National Diet and Nutrition Survey (NDNS) Bioresource

Governance Policy and Procedures

1. Introduction

The UK has a longstanding programme of National Diet and Nutrition Surveys (NDNS) which offers a valuable resource that can be utilised for further health related research in the public interest. Simple and streamlined access procedures are required to encourage and facilitate fair and appropriate use.

Findings from NDNS are regularly published through government reports and are made publically available via the UK Data Service (UKDS) following publication. The ***NDNS Bioresource*** has been founded to govern and facilitate access to the overall resource comprising:

- Biological samples (including repository and residual samples) from the following surveys:
  - NDNS Rolling Programme (RP) 2008 - ongoing
  - Urinary sodium surveys from 2011 in England, Scotland and Northern Ireland
  - Participants from NDNS RP
- participants willing to be contacted for future research from NDNS RP and the Diet and Nutrition Survey of Infants and Young Children (DNSIYC)
- Data not available via UKDS, including detailed demographic information Opportunity for NHS data linkage for NDNS RP participants who have consented to be linked to the NHS Central Register and Cancer Register (see 5.3).

This governance document provides information on the management, governance and functioning of the NDNS Bioresource and the policy for access.

2. The UK Nutrition Surveys (NDNS RP, urinary sodium surveys, DNSIYC)

The NDNS RP is a survey of the food consumption, nutrient intakes and nutritional status of people aged 1.5 years and older living in private households. The survey is carried out in all four countries of the United Kingdom (UK) and is designed to be representative of the UK population. Fieldwork runs continuously throughout the year.

Since 2008, NDNS has operated with continuous fieldwork that provides a responsive framework for dietary surveys, giving opportunities to identify and analyse trends, identify emerging policy issues, and respond more rapidly to changing health/data needs.

The NDNS RP is jointly funded by the Department of Health and Social Care,[1] and the UK Food Standards Agency (FSA). Additional recruitment in the devolved countries is funded by Government bodies in Scotland, Wales and Northern Ireland. The RP is currently delivered by a consortium consisting of NatCen Social Research (NatCen) and MRC Epidemiology Unit (MRC Epi), University of Cambridge[2].

The NDNS collects data on participants' dietary intake over four days through a food diary. Socio-demographic data including physical activity through questionnaires.

[1] Funder by Public Health England until 1st October 2021

[2] MRC Elsie Widdowson Laboratory (EWL, formerly known as MRC Human Nutrition Research (HNR) were nutrition partner for NDNS RP between 2008-2018 and University College London were also part of the Consortium during NDNS RP years 1-5 (2008-2013)

Physical/Anthropometric measures, and nutrient status through analysis of biological samples. Specific measurements can vary between ad hoc surveys and NDNS RP years.

Assessment of dietary sodium intake forms part of the NDNS series to provide population data for estimated salt intake. Measurement, based on 24-hour urinary sodium excretion, is through country-specific surveys.

DNSIYC was a standalone survey commissioned by Department of Health and the Food Standards Agency to provide detailed information on the food consumption, nutrient intakes and nutritional status of infants and young children aged 4 to 18 months living in private households in the UK. Fieldwork was carried out between January and August 2011.

Regular results reports are published by government, following which comprehensive data is made available for public access via the UKDS.

3. Custodianship of NDNS biological samples

UKRI MRC and the University of Cambridge are currently custodians of the NDNS biological sample collection. Applications for use should be directed to ndns.bioresource@dhsc.gov.uk.

4. Custodianship of NDNS data and participant consent

NatCen is currently the custodian for participant data, consent, and data linkage for the NDNS RP and DNSIYC. The addition of new variables arising from research utilising the NDNS Bioresource will be added to the relevant archived dataset via NatCen.

4.1 NatCen Data Release Panel

NatCen operate a Data Release Panel to deal with requests from NDNS data users for more detailed/refined geographical information not included in the datasets deposited at the UKDS. Applications should be made directly to Beverley Bates Beverley.Bates@natcen.ac.uk. Fees will apply.

