

Nuffield Department of Population Health

Richard Doll Centenary Archive

Data Access and Sharing Policy for the Nuffield Department of Population Health University of Oxford

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1 Version History

Version	Author(s)	Date	Description/changes
1.1	Jane Green	June 2015	Revised from CTSU policy v1.7, for CTSU/CEU under RDCA
2.0	Jane Armitage	07Jul2016	Major update from Version 1.1 to cover all NDPH and use RDCA terminology
3.0	Jane Armitage	26Aug2016	Incorporating comments from NPEU and Senior Management Group

2 Document Storage, Availability and Change Control Procedure

Approved versions of this document are kept in the electronic data management system (EDMS).

Routine biennial review and alteration is the responsibility of the NDPH members of the RDCA Oversight Committee.

Approval of the document is the responsibility of the NDPH Senior Management Committee.

Approved copies of the document will be made available via EDMS and the external NDPH website.

3 Approvals

Approvals will be given and recorded via the EDMS electronic document management system. The EDMS approver must be a member of the Data Access Oversight Committee.

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5 Definitions and terminology

- Access agreement: an agreement covering the transfer of data or material
- CEU: Cancer Epidemiology Unit, part of NDPH
- CTSU: Clinical Trial Service Unit & Epidemiological Studies Unit, part of NDPH
- Custodian: the person, organisation or committee with responsibility for a data collection or an active study; generally this is the Principal Investigator(s) or Chair of the Steering Committee. For inactive studies the RDCA acts as custodian.
- EDMS: Electronic Document Management System
- FOI: Freedom of Information
- Information Governance Lead (IGL): an individual charged with managing Information Governance issues across NDPH who is a member of the RDCA Oversight Committee
- IPD: individual participant data
- NDPH: Nuffield Department of Population Health, University of Oxford
- NPEU: National Perinatal Epidemiology Unit, part of NDPH
- Requester: an individual or group of researchers seeking access to data or samples from a study
- RDCA Data Access Oversight Committee: a committee allowing independent oversight of the RDCA
- RDCA: the Richard Doll Centenary Archive, a term covering the collection of study datasets held by NDPH

6 Introduction

This document describes the Data Access and Sharing Policy for the Nuffield Department of Population Health (NDPH), University of Oxford. Its purpose is to define policy and procedures within NDPH to ensure adherence to the Research Councils UK and Expert Advisory Group on Data Access common principles on data policy (1-3) and to allow appropriate data sharing for scientific research. This policy does not cover Freedom of Information requests or Data subject access requests under the Data Protection Act.

The policy covers raw data, summary tables and analyses which are not released in publications or on-line from all studies held by NDPH, regardless of the original study location or the source of funding. Study-specific policies should adhere to the same principles and must not conflict with this policy. In addition, this policy is in line with NDPH Information Security Policies, with which NDPH personnel must comply. It does not cover National Registers held in the National Perinatal Epidemiology Unit for which the NPEU is not the data controller that already have nationally agreed data sharing policies which are overseen by the data controller.

The data collections of NDPH are held under the umbrella of the Richard Doll Centenary Archive which was set up in 2012 to mark the centenary of the birth of Professor Sir Richard Doll and to provide coordinated mechanisms for data access and sharing.

The aims of the NDPH 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. NDPH welcomes lawful data sharing that furthers these aims. Data is also widely shared through collaboration. NDPH reserves the right (where members of staff have relevant expertise) to propose a partnership to the requesters in the first instance.

6.1 What is Data Access and Sharing?

Publicly funded research data are a public good which should be made openly available with as few restrictions as possible. To enable research data to be re-used effectively by others, research organisations need to have policies and practices in place to ensure that the legal, ethical or commercial constraints are recognised and that such data are made available for new research purposes in a timely, affordable and responsible manner.

