

Nuffield Department of Population Health

Richard Doll Centenary Archive

**Data Access and Sharing Policy
for the Clinical Trial Service Unit and
Epidemiological Studies Unit (CTSU) and
the Cancer Epidemiology Unit (CEU)**

University of Oxford

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1. Introduction

This document describes the Data Access and Sharing Policy for the Clinical Trial Service Unit and Epidemiological Studies Unit (CTSU) and the Cancer Epidemiology Unit (CEU) of the Nuffield Department of Population Health (NDPH), University of Oxford. Its purpose is to define policy and procedures within CTSU and CEU 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.

The policy covers data from all studies held by CTSU and CEU, regardless of original study location or the source of funding. Study-specific policies should adhere to the same principles. In addition this policy is in line with NDPH Information Security Policies, with which NDPH personnel must comply.

The data collections of CTSU and CEU are held as the **Richard Doll Centenary Data Archive**, set up in 2012 to mark the centenary of the birth of Professor Sir Richard Doll, and to provide coordinated mechanisms for data sharing and data archiving.

The aims of the NDPH are to study the major causes of morbidity and mortality in adults by conducting high quality research that generates reliable results about the causes of, and treatments for, such diseases. NDPH welcomes data sharing that furthers these aims.

1.1 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 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 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. CTSU and CEU have 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.

CTSU and CEU policy on data access is based on the need to:

- **protect 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 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
- **ensure high quality** research is fostered

1.2 Terminology

Collection	Any dataset, including summary datasets, or set of human samples with associated data
Custodian	The person, organisation, body or committee with responsibility for a collection; for an active study this is typically the Principal Investigator(s) or Chair of the Steering Committee; for inactive studies the Richard Doll Centenary Archive acts as Custodian
Access Agreement Requester	Agreement covering data or material transfer An individual or group of researchers seeking access to data and/or samples from a collection

1.3 Data Access Coordinator

The primary tasks of the Data Access Coordinator, in conjunction with the Richard Doll Centenary Archive Data Access Leads (designated members representing Senior Management Groups of CTSU, CEU and/or NDPH) are:

- to act as first point of contact for data requests; to direct enquiries to the appropriate person or group; to maintain records of data enquiries and outcomes
- to document the custodianship and location of CTSU and CEU data collections and, if required, to manage sections of the CTSU and CEU websites concerned with data access
- to act as secretariat for the archive's Access Oversight Committee
- to inform the Data Access Leads of changes in policy

1.4 Oversight Committee

An independent Data Access Oversight Committee will provide advice and governance for the Archive on data access and sharing procedures. The Committee will be required to monitor data sharing requests and decisions made for active studies (Principal Investigators or its Advisory or Steering Committee of such studies will be considered Custodian and will normally make decisions about applications for data access). Any requestor 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 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 from time to time. The Committee will meet as and when required, but at least once a year. Meetings (in person or by telephone) will be convened and managed by the Data Access Coordinator. At least one senior researcher from the CTSU and one from the CEU will attend any meeting, in addition to the Data Access Coordinator, and at least 2 independent members, one of whom will act as chair of the Committee.

1.5 Management Support

The NDPH Senior Management Group actively supports Data Sharing throughout NDPH, including through the Richard Doll Centenary Archive. Key responsibilities, which may be delegated to a subcommittee, are to:

- review the Data Access Policies of NDPH groups
- provide clear direction for data sharing initiatives
- provide the resources and funding needed for data sharing
- approve assignment of specific roles and responsibilities for data sharing procedures across NDPH

The Senior Management Teams of CEU and CTSU oversee data sharing within their Units.

2 Access for data sharing

2.1 Eligibility and preliminary contact

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. Those requesting access should apply through the Richard Doll Centenary Archive preliminary enquiry form in the first instance.

2.2 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 CTSU/CEU members of the Oversight Committee, who will designate a senior scientist to be the acting 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 CV 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.

2.3 Deciding on data sharing requests

For active studies the Custodian will decide whether or not to accept the proposal. Agreed proposals will be reviewed at the next appropriate Oversight Committee meeting as part of their monitoring of data sharing requests. Sharing 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.

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 CTSU or CEU study. Local Research Governance approval and R&D approvals, if required, are the responsibility of the requester.

2.4 Limitations on use of collections

The data collections will be used for the purposes of medical research only and within the constraints of the consent 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.

3 Access process

3.1 Access Agreement

Access to the collection, whether tabular data, individual participant information, or biological samples will be permitted by application only and under an Access Agreement only. 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 the Ethics and Governance, and participants' consent and to the Richard Doll Archive Data Access Policy.

3.2 Terms of access

Identifying data will not be made available to research collaborators. All data provided to a requester will be anonymised; the processes for anonymisation 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.

Recipients must agree not to link the anonymised data provided with any other data set without the permission of the Custodian. Recipients must not attempt to identify any individual from the data provided. Should recipients believe that they have inadvertently identified any individual, they must not record this, share the identification with any other person or attempt to contact the individual. Applications for funding for research including data from CTSU/CEU research studies will be required to include a study investigator as a co-applicant.

Requesters will be required to submit regular progress reports to the CTSU/CEU Custodian or Study Steering Committee.

3.3 Dissemination of research results and transparency

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 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 CTSU and/or CEU 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.

3.4 Fees

The recipient may be required to cover the costs of administering the data sharing (including legal fees if applicable), retrieving, processing and sending 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.

3.5 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.

References

1. Research Councils UK common principles on data policy:
<http://www.rcuk.ac.uk/research/datapolicy/>
2. MRC Policy and Guidance on Sharing of Research Data from Population and Patient Studies <http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC008302>
3. 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>

Related Documents

[Richard Doll Centenary Archive Data Access and Sharing Policy](#)

[RDCA Preliminary Enquiry Form](#)

[RDCA Data Access Application Form](#)

[RDCA Draft Data Transfer agreement](#)

Annex

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

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)

CTSU/CEU Academic members
Professor Jane Armitage (CTSU)
Professor Sarah Parish (CTSU)
Professor Jane Green (CEU)

Secretariat: Archive Data Access Coordinator (Ms Hayley Abbiss)

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