Mexico City Prospective Study

Data and Sample Sharing Policy (version 4.3)

1. Overview

The Mexico City Prospective Study (MCPS) (originally called '*Proyecto Coyoacan*') is a blood-based prospective study of ~160,000 Mexican adults. Its main aims are to study the relevance of lifestyle, environmental, biochemical and genetic factors for major chronic diseases (e.g. stroke, heart disease, cancer, diabetes) in Mexican adults, to improve the prevention and treatment of these diseases.

Participants were recruited from 1998-2004. They were interviewed, had a range of physical measurements taken, gave 10 ml of blood (for long-term storage in Oxford of plasma and DNA-containing buffy coat), and gave permission for their subsequent health status to be tracked. Long-term follow-up for mortality is via electronic linkage to Mexico's national death register. A resurvey of 10,000 surviving participants was carried out 2015-2019. This large collaborative research project was designed and is being run jointly by the Nuffield Department of Population Health (NDPH) in the University of Oxford and the National Autonomous University of Mexico (UNAM) in Mexico City.

Access to biological samples is limited by the small volume available. Consideration is given to collaborations that involve an extensive range of quality-controlled assays of all – or large numbers of – samples using high-throughput and cost-effective assay methods. The MCPS study group is actively seeking funding for assay strategies that will transform the available samples into accessible data for use by researchers in Mexico, UK and elsewhere.

At recruitment, as was consistent with standard practice at the time, the participants were not asked specifically for consent to data sharing with outside bodies. However, we understand that the consent was sufficient to permit the supply of pseudonymised data to *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.

Within the above constraints, the MCPS study group welcomes proposals for access to data from researchers in Mexico and around the world. This document describes the access policy and procedures, and is summarized in the **Appendix**. It has been developed in concordance with the general principles of data sharing promoted by various research organisations worldwide including the UK Research and Innovation's common principles on data policy (www.ukri.org/funding/information-for-award-holders/data-policy/common-principles-on-data-policy) and the Data Access and Sharing Policy of the Nuffield Department of Population Health, University of Oxford.

2. Terminology

Data	Any MCPS study dataset, including summary datasets, baseline survey data, re-survey data, follow-up information, blood assay results, genetic data.
Data Sharing Agreement	Agreement covering the terms of data access to a Requestor of Open Access Data.
Collaboration Agreement	Agreement covering the terms of data access to a Requestor working with a member of the MCPS study team in either Mexico or the UK.
Open Access Data	Data being made available to external *bona fide* researchers through this Data and Sample Sharing policy.
Restricted Data	Data stored in the MCPS data repository which has limitations placed on its use or wider distribution.
Requestor	An individual or group of researchers seeking access to data and/or samples from the MCPS study.
Data User	An individual or group of researchers that has been granted access to data and/or samples from the MCPS.

3. Principles of data sharing

As the MCPS has information on many different exposures and health outcomes over a period of years, a wide range of investigators should be involved in determining which questions to address and how best to address them. As data custodian, the MCPS study group must maintain the integrity of the database for future use and regulate data access. Data can be released outside the MCPS research group only with appropriate security safeguards and approvals. This policy on data access is based on the need to:

- Protect participants and act within the scope of their signed consent.
- Ensure compliance with all laws and regulations which apply to its use, storage and disposal of the data and/or samples.
- Ensure high quality research is fostered that will advance knowledge. Applications that include Mexican collaborators are particularly welcome since they would help to develop and strengthen the research capacity of local investigators.
- Ensure that the data security and participant confidentiality are maintained.
- Support local capacity building. There is a desire that the data from the MCPS are not only used to generate important research findings but also to help to build research capacity locally.
- Provide academic return and training for the investigators developing the study, in particular for doctoral students and early career researchers who are developing their scientific skills while working on the cohort.

3.1. Key components of this data access policy:

- **Collaborations:** The MCPS research group is actively seeking and responding to requests for scientific collaborations on specific projects, especially when framed in ways that help strengthen Mexican research capacity. This model of facilitated collaboration with external researchers is adopted where it can increase the value and quality of the data. Collaborations are governed by a separate Collaboration Agreement, which: (i) identifies a dedicated project lead from within the MCPS study group in either Mexico and/or the UK; (ii) details arrangements for co-authorship or papers; (iii) covers intellectual property issues; and (iv) details financial commitments where appropriate.