Unregulated access to study data is not possible. A general principle is that data users must not undertake research using personally-identifiable data unless there is consent or an alternative legal basis in place to do so. For cohort studies and clinical trials begun before about 2000 (e.g. the Million Women Study and Heart Protection Study), participants were not asked specifically for consent to data sharing with outside bodies; this was consistent with standard practice at the time. Information was received in confidence from study participants, and they were told that information and biological samples would be treated with absolute confidentiality and used only for medical research. NDPH has the responsibility to ensure that data and samples are accessed only by *bona-fide* researchers of high scientific probity who have agreed to abide by the requirements described in this document and by any contractual arrangements with funders and external suppliers of the data relevant to the datasets, and have any necessary ethics and regulatory approvals in place.

This policy on data access is based on the need to:

- **protect study participants**, honour our commitments to them and act within the scope of their informed consent
- **ensure compliance** with legal and regulatory requirements (e.g. the Freedom of Information Act 2000, the Data Protection Act 1998 and the Human Tissue Act 2004)
- **prioritise access** to those parts of the resource which are limited in availability, especially the depletable resource of biological samples
- **foster high quality research**

6.2 RDCA Data Access Coordinator

The primary tasks of the RDCA Data Access Coordinator, in conjunction with the NDPH Data Sharing Leads (designated members of the Senior Management Group of NDPH) are to:

- act as first point of contact for data requests;
- direct enquiries to the appropriate person or group;
- maintain records of data enquiries and outcomes;
- work with the NDPH Information Governance Lead to ensure there is documentation and designated custodianship of NDPH data collections and their location;
- manage sections of the NDPH websites concerned with data access;
- act as secretariat for the RDCA Oversight Committee;
- advise and educate NDPH staff about the data access policy and process;
- keep up to date with current and related legislation and national policies on data access.

6.3 RDCA Data Access Oversight Committee

The RDCA Data Access Oversight Committee with an independent Chair and members provides advice and governance for the Archive on data access and sharing procedures. The Committee will monitor data sharing requests, decisions made for active studies and monitor the lifecycle of any data agreements. Any person requesting data can appeal to the Oversight Committee if their request is denied and they disagree with the decision. The Oversight Committee will be asked to decide on requests for data access and sharing for inactive studies that no longer have an active Custodian.

Membership of the Oversight Committee (5-10 members) will be agreed by the NDPH Senior Management Group and reviewed every 2 years. The Committee will meet as and when required, but at least once a year. Meetings (in person, via the internet or by telephone) will be convened and managed by the Data Access Coordinator. At least two senior academic researchers will be members of the committee, with the department Information Governance lead, in addition to the Data Access Coordinator, and at least 2 independent members, one of whom will act as chair of the Committee.

6.4 Management Support

The NDPH Senior Management Group actively supports Data Access and Sharing throughout NDPH. Key responsibilities, which may be delegated to a subcommittee, are to:

- review any Data Sharing and Access Policies for particular studies
- provide clear direction for data sharing initiatives
- ensure sufficient resources are available for data sharing
- approve assignment of specific roles and responsibilities for data sharing procedures across NDPH
- regularly review the live data sharing agreements and their lifecycle

7 Data Access

Active studies which may hold data and their key contacts are identified on the NDPH website www.ndph.ox.ac.uk. Specific groups within NDPH which hold datasets include CTSU, CEU and NPEU. Those interested in seeking data access are advised to look at the relevant websites in the first instance. Preliminary informal enquiries can be made to the key contact person or principal investigator copying in the RDCA (richard.doll.archive@ndph.ox.ac.uk) before completing a preliminary enquiry form.

7.1 Eligibility and preliminary contact

Those requesting access are asked to apply through the Richard Doll Centenary Archive preliminary enquiry form [see Section 9.1]. Requesters should be employees of a recognised academic institution, health service organisation or commercial research organisation with experience in medical research; and should be able to demonstrate, through their peer reviewed publications in the area of interest, their ability to carry out the proposed study.

