National Child Development Study – Ethical review and Consent

Introduction

1. This note reports on the approach adopted to ethical review and informed consent for the various stages of the National Child Development Study (NCDS) - a continuing, multi-disciplinary longitudinal study which takes as its subjects all the people born in one week in England, Scotland and Wales in one week in 1958.

2. Below, a brief summary of the background to the study is followed by an account of how the approach to ethical review and consent has changed over the course of the study to date. Examples of letters, leaflets and consent forms used for various NCDS surveys are provided in an Annex

Background

3. NCDS has its origins in the Perinatal Mortality Survey. Sponsored by the National Birthday Trust Fund, this was designed to examine the social and obstetric factors associated with stillbirth and death in early infancy among the children born in Great Britain in that one week. Information was gathered from almost 17,500 babies. NCDS was the second in a series of four similar birth cohort studies, the others being based on a week's births in GB in 1946 and 1970, and on births in selected UK areas in 2000/01[1]. Each has formed the basis of a continuing, national longitudinal study. The studies present, both individually and in combination, an unprecedented opportunity to investigate the forces and patterns that have shaped and continue to shape the lives of four generations of people in the GB and the UK[2].

4. Following the initial birth survey in 1958, there have to date been eight attempts to trace members of the birth cohort in order to monitor their health and their physical, educational, social and economic development. These were carried out by the National Children's Bureau at 7-years (1965), 9-years (1969), 16-years (1974), and 23-years (1981); by the Social Statistics Research Unit, City University, at 33-years (1991); and by the Centre for Longitudinal Studies, Institute of Education, University of London at 42-years (2000), 46-years (2004).50-years (2008) and 55 years (2013)[3].

5. Anonymised data from the surveys is made available to the research community via the UK Data Service[4].

6. During the age 33 survey (1991), a special study was also undertaken of the children of a one in three sample of the cohort members this, including assessments of the behaviour and cognitive development of approximately 5,000 children. There have also been surveys of large and small sub-samples of the cohort, including the Biomedical Survey at age 44 years (2002) when nurse-interviewers gathered measures of: vision, hearing, lung function, blood pressure, pulse; weight, standing and sitting height, waist and hip size and mental health. Samples of blood and saliva were also taken. Where appropriate consent was obtained immortalised cell lines have been created and DNA extracted and stored. The NCDS DNA collection is available via a separate route[5].

NCDS and ethical review

7. The NCDS was fifty years old in 2008. Over the years, those responsible for the study have been concerned that appropriate procedures for ethical review and consent are followed but the approach has changed significantly. Currently in the UK, probably the most important route for ethical

[1] The *National Survey of Health and Development (NSHD) and the 1970 British Cohort Study (BCS70),* based on births in GB during one week in 1946 and 1970 respectively; and the *Millennium Cohort Study* (MCS), based on births in selected areas of the UK over one year beginning 2000.

[2] GB (Great Britain) comprises England, Wales and Scotland. UK (United Kingdom comprises GB and Northern Ireland.

[3] The birth cohort was augmented by including immigrants born in the relevant week in the target sample for the first three follow-ups (NCDS 1-3).

[4] http://www.ukdataservice.ac.uk/

[5] See: Access Committee for CLS Cohorts (ACCC)

approval for studies like NCDS is the National Health Service (NHS) Research Ethics Committee (REC) system. This remains a decentralised system. Local research ethics committees (LRECS), based in each Health Authority, were the first to be established; and smaller number of multicentre research ethics committees (MRECs) later removed the need for national studies (like NCDS) or those covering more than one Health Authority area to approach many/all LRECs.

8. NHS Research Ethics Committees (RECs) are appointed by the Strategic Health Authorities in England, their equivalents in Scotland and Wales and the Health and Social Care Business Services Organisation in Northern Ireland. RECs safeguard the rights, safety, dignity and well-being of people participating in research. They review applications for research and give an opinion about the proposed participant involvement and whether the research is ethical. Each consists of between seven and 18 volunteer members. At least one-third of the members must be 'lay' whose main personal or professional interest is not in a research area. The remainder of the committee are expert members, who are specialists including doctors, other healthcare professionals and academics.

9. MREC ethical approval has been sought for NCDS follow-ups from 2000 on, and for the Biomedical Survey, as indicated in the table below. The 1958 and 1965 follow-ups pre-dated the establishment of ethics committees, the 1969, 1974, 1981 and 1991 follow-ups came before the establishment of the MREC system. Available records suggest that there was only internal ethical review for these surveys[6].

NCDS Ethical approval 1958-2013

Survey	Age	Year	Source of approval	REC reference
PMS	Birth	1958	Internal review only*	na
NCDS1	7	1965	Internal review only*	na
NCDS2	11	1969	Internal review only**	na
NCDS3	16	1974	Internal review only**	na
NCDS4	23	1981	Internal review only**	na
NCDS5	33	1991	Internal review only**	na
NCDS6	42	2000	London MREC(North Thames?)	
NCDS Biomedical	44	2002	South East MREC	01/1/44
NCDS7	46	2004	Internal review only***	na
NCDS8	50	2008	London MREC	~~08/H093/34 or~~ 08/H0718/29
NCDS9	55	2013	London – Central	12/LO/2010

* = Predates establishment of ethics committees in 1966
** = Predates establishment of MRECs in 1997
***= Not sought as telephone survey involved no medical assessment/measurement

NCDS and consent

10. The approach to consent has also changed over the last fifty years. In 1958, when the birth survey was carried out, consent to participate in surveys was gained by respondents agreeing to be interviewed or respondents returning the completed questionnaire to the study team. Involvement in subsequent surveys adopted the same approach. Individuals could withdraw from the study at any time by simply expressing the wish to do so. Currently, MRECs are most often concerned to see explicit written consent to all or particular elements of a survey.

11. NCDS sought informed parental consent for the 7-year (1965), 11-year (1969) and 16-year (1974) surveys - see below. Copies of the relevant letters are not available. There is no evidence that written consent was obtained.

