NCDS
Age 62 Survey Technical report Appendix B: Biomedical Protocols

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1 Overview of NCDS

1.1 Background

Welcome to the 1958 National Child Development Study (NCDS) 2020-23 Survey. This document provides you with an overview of the study and all the information you will need to work on the survey. Note that this year's survey is being referred to as the "Life in Your Early 60s" Survey to the cohort members, although they will know the project as a whole as the National Child Development Study (NCDS).

NCDS follows the lives of over 17,000 people born in England, Scotland and Wales in a single week of 1958. The main aim of the study is to collect information on physical and educational development, economic circumstances, employment, family life, health behaviour, wellbeing, social participation and attitudes. Because these individuals have been followed up over time, it is possible to examine how early experiences can shape later life circumstances.

Britain is unique in the extent of its national birth cohort studies, which follow the same group of people from birth into and through adulthood, providing a picture of whole generations, and helping us to understand what matters for healthy and happy lives across the life span.

There are four such surveys, and NCDS is the second:

- National Survey of Health and Development (started in 1946)
- National Child Development Study (started in 1958)
- 1970 British Cohort Study (started in 1970)
- Millennium Cohort Study (started in 2000)

In addition, Next Steps, also run by CLS, follows those born in 1990 but started in 2004 when participants were 13-14.

The existence of the different cohorts also makes it possible to see how things have changed for children of different generations: how their experiences of growing up have differed, and which circumstances have become important for future outcomes or have ceased to be so.

NCDS is run by the Centre for Longitudinal Studies (CLS), a research centre in the UCL Social Research Institute, which is part of University College London (UCL).

NatCen and Kantar Public have been commissioned to conduct the fieldwork for the 2020-23 Survey. NatCen and INUVI nurses will carry out the health visits.

Since the birth survey in 1958, there have been ten further 'sweeps' of all cohort members at ages 7, 11, 16, 23, 33, 42, 44, 46, 50 and 55. The survey at age 44 was a

special bio-medical survey which was conducted by nurses and involved a series of health measurements.

Data for NCDS have so far been collected from a number of different sources: the midwife present at birth, parents, schools, health service personnel, the cohort members themselves, their spouses, cohabitees and children. Data has been collected using a variety of methods: paper, electronic and self-completion questionnaires, clinical records, medical examinations, physical measurements, ability tests, educational assessments and diaries. Most of the previous follow-ups have been carried out by face-to face visits to cohort members in their homes, but the Age 46 survey in 2004 was conducted by telephone and the most recent survey, at age 55 in 2013, was a mixed-mode survey conducted by web and telephone. The 2020-2023 main interview at age 62-65 is mainly face-to-face with the option to have a video call interview if preferred.

1.2 The impact of COVID-19 on NCDS

Mainstage fieldwork began in January 2020 and was paused in March 2020 due to the COVID-19 pandemic (Waves 1 and 2). Whilst fieldwork was paused, NCDS study members were asked to participate in a series of web surveys between May 2020 and March 2021. They were also invited to take part in a serology study in April 2021 to test for COVID-19 antibodies.

Following a small pilot study in April – May 2021, mainstage interviews resumed by video call (wave 3) and face-to-face health visits resumed in November 2021. Since April 2022 (wave 4 onwards), all fieldwork has been face-to-face with the option of a video interview for the main interview if preferred.

1.3 Participation in previous sweeps

In the first birth survey in 1958, 98.1% of all babies born between the 3rd and 9th of March took part. CLS remain in contact with around 12,500 of the original cohort members. The table below shows the main respondent and the number of cohort members who took part in each of the previous sweeps of the study.

Main respondent and no. of cohort members for each sweep of NCDS		
Year	*Main respondent*	*Response rate*
1958	Mother	17,415
1965	Parents	15,425
1969	Parents	15,337
1974	Cohort member & parents	14,654
1981	*Cohort member*	*12,537*
1991	*Cohort member*	*11,469*

Main respondent and no. of cohort members for each sweep of NCDS		
2000	*Cohort member*	*11,419*
2003	*Cohort member*	*9,377*
2004	*Cohort member*	*9,524*
2008	*Cohort member*	*9,790*
2013	*Cohort member*	*9,137*

The reduction in participants over time has resulted from deaths, emigration (those moving outside of Britain are not followed up), withdrawals from the study and simply losing touch.

