

The Health Survey for England Bloodbank Project

**Requests for extraction and analysis of
stored HSE blood samples**

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Introduction

The Health Survey for England

The Health Survey for England is a series of annual health interview and examination surveys and has been collecting blood samples for analysis since 1991, which have subsequently been stored since 1994. There are around 80,000 samples currently in storage.

Since 1994 the Health Survey for England (HSE) has been carried out by the Joint Health Surveys Unit (JHSU), a partnership of NatCen Social Research (NatCen) and the Research Department of Epidemiology and Public Health at UCL (University College London), and commissioned by NHS Digital (formerly the Health and Social Care information Centre).

It has been agreed by NHS Digital and the JHSU that these samples should be made available for further research, where the research meets the criteria for the purpose that it was originally collected. These samples will be provided for free, given that any costs incurred in selecting, extracting, preparing, transporting and analysing the samples are borne by the applicant. We would also expect to be able to append this data to the records in the UK Data Service after the main findings are published, so that other researchers are able to use this information.

NHS Digital - formerly the Health and Social Care Information Centre (HSCIC)

HSCIC was created on 1 April 2005 as a special health authority under the Health and Social Care Information Centre (Establishment and Constitution) Order 2005 and subsequently transformed into a non-departmental public body (NDPB) in April 2013 under The Health and Social Care Act (2012). Since April 2016 HSCIC was re-named as NHS Digital, and inherited various information-related functions from the NHS Information Authority, the Department of Health, West Yorkshire Strategic Health Authority and NHS Estates. NHS Digital has continued to commission a programme of population based health-related surveys, whose principal component is the annual Health Survey for England (HSE).

Working with health and social care providers, we collect data, analyse it and convert it into useful information for clinicians, managers, policy-makers, patients, service users, members of the public, regulators, academics and researchers. We aim only to collect data that has a positive effect on health and social care and the quality and timeliness of our information is key. It is independent and trustworthy.

For more information about NHS Digital, please visit our website: <http://digital.nhs.uk>

For more information about the application process, please contact a member of the Surveys team by emailing: surveys.queries@nhs.net

NatCen Social Research



NatCen Social Research (NatCen) is the largest independent social research institute in Britain. We are a registered charity and only conduct surveys that will contribute to public policy. We have been designing, carrying out and analysing research among members of the public for over 30 years.

To find out more about NatCen, please visit www.natcen.ac.uk

For more information about HSE, please contact: anne.conolly@natcen.ac.uk

Anne Connolly,
Research Director
NatCen Social Research
Tel: 020 7549 7012

The Research Department of Epidemiology and Public Health at UCL



The Research Department of Epidemiology and Public Health at UCL (University College London) aims to develop a better understanding of health and prevention of ill health through vigorous research and the development of research methodology.

To find out more about the Department of Epidemiology, please visit www.ucl.ac.uk/epidemiology

For more information about HSE research, please contact: j.mindell@ucl.ac.uk

Dr Jennifer Mindell
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The Royal Victoria Infirmary, Newcastle



For more information about the storage, preparation or tests performed on the HSE blood samples, please contact: julie.day@nuth.nhs.uk

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Department of Clinical Biochemistry
Newcastle upon Tyne Hospitals NHS Foundation Trust
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Tel: 0191 282 4585

About the Health Survey for England

The Health Survey for England

The Health Survey for England (HSE) is unique in that it combines questionnaire answers collected by an interviewer along with physical measurements and other objective measures (some of which are taken as part of a later nurse visit) such as height and weight, blood pressure, analysis of blood samples, lung function tests etc.

The survey includes a set of core modules which are repeated most years, each year the survey also includes one or more modules on topics of special interest. The adult sample size is around 8,000 most years. Details on the special interest topics and sample size can be seen in the table below.

In addition, between 2006 and 2010, and in 2015 a boost sample of children was included to enable DH to monitor the Public Service Agreement target on obesity.