[6] For more details see the NHS National Research Ethics Service website: http://www.nres.npsa.nhs.uk/

> "…once the study members were traced, the next step, at each follow-up, has been to send a letter to the parents, via the school, in order to explain what we should be doing, to enlist their co-operation – but to give them the opportunity to opt out totally or in part, if they so wished…"[7]

12. For surveys at 23-years (1981), 42-years (2000) and 46-years (2004), 50-years (2008) and 55-years (2013) the approach was similar. During fieldwork, study members were sent an advance letter advising them about the survey. The letter was accompanied by an information leaflet explaining what is involved. Study members had the opportunity to request further information, or to opt out of the survey at this point. They could also seek further information, or refuse further involvement when the interviewer attempted to make an appointment to visit; when the interviewer visited and at any point during the administration of any elements of the surveys.

13. A similar approach was adopted for the NCDS5 survey at 33-years (1991) but, where appropriate, explicit written consents were also obtained to permit the contacting of any doctor or hospital named during the course of the interview; and the participation in the survey of the natural or adopted children of a 1 in 3 sample the study members.

14. As shown below, consent rates were high.

Consent to contact doctors/hospitals and to assess natural/adopted children

	Target	Number obtained	Percent
Consent to approach named doctor/hospital to obtain further information about consultations and hospital attendances	11,407	10,392	91.1
Consent for co-resident natural/adopted child of 1 in 3 sample of cohort members to participate in study involving measurements of mathematical, language and memory development	3,595	3,467	96.4

15. Further details may be found in the NCDS5 Technical Report available at: http://www.cls.ioe.ac.uk/shared/get-file.ashx?id=48&itemtype=document

16. The 2008 survey also used the approach outlined at paragraph 12 above but, on this occasion, explicit written consent was sought to link to routine health and economic records for both the study member and any co-resident partner. Consent was also sought from the cohort member to contact any living parent(s).

17. As shown below, for cohort members, the consent rate to link health records (78.7%) was slightly higher than that for economic records (70.6%) – see below.

Consent to data linkage – cohort members

	Number	Percent
Base: All productive personal interviews (excluding proxies)	9,768	100.0
Health data linkage – consent	7,689	78.7
Economic data linkage – consent	6,897	70.6

18. Some 7,746 (79.3%) of the cohort members who completed a personal interview had co-resident partners. Of partners present during the interviewer's visit, 67% gave consent to health records linkage and 61% to economic records linkage. Of partners not present, 25% gave health consent to health records linkage and 29% gave consent to economic records linkage. Overall, consent rates were 43.9% and 39.5% respectively.

Consent to data linkage – partners

	Number	Percent
Base: All personal productive interviews having co-resident partners	7,746	100.0

[7] Fogelman, K. (1983) *Growing Up in Great Britain: collected papers from the National Child Development Study*, page 4

Of which, co-resident partners PRESENT at time of interview	3,658	47.2
Health data linkage – consent	3,400	43.9
Economic data linkage – consent	3,060	39.5

19. Cohort members who had at least one parent alive were asked for consent to contact the parent(s) for a potential further stage of the study. A total of 7,056 cohort members had a living parent, and of these 68 per cent provided parent contact details for follow-up. See table below.

Consent to contact parents

	Number	Percent
Base: Cohort member's with at least one parent alive	7,056	100.0
Consent given to contact parents	4,796	68.0

20. Further details may be found in the NCDS8 Technical Report available at: http://www.cls.ioe.ac.uk/shared/get-file.ashx?id=811&itemtype=document

21. As noted above, during the Biomedical Survey, nurse-interviewers gathered measures of: vision, hearing, lung function, blood pressure, pulse; weight, standing and sitting height, waist and hip size and mental health. Samples of blood and saliva were also taken. Explicit, written consent was sought for all measurements and samples, for feedback of results to the respondent's GP, for archiving of the data in the UK Data Archive and for access to NHS administrative records. Where appropriate, consent was also sought for the creation of immortalised cell lines and the extraction and storage of DNA.

22. As shown below, consent rates were, generally, very high. They were lowest for the taking and processing of blood samples and for sending the test results to the GP.

NCDS Biomedical Survey consents

	Number	Percent
Tests of near and distant vision	9,332	99.9
Blood pressure and pulse rate	9,315	99.7
Pure tone audiometry tests of hearing threshold	9,295	99.5
Standing and sitting height	9,296	99.5
Body weight	9,287	99.4
Waits and hip circumference	9,288	99.4
Lung function using a spirometer	9,243	99.0
Structured interview about mental health	9,288	99.6
Consent to blood collection	8,754	93.7
Consent to blood storage	8,510	91.1
Consent to extraction and storage of DNA	8,405	90.0
Consent to cell cultures	8,338	89.3
Consent to give saliva/sue sample	9,123	97.7
Consent to send results to GP:		
- Vision	8,746	93.6
- Blood pressure and resting pulse	8,732	93,5
- Hearing	8,690	93.0
- Height, weight and measures of body size	8,706	93.2
- Lung function test results	8,565	91.7
- Blood test results for blood cholesterol and glycosylated haemoglobin	7,828	83.8
Archive deposit	9,266	99.2
Use of information from NHS records	9,005	96.4
All NCDS Biomedical Survey participants	9,340	100.0

23 Further details may be found on the CLS website – see: http://www.cls.ioe.ac.uk/page.aspx?&sitesectionid=776&sitesectiontitle=Biomedical+Survey+(2002)

Letters, leaflets and consent forms

24. Examples of letters, leaflets and consent forms used for various NCDS surveys are provided in the Annex below.

Further information

25. Further information is available from the CLS website (http://www.cls.ioe.ac.uk/) or by emailing: clsfeedback@ioe.ac.uk. This document will be updated as new NCDS datasets are available.

ANNEX: Examples of letters, leaflets and consent forms

Examples of letters, leaflets and consent forms used for various NCDS surveys are reproduced below as follows

NCDS5: Medical Consent Form

NCDS - National Child Development Study
A study of everyone living in Great Britain born in the week 3-9 March 1958

Social Statistics Research Unit * City University * Northampton Square * LONDON EC1V 0HB * (071) 253-4399

NATIONAL CHILD DEVELOPMENT STUDY – STAGE 5, 1991

MEDICAL CONSENT FORM

SERIAL NUMBER | | | | | | | |

TO: ALL HOSPITAL/DOCTORS CONCERNED

I have been interviewed as part of the National Child Development Study in 1991.