1.4 Funding and content

From the original focus on the circumstances and outcomes of birth, the study has broadened in scope to map all aspects of health, education and social development of the cohort as they passed through childhood and adolescence. In later follow-ups, the information collected has covered education and training, labour market activity, housing, family life, income, health and values and attitudes. The study is core-funded by the Economic and Social Research Council (ESRC). The 2020-23 Survey is additionally co-funded by the Department for Work and Pensions (DWP), the Medical Research Council (MRC) and the U.S. National Institutes of Health (NIH).

1.5 Results, media and publications

The NCDS survey has produced a wealth of data which has been at the forefront of ground-breaking insight into how different backgrounds, experiences, social factors and life choices can impact on wages, jobs, relationships and health in later life. It was research using NCDS data which first uncovered the wide-reaching negative effects of mothers' smoking during pregnancy.

More recently, NCDS has featured in the news through some research which has been conducted using essays which were written by cohort members back in 1969, when they were 11 years old. The cohort members were asked to 'imagine what their lives would be like at age 25' and these essays have since been analysed using new technology to pull out cues to their economic status, physical activity, health and cognitive function in later life.

NCDS is not only a useful source of information looking at impacts over time; it is also a valuable source in understanding life at particular ages. As our cohort members will be 62-65 years old when they are interviewed, this cohort is the best resource we have for understanding how retirement and ageing are changing in Britain and how people of this age group are preparing for their forthcoming retirement.

It is not only the survey data we collect which provides useful insight, we have also collected a range of health measurements and biological samples and will be doing so again this time. Data collected previously from NCDS study members has been part of the largest ever investigation into the genetic underpinnings of common medical conditions such as diabetes, rheumatoid arthritis and coronary heart disease.

If you would like to review further details on research which has been produced using NCDS data, this is detailed in the 'Life in Your Early 60s – Survey Guide' as well as the NCDS website: **www.ncds.info**

1.6 Keeping in touch with cohort members between sweeps

CLS send a birthday card to every cohort member each year. The last birthday mailing took place in March 2021, and marked cohort members' 63rd birthday. A 'Change of Address' card was included in this mailing for cohort members to complete and return should they have any updates in their address details.

CLS has produced a book for cohort members which celebrates the 60th anniversary of the study. The book was sent to cohort members with their birthday card in at the beginning March 2019.

CLS also maintains a website for cohort members (www.ncds.info), a Freephone number, Freepost address and email address, and cohort members are encouraged to get in touch to let us know of any changes of details. These contact details are given to cohort members in letters and leaflets.

In advance of each wave and the main interview, cohort members are sent an advance letter and the survey guide leaflet by the NatCen office around a week before interviewer fieldwork.

2 Equipment overview

Blood pressure	
Item	**Purpose**
Omron HEM 907 blood pressure monitor	For measuring BP
AC adapter for monitor	For charging monitor at home
Small (17-22cm), standard (22-32cm), large (32-42cm) and extra-large (42-50cm) adult blood pressure cuffs	For measuring BP
Stopwatch	For standing BP module
Digital thermometer and probe	For measuring ambient air temperature during the BP module
Disposable arm sleeves	For measuring BP (if needed)

Grip	
Item	**Purpose**
Jamar Plus Digital Dynamometer	For measuring grip strength
Antibacterial wipes	For cleaning dynamometer

Leg raise (balance)	
Item	**Purpose**
Stopwatch (as above)	For measuring time respondent was able to stand on one leg for.