5. The NDNS Bioresource Scope

The NDNS Bioresource incorporates:

- The NDNS Biorepository – Archive of biological samples collected and stored for future research from NDNS RP participants, urinary sodium studies and DNSIYC (see section 5.1)
- Participants from NDNS RP and DNSIYC participants willing to be contacted for future research (see section 5.2)
- NDNS RP participants who have consented to be linked to the NHS Central Register and Cancer Register (see section 5.3)
- Data from all the surveys are made publicly available on the UKDS following publication of results by government (see section 5.4)

The NDNS Project Board will also consider applications for add-on studies to be included as part of the core survey. Examples might include an additional question in the interview, a new physical measurement or a new biological sample analyte. The Project Board would consider the impact of add-ons on the core survey, in particular the burden on participants and the organisation of the survey. Applicants should consider using the NDNS Bioresource in the first instance and would need to justify why this was not suitable for the proposed work. Enquiries about add-on studies should be made through Office for Health Improvement and Disparities (OHID) (ndns.bioresource@dhsc.gov.uk) in the first instance.

5.1 NDNS **Biorepository**

Repository and residual biological samples collected from the following surveys have been stored to be available for further research, with the opportunity for data linkage at the individual level.

Different considerations and complexities apply for the different surveys (including ethical and logistical issues) which may impact on samples and data availability.

Further information is provided on the NDNS Bioresource website

5.2 Follow-up of NDNS RP and DNSIYC participants

NDNS RP participants aged 16 and over and parents of DNSIYC participants are/were asked whether they are willing to be contacted for future research. Terms of consent may differ slightly across survey years. Under the current contract, re-contacting NDNS RP and DNSIYC participants is managed and enabled via NatCen.

5.3 Data linkage – NHS Central Register and Cancer Register

NDNS RP participants have been asked to provide consent for their research data to be linked to the National Health Service Central Register[3] and the National Cancer Registry[4]. Mechanisms for data linkage are complex and are subject to external governance and approval. In the future, it is intended that NHS data linkage for NDNS RP participants who have consented to be linked to the NHS Central Register and Cancer Register will be possible. Applicants interested in this opportunity are invited to register their interest by emailing ndns.bioresource@dhsc.gov.uk.

Under the current contract data linkage for NDNS RP participants is managed and enabled via NatCen.

6. The NDNS Bioresource Panel

The NDNS Bioresource Panel acts on behalf of the NDNS Project Board and has the remit to review and approve requests (via formal application) to access the NDNS Bioresource. The panel includes representatives from the Survey funders, the Scientific Advisory Committee on Nutrition (SACN) and the Consortium.

The secretariat for the NDNS Bioresource Panel is provided by OHID and can be contacted at ndns.bioresource@dhsc.gov.uk.

[3] The National Health Service Central Register lists all individuals in the country and their NHS number. When the participant dies, the NHS Register provides the NDNS team with a replica of the participant's Death Certificate (something that is publicly available). The information on the Death Certificate is then attached to the data file.

[4] The National Cancer Registry is run by the Office for National Statistics and collects details about all types of cancer. If a participant is diagnosed with cancer, a code indicating which sort of cancer it is will be added to the data file.

7. Objective of the Access Procedures

The objective of these Access Procedures is to facilitate and encourage access to the NDNS Bioresource so that it is maximised and utilised for health related research in the public interest, while ensuring that such usage is in accordance with the undertaking given to survey participants and terms of consent.

The NDNS Bioresource is a finite resource in respect of numbers/volumes of biological samples and participants' willingness to be involved in future research. Requests to access the NDNS Bioresource are therefore subject to review and assessment against pre-set criteria.

These access procedures are intended to be clear and transparent, and appropriate for implementation in a proportional, fair and accountable way, to enable equitable access to the Bioresource, which is lawful, ethical and to the best use of the collection

Procedures will be kept under review by the NDNS Bioresource Panel accountable to the NDNS Project Board.