During the course of this interview I gave details of medical consultations and hospital attendances over a number of years, including the name and address of each doctor or hospital.

I understand that the National Child Development Study may wish to obtain further information about my contact with each doctor or hospital. I give permission for you to release the information requested.

I have been assured that all the information will be treated in the strictest confidence. None of it will be released by the Study, except in the form of a summary report. Neither will my name or address be identified with the results in any way.

Signed: _____

Name in Capitals: _____

Full Address: _____

_____

Date: _____

NCDS5: Child Permission Form

NATIONAL CHILD DEVELOPMENT STUDY - STAGE 5 1991

CHILD PERMISSION FORM

PERMISSION TO INTERVIEW CHILD

(to be signed by parent or guardian of child)

I have been requested by the staff of NOP, RSGB and SCPR, on behalf of the National Child Development Study, to permit my child, _____, to participate in a study of the development of children.

This study will focus on the measurements of mathematical, language and memory development of each participating child.

I understand that my child's identity and any information that could identify him/her will be held strictly confidential, will be used solely by persons conducting this study, and will not be disclosed to other persons for any purpose.

I consent to my child's participation in this study.

Signature: _____

Date: _____

NCDS 2008: Pre-notification Letter

Date

Dear

50 years of the National Child Development Study

In March 2008 the National Child Development Study celebrated its 50th anniversary. At around that time we sent you a timeline covering the 50 years since the study began which contained a brief summary of some of the study's findings and most significant policy impacts.

In July 2008 a 60-page report called 'Now we are 50' containing key findings from the study was published. A summary version of this report is enclosed. I hope that you find this interesting. The full length report and additional copies of the enclosed summary report can be downloaded from the study website www.ncds.info. A printed copy of the full report is available, free of charge, to cohort members. If you would like us to send you a copy of the report, please let us know by completing the enclosed reply slip and returning it in the freepost envelope provided. If you do not wish to receive a copy of the report, there is no need to return the reply slip. We will aim to send the report to cohort members who request a copy in about 4-6 weeks.

The next stage of the study will take place in a few months time and we hope that you will be happy to take part again. The interviews will be carried out by the National Centre for Social Research (NatCen), an independent research organisation who also carried out the previous two surveys in 2000 and 2004.

I will write to you again nearer the time to give you more details about this latest survey and to invite you to take part. An interviewer from NatCen will then get in touch to find out whether you wish to be involved this time.

Meanwhile, please let us know if you move to a new address – or if this letter has reached you at a different address - in order that we can contact you to invite you to take part in the survey.

You can do this by:

- Completing the contact form on the study website www.ncds.info
- Emailing us at ncds@ioe.ac.uk
- Calling us free on 0500 600 616
- Writing to us at National Child Development Study, FREEPOST KE7770, London, WC1H 0BR (you won't need a stamp if you post your letter in the UK).

If you have any questions, please call us on the Freephone number above.

Thank you for your continuing help with the study. It is greatly appreciated.

With kind regards,

Jane Elliott
Study Director

NCDS 2008: Advance Letter

Reference: P2721/

50 years of the National Childhood Development Study

This year the NCDS celebrates its 50th anniversary. As a valued member of the National Child Development Study (NCDS) we are writing to ask for your help as the next stage of the study begins. We hope we can count on you to take part in the study in this very special year.

This latest stage of the study is being carried out by the National Centre for Social Research (NatCen), an independent research organisation, on behalf of the Centre for Longitudinal Studies (CLS) at the Institute of Education in London.

We have enclosed a leaflet which provides information about this year's study and explains exactly what taking part will involve. Your interviewer_____ _____ will be in touch in the next couple of weeks to invite you to take part and, if you are willing, they will arrange a convenient time to visit you.

If you would like to contact your interviewer to arrange an appointment or change an appointment you may have made please contact NatCen on 0800 652 4572 or by email: ncds@natcen.ac.uk.

If you have any further queries about the study please call us at CLS on Freephone 0500 600 616 or email us at ncds@ioe.ac.uk.

We hope you enjoy taking part in the study this time around. Your continued support and involvement is vital to the success of the study and is greatly appreciated.

Thank you for your help.

Yours sincerely,

Jane Elliott
Study Director

Matt Brown
Survey Manager

NCDS 2008: Consent Leaflet

NatCen
National Centre for Social Research

CLS

Health and Economic Records – INFORMATION ON GIVING CONSENT

We would like to obtain some additional information about you from health and economic records that are routinely collected by government departments or agencies and other public sector organisations. To do this, we need your written permission.

Information from routine health records

We would like to access information from routine medical and other health-related records about you and your partner.

The National Health Service (NHS) maintains information on all patients accessing the health services through routine medical and other health-related records. These health records are held within statistical health databases, which may record information about:

- Admissions or attendances at hospital (including dates of admission, discharge or attendance, diagnoses received, treatments given, surgical procedures)
- Visits to your family doctor or other health professional e.g. midwife
- Records of specific conditions such as cancer or diabetes
- Prescriptions given

Why?

This information will tell us a lot about health and illness within families and will allow researchers to gain deeper understanding of the ways in which an individual's health and the health of those around them can impact upon their path through life.

Information from routine records of economic circumstances

We would also like to access information about you and your partner from standard economic records.

- Benefits (e.g. Child Benefit, Income Support) and other DWP programme activity (e.g. New Deal for Lone Parents, New Deal 25 plus) since April 1999. The Department for Work and Pensions (DWP) holds this information.
- Employment, earnings, tax credits and occupational pensions data since April 1998 and national insurance contributions (NICs) since the early 1970s. This information comes from Her Majesty's Revenue and Customs (HMRC) records.

Why?

This information will give us as full a picture as possible of your family's economic circumstances – at present, in the past and in the future – without asking additional questions in the interview. This will allow researchers to examine how family economic circumstances impact upon other aspects of life in greater detail.