The core modules are:

- General health (long standing illness and acute sickness)
- Fruit and vegetable consumption(since 2001)
- Social Care (since 2011)
- Smoking
- Drinking
- Background demographics
- Height, weight, used to calculate BMI
- Blood pressure
- Blood samples (analytes vary from year to year according to topic)

The focus topics were as listed in the table below:

Focus topic	Years included	Sample Size
CVD and risk factors	1991-1994, 1998-2000, 2003-2006, 2011	Whole of general population sample
Older people	2000, 2005	Half
Children and young people	1997,2002	Half
Respiratory conditions, Asthma	1995-1997, 1999, 2001, 2002, 2004, 2010	Whole
Accidents	1995,1996,2001	Whole
Disability	1995, 1996, 1997, 2001, 2002	Whole
Ethnic minorities	1999, 2004	Half
Attitudes to general health	2007	Whole
Physical activity	1997, 1999, 2002-2004, 2006-2008, 2012	Whole population for self-reported physical activity and a sub-sample for an objective measure of physical activity using an accelerometer
Social Care	2013	Older population only (aged 65+)
Hearing, mental health, planning for social care	2014	Whole
Child Health	2015	Whole
Physical activity	2016	Whole (self-reported physical activity was asked of adults only)

For more detail on the Health Survey for England please contact the Surveys team: surveys.queries@nhs.net

Blood samples taken for the HSE

Blood samples were taken as part of the HSE from 1991, but were only stored from 1994 onwards. There are approximately 80,000 frozen blood samples from consenting adult respondents stored at RVI in Newcastle. These samples have been available for further research since 2008.

The samples are collected and stored under the following conditions

- HSE blood samples are taken by a trained nurse in the respondent's own home. The samples are then posted that day or the following day (or up to two days later if taken on a Saturday) to the laboratory, where they are spun, analysed, and any remaining serum is frozen and stored at -40°C. For most of the time during transit the samples are at room temperature.
- The table below gives the estimated number of samples based on the respondents who gave consent for storage. Not all individuals who gave such consent will have a stored sample, since there may have been no 'spare' blood to store following initial survey analysis, and some may have been lost due to freezer failure.
- If the intended sample includes older samples, you will need to take into consideration the viability of the sample. In addition, if you intend to request pre-1997 blood samples, you will need to make provision for the cost of RVI Newcastle cataloguing these.
- Consent has been acquired which stipulates what the samples can be used for, which has changed over time (see Table 2).

Table 1 : Number of individuals giving consent for storage of blood samples

Survey Year	Number of samples available/remaining in storage	Sub-group of participants from whom blood samples taken
1994	9,311	Aged 16+
1995	11,382	Aged 11+
1996	11,482	Aged 11+
1997		No samples remaining
1998		No samples remaining
1999		No samples remaining
2000	11,73	Aged 65+
2001	9,586	Aged 11+
2002	2,629	Aged 11+
2003		No samples remaining
2004	2,333	Minority ethnic groups only
2005	2,040	Aged 65+
2006		No samples remaining
2007		Not collected
2008	3,536	Aged 16+
2009	2,199	Aged 16+
2010	3,605	Aged 16+
2011	3,869	Aged 16+
2012	3,850	Aged 16+
2013	4,344	Aged 16+
2014	3,758	Aged 16+
2015	3,766	Aged 16+
2016	TBC	Aged 16+
2017	TBC	Aged 16+

Consent

The wording of the consent form signed by HSE respondents has changed over time as the restrictions for secondary use have been more explicitly stated. Table 2 shows the wording of the forms and the years in which they have applied. Applications must meet the criteria listed in the consent, ideally meeting the stricter, more explicit version of the wording used from 2005 onwards.