Anthropometry	
Item	**Purpose**
Tanita Body Fat Scales & bag incl. batteries & spares	For measuring weight and body fat percentage
EasyCheck – extra-long (200cm) retractable tape measure	For measuring waist and hip circumference
Antibacterial wipes (as above)	For cleaning equipment

Timed walk	
Item	**Purpose**
Stopwatch (as above)	For measuring time respondent takes to complete walk
Measuring tape (rigid)	For measuring out the walking distance

Blood sample		
Standard equipment		
Reliswabs (70% alcohol)		
Reliwipes (non-alcohol)		
Antibacterial wipes/hand gel		
Surgical (non-latex) gloves (S/M/L)		
Tournistrips tourniquets (single use)		
BD Straight Vacutainer Needles (21G/23G)		
BD Multiway Vacutainer Needles (21G/23G)		
Gauze		
Micropore tape (if spot plater not to be used)		
For each cohort member (CM)		
Blood tubes (5)		
Type	**Colour of top**	**Quantity per CM**
5 ml / Rapid serum tube (RST)	**Orange**	1
2.5 ml / SST tube	**Gold**	1
3 ml / K_2 EDTA tube	**Lilac**	1
6 ml / K_2 EDTA tube	**Purple**	1
5 ml / PPT EDTA tube	**White**	1
Plastic clamshell dispatch pack with 2 slots for blood tubes (for RVI lab)		
Plastic clamshell dispatch pack with 5 slots for blood tubes (for Bristol lab)		

PINK polybag (with tracked 48H labels for RVI lab attached)
BLACK polybag (with tracked 48H labels for Bristol lab)
Centrifuge equipment
Centrifuge (Horizon 642 VFD)
Power lead
6 red tube carriers in an A5 jiffy bag
1 balancing tube filled with green water

PPE
Standard equipment
Face masks
Pack of disinfectant wipes
Hand sanitiser
Disposable gloves
Disposable aprons
Laminated COVID screener

3 NatCen NCDS protocol for blood pressure measurement

3.1 Overview

Blood pressure is the exertion that the blood applies to the arterial walls as it is pumped through the circulatory system by the heart. Having a high blood pressure is a contributory risk factor for cardiovascular disease and stroke. It is important that we examine blood pressure using a standard method to see the distribution of blood pressure measurements across the population and changes over time.

In the NCDS 2020-23 Survey we are taking 2 rounds of blood pressure measurements while the participant is seated and 1 measurement while standing. The difference between standing and resting blood pressure has been shown to be more predictive of cardiovascular events than resting blood pressure alone.

1. **Seated:** Near the beginning of the health visit you will take 2 BP measurements while the respondent is seated. This will be after **4 minutes rest**

2. **Standing:** Immediately after that, you will ask the respondent to stand up for 1 minute and then you will take another BP measurement whilst they're still standing.

All BP measurements for NCDS should be taken on the **left arm** whenever possible so it is comparable with previous waves which have used the left arm too.

3.2 Blood pressure COVID-19 protocol

- An arm sleeve will be provided for the respondent to put on under the BP cuff, if they are not already wearing an appropriate long sleeve top, to avoid direct contact with bare skin.
- Written consent to give their BP results to their GP will be collected later when they consent to the blood sample.
- After the cuff has been placed on the respondent, to the extent it is possible, you should maintain social distance from the cohort member.

3.3 Equipment

You will need **(NCDS-specific BP equipment in bold)**:

- An Omron HEM 907 blood pressure monitor
- Small cuff (17-22 cm)
- Standard cuff (22-32 cm)

- Large cuff (32-42 cm)
- Extra-large cuff (42-50cm)
- An AC adapter (for putting Monitor on charge at home)
- Stopwatch
- Thermometer (to measure air temperature)
- Disposable arm sleeve

3.4 Seated Blood Pressure

Remember that you should:

- Only get the respondent to **rest for 4 minutes**.
- Measure it on the **left** arm whenever possible.
- Ask the respondent to wear the arm sleeve if they are bare-armed before proceeding with the measurement.

As the standing BP measurement follows immediately after seated BP, do not remove the cuff from their arm.

3.5 Standing Blood Pressure

If the cohort member has agreed to have their standing blood pressure measured, the standing blood pressure measurement will follow immediately after the seated blood pressure measures.

The Omron automatically carries out three measurements with a one-minute gap between each reading, so you do not need to adjust anything on the Omron for the standing measurement.