It is completely up to you which permissions you choose to give and you can withdraw your permission at any time in the future. We will ask for permission from you and your partner separately by asking you each to complete a consent form. These forms can be left behind by the interviewer if your partner is not available to sign it at the time of your interview. Your participation in the study will not be affected by your decision. **Please be assured that all information obtained from these sources will be treated in strict confidence in accordance with the Data Protection Act and used for research purposes only.**

We will need to provide the following information to the holders of the records: full name, sex, date of birth and address. It would also be very useful to have the National Insurance numbers for you and your partner. This information will only be used for accessing the records - it will not be included in any data that is made publicly available. No information provided by you as part of the National Child Development Study will be disclosed to the NHS, DWP or HMRC for any other purpose. If you have any further questions about this please contact us at CLS on Freephone 0500 600 616 or email us at ncds@ioe.ac.uk.

NCDS 2008: Consent form

NatCen
National Centre for Social Research

CLS

National Child Development Study
Health and Economic Records
COHORT MEMBER CONSENT FORM

Forename (print)

Surname (print)

Please complete this form to indicate whether or not you are happy to give us permission to access each type of information. You do not have to give permission to allow us to access your health and economic records. This will not affect your future participation in the study.

Health records

I give my permission for information from my routine health records to be released to the National Child Development study.

Please place a tick in one of the boxes to indicate whether or not you give permission. Yes ☐ No ☐

Economic records

I give my permission for information from my routine economic records to be released to the National Child Development study.

Please place a tick in one of the boxes to indicate whether or not you give permission. Yes ☐ No ☐

National Insurance Number: ☐☐ ☐☐ ☐☐ ☐☐ ☐

Confirmation

I have read or been read the 'information about giving consent' leaflet and have had the opportunity to ask questions. I understand that the information released will be treated in strict confidence in accordance with the Data Protection Act and used for research purposes only. I understand that this consent will remain valid and ongoing unless revoked by me in writing and that I may withdraw my consent at any time by contacting the National Child Development Study at the address below, without giving any reasons.

National Child Development Study, FREEPOST, KE7770, London, WC1H 0BR (no stamp required if posted in the UK).

Signed by cohort member **Date**

Interviewer confirmation

I confirm that I have explained how health and economic records will be used and the nature of this consent.

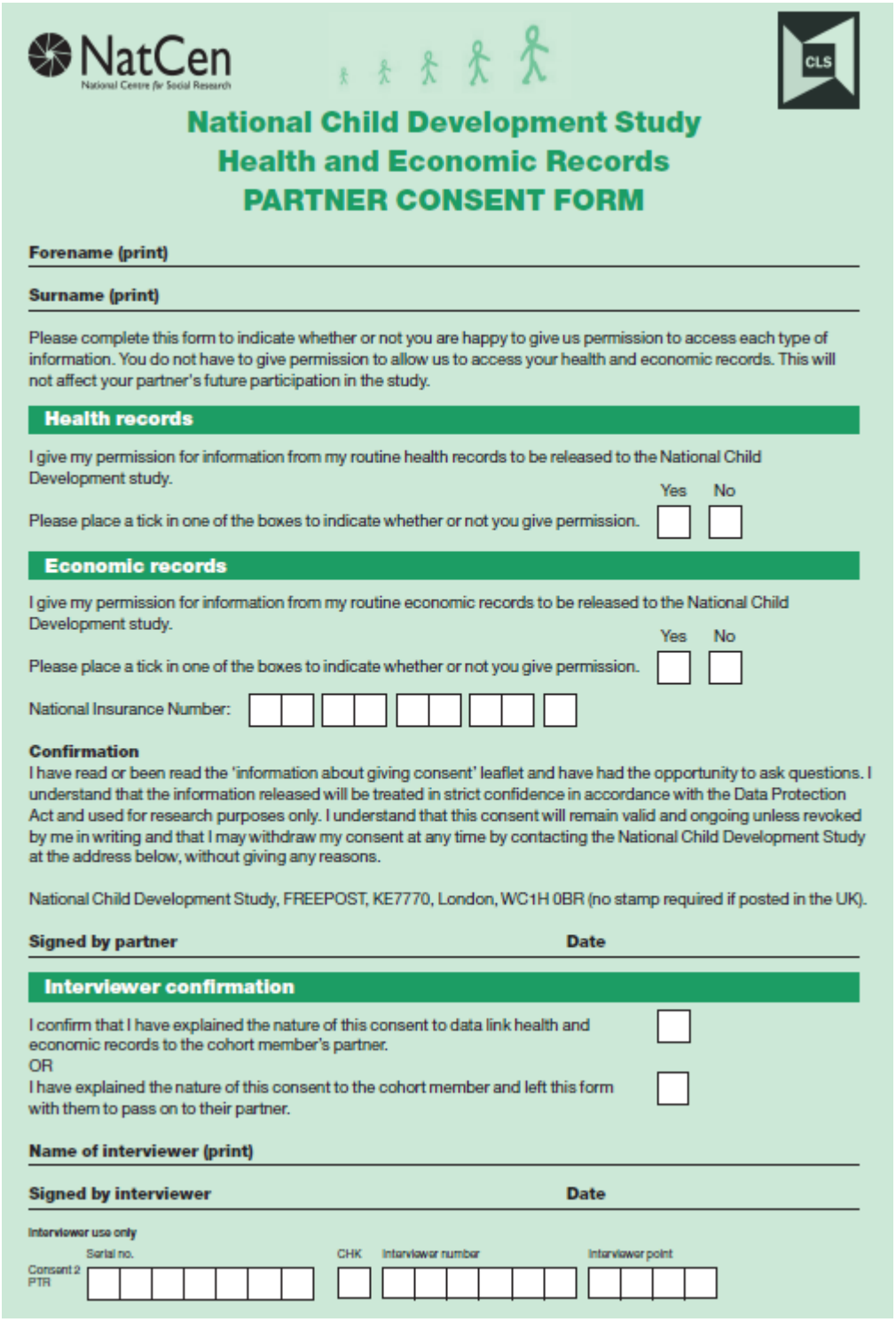
Name of interviewer (print)

Signed by interviewer **Date**

Interviewer use only

	Serial no.	CHK	Interviewer number	Interviewer point
Consent 1 CM	☐☐☐☐☐☐☐	☐	☐☐☐☐☐☐	☐☐☐☐

NCDS 2008: Partner consent form



NatCen
National Centre for Social Research

CLS

National Child Development Study
Health and Economic Records
PARTNER CONSENT FORM

Forename (print)

Surname (print)

Please complete this form to indicate whether or not you are happy to give us permission to access each type of information. You do not have to give permission to allow us to access your health and economic records. This will not affect your partner's future participation in the study.