8. Factors affecting access

a) Participant consent, confidentiality of personal information, anonymity

   The Panel will assess each request in respect of whether the request is within the terms of consent obtained at data/sample collection, and that the facilities and arrangements are substantial enough to maintain participant confidentiality and anonymity. (Consideration will be taken with reference to data linkage and data availability with the UK Data Archive)

b) Equity of access

   Access is available to all researchers and applications will be assessed on their own merits in accordance with agreed access and assessment criteria (see below). Given the substantial investment and funding by government, applications for research funded by the survey funders will take priority; otherwise priority will be given to applications relevant to public health nutrition and food safety, particularly in relation to access to finite resources.

   Where two or more fundable applications are received to undertake similar work using the same biological samples, access to samples would be granted to the applicant with the strongest proposal. Applicants will be encouraged to work in partnership to make best use of the available resource.

9. Application and review Process

Access to the NDNS Bioresource is via formal application to the NDNS Bioresource Panel.

The application and approval process is summarised in the Access Flow chart (see separate document). Where approval is granted, access is subject to legally binding terms.

10.1 Information required from Applicants

Requests for access are via completion of the NDNS Bioresource application form available on the NDNS Bioresource website.

The following information is required on application:

- Details of PI and research team including collaborators and/or sub-contractors (names, institutions, experience)
- Lay summary of research project
- Explanation of why the NDNS Bioresource is suitable/necessary for the research proposed
- Scientific rationale of project (background, pilot data, experimental details & design, power calculations, proposed lab/data analyses and methods, proposed participant measures and/or tests where applicable, expected value/impact of results, references)
- Detail of requirements: e.g. data and/or quantity and type of samples, any need for re-contacting NDNS RP/DNSIYC participants, with a brief justification
- Protocols for storage of data and/or samples (including data security, physical security, expectations for handling participant withdrawal)
- Ethical andissues related to the proposal
- Projected timelines (start, duration, timelines for analysis/participant follow-up/add-on study, availability of results, submission of publication)
- Details and status of funding
- Details of any peer review (actual/proposed)
- Other information on request

Where permission is being sought to re-contact NDNS RP/DNSIYC participants, the information required will include details of the proposed measures and tests on participants, consideration of ethical issues including participant burden, in addition to the relevant parameters from the list above. Applicants will be expected to obtain relevant ethical approvals for their research.

All information requested should be provided on application as missing information may delay consideration of the application.

10.2 Assessment Criteria

NDNS Bioresource Panel will review all requests to access the Bioresource and will assess applications on merits using standardised scoring criteria. to include consideration of:

- Priority and importance of research
- Relevance to public health nutrition or food safety
- Track record of applicants
- Scientific and technical merit and feasibility of research proposal
- Suitability of the NDNS Bioresource for the proposed research
- Funding / funding status
- Ethical considerations
- Quality control and assurance, compliance with data protection, data/sample security
- Plans for data sharing

Depending on whether the request involves the use of biological samples or following up NDNS RP/DNSIYC participants, assessment will also include consideration of the following:

Biological samples

- Volume of specimen required (both assay and total required)
- Suitability of sample for proposed analyses
- Sample transportation, feasibility & calibre of laboratory, equipment and assay methods

Participant follow-up

- Number of NDNS RP/DNSIYC participants requested (and where) and requirement for linked information. Detail of proposed measures including burden, risk & ethical considerations

10.3 Overview of application and approval process

The application and approval process is summarised in the Access Flow chart (see separate document).