You must **restart the stopwatch** when you ask the cohort member to stand. This is so that you can record the time between asking the cohort member to stand and the measurement being taken in case the measurement is interrupted.

You can **help the cohort member to stand** if they need help.

If the standing time is interrupted (for example, if the cohort member needs to answer the front door), then you should change the Omron **MODE** selector knob to **SINGLE**. If the interruption has caused the cohort member to move around (e.g. answer the door), have the cohort member sit for 2 minutes, then ask them to stand, re-starting the stopwatch, and take the measurement after 1 minute. If the standing time is interrupted due to an error reading, etc, take the measurement as soon as the cohort member is standing and ready, stopping the stopwatch as the measurement starts.

The CAPI will ask you whether the standing measurement was taken as the 3rd automatic reading. In these situations, you should say **No**. You will then be prompted to record the time on the stopwatch.

3.6 Feedback to participants

Respondents will only be given their seated blood pressure measurements. The computer tells you which readings to write on the respondent's measurement record card and what advice to give about when they should see their doctor (if at all). If the respondent wishes we can send their BP results to their GP. They need to give written consent for this – this will now be done at the same time as collecting consent for the blood sample.

4 NatCen NCDS protocol for grip strength measurement

4.1 Overview

Hand-grip strength affects everyday function (such as raising the body weight or holding heavy objects) and declines with age. An indicator of general muscle strength, grip strength has been found to be predictive of disability, cardiovascular health and mortality. It is measured with a hand-grip dynamometer which consists of a gripping handle and an amplifier with digital displays.

In NCDS:

- We are using a digital dynamometer (so the results are comparable with the 1946 Cohort)
- Respondents should do the test sitting down (**NOT standing**), with the dynamometer **supported by the nurse**
- We are only taking 2 measurements on each hand
- The order of the measurements is L, R, L, R (regardless of which is the dominant hand)
- You should NOT ask the respondent to practice.

4.2 Grip Strength COVID-19 protocol

- The respondent will move the dynamometer from one hand to the other (rather than the nurse doing this).
- Ensure equipment is cleaned before and after use.

4.3 Equipment

- Jamar Plus digital dynamometer
- Antibacterial wipes

4.4 Eligibility

Exclusion criteria:

- swelling or inflammation, severe pain or recent injury in their hands
- surgery to the hand in the last 6 months (if there is a problem with one hand only use just take measurements on the other hand)
- Seated systolic blood pressure over 200 or diastolic blood pressure over 120.

- If the participant is unwilling or unable to do this test you will be asked to record full details about the reason for this in the CAPI. Please provide as much information as you can.

4.5 Procedure

4.5.1 Determining measurements to be taken

1. **READ OUT**: *"Can I just check, have you had a recent hand injury, swelling or surgery to either hand in the last six months?"*
    a. If yes, do not attempt the grip strength measure with the affected hand(s). If the respondent cannot use hand(s) for this or any other reason, you will code this in the CAPI.
    b. If the respondent has use of only one hand, the CAPI will instruct you to perform two measurements with only that hand.

2. **READ OUT**: *"Now I would like to assess the strength of your hand in a gripping action. Are you willing to have your grip strength measured?"*

    If the participant is unwilling or unable to do this test you will be asked to record full details about the reason for this in the CAPI. Please provide as much information as you can. This is the end of the module for these participants. If the participant is willing to do the test, please select 'Yes' and proceed with the test.

3. If the participant is willing to do the test and has use of at least one hand, **READ OUT***: "Which is your dominant hand?"*

    Proceed with the tests (if participant has use of both hands the order of the tests will be: Left hand, Right hand, Left hand, Right hand).