Health records

I give my permission for information from my routine health records to be released to the National Child Development study.

Please place a tick in one of the boxes to indicate whether or not you give permission. Yes ☐ No ☐

Economic records

I give my permission for information from my routine economic records to be released to the National Child Development study.

Please place a tick in one of the boxes to indicate whether or not you give permission. Yes ☐ No ☐

National Insurance Number: ☐☐ ☐☐ ☐☐ ☐☐ ☐

Confirmation

I have read or been read the 'information about giving consent' leaflet and have had the opportunity to ask questions. I understand that the information released will be treated in strict confidence in accordance with the Data Protection Act and used for research purposes only. I understand that this consent will remain valid and ongoing unless revoked by me in writing and that I may withdraw my consent at any time by contacting the National Child Development Study at the address below, without giving any reasons.

National Child Development Study, FREEPOST, KE7770, London, WC1H 0BR (no stamp required if posted in the UK).

Signed by partner **Date**

Interviewer confirmation

I confirm that I have explained the nature of this consent to data link health and economic records to the cohort member's partner. ☐

OR

I have explained the nature of this consent to the cohort member and left this form with them to pass on to their partner. ☐

Name of interviewer (print)

Signed by interviewer **Date**

Interviewer use only

Consent 2 PTR | Serial no. ☐☐☐☐☐☐☐ | CHK ☐ | Interviewer number ☐☐☐☐☐☐ | Interviewer point ☐☐☐☐

NCDS Biomedical Survey: Advance Letter

NCDS
National Child
Development Study
A study of everyone in Britain
born in one week in 1958

[cohort member's name and address]

[unique reference]

[date]

Dear [cohort member's name]

The National Child Development Study 2002-3

In the past, you have kindly agreed to be interviewed about various aspects of your life, including your health. This information you have given has been invaluable in revealing how common problems such as asthma, obesity and mental health change over time from childhood to adulthood.

The Medical Research Council now recognises the unique value of the NCDS and is funding a more detailed survey of health. This survey will be carried out by the National Centre for Social Research, who conducted interviews with most members of the NCDS in 1999 and 2000.

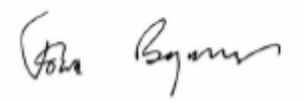
We are now writing to ask if you would be willing to offer some more of your time so that a research nurse can visit you in your home to take some simple medical measurements. These tests last about 1½ hours and are described in more detail on the enclosed information sheet.

As always, all the information you supply will be treated as strictly confidential. None of it will be released in any way which enables you to be identified.

What next?

Someone from the National Centre will be in touch with you shortly to arrange a convenient time for the nurse to visit. If your address or telephone number has changed please let us know by calling freephone 0500 600 616.

We very much hope that you will agree to help us with this important research. If you have any queries, please do not hesitate to telephone us on freephone 0500 600 616.



Yours sincerely

John Bynner

Centre for Longitudinal Studies • Institute of Education • 20 Bedford Way • London WC1H 0AL
Tel 0207 612 6860 • Fax 0207 612 6880 • Email cohort@ds.ioe.ac.uk • Director Professor John Bynner

NCDS Biomedical Survey: Information Leaflet

What does the survey involve?

The measurements include:

- *Height, weight and other body measures.* We would like to measure your height, both when you are standing and when you are seated, and also your waist and hip size, using a tape measure over light clothing. You will be asked to remove shoes and heavy clothing.

- *Blood pressure.* Blood pressure is measured using an inflatable cuff that goes around the upper arm, after a few minutes rest. In this survey we shall use an automatic device which also measures pulse rate. The nurse will tell you your blood pressure and indicate its meaning. Without taking several measurements s/he cannot diagnose high blood pressure and may advise you to check with your doctor.

- *Lung function.* Another measurement of health and fitness is the amount of air you can breathe out of your lungs and how quickly you can blow it out.

- *Eyesight tests.* You will be asked to read from standard charts at your normal reading distance and at a distance of about 1.5 metres. A special card will be used to test three-dimensional (3D) vision. Some people will also have a test of their focusing power. If you wear spectacles or contact lenses you may be asked to remove these for parts of the final test.

- *Hearing tests.* You will be asked to wear a pair of headphones and to tell the nurse whether you can hear bleeps of different pitch and loudness.

- *Mental wellbeing questionnaire.* We would like to measure the different types of feelings and emotions that you experience. This will involve the nurse interviewing you for a few minutes using a computer-assisted questionnaire, and some additional questions which you answer privately. Some of the questions are about relationships in your family when you were a child. For a few people this may cause unpleasant memories. As with every part of the survey, you may choose not to answer these questions if you wish.

- *Saliva sample.* We would also like to measure whether "stress" affects health with a hormone called cortisol, which is contained in saliva. Because cortisol varies during the day, the saliva needs to be collected first thing in the morning and then again a few hours later. This involves placing a cotton wool swab between your cheek and gums for a few minutes, which is then posted to the laboratory.

- *Blood sample.* We would be very grateful if you would agree to provide us with a sample of blood. This will be analysed in a number of ways, and some of it will be stored for more advanced tests in the future. This is therefore a very important and informative part of the survey. You can of course choose whether to give a blood sample. The nurse will ask for your written permission to take a blood sample and also to store portions of the blood and the DNA which it contains. This is explained in more detail in a separate leaflet, which you have been given.

  The nurse will take a small amount of blood (no more than five teaspoonfuls) from your arm, which is then posted to a laboratory for tests of cholesterol and glycosylated haemoglobin, two substances in the blood which are related to hardening of the arteries (atheroma). We shall inform you if either of these tests is high enough to need medical attention. With the blood sample we are also planning to measure substances related to blood clotting. We shall also test for an antibody (IgE) which is involved in allergies to things like grass pollen and house dust mites.

/

In the future, there may be new scientific ideas which can be tested on the stored blood samples. If you agree to frozen storage of your blood sample, this will be used only for non-commercial medical research purposes. The stored blood will be controlled by a steering committee including representatives of the Institute of Education and the scientific investigators on the survey team. Blood samples from this survey will never be tested for the HIV virus which causes AIDS.