- **Open Access Data Availability:** Before data is approved for any analysis, relevant members of the MCPS team responsible for generating the data must first undertake required cleaning, processing, quality control and integration. As soon as the data are clean, it will be made immediately available for open access sharing with researchers applying from within a Mexican institution, as long as the proposed project does not overlap significantly with projects already being conducted by the Mexico or Oxford-based investigators (see **Appendix**). This period of **exclusive access for Mexican researchers will be for 2 years**, after which the datasets will be made available for open access sharing with any *bona fide* researcher worldwide. Details of the currently available data are provided in the **Appendix** of this document.

- **Independent Oversight of Access:** Initial decisions on data requests are taken by the MCPS study team. The Nuffield Department of Population Health Data Access Oversight Committee provides further scrutiny and governance advice where necessary. A Requestor can appeal to this committee if they disagree with a study decision on access.

- **Protecting the Identity of Participants:** Safeguards are maintained to ensure the anonymity and confidentiality of participants' data. Researchers will need to enter a legal agreement not to make any attempt to identify participants, and the data provided to researchers will not contain any personally identifiable variables (i.e. every data set provided will be "pseudonymised" with uniquely encrypted participant identifiers [PIDs]).

- **Data Security:** All MCPS data is held on secure servers in a central data repository that is compliant with internationally recognised information governance standards. A data management team acts as gatekeepers and ensure that any shared data is delivered though a secure data delivery system and in an appropriate format.

- **Sample Preservation and Access:** Only 10 ml of blood was taken at baseline and resurvey from each participant, which, in each instance, was divided into 1 buffy coat sample and 2-3 plasma samples that are stored in Oxford. At resurvey, a urine sample was collected from just under half the participants (from the latter part of the recruitment period). Given the very limited amount of these

depletable resources, access to these samples needs to be carefully controlled. Consequently, rather than assay samples on a nested case-control basis (which is cost-effective for studying a particular condition but not for a resource that is to be used to study many different conditions by different researchers), assays of the samples from all participants is far preferable. Such a strategy maximises the information available to researchers while minimizing sample depletion and facilitating different comparisons across the cohort since the assay methodology and quality control would be consistent. Suggestions for particular assays to be included are welcomed, and all assay values will become part of the available dataset. In general (as is the case in UK Biobank), it is not expected that requests for direct access to samples will be agreed to by the Access Committee.

- **Fees for data access:** Open Access Data is available free of charge to applicants from low and middle income countries. Researchers in high-income countries will incur an Access Charge for each approved data request (currently £2500 GBP prior to Data release). This contributes to the administrative costs incurred in managing and reviewing the application, and in preparing the individual datasets. Collaborating researchers may also be required to cover the costs of administering the data sharing (including legal fees if applicable), retrieving, processing and sending the data or samples. Estimated costs for a particular request will be provided during the development of the project proposal.

4. Data access process

Potential Collaborators and Data Requestors should first contact MCPS Investigators or review the MCPS study website (including previous MCPS publications) and **Data Showcase** (https://datashare.ndph.ox.ac.uk/mexico/) to gain an understanding of the available study data and of projects that have previously been completed. The MCPS Data Showcase aims to present the data available from the study for health-related research in a comprehensive and concise way, and to provide additional information for researchers considering applying to use the resource.

4.1 Collaboration requests

Researchers who are interested in collaborating on projects with MCPS researchers in Mexico or the UK are encouraged to approach the MCPS study group informally in the first instance by email to mcps-access@ndph.ox.ac.uk or to contact relevant MCPS investigators to discuss research ideas and feasibility. Enquiries should include a project title and brief outline of the research project and the relevant data of interest. Each project will require a co-investigator from within the MCPS study group who has a common interest in the project and relevant or complementary research expertise. Once identified, the collaborator and the co-investigator will co-develop a research proposal which will then be reviewed by the MCPS Steering Committee.

4.2 Open Access Data requests

Registration / eligibility

All Open Access Data Requestors are first required to complete the ***MCPS Data Access Registration form*** (available in English and Spanish) and send it to mcps-access@ndph.ox.ac.uk. Requestors should be employees of a recognized academic institution, health service organization or charitable research organization with experience in medical research. They should be able to clearly demonstrate, through their peer reviewed publications in the area of interest, their ability to conduct independent research.