In summary, the process includes the following key stages (Stages i and ii are performed by the applicant):

i. Determining the suitability of the NDNS Bioresource collection for the proposed research purpose i.e. in respect of samples, data, participant re-contact, data linkage. Information will be available to applicants online and further information is available on request via OHID: ndns.bioresource@dhsc.gov.uk

ii. Completion of NDNS Bioresource Access Application (available online) and provision of supporting information as required (submission to NDNS Bioresource Panel via OHID: ndns.bioresource@dhsc.gov.uk)

iii. Application check by secretariat (clarification follow up with applicant if necessary)

iv. Assessment (including request for further clarification if necessary) and decision by NDNS Bioresource Panel

v. Communication of decision to approve or decline

vi. Where approved, contractual legally binding agreement to conditions of access

10.4 Timing

Applications for access to the NDNS Bioresource may be submitted at any time. Applications received will be held and reviewed at set intervals. The deadlines for the application assessment intervals are:

January 31st
May 31st
September 30th

Once each proposal deadline has passed, the NDNS Bioresource Panel will consider all applications received.

Applications for access will be submitted using the standard application form available from NDNS Bioresource website and submitted to ndns.bioresource@dhsc.gov.uk.

Applications will be acknowledged within 7 days of receipt by the secretariat. The NDNS Bioresource Panel will provide a decision within 3 months from the relevant assessment interval deadline.

Applications to access the NDNS Bioresource can be made before funding and ethical approval have been obtained. In these cases, should the application be approved, access will be subject to the applicant demonstrating appropriate ethics approval, and confirmation of funding. Other conditions may be imposed before samples / data are released and/or participant contact can be initiated.

10.5 Process for Panel review

Panel members will independently assess applications using standardised scoring criteria. Panel discussion and consideration will generally be by tele or video conference, moderated by the Panel Chair.

11.Conditions of access

Access to data, samples, participant follow up, data linkage, inclusion of any add-on project will be subject to formal written agreement before access or any release of data or materials. A summary of general terms and conditions are below. Individual projects may require additional conditions / terms. Terms will be agreed in writing for each approved project with all relevant parties.

11.1 Standard Conditions/Terms

Summary information about approved projects will be listed on the NDNS Bioresource website (including title, lay summary, PI name & institution).

Researchers will need to ensure all necessary approvals from an appropriate Research Ethics Committee before access to samples/participants is granted for approved projects.

If funding and/or ethics confirmation are not obtained within 6 months of project approval, the approval to use NDNS samples and follow up of NDNS RP participants will be reviewed by the NDNS Bioresource Panel and a request for extension may be required. Permission for access may be withdrawn.

11.2 Data and material handling; storage, transportation and return/disposal of samples at the end of the study

All sharing of data and materials will be in accordance with relevant legislative and regulatory frameworks (including human tissues, data protection, information security, good research practice, research ethics

Data/materials will be shared according to set terms for the project, under express permission of OHID via NatCen/University of Cambridge. Data/samples/information obtained from the collection must only be used for the purposes stipulated and described in the Agreement.

Data/ samples/information obtained from the collection may not be transferred to individuals outside of the requestor's research group/named project collaboration. All collaborators must be identified at application stage and any changes notified to the Panel.

Conditions for sample transportation and storage will be stipulated by the custodian and in the Agreement. Surplus biological samples need to be returned to the custodian where specified. Evidence of disposal where expected may also be required. Expectations and/or restrictions for the use and documentation of samples by the Applicant will be stipulated in the Agreement.

11.3 Data sharing and publication

Applicants will be expected to share findings and results arising from their project through accepted mechanisms for data sharing and publication in order to enhance the NDNS data collection. Usual expectations are summarised below and will be included in the Agreement for all approved projects. See also 11.5

Applicants are expected to submit their results to a peer-reviewed publication, generally within 12 months of completing their study.

Publications should also be deposited in the European PubMed Central database, generally within 18 months of publication.

Applicants should aim to publish the results of all studies, including negative results. If it is not possible to publish negative findings, the manuscript should be submitted to OHID for inclusion within the NDNS data collection.

Applicants will be expected to provide a copy of any publications based on data or samples from the collection to OHID and are expected to provide new variables for inclusion with the original data in the UKDS (see 11.5).