If you later change your mind about the use of stored samples of your blood or your DNA, you may withdraw your permission by writing to the National Centre for Social Research. The biological samples relating to you will then be destroyed.

Letting you know your results

At the end of the visit, the nurse will give you a written summary of the measurements she has made on the day. This will not include laboratory tests, nor a detailed medical interpretation of the results. After a few weeks, you will receive a "thank-you" letter including fuller feedback. We will not send any information to your doctor (GP) without your permission, but if you agree, the results of all your measurements and laboratory tests will be sent to your doctor in a separate letter.

In future it may be useful for medical research purposes for us to consult your NHS medical records. Although there are no immediate plans to do this, we seek your written permission at this stage so that we do not need to trouble you for this later.

Answering other questions

We hope that this leaflet answers your questions. If you have others which you feel cannot be addressed by the nurse when she visits, please contact the National Centre for Social Research at the address opposite. If they are unable to provide a direct answer, they will put you in touch with one of the medical investigators. Thank you very much for helping us with the development of this important survey.

The members of the research team are:

Liz Fuller
National Centre for Social Research
35 Northampton Square
London EC1V 0AX
Tel: 0207 250 1866

Professor John Bynner
Centre for Longitudinal Studies
Institute of Education
20 Bedford Way
London WC1H 0AL

Professor Christine Power
Centre for Paediatric Epidemiology & Biostatistics
Institute of Child Health
30 Guilford Street
London WC1N 1EH

Professor David Strachan
Department of Public Health Sciences
St George's Hospital Medical School
Cranmer Terrace
London SW17 0RE

NCDS Biomedical Survey – Genetic Leaflet

What is DNA?

DNA is the substance of which genes are composed. Genes are found on structures called chromosomes. There are 23 pairs of chromosomes (46 in total) present in each of the cells of our bodies.

Each chromosome contains a long thin tightly packed thread. This is the DNA. The DNA strand is divided up, along its length, into the genes. One chromosome contains hundreds or thousands of genes. Each gene lies at an exact place on a specific chromosome. Pairs of chromosomes contain the same set of genes in the same order, but they may carry a different form of the same gene.

It is this genetic variation in the DNA that will be studied in the genetic part of the project.

How will the DNA be collected?

DNA can be obtained from any cell in the body. Since we wish to take a blood sample anyway for your biochemical tests we would like to use this to prepare DNA. We shall seek your written consent to do this.

As well as DNA, a sample of the blood cells can be stored frozen, if you agree. The cells can then, at some future date, be grown in culture to prepare much larger amounts of high quality DNA if we need it.

Future genetic studies may involve looking at whole chromosomes or at cell metabolism. If only the DNA is stored, then whole chromosomes cannot be studied. This is because the structure of the chromosomes is disrupted in order to get the DNA. Storing cells would allow the study of both whole chromosomes and cell metabolism in the future.

If these blood cells are not stored, then the potential for future genetic studies will be more limited.

What type of genetic studies will be done?

Some studies will simply find out how many people have a certain type of gene. In the future, if a certain gene is found to be associated with a certain illness, then knowing how common that gene is will help to plan and develop health care. Because the NCDS is a cross-section of the whole British population of your age, it can be very useful to compare your genetic make-up with that of other people outside the cohort who have diseases. One of the first such comparisons will be with a large nationwide collection of children and young adults with diabetes. Finding the genes which are more common among young diabetic people will help in the search for preventable causes of this condition.

Other studies will see if there is a link between certain genes, the environment and health among NCDS cohort members. Genetic results will be compared with information in your interview, and your physiological and biochemical test results, to see if there are common underlying factors.

How will the results be published?

The results would be in the form "1 in 200 people have that type of gene".

No names of individuals will ever be revealed or identified in the presentation of the results.

How will the genetic information be stored?

Each blood sample in the project will be given its own number. This number will be different to your survey number, which appears on the questionnaire and the consent form. Only this number, and not your name, will appear on the prepared DNA samples and the stored materials. As in previous NCDS surveys, the 'paperwork' which links you to your results will be kept on a secure computer at the Institute of Education, London.

Can I withdraw my consent?

Initial consent to the collection, storage and use of the samples in the genetic project is given by you. It is not possible to "opt in" to certain genetic studies and "opt out" of others, but you can opt out of the whole genetic project at any time. If you feel unhappy about agreeing for your cells to be stored for future use, you can choose not to sign that part of the consent form.

Who gives ethical approval for genetic studies?

National Health Service Research Ethics Committees operate within the framework of guidance from the Departments of Health, the Royal College of Physicians and other professional bodies, and the principles contained in the Declaration of Helsinki. They have to be satisfied that the scientific merits of the study and the interests of everyone taking part in it have been considered.

Also, a group of independent doctors and scientists, and representatives of the Medical Research Council, form a steering committee to oversee the ethical aspects of this project and control future use of the biological specimens obtained from you and everyone else who takes part.

Each genetic study may raise different ethical issues and will be carefully planned with advice from the steering committee. When the details have been finalised, the proposed study will be submitted to one of the NHS Research Ethics Committees for their approval.

Only studies approved by these Research Ethics Committees will be undertaken.

Will the DNA samples be used for other things?

If you agree, the DNA sample will be made available for future studies relating to health which have received ethical approval. The information will not be available for life insurance, mortgage applications, police records or AIDS/HIV testing.

Answering other questions

We hope that this leaflet answers your questions. If you have others, please contact the medical investigators at the address below. Thank you very much for helping us with the development of this important survey.

Prof David Strachan
Department of Public Health Sciences
St George's Hospital Medical School
Cranmer Terrace
London SW17 0RE

Tel: 020 8725 5424

NCDS Biomedical Survey: Appointment Record

NCDS
National Child
Development Study
A study of everyone in Britain born in one week in 1958

National Centre *for* Social Research

APPOINTMENT RECORD

In the next week or so, someone from the Telephone Unit at the National Centre for Social Research will contact you to make an appointment for the nurse to come to interview you. Please use this card to record the appointment details.

A qualified nurse _____

will call on _____ at _____

She will be able to give you more information about the measurements.