Submission of a data request

Once approved, Data Requestors will be sent an ***MCPS Project Description and Data Request form*** and will need to return the completed form to mcps-access@ndph.ox.ac.uk. This form requires the Requestor to provide: a project title and abstract; scientific rationale / methodology; anticipated outputs and project timeline. Additional questions cover ethical issues, collaborators / research team, funding support and data security, and the data variables they would like to receive.

Review of a data request

Open Access Data requests will initially be assessed by the MCPS study investigators. Each application will be considered on its individual merit. If necessary, independent peer review will be sought. Approved projects will: (i) have clearly defined objectives; include a sound methodology that is likely to generate meaningful results; (ii) be based on an appropriate and available selection of data; (iii) have clearly defined timelines and outputs (e.g. 1-2 papers in peer-reviewed journals). Projects that overlap significantly with approved and/or completed projects may be rejected (see **Appendix 3**).

The MCPS team aim to review and respond to Data Requests within 2-4 weeks. A Requestor can appeal to the Nuffield Department of Population Health's Independent Data Access Oversight Committee if their request is denied by the project team, by completing this form.

5. Terms of data access

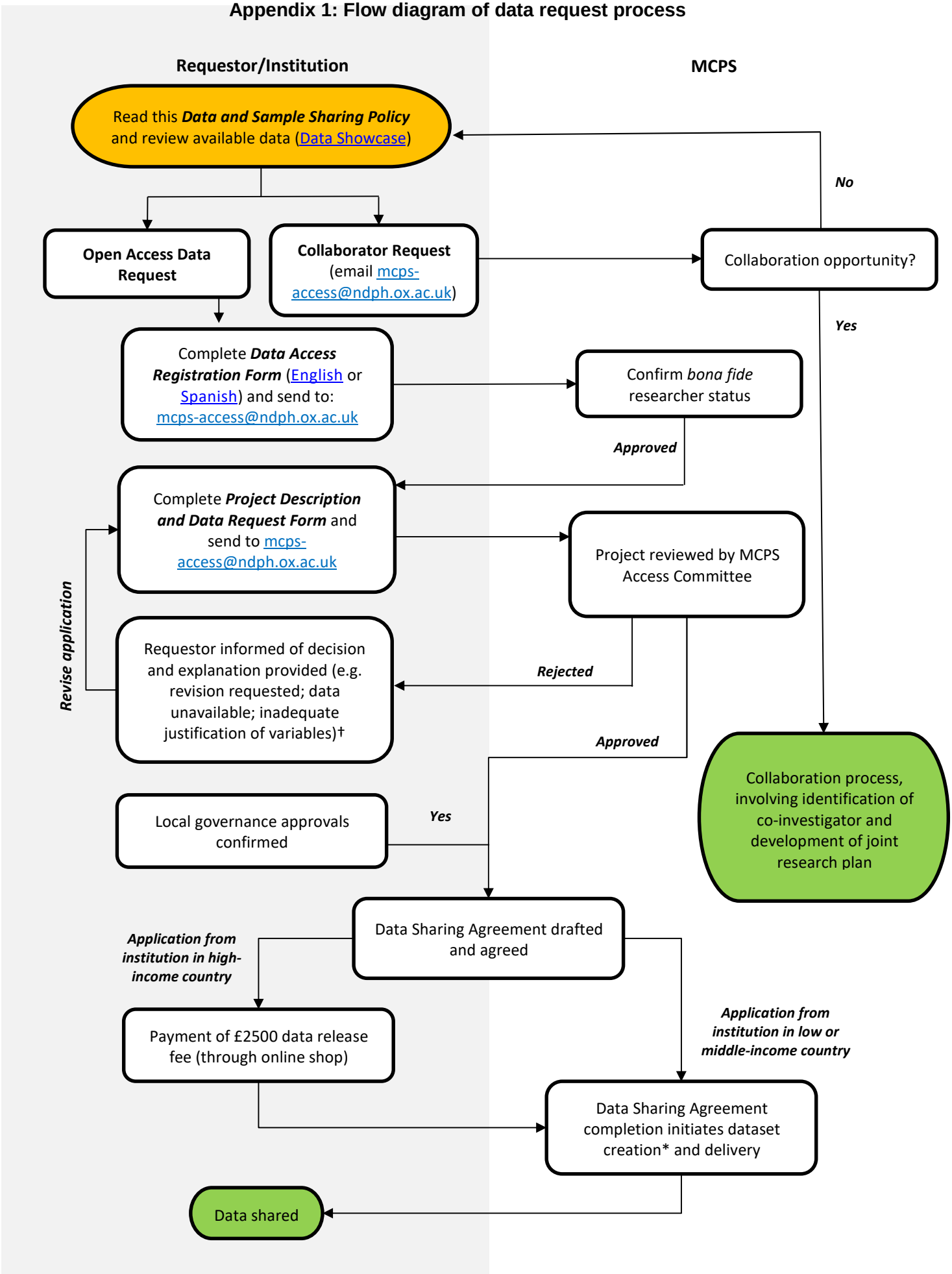
Once proposals are approved the following conditions and undertakings are required as conditions of access:

- **Data Sharing Agreement**. Before any data are shared a signed sharing agreement must be in place between the Requestor's institution and the University of Oxford. This agreement will be sent to the Requestor once their application is approved, and will include a copy of the approved project proposal as a Schedule.
- **Signing Authority**. Requestors should be acting as members of a recognised academic institution, research organisation or health organisation. Their request should come from a recognised email domain. Their organisation should have formal policies and procedures (i.e. IG Toolkit, ISO 27001 certification or System Level Security Policy assessment) to comply with any legal, ethical or data protection constraints and to ensure that the dataset is stored securely and used responsibly.
- **Ethics and Research Governance Approval**. Where applicable Ethics Committee approval for the research is the responsibility of the Requestor. The Requestor, in conjunction with study investigators, may also need to obtain approval from the Research Ethics Committees responsible for the MCPS study. Local Research Governance approval and R&D approvals, if required, are the responsibility of the Requestor. Approvals will need to be in place before any data are shared.
- **Limitations on Use**. The data 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 MCPS study and its funders or external data sources. Access will be permitted only for research that is consistent with the originally-submitted project description, has been ethically and scientifically approved by appropriate independent reviewers and where the use of the data will be for the demonstrable benefit of health and/or social care. Data supplied may only be shared with Requestors 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 cannot be shared with individuals outside the Requestor's research group without formal approval by the MCPS Principal Investigators.
- **Identifying Data**. The data provided to researchers will not contain any personally identifiable variables. Data sets will be "pseudonymised" with encrypted participant identifiers (PIDs). The Access Agreement will contain confidentiality undertakings to further safeguard participants' privacy. Recipients must agree not to link the pseudonymised data provided with any other data set without permission. 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.
- **Intellectual Property**. All Intellectual Property Rights in the Data are and shall remain at all times the property of UNAM and the University of Oxford. All Arising Intellectual Property shall vest in and be owned by the Requestors. The Requestors will cover any cost for the protection of arising Intellectual Property. The Requestors shall promptly disclose any such Arising IP in writing to the Principal Investigators. UNAM and the University of Oxford will be granted rights to use all Arising Intellectual Property for academic and research purposes, including research involving projects funded by third parties provided that those parties gain or claim no rights to such Arising Intellectual Property.
- **Payment of Access Charges**. Data Requestors from institutions in high-income countries are expected to pay Access Charges to contribute to the administrative cost to the study of reviewing the application and preparing data for sharing, etc. Where these are applied, no Data will be provided to the Data Requestor until or unless the Access Charges are received in full.
- **Data Release and Delivery.** Once the proposal is approved and the Access Agreement signed, phenotypic data and its documentation will be generated in CSV (or any other pre-specified) format, encrypted and released in a secure manner. The genetic data will be shared by granting access to an online research analysis platform enabled by DNAnexus technology and powered by Amazon Web Services (AWS), where researchers will be able to access both the genetic and non-genetic data, perform their analyses and download their results.
- **Publicity and Dissemination.** The MCPS study team 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. Requestors who do not wish details of their study to be openly available need to state this in their data request and give the reason. The Requestor shall not use the name or any trademark or logo of UNAM or the University of Oxford in any press release or product advertising, or for any other commercial purpose, without prior written consent.

