

# **The Information Centre for Health & Social Care**

## **REQUESTS FOR EXTRACTION OF HSE STORED BLOOD SAMPLES**

### **Application Pack**

## **CONTENTS**

- Section 1            Introduction**
- Section 2            About the Health Survey for England and blood samples  
in storage**
- Section 3            Process for Approval of Proposals to use blood samples**

**(the application form is available separately)**

## SECTION 1: 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, and subsequently stored since 1994. There are around 100,000 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 the National Centre of Social Research (NatCen) and the Department of Epidemiology and Public Health at the Royal Free and University College Medical School (UCL), and commissioned by the Information Centre for health and social care (IC) (formerly the Department of Health).

It has been agreed by the IC and 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 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 Archive after the main findings are published, so that other researchers are able to use this information.

### The Information Centre

The IC was created on 1 April 2005 as a special health authority under the Health and Social Care Information Centre (Establishment and Constitution) Order 2005. The IC inherited various information-related functions from the NHS Information Authority, the Department of Health, West Yorkshire Strategic Health Authority and NHS Estates. The IC has continued to commission a programme of population based health-related surveys, whose principal component is the annual Health Survey for England (HSE).

The IC is England's authoritative and independent source of health and social care information. We are a special health authority and our role is to support better health and social care by providing trusted, high-quality information that helps national and local organisations make the best decisions to improve people's care and well-being.

Working with more than 300 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 the Information Centre, please visit our website: [www.ic.nhs.uk](http://www.ic.nhs.uk)

For more information about the application process, please contact a member of the Surveys Team by emailing: [surveys.queries@ic.nhs.uk](mailto:surveys.queries@ic.nhs.uk)

## The National Centre for Social Research

The **National Centre for 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](http://www.natcen.ac.uk).

For more information about HSE data, please contact

Rachel Craig, Research Director: 020 7549 7012

## The Department of Epidemiology and Public Health at University College London



The Department of Epidemiology and Public Health at **University College London (UCL)** 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](http://www.ucl.ac.uk/epidemiology).

For more information about HSE research, please contact

Dr Jennifer Mindell  
Clinical Senior Lecturer  
University College London  
Health and Social Surveys Group  
Department of Epidemiology & Public Health  
1-19 Torrington Place,  
London WC1E 6BT

Tel: 020 7679 1269

## The Royal Victoria Infirmary, Newcastle

For more information about the storage, preparation or tests performed on the HSE blood samples, please contact

Ian Gibb: 0191 282 4585 or [ian.gibb@nuth.nhs.uk](mailto:ian.gibb@nuth.nhs.uk)

## SECTION 2: 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 interviewer with physical measurements and other objective measures (some of which are taken as part of a later nurse visit) such as analysis of blood samples, lung function tests etc.

The survey includes a set of core modules which are repeated most years, and each year the survey also includes one or more modules on topics of special interest. The sample size is around 16,000 most years, with some 'half size' years. Details on the special interest topics and sample size can be seen in the table below.

In addition, since 2005, a boost sample of children has been 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)
- Smoking
- Drinking
- Background demographic
- Height, weight, used to calculate BMI
- Blood pressure
- Blood samples (analytes vary from year to year according to topic)

The special topics were as listed in the table below:

Special topic	Years included	Sample Size
CVD and risk factors	1991-4, 1998, 2003, 2006	Whole of general population sample
Older people	2000,2005	Half
Children and young people	1997,2002	Half
Asthma	1995,1996,2001	Whole
Accidents	1995,1996,2001	Whole
Disability	1995,2001	Whole
Ethnic minorities	1999,2004	Half
Attitudes to general health	2007	Half
Physical activity	2008	Whole population for self-reported physical activity and a sub-sample for an objective measure of physical activity using an accelerometer

For more detail on the Health Survey for England use the following link:

<http://www.ic.nhs.uk/statistics-and-data-collections/health-and-lifestyles-related-surveys/health-survey-for-england>

## Blood samples taken for the HSE

Blood samples were taken as part of the HSE from 1991, but were only stored after initial analysis from 1994 onwards.