7.2 Submission of full data sharing request

Preliminary applications will be forwarded to the appropriate Data Custodian for active studies. For inactive archived studies applications will be forwarded to academic members of the Data Oversight Committee, who will designate a senior scientist to act as Custodian for the application. At this stage the requester and the Data Custodian have the opportunity for initial discussions before a full application is submitted using the Richard Doll Archive's full application form, which

asks for details of the proposed study and requested data/samples. Requesters are asked to provide their curriculum vitae and details of their current affiliation. The Richard Doll Centenary Archive reserves the right to contact the requester's institution as part of the process of confirming the requester's status.

7.3 Deciding on data sharing requests

For active studies, the Custodian will decide whether or not to accept the proposal. Accepted (for both active and archived studies) proposals will be reviewed at the next appropriate Oversight Committee meeting as part of their monitoring of data access and sharing requests. Requests that are refused will also be reviewed by the Committee and requesters may appeal to the Oversight Committee if they disagree with the custodian's refusal. For inactive studies provisional agreement between an acting custodian and the requester will be reviewed by the Oversight Committee in person, by telephone or by email and a final decision made on approval or further action. The custodian and/or Overview Committee reserve the right to send an application for scientific review by independent peer reviewers.

7.4 Ethics and other approvals and resources

Obtaining Ethics Committee approval for the research is the responsibility of the requester. The requester, in conjunction with study investigators, may also need to obtain approval from the Research Ethics Committee responsible for the existing NDPH study. Local Research Governance approval if required, is the responsibility of the requester. Obtaining approval(s) required from any other body (for example the Confidentiality Advisory Group of the Health Research Authority) is the responsibility of the requester but applications should be made in conjunction with the study investigators. Linked health data provided to studies from external sources (eg information on deaths and hospital admissions) may be subject to specific regulations on sharing with third parties. Linked data may not be available for sharing without separate application to the data provider, and all such applications are the responsibility of the applicant.

When considering a request for data sharing, the likely commitment of NDPH staff needs to be realistically assessed and that the requester will need to confirm that funding is available to cover NDPH costs.

7.5 Limitations on the use of data

The data collections will be used for the purposes of medical research and education only and within the constraints of the consent (and any other legal basis) under which the data were originally gathered, and of any contractual agreements between the study from which data are requested and its funders or external data sources. Where demand for material exceeds its availability or staffing resources are insufficient to make data available, access will be prioritised by the Oversight Committee on scientific merit.

Data or samples supplied from the collection may only be transferred to Requesters named at the time of the original application or in subsequent applications and specified in the Access Agreement or later amendments. Data from the collection may not be transferred to individuals outside the Requester's research group.

Students wishing to have access to data should ask their supervisor to make a request on their behalf.

NDPH considers that it is entitled (and obliged) to first publication of the data it has generated and to a reasonable but limited period of exclusivity for itself and its external collaborators. This period

will be determined for each study and will usually be a minimum of five years from the end of the study or from the date of the data provided if individual participant information is required, however reasonable requests for summary data or analyses will be considered within the 5 year period.

8 Access process

8.1 Access Agreement

Access to anonymised individual participant information or biological samples from a data collection will be permitted by application only and under an Access Agreement. Tabular data or specific requested analyses can be shared without a formal agreement if the Custodian feels this is appropriate. The Access Agreement will include standard terms as to ownership, exploitation and dissemination of results, including the return of any results to the research study for incorporation into the resource. It may specify a fee payable and include requirements that the user conform to the terms of any ethics and governance approval, and participants' consent and to the Richard Doll Archive Data Access Policy.

8.2 Terms of access

Identifying data will not typically be made available to research collaborators. The processes for anonymisation of provided data will be as stated by the relevant study Steering Committee or Data Access Oversight Committee. The Access Agreement will contain confidentiality undertakings to further safeguard participants' privacy.

