the use of the Department's many large-scale data resources.

The Department welcomes data access requests that further these aims.

The Department will make the data from its studies readily available to external researchers in accordance with the Research Councils UK (RCUK) 'Guidance on best practice in the management of research data'¹, the UK Concordat on Open Research Data², and the Expert Advisory Group on Data Access.³ We aim to ensure that each individual data resource complies (wherever possible within legal and practical constraints) with the 'FAIR principles' that data should be Findable, Accessible, Interoperable and Reusable.⁴

The purpose of this over-arching Data Access Policy is twofold:

- to set out the high-level Departmental strategy, as well as to outline general considerations which may be relevant to access to different data sets; and
- to outline approaches and considerations that the Department's investigators responsible for particular studies have taken into account when developing study-specific access policies and procedures. (For example, the arrangements for accessing data from the Department's large cohort studies differ from those, such as meta-analyses of individual patient data from randomised trials, where study data cannot legally be shared.)

It covers access to raw data, summary tables and analyses which are not released in publications or online from all studies held by the Department, regardless of the original study location or the source of funding. Access to data may be through provision of datasets, results resulting from analyses conducted *de novo* by the study team (eg tables or figures) or in collaboration with external researchers. It does not cover Freedom of Information (FOI) requests, data subject access requests under the Data Protection Act (DPA) 2018, or requests for access to biosamples.

Departmental guidelines for data access

Information for researchers:

For each data resource held within the Department (eg cohort study, randomised trial or meta-analysis), a named principal investigator is responsible for maintaining up-to-date details of the following on the Department's website:

- *Access policy and procedures:* All policies governing access to data for particular studies are consistent with the Department's overall guidelines, which will include a requirement that all requests for data access from external researchers receive a reply within 4 weeks.
- *Data available:* This includes summary descriptions (eg, data dictionaries) of what data are available and (where appropriate) a timetable for data releases;
- *Data sharing statistics:* This will include the numbers of applications, data sets provided, collaborative analyses conducted, and resultant publications.

Requirements for accessing individual participant data (IPD)

Those wishing to access IPD must meet the following criteria:

- *Applicant and their institution:* the applicant must be a *bona fide* researcher registered with an appropriate institution;
- *Research that is in the public interest:* a detailed proposal must be provided for health-related research that is demonstrably in the public interest;
- *Privacy considerations:* participant level data are always pseudonymised, and applicants will be required to undertake not to attempt to identify participants;
- *Data-transfer agreement:* an applicant's institution must sign a data-transfer agreement (with efforts made within the Department to standardise such agreements to the extent possible) which will require that the data will be held securely and results published;
- *Return of derived data:* applicants must undertake to provide to the Department, within a specified period, any derived data not requiring linkage to other studies.

Constraints on access to data resources

Whilst the Department encourages data sharing to maximise the value of its studies for researchers, there are some considerations that impact on access to particular data resources, especially those that were developed and recruited before data-sharing became the norm or which involved populations recruited outside the UK in collaboration with local investigators.

Where constraints exist then an explanation is provided within a particular study's data sharing policy, along with a clear justification. Examples of constraints that limit data-sharing include:

- *Consent/legal:* the scope of the consent obtained from study participants determines the extent of the ability to share data. For example, commercial usage was not commonly specified in many projects until relatively recently. There may also be legal restrictions on the extent to which certain types of data (eg material transfer agreements related to health outcome linkages) can be shared with external researchers.
- *Ownership/control:* where data that the Department holds is owned by, or controlled by, a third party (eg clinical trial data produced under a co-sponsoring agreement; data provided for meta-analyses by external investigators) then our ability to share these data may be restricted/prevented.

- *Capacity building:* studies established in low- and middle-income countries are not only used to generate important research findings but also to help build research capacity locally. As a consequence, there may be a need to ensure that local researchers (not just those involved directly in the conduct of a study) have preferential access before the data are made available to external researchers with greater analytical capacity who could ‘scoop’ local researchers.
- *Academic return and training:* a substantial amount of work often has to be put in over a prolonged period before observational studies and clinical trials yield any academic reward. There may, therefore, need to be a period of preferential access to data for investigators who have spent many years establishing and nurturing the resource, as well as for doctoral students and early career researchers developing their scientific skills while working on these cohorts. Details of any such ‘exclusivity periods’ can be found in the area dedicated to a particular study on the Departmental website.
- *Political sensitivities:* in some countries, there are political concerns about how data (particularly genetic data) as well as samples are made available to external researchers. Unless care is taken about the way in which data are made available to external researchers, there is a serious risk that the data will not be available to anyone.

The aim will be to minimise any delay prior to making data available for general release, but we will also give due consideration to the period required to allow for the data to be cleaned and prepared for analysis, as well as the time for analysing and writing up results (including, for example, work that forms the basis of a student’s PhD thesis and publications deriving from it). These issues are recognised in UKRI’s Common Principles on Data Policy¹ (in particular, in Principle 5).

Governance of access to NDPH data

NDPH data access committee

This group, which is chaired by the Head of Department (Professor Sir Rory Collins), is responsible for oversight of the Departmental and study-specific data access policies, procedures and timelines for data availability, development of IT infrastructure required to support data-sharing, development of website materials and communications, procedures for data extraction and provision of supporting services, reviewing publications to ensure compliance with data-sharing rules (eg confidentiality, acknowledgement of funders), and reviewing metrics (eg on applications, timelines and resulting publications) relevant to the Department’s data-sharing activities.

NDPH data access management team

This team is responsible for supervising all the practical procedures and processes involved in accessing data held by the Department. This includes: management of the approval system for data access requests; supervision of data extraction and provision of associated services; tracking of applications, decisions and outputs; maintaining accurate and up-to-date information on all studies at the Department’s website, and the provision of advice to data requesters.

International Advisory Board

The Department's International Advisory Board (IAB) is responsible for:

- Providing advice and oversight on the Department's data access policy, with particular attention to ensuring that the policy develops appropriate responses to ethical, geo-political, and strategic issues;
- Advising on study-specific access policies and procedures;
- Providing an advisory and appeals function for data access requests that are declined (as required).
- Reviewing progress with data sharing by the different groups and studies, and advising on whether procedures could be adjusted to improve performance;
- Reviewing publication metrics and the scientific contribution resulting from data-sharing.

Membership of the IAB will include senior figures from a wide range of backgrounds, including academic specialties (such as epidemiology, genetics, and clinical specialties relevant to the Department's research interests), medical ethics, and lay representation. Meetings will be convened twice a year (in person or via video/tele-conference).

References:

1. <https://www.ukri.org/files/legacy/documents/rcukcommonprinciplesondatapolicy-pdf/>
2. <https://www.ukri.org/files/legacy/documents/concordatonopenresearchdata-pdf/>
3. <https://wellcome.ac.uk/what-we-do/our-work/expert-advisory-group-data-access>
4. <https://www.force11.org/fairprinciples>