Table 2: HSE Consent Form: Undertakings and Consents by Survey Year

Year of HSE survey	Wording of undertaking respondents/respondent consent form
1994-2001	"I consent to any remaining blood being stored for future analysis. The sample will not be used to test for viruses (e.g. HIV test)."
2002-2003	"The blood sample will not be used to test for HIV virus". "I consent for any remaining blood being stored for future analysis. This blood sample may be used for future ethically approved studies of the causes, diagnosis, treatment, and outcome of disease. I understand that the blood samples and related information will be coded and used anonymously and will not be available for commercial purposes."
2004	"The blood sample will not be used to test for HIV virus." "I consent for any remaining blood being stored for future analysis. This blood sample may be used for future studies of the causes, diagnosis, treatment, and outcome of disease, provided that the studies are approved by an NHS ethics committee. I understand that the samples will be stored with no identification except a coded study number: only authorized members of the research team for this study would be able to find out who the codes referred to. Before being used in future research, some details of my medical history (but not any details which would identify me) may be attached to the sample, but the study number code will then be removed from the blood sample and the medical details. The stored blood will not be available for commercial purposes. When the sample is tested for research, it will no longer be possible to link it to me, so I will not be told the results of the testing."
2005-2009	"The blood sample will not be used to test for HIV virus or used for genetic testing." Then reads as for 2004 and finishes with "I understand that it will not be possible to remove my results from reports, as the results cannot be linked to me. I understand that I can withdraw my consent to store my blood at any time, without giving any reason, by asking the investigators in writing for my blood to be removed from storage and destroyed."
2010 onwards	The wording was amended to include the option for DNA or genetic testing, it now reads; 'blood samples will not be tested for the HIV (AIDS) virus. The initial tests we do now will not involve DNA or genetic analysis, but if you agree that we can store some of your blood, it is possible that at some time in the future, the anonymous samples might be tested for DNA or genetics. Any analysis like this could not be linked to you. Stored blood will only be analysed in future studies if permission for that particular study is obtained from NHS Digital and from an NHS Research Ethics Committee.'

Suitability of sample for analysis

The information above is provided in good faith to allow the applicant, and any expert they choose to consult, to show if the samples are likely to be useful in their research. The samples are provided on the understanding that the applicant is responsible for determining if the blood samples are likely to be suitable for their purpose. NHS Digital, NatCen and RVI hold no responsibility for any experimental failure of the samples to yield any expected analytes.

Practical issues around analysis

The samples are currently kept in storage freezers at RVI in Newcastle. These samples are marked with an anonymous serial number, which is identifiable only by linking to the database held by NatCen. Until a sample is removed, it is not known what the volume or the viability of the sample is.

Applicants will be responsible for all costs associated with identifying and selecting samples from the database (NatCen), linking archived data to the samples (NatCen), extracting samples from storage (RVI), preparing the aliquots for transport (RVI), and all aspects of analysis of the sample.

It is expected that most samples will be re-analysed at RVI, as they have highly trained staff and state of the art facilities and this reduces the need to transport the samples. Similar projects will be processed at the same time where possible to reduce costs and minimise the times that the samples are thawed and re-frozen.

If the samples are to be analysed in a laboratory other than at RVI, the applicant will be responsible for ensuring that the samples are stored in a secure and suitable manner for biological products and ensuring that the laboratory meets all necessary standards for dealing with bio-hazardous material, and all appropriate Control Of Substances Hazardous to Health (COSHH) assessments are undertaken.

Please contact Anne Conolly at NatCen anne.conolly@natcen.ac.uk about costs associated with sample selection and the appropriate data variables you require.

Please contact Julie Day at RVI Newcastle julie.day@nuth.nhs.uk about costs associated with extracting and preparing the blood samples you require.

Additional HSE data to provide context to samples

Additional anonymised data collected as part of the HSE for sample respondents can be provided by NatCen, under the condition that this does not breach confidentiality. Information such as name, date of birth and postcode are all considered identifiable and will not be supplied. This data must be sent to a named person who is responsible for its security and correct use, must not be passed on to any third party, and must be destroyed after its use. A breakdown of the variables that are available can be found at the UK Data Service: <http://discover.ukdataservice.ac.uk/series/?sn=2000021>

All data variables requested must be approved by NatCen's Data Release Panel (DRP) as well as being covered by a data sharing agreement with NHS Digital. If the recommendation from the DRP is the variables requested are likely to be potentially disclosive, a further application is required to be submitted to the NHS Digital Independent Group Advising on the Release of Data (IGARD) for approval.

Process for approval of proposals to use blood samples

Application process

There are three purposes to the application process;

- Ensure that the blood samples are used only within the limits of what the respondents agreed they could be used for, and respondent confidentiality is maintained
- Ensure that the blood samples are analysed appropriately, and that the samples are likely to provide a useful result
- Ensure that the limited resource of blood samples is distributed fairly and openly.