If, however, the nature of the research is such that personal identifiers are required in order to carry it out, the Custodian must satisfy themselves of the necessity of providing the identifiers; consideration will be given to whether it is possible to avoid release of identifying data to requesters, for example by using a Trusted Third Party to perform data linkage. If release of identifiers is required, the Custodian will need to verify that the requester has adequate procedures and equipment in place to handle and protect the data. In all cases where release of personal identifiers is being considered, the Custodian must seek the advice and approval of the Information Governance Lead. A CAG approval (s251 approval from the Confidentiality Advisory Group of the Health Research Authority or equivalent) will be required where identifiable data are required and when a) original consent has been obtained, but does not include the scope of the request; or b) identifiable data have been collected without consent. Where confidential information concerning personal details is to be shared, consideration should be given to encryption and contractual confidentiality. A specific "owner" for the information in the requester's organisation should be identified where practical.

Recipients must agree not to link data provided with any other data set without the permission of the Custodian. Recipients must not attempt to identify any individual from anonymised data provided. Should recipients believe that they have inadvertently identified any individual, they must immediately notify the Custodian, and must not record the relevant identity, share the identification with any other person or attempt to contact the individual.

Applications for funding for research including data from NDPH research studies would be expected to include a study investigator as a co-applicant.

8.3 Dissemination of results

The Richard Doll Centenary Archive reserves the right to publish the title, the names(s) and affiliations(s) of the Chief Investigator(s), a lay summary and a scientific abstract of each piece of

collaborative research for which sample or IPD access to the resource has been granted, before identification or publication of results. Requesters who do not wish details of their study to be openly available should state this in their application to the collection and give the reason.

In order to recognise the contribution made by past and current NDPH staff and collaborators (in the UK and/or internationally) to setting up and maintaining study collections, it would be expected that a representative of the study would be offered co-authorship. It may also be appropriate to acknowledge individual members of the study staff who have contributed directly to the study in order that they may claim authorship as members of the study team. Each report to be submitted for publication by collaborators must be forwarded to the Data Custodian for consideration at least 28 days before submission.

8.4 Fees

The recipient will usually be required to cover the costs of administering the data sharing (including legal fees if applicable), retrieving, processing and sending or providing access to the data or samples. The basic rates of these costs can be obtained from the Richard Doll Centenary Archive administrator. Estimated costs for a particular request will be provided after initial review of the full application.

8.5 Usage limitation

Data or samples supplied from the collection must be used only for the purpose stipulated by the Custodian and described in the data or materials sharing agreement. Any proposal that unblinds, or potentially unblinds, randomised comparisons in active studies will be rejected. Any proposal which seeks to identify individuals from data previously de-identified will also be rejected.

9 References

Research Councils UK common principles on data policy:
<http://www.rcuk.ac.uk/research/datapolicy/>

MRC Policy and Guidance on Sharing of Research Data from Population and Patient Studies <http://www.mrc.ac.uk/publications/browse/mrc-policy-and-guidance-on-sharing-of-research-data-from-population-and-patient-studies/>

Expert Advisory Group on Data Access Report, Governance of Data Access. June 2015, Cancer Research UK, ESRC, MRC, Wellcome Trust: <http://www.wellcome.ac.uk/About-us/Policy/Spotlight-issues/Data-sharing/EAGDA/wtp059350.htm>

9.1 Related Documents

[RCDA Preliminary Enquiry Form](#)

[RDCA Data Access Application Form](#)

[RDCA Draft Data Transfer agreement](#)

10 Annex 1

Membership of the Richard Doll Centenary Archive Data Access Oversight Committee:

(July 2016)

Independent Chair: Professor Dame Anne Mills (London School Hygiene & Tropical Medicine)

External Members: Professor John Danesh (University of Cambridge)

Professor Peter Sandercock (University of Edinburgh)

Mr Jonathan Sellors (Legal Counsel, UK Biobank)

NDPH Academic members:

Professor Jane Armitage (CTSU)

Professor Sarah Parish (CTSU)

Professor Jane Green (CEU)

Professor Jenny Kurinczuk (NPEU)

The Information Governance Lead

Secretariat: Archive Data Access Coordinator
(Ms Hayley Abbiss: richard.doll.archive@ndph.ox.ac.uk)