In all there are approaching 100,000 frozen blood samples from HSE respondents stored at the RVI in Newcastle. These samples have not been used for any research to date, nor have they been measured beyond the measurements taken initially as part of the initial survey analysis for the particular HSE survey year. The samples have been 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. For most of the time during transit they are at room temperature.
- Aliquots are of variable quantity, but are at least 0.5ml. For each participant two aliquots were stored, whole blood samples with EDTA were stored at -20°C, and spin serum was stored at -40°C.
- No audit of the frozen samples been carried out since initial storage. 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**

HSE Survey Year	Number giving both blood samples and consent to storage of blood sample	Sub-group of participants from whom blood samples taken
1994	11,037	Aged 16+
1995	11,910	Aged 11+
1996	12,573	Aged 11+
1997	456	18-24 year olds only
1998	10,929	Aged 11+
1999	696	Minority ethnic groups only
2000	1,786	Aged 65+
2001	9,703	Aged 11+
2002	2,703	Aged 11+
2003	8,364	Aged 11+
2004	2,728	Minority ethnic groups only

2005	2,217	Aged 65+
2006	7,741	Aged 16+
2007	Not collected	N/A
2008	7,337	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 in 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."

## Suitability of sample for analysis

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

Preliminary tests show that EDTA samples taken in 2003 and reanalysed for glycated haemoglobin in 2007 show some correlation. However, the degree of degradation would suggest that these older samples should not be used to give absolute values of glycated haemoglobin, but could be used to compare within the sample.

## Practical issues around analysis

The samples are currently kept in storage freezers at the 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 indeed the viability is.

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

It is expected that most samples will be re-analysed at the RVI, as they have highly trained staff and state of the art facilities and this reduces the need to transport the samples. We will endeavour to process a number of similar projects 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 the RVI, the applicant will be responsible for ensuring that the samples are transported in a secure and suitable manner for biological products. The applicant will also be responsible for 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 Rachel Craig at NatCen about costs associated with extracting the dataset you require.

Please contact Ian Gibb at RVI Newcastle 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 Archive:

<http://www.data-archive.ac.uk/findingData/hseTitles.asp>

## SECTION 3: 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
- Ensure that the blood samples are analysed appropriately, and that the samples are likely to provide a useful result
- Ensure that the limited resources 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 the IC and JHSU 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.
- Project synopsis and full design and methodology to demonstrate samples will be used to produce meaningful result
- 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

The application outline should be sent as an excel document via email (preferred) to [surveys.queries@ic.nhs.uk](mailto:surveys.queries@ic.nhs.uk) or hardcopy to the IC when complete. Where necessary, the IC and JHSU are happy to advise on any aspects of the application process.

**The application form has been designed to collect the 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 IC will check the application is complete. If any compulsory sections are empty, it will be returned.

Applications between 1<sup>st</sup> July 2008 and 31 January 2009 have been evaluated and successful applicants have been contacted. Any applications received after 31<sup>st</sup> January 2009 will be considered on an ad-hoc basis, assuming the samples of bloods are still available.

The JHSU will assess the project on the following criteria;

- a) The proposed research should be tackling an important public health problem (severe and/or common) and attempting to answer an 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 the quality

The JHSU will then recommend to the IC either ;

- Approval to supply samples as requested
- Approval to supply samples, with amendments/restrictions to the original application
- Rejection

The IC will then consider the application 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 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 releasing 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 that contain an attribution of the role of the IC and JHSU in making the samples available.

The IC will then decide either:

- Approval to supply samples as requested
- Approval to supply samples in principle, 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
- 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 the IC has agreed that the samples can be released, JHSU and RVI will be given the go-ahead to proceed.

It is anticipated that most projects will use the analysis function offered by the 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 number 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 the RVI