- **Authorship and Approvals.** Collaboration Agreements and Access Agreements will specify expectations regarding authorship and acknowledgements on research outputs. Collaborations require at least one co-author from the MCPS study group. For Open Access Agreements no authorship from the MCPS team is required, but Requestors are nevertheless asked to submit proposed publications to the MCPS team for review not less than 30 days in advance of the submission for publication.
- **Publications and Open Access.** All publications of the Results in a peer-reviewed journal, or as a scholarly monograph or book chapter, must be made available from PubMed Central and Europe PubMed Central as soon as possible and no later than six months from the date of final publication. Journal requirements for data release and deposition that may be requested following publication of an article must be discussed with and approved by the Principal Investigators prior to submission of a manuscript.
- **Integration of the Data.** After completion of work using released MCPS data, the original dataset as well as any derived dataset and/or variables generated during the research must be returned to the MCPS central data repository for archiving and/or merging with the main database for future use. If considered appropriate, the MCPS staff may carry out independent checks and/or validation of the data and results to ensure the continued data integrity and reliability of the study findings.
- **Monitoring and Accountability.** The Data Requestor shall be required to submit annual reports and any other information reasonably requested to evidence the work undertaken in connection with the proposed project. If there is substantial deviation or change in the planned use of the data, further approval will be needed. If there is substantial delay or difficulty in completing the planned research, the MCPS study team will have the right, after consultation with the Nuffield Department of Population Health Data Access Oversight Committee, to terminate the work if in its view there is little chance that the problem will be rectified. Under such circumstances, all Data that have been provided must be deleted and a deletion certificate provided.

Appendix 1: Flow diagram of data request process



† The requestor may appeal the decision as described in the NDPH Data Access Policy.
** All data sets pseudonymised with unique participant identifiers, download uses secure encryption.*

Appendix 2: Data available for sharing

For full details of available data, please review the online MCPS **Data Showcase** (https://datashare.ndph.ox.ac.uk/mexico/). The Showcase displays all the data types currently available, in a grouped format (i.e. not at the individual participant level), along with further information about each data field (for example, background information about how measures were taken). An online variant browser summarising the genetic variation is also available at: https://rgc-mcps.regeneron.com/.

Table 2a below summarises the data currently available to researchers worldwide while **Table 2b** overleaf summarises the **additional** data available to researchers in Mexico.

Table 2a: Details of data available to researchers worldwide

Baseline data (1998-2004)
Available for 159,517 participants

Month and year of recruitment

Socio-demographic
- Age
- Sex
- Area of residence
- Marital status
- Educational achievement
- Occupation
- Income
- Health service provider

Lifestyle characteristics
- Smoking
- Passive smoking
- Alcohol consumption
- Physical activity
- Sleep duration
- Fruit/vegetable intake
- Fried food intake
- Type of cooking oil used

Prior diseases and medication

Reproductive history (women)
- Menopausal status
- Hysterectomy
- Oophorectomy
- Hormone replacement therapy
- Contraceptive use
- Age at first sexual relationship
- Age at first pregnancy
- Number of pregnancies

Physical measurements
- Height
- Weight
- Waist circumference
- Hip circumference
- Systolic blood pressure
- Diastolic blood pressure

Blood samples
- Time of blood sampling
- Time since last meal
- Glycosylated haemoglobin

Resurvey data (2015-2019)
Available for 10,143 participants. Similar data to that collected at baseline plus:

Additional questionnaire data
- Diabetes control questions
- Diabetes consequences *(eg, eyes, amputations, dialysis)*
- Fractures/fall
- Treatment for breast cancer
- Additional dietary questions *(eg, sugary drinks, added salt, meat, fish, desserts, diets)*
- Cognitive function (MMSE)

Additional measurements
- Bioimpedance *(fat mass, fat free mass, muscle mass, muscle score, bone mass, body water, degree of obesity, visceral fat rating, basal metabolic rate, metabolic age, Rohrer's index)*

Additional samples
- Time of urine sampling
- Urinary creatinine
- Urinary albumin

Mortality data (up to 31st September 2022)
- Date of death
- ICD-10 underlying cause
- ICD-10 contributory causes
- Timing/duration of diseases
- Location of death
- Seen by doctor before death

Table 2b: Details of <u>additional</u> data currently available only to researchers in Mexico

Baseline NMR metabolomic data using the Nightingale Health platform (subset of 40,297 participants)

14 lipoprotein subclasses
- XXL VLDL
- XL VLDL
- L VLDL
- M VLDL
- S VLDL
- XS VLDL
- IDL
- L LDL
- M LDL
- S LDL
- XL HDL
- L HDL
- M HDL
- S HDL