11.4 Acknowledgement of the Resource

Any publication or presentation using data or samples from the collection should include an acknowledgement of the NDNS Bioresource using the text below:

> Biological samples used in this study were obtained from the National Diet and Nutrition Survey (NDNS) Bioresource. The authors acknowledge the funders of the NDNS: the Office for Health Improvement and Disparities and the UK Food Standards Agency; and the NDNS Consortium and custodians of the biological samples and participant data: Medical Research Council Epidemiology Unit, University of Cambridge and NatCen Social Research.
>
> Access to participants who took part in this study was provided through the National Diet and Nutrition Survey (NDNS) Bioresource. The authors acknowledge the funders of NDNS: the Office for Health Improvement and Disparities and the UK Food Standards Agency; and the NDNS Consortium and custodians of the biological samples and participant data: Medical Research Council Epidemiology Unit, University of Cambridge and NatCen Social Research.

11.5 Enrichment of the national surveys collection

Applicants will be expected to provide any new variables for addition to the original datasets held in the UKDS *(https://ukdataservice.ac.uk/)*. Such data should normally be provided to the data custodian (NatCen) within 3 months of publication. Expectations will be agreed in writing as part of the terms and conditions for each project approved.

Submission of results to the collection does not affect the requirement for recipients to maintain their own research records.

11.6 Protection of Intellectual Property (IP)

Although the collection has waived its right to any IP arising from the data or samples provided, recipients must make every effort to protect this in line with the policies of their host institution and funders.

11.7 Consent Terms

Blood and urine samples have been obtained where written consent has been provided by individual participants. The terms of consent includes consent to store samples for future research. Terms may differ between different surveys. We do not have consent for genetic analyses.

11.8 Withdrawal of consent

Participants may withdraw their consent at any time. However withdrawal of consent to use biological samples or data is very infrequent. If consent is withdrawn for samples that have been issued for a follow-up project, the PI will be informed of the relevant sample IDs and asked to destroy any unused samples and certify that they have done so, or return them to the custodian for destruction. Results obtained from samples that have already been used for research need not be destroyed.

The sample fee is non-refundable if participant consent is withdrawn.

Participant follow up and/or inclusion in add-on studies

Participants will be approached only if they agreed to follow-up in the consenting procedure. They will be free to decide if they wish to participate in the new research and can withdraw at any time. See also 5.2 above.

11.9 Protection of anonymity:

During analysis, the applicant will have no access to other data on individuals for whom samples are provided because IDs are scrambled on the UKDS.

Applicants must agree not to link the anonymised data/samples provided with any other data set without the permission of the custodian.

Applicants must not attempt to identify any individual from the data or samples 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.

If recipients believe that they have inadvertently identified any individual from the data or samples provided, they must inform the custodian, MRC Epidemiology, and provide details of the circumstances under which this infraction occurred.

12 Fees

Charges will be applicable (including for sample or data retrieval, data linkage, administrative, logistic costs to facilitate access to data or NDNS RP / DNSIYC participants). These costs will be met by applicants. Costs may include:

Data: *no fee if data is solely obtained by the applicant from the* UKDS *(http://www.data-archive.ac.uk)*

Data not publically available: Costs on request via NatCen Data Access Panel

Data linkage post-sample analysis: *Costs on request via NatCen*

Data Linkage with NHS Cancer and Central Registers: The recipient will be required to cover costs, provided on request

Biological Samples*:* The recipient will be required to cover costs of sample retrieval, processing, dispatch, disposal and/or return (as per approved project contract terms) by/to MRC Epi. Details of these costs are available on request.

Re-contact with participants: NatCen will provide contact details depending on terms of consent. Arrangements and costs on request.

Additional charges

Further costs may be applicable for example if new weightings are required. Costs can be provided on request.

13 Further information

Further information is available via websites or from ndns.bioresource@dhsc.gov.uk, OHID and the survey consortium organisations, NatCen and MRC Epidemiology.

Opportunities may also be available for collaboration. The NDNS Project Board will also consider applications for add-on studies to be included as part of the core survey. Discussion is welcomed.