If for any reason you cannot keep this appointment, please telephone our Project Team on freephone 0800 652 0157

Overleaf there is some information about the interview and what to expect.

The interview will include a number of questions about your health, as well as the measurements described in the information leaflet you have been given. To help the nurse, and to save time during the interview, please could you be prepared in the following ways:

- Wear **light clothing**. So that your hip and waist can be measured accurately, please do not wear tight clothing (e.g. lycra, tight-fitting jeans) or thick belts.
- If possible, **do not smoke, drink alcohol** or do any **vigorous exercise** for half an hour before the nurse arrives, as this could affect your blood pressure readings.
- The nurse will need to record any **prescribed medicines** that you may be taking, so have the containers ready. If you take any **vitamins, minerals or food supplements**, whether or not they have been prescribed by a doctor, please could you have these containers ready as well.
- If you wear **glasses for reading or for distance vision** please have these ready, as the nurse will need them for testing your vision.
- If you wear **contact lenses** for vision correction, please have them in when the nurse arrives. You may be asked to remove them for one of the measurements, so it will be convenient if you could have your storage case to hand. In addition, please could you have your spare glasses available, as the nurse will need to look at them.
- Finally, if you are registered with a GP, you may be asked for his or her name and the surgery address, so make sure you can find this information easily.

NCDS Biomedical Survey: Consent Forms

National Centre for Social Research

Head Office
35 Northampton Square
London EC1V 0AX
Telephone 020 7250 1866
Fax 020 7250 1524

Operations Department
100 Kings Road, Brentwood
Essex CM14 4LX
Telephone 01277 200 600
Fax 01277 214 117

NCDS Medical follow-up
CONSENT BOOKLET – OFFICE COPY

P2107

Please use capital letters and write in ink

NAME/ADDRESS – WRITE IN:

RESPONDENT NAME:
ADDRESS:

POSTCODE:

ATTACH SERIAL NUMBER BAR CODE LABEL:

1. Nurse number

2. Date schedule completed — DAY ___ MONTH ___ YEAR ____

3. Full name (of person tested) _____

Name by which GP knows person (if different) _____

4. Sex — Male 1 / Female 2

5. Date of birth: DAY ___ MONTH 0 3 YEAR 1 9 5 8

6. **GP NAME AND ADDRESS**
Dr: .....
Practice Name: .....
Address: .....
.....
Town: .....
County: .....
Postcode: .....
Telephone no: .....

7. **NURSE USE ONLY**

GP address complete	1
GP address incomplete	2
No GP	3

8. SUMMARY OF CONSENTS – RING CODE FOR EACH ITEM

	YES	NO		YES	NO
a) Vision tests **to GP**	01	02	g) Sample of blood to be **taken**	13	14
b) Hearing tests **to GP**	03	04	h) Blood sample results **to GP**	15	16
c) Height and Weight **to GP**	05	06	i) Blood sample for **storage**	17	18
d) Waist and Hip measurement **to GP**	07	08	j) Blood sample for **DNA extraction**	19	20
e) Blood pressure **to GP**	09	10	k) Blood sample for **cell cultures**	21	22
f) Lung function **to GP**	11	12	l) Blood sample result to **respondent**	23	24

CONSENT FORM 1 - Measurements

I, *(name)* _____

give my consent to _____ *(qualified nurse)*

to measure the following:

		Ring one code on each line	
1)	Tests of near and distant vision	Yes	No
2)	Blood pressure and pulse rate	Yes	No
3)	Pure tone audiometry tests of hearing threshold	Yes	No
4)	Standing and sitting height	Yes	No
5)	Body weight	Yes	No
6)	Waist and hip circumferences	Yes	No
7)	Lung function using a spirometer	Yes	No

I am willing to complete a structured interview about mental health Yes No

I have read the letter of introduction and the information leaflet about the medical examination for the National Child Development Study. I have discussed any outstanding questions with the nurse named below and I wish to participate in the examination. I understand that I can stop the interview and examination at any point or decline any part of it, and that all information will be treated in the strictest confidence and used for research purposes only.

Signed _____ Date _____

Countersignature by nurse

I confirm that I have explained the nature of the proposed studies to the person named above and have left a copy of the information sheet and this consent form with them for future reference.

Signed _____ (Nurse) Date _____

CONSENT FORM 2 – Blood samples

I, *(name)* _____

a) Give my consent to _____ (qualified nurse) to collect a sample of my blood to be tested for cholesterol, glycosylated haemoglobin, fibrinogen, total and allergen-specific IgE. I understand that the blood samples and related information will be coded and used anonymously for non-commercial research purposes only, and will not be tested for HIV.

Signed _____ Date _____

b) Give my consent to storage of frozen portions of my blood sample for use in future medical research studies of the causes, diagnosis, treatment or outcome of disease. I understand that the blood samples and related information will be coded and used anonymously for non-commercial research purposes only, and will not be tested for HIV. I understand that I may withdraw this consent at any time by contacting the investigators in writing, without giving any reasons.

Signed _____ Date _____

c) Give my consent to extraction and storage of DNA from my blood sample for use in future medical research studies of the causes, diagnosis, treatment or outcome of disease. I understand that the DNA samples and related information will be coded and used anonymously for non-commercial research purposes only, and that no information found in the DNA will be given to me. I understand that I may withdraw this consent at any time by contacting the investigators in writing, without giving any reasons, and the DNA extracted from my blood samples will then be destroyed and any genetic data obtained from it will be deleted.

Signed _____ Date _____

d) Give my consent to storage of white blood cells for future creation of cell cultures. I understand that these cells will provide a renewable source of DNA for use in future medical research studies of the causes, diagnosis, treatment or outcome of disease. I understand that the cells, DNA samples and related information will be coded and used anonymously for non-commercial research purposes only, and that no information found in the DNA will be given to me. I understand that I may withdraw this consent at any time by contacting the investigators in writing, without giving any reasons, and the cell cultures and DNA obtained from them will then be destroyed.

Signed _____ Date _____

CONSENT FORM 3

Saliva sample

I, *(name)* _____ give my consent to use of samples of my saliva for tests of cortisol and future medical research studies of the causes, diagnosis, treatment or outcome of disease. I understand that the saliva samples and related information will be coded and used anonymously for non-commercial research purposes only, and will not be tested for HIV. I understand that I may withdraw this consent at any time by contacting the investigators in writing, without giving any reasons.