There are three steps to the process;

1. Application
2. Approval
3. Retrieval

1. Application

There are some key pieces of information that NHS Digital, NatCen and RVI will use in assessing and approving release of blood samples;

- Details of the research team, their credentials and facilities to ensure that the samples will be safely and correctly used;
- Project synopsis and full design and methodology to demonstrate samples will be used within the constraints of the respondent consent given;
- Sample size and its rationale to ensure the results will provide statistically useful results;
- Attributes of the respondents of interest (age, ethnicity, disease status) to understand the demands upon the bloodbank. If data not available in the UK Data Service is requested, a further data sharing application is required.

The application should be sent as an MS Word document via email to surveys.queries@nhs.net Where necessary, NHS Digital, NatCen and RVI are happy to advise on any aspects of the application process.

The application form has been designed to collect information required to assess the application, and word limits have been introduced in order that the evaluation process is not too burdensome. Please keep your responses as succinct as possible. If you feel that additional information is necessary, feel free to forward your research proposal, but it will not necessarily be read as part of the evaluation.

2. Approval

Upon receipt the application will be checked to ensure it is complete, if any compulsory sections are missing it will be returned. All applications received will be considered on an ad-hoc basis in order of receipt, assuming the samples of bloods are still available.

NatCen and RVI will assess proposals using the following criteria;

- a) The proposed research should be tackling an important public health problem (severe and/or common) and attempting to answer important and well-defined question(s) within that topic.
- b) The findings of the research should be capable of answering the question(s) posed, having:
 - An appropriate study design,
 - A suitable sample size (i.e. adequate as shown by power calculations), but should not be excessive.
- c) The team of researchers conducting the research should demonstrate appropriate experience and skills.
- d) The project is sufficiently resourced to carry out the research to completion and to a suitable standard of quality.

NatCen and RVI will then consider the proposal using the same criteria as above, with the addition of the following;

- e) Does the use of samples in the project adhere to the constraints of the respondent consents?
- f) Does the project represent a fair use of the limited resources available?
- g) Opportunity and cost of the proposal in terms of potential other uses of the proposed sample, giving preference to studies that:
 - Use small volumes,
 - Can re-freeze the remaining unused serum for future use.
- h) Evidence that suitable Ethics Committee approval is in place before agreeing to the release of blood samples.
- i) Evidence that suitable funding is in place to allow for the project to proceed.
- j) Any published papers or reports on the findings should be of a suitable standard (preferably peer reviewed) and cite the HSE as the source.

NHS Digital will then make the decision, either;

- Approval to supply samples as requested, subject to relevant data sharing application;
- Approval to supply samples in principle, subject to relevant data sharing application, pending final MREC and funding evidence. This will remain valid for 12 months, after which another application must be made;
- Approval to supply samples, with amendments/restrictions to the original application, subject to relevant data sharing application;
- Rejection.

Where an amendment or restriction is required, we will contact you to discuss the implications to your project.

If a project is rejected, reasons for the rejection will be given, and the application may be resubmitted if the reasons for rejection are addressed.

3. Retrieval

Once NHS Digital has agreed that the samples can be released, NatCen and RVI will be given the go-ahead to proceed.

It is anticipated that most projects will use the analysis function offered by RVI, as this process reduces the risk of samples being lost in the process of transportation, and can reduce costs. Where possible, RVI may analyse the samples for multiple projects in a single batch to reduce costs.

- 1) Using the specification for the sample, NatCen will identify individuals for whom the samples will be pulled and provide anonymised serial numbers to RVI.
- 2) RVI will retrieve the samples outlined by NatCen. Where no viable sample is available RVI will inform NatCen and a serial number for another suitable respondent will be provided where possible.
- 3) RVI will prepare the samples as outlined in the specification, decanting the required volume into a vessel suitable for transport where necessary.
- 4) RVI may analyse samples as required, or release to courier firm approved for transport of potentially hazardous biological material.
- 5) NatCen will provide anonymised dataset linked to the samples provided by RVI.

If you require any further information about the HSE survey, please contact us in the following ways: Surveys team: surveys.queries@nhs.net

General enquiries: enquiries@nhsdigital.nhs.uk or call our Contact Centre on 0300 303 5678