7 lipid measures for each subclass
- Particle number
- Cholesterol
- Free cholesterol
- Esterified cholesterol
- Triglycerides
- Phospholipids
- Total lipids

Lipoprotein mean particle sizes & apolipoproteins
- VLDL-D
- LDL-D
- HDL-D
- Apo A1
- Apo B

Fatty acids
- Polyunsaturated fatty acids
- Monounsaturated fatty acids
- Saturated fatty acids
- Docosahexaenoic acid
- Linoleic acid
- Omega-3
- Omega-6
- Total fatty acids

Cholines and glycolysis-related
- Total cholines
- Phosphatidylcholine
- Sphingomyelin
- Lactate
- Citrate
- Glucose

Amino acids
- Alanine
- Glutamine
- Histidine
- Isoleucine
- Leucine
- Valine
- Phenylalanine
- Tyrosine

Ketone bodies, inflammation and kidney function
- Acetate
- Aceto-acetate
- β-hydroxy-butyrate
- Albumin
- Creatinine
- Glycoprotein acetyls

Genomic Data

Described fully in Ziyatdinov et al. 2023[†]

Genome–wide genotyping with the Illumina Global Screening Array (GSA) version 2
- Non-filtered dataset (140,831 participants)
  650,381 variants: 619,501 autosomal variants; 30,101 sex chromosome variants; 779 mitochondrial variants.
- Quality controlled dataset (138,511 participants)
  559,923 variants: 539,315 autosomal variants; 19,954 sex chromosome variants; 654 mitochondrial variants.

Whole Exome Sequencing (WES)
- Non-filtered dataset (141,046 participants)
  13,331,228 variants: 12,957,291 autosomal variants; 368,300 chromosome X variants; 5,637 chromosome Y variants

Whole Genome Sequencing (WGS)
- Non-filtered dataset (9950 participants)
  158,464,363 variants:151,639,445 autosomal variants; 6,342,270 chromosome X variants; 482,648 chromosome Y variants.
- Phased WGS Imputation Reference Panel (MCPS10k)9,948 whole genome sequenced phased samples
- Total of 134,337,444 variants distributed across 22 autosomes and chromosome X
- Data available in four file formats.

TopMed Imputed
- Non-filtered dataset (140,831 participants)
  307,624,124 variants: 292,293,083 autosomal variants; 15,331,041 chromosome X variants.

Apo−A1=apolipoprotein A1; Apo−B=apolipoprotein B; HDL=high density lipoproteins; HDL−D=high density lipoprotein particle diameter; IDL=intermediate density lipoproteins; L=large; LDL=low density lipoproteins; LDL−D=low density lipoprotein particle diameter; M=medium; S=small; VLDL=very low density lipoproteins; VLDL−D=very low density lipoprotein particle diameter; XL=very large; XS=very small; XXL=extremely large

[†]https://doi.org/10.1038/s41586-023-06595-3

Appendix 3: Completed and protected projects (with currently available data [appendix 2])

To date, the MCPS research teams in Oxford and UNAM have focused on studying the relevance to cause-specific mortality of major disease risk factors, including diabetes[1-3], adiposity[4-7], blood pressure[8], smoking[9] and low levels of education[10], and has also published several cross-sectional analyses related to these[11-13] and other cardiometabolic risk factors including lipids and other biomarkers[14-15]. In addition, current analyses (anticipated for publication in 2024) will report the relevance of alcohol consumption, physical activity and renal function to cause-specific mortality, as well as the combined relevance of these major disease risk factors to cardiovascular risk. If you are interested in studying any of these risk factors we therefore recommend that you review these previously published papers (or contact us) to see what has already been published from the study or soon will be.

In addition, several areas of research are currently being explored by PhD or researchers at Oxford and UNAM, and are therefore considered 'protected' until the completion of the project. These include, but are not limited to, studying the genetics of diabetes, kidney function, adiposity, blood pressure and blood lipids, Mendelian randomization studies of these phenotypes, and use of polygenic risk scores for predicting cardio-metabolic mortality. Applications for projects that overlap significantly with protected projects may therefore require further discussion before approval. This may also be the case where an application overlaps significantly with an external project that has already been approved (a list of approved external projects is available on our website).

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