Signed _____ Date _____

Consent to send results to GP

I, *(name)* _____ wish these results to be sent to my general practitioner so that they can be used to help monitor my health. I understand that my GP may wish to include the results in any future report about me:

		Ring one code on each line		
a)	Vision test results	Yes	No	Not measured
b)	Blood pressure and resting pulse rate	Yes	No	Not measured
c)	Hearing test results	Yes	No	Not measured
d)	Height, weight and measures of body size	Yes	No	Not measured
e)	Lung function test results	Yes	No	Not measured
f)	Blood test results for blood cholesterol and glycosylated haemoglobin	Yes	No	Not measured

Signed _____ Date _____

CONSENT FORM 4 – Archiving of data and Consent to obtain information from National Health Service medical records

I, *(name)* _____

a. Give my consent for measurements, laboratory test results and other information obtained from me as part of the medical examination of the National Child Development Study to be deposited at the Economic and Social Research Council Data Archive, as part of the National Child Development Study dataset. I understand that the archived information will be coded and used anonymously for research purposes only, and will not include my name or address.

Signed _____ Date _____

b. Give my consent to use of information from my National Health Service medical records in future medical research studies of the causes, diagnosis, treatment or outcome of disease. I understand that the information obtained by the investigators will be coded and used anonymously for research purposes only, and will not include my name or address. I understand that I may withdraw this consent at any time by contacting the investigators in writing, without giving any reasons.

Signed _____ Date _____

NCDS9: Email invitation to participate

Personal ref: [cserial]
Survey ref: 110967
[month] 2013

National Child Development Study (NCDS) – Age 55 Survey

Dear [CM first name],

I am writing to let you know that the next stage of the National Child Development Study (NCDS) is now underway. I do hope you will take part. **Your continued support and involvement is vital to the success of the study and is greatly appreciated.**

This latest stage of the study is being carried out by TNS BMRB, an independent research organisation, on behalf of the Centre for Longitudinal Studies at the Institute of Education in London.

You can access a leaflet which provides more information about the survey and explains exactly what taking part will involve by clicking the link below:

[Hyperlink to leaflet]

For the first time, the Age 55 survey can be completed online. To take part online please click on the web link below and enter your Unique ID number when prompted:

Website: www.ncdssurvey.co.uk
Unique ID: <unique ID>

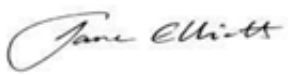
If for any reason you can't complete the survey online, it can also be completed by telephone. However we do not currently have your telephone number. If you would like to take part by telephone please tell us your telephone number using the contact details below.

The survey will take around 35 minutes to complete. We do hope you will decide to take part.

If you have any questions about the study please call TNS BMRB on 0800 015 0655 or email ncds@tns-bmrb.co.uk.

We hope you enjoy taking part in the study this time round.

Yours sincerely,



Professor Jane Elliott
Study Director

NCDS: Advance letter

[CMTitle] [CM first name] [CM surname]
[Address line 1]
[Address line 2]
[Address line 3]
[Address line 4]
[Postcode]

Personal ref: [cserial]
Survey ref: 110967
[month] 2013

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Unique ID: <unique ID>

If for any reason you can't complete the survey online, it can also be completed by telephone. However we do not currently have your telephone number. If you would like to take part by telephone please tell us your telephone number using the contact details below.

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We hope you enjoy taking part in the study this time round.

Yours sincerely,

Professor Jane Elliott
Study Director

NCDS9: Leaflet

1958 NATIONAL CHILD DEVELOPMENT STUDY

What will happen to the information I give you?

The data you provide will be stored securely and will be treated in strict confidence in accordance with the Data Protection Act, and used for statistical research purposes only. This means that:

- Names and addresses are never included with the results of our research studies
- Neither households nor individuals are identified in any published report

1958 NATIONAL CHILD DEVELOPMENT STUDY

How can I find out more about the Age 55 survey?

If you would like more information about the Age 55 survey please contact TNS BMRB:

Freephone: 0800 015 0655
Email: ncds@tns-bmrb.co.uk

For further information about NCDS in general you can contact the Centre for Longitudinal Studies on Freephone 0500 600 616, email ncds@ioe.ac.uk or visit the study website: www.ncds.info.

Who can I contact for further advice?

If you would like any advice on any of the issues included in the survey then the Citizen's Advice Bureau (www.adviceguide.org.uk) or Supportline (www.supportline.org.uk or 01708 765200) will be able to help.

1958 NATIONAL CHILD DEVELOPMENT STUDY

AGE 55 SURVEY

INFORMATION LEAFLET

TNS

1958 NATIONAL CHILD DEVELOPMENT STUDY

Why is the 1958 National Child Development Study (NCDS) important?

NCDS follows the lives of over 17,000 people, who were all born in the same week as you in 1958.

Now that you are 55, the information that you have shared with us over the years allows us to understand where you are now and how you got there. There is no other study that focuses on your generation, and the factors that have influenced your journey through life.

NCDS continues to be extremely valuable in helping scientists and researchers understand changes in society and transitions which occur in people's lives. The information you provide can help policymakers and providers of services to plan for the future and improve the lives of people in Britain.

Findings from the study have had, and will continue to have, a significant impact on government policy and service provision across a whole range of areas including health, education and employment.

What will the Age 55 survey involve?

The Age 55 survey will be conducted on the telephone.

One of our interviewers will call you over the next few weeks and take you through the survey over the phone. If it is not convenient when they first call another suitable time can be arranged.

The interview should take around 35 minutes.

What will the survey cover?

Some of the topics that will be covered in the interview are:

- Your family and who you live with
- Your housing situation
- Employment and what you think about work
- Your health
- What you do in your spare time

You do not have to answer any question you do not wish to.

Who is carrying out the study?

The study is run by the Centre for Longitudinal Studies (CLS), a research centre in the Institute of Education at the University of London. It is being funded by the Economic and Social Research Council. The Age 55 survey is being carried out by TNS BMRB, an independent research company that specialises in conducting large-scale social surveys.