4.5.2 Taking the measurement

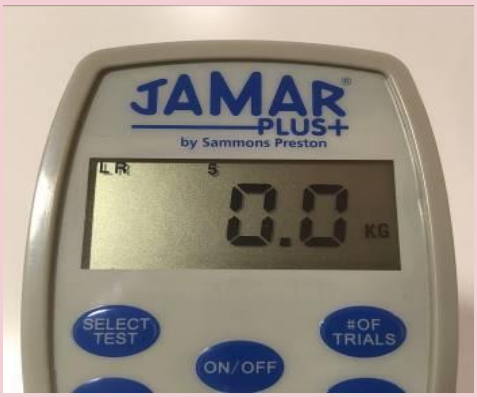
1. Remove the dynamometer from its case. The CAPI will instruct you to set the grip size to the second position. All cohort members should use the second position. This is done as follows:
    a. Detach the lower part of the moveable handle from the metal slots
    b. Detach the upper part of the moveable handle from the metal slots
    c. Reattach the upper part of the moveable handle to the second metal slot (that is, the slot second closest to the handle).
    d. Reattach the lower part of the moveable handle.

2. The CAPI will instruct you to set the dynamometer to the correct setting. The display panel should show KG on the right-hand side and LR 5 in the top left-hand corner.

Setting the dynamometer display to LR 5

a. Press **[SELECT TEST]** until it reads “LR1” in the top left hand corner of the display panel
b. Then press **[# OF TRIALS]** until the number “5” is displayed on the panel. You will only need to do 4 measures (2 on each hand), but the LR5 setting allows you a total of ten, in case of mistakes.

LR1



LR5

3. You will then demonstrate the measure to the respondent. You will first demonstrate the correct position to the respondent.

Correct position:

The measurement MUST be taken with the respondent in the following position:

- Seated, at the front of the chair
- Both feet flat on the floor
- Arm close to, but not touching, their side
- Elbow at a 90 degree angle
- Their thumb facing upwards
- Their wrist in a neutral, but slightly extended position.

Arm at a 90-degree angle

Why is it important to support the dynamometer for the CM?

We want to make sure we are measuring *grip strength*, not overall strength. If you do not support the dynamometer, they will have to use their muscles to hold the dynamometer up. Some will find this harder than others, and it may affect our measurement of their grip strength unfairly.

Arm far from body

Arm close to body

Arm close to body but not touching

4. Ask the respondent if they have any questions.
5. Once the respondent is happy to proceed, place the dynamometer in the respondent's hand (the CAPI will tell you which hand). Large rings may need to be removed.
6. **READ OUT:** "*After I say 'And go' squeeze this handle as hard as you can for a couple of seconds and then let go*".
7. Press the "**TEST**" button. The dynamometer will beep to indicate that it is ready. Check that a number in the left-hand corner of the display is flashing and that the display reads 0.0.

8. Support the bottom of the dynamometer (as shown above).
9. **READ OUT:** "*And go! Squeeze, squeeze, squeeze!"* Make sure you say "squeeze" exactly **three** times, and not more.
10. After a few seconds, tell the respondent to stop. Record the result into the CAPI to the nearest 0.1kg.
11. You will now repeat the measure again, up to three more times, depending on whether the respondent has use of both hands. The CAPI will tell you which hand to use at each stage.
12. Once all four measures (or two measures if the participant only has use of one hand) are recorded turn the dynamometer off by pressing the **[On / Off]** button.
13. Wipe the grip of the dynamometer with an antibacterial wipe.
14. Reset the grip position to the minimum (1st position) and place the dynamometer back in the box.
15. Record any problems with the measurements into the CAPI.
16. Ask the respondent if they would like their measurements recorded on their measurement record card. Averages will be displayed by the CAPI for each hand.

5 NatCen NCDS protocol for blood sampling (non-fasting) and centrifugation

5.1 Overview

The protocol for taking blood samples set out below is written in accordance with the Clinical Procedure Guidelines: Venepuncture. All nurses are to read this document before carrying out any venepuncture procedure.

Blood samples are taken from participants as they provide information on various analytes, giving a detailed description of the health of an individual. They are integral to the research NatCen undertakes as they give a comprehensive representation of the health of the population that cannot be obtained from any other source.

Blood samples will **not** be tested for any viruses, such as HIV (AIDS).

The collection of blood samples in the NCDS 2020-23 Survey will provide a range of invaluable biomarker data. The planned analytes will provide indicators of participant's lipid profile, inflammatory markers, glycaemic status and metabolic markers of heart failure.

The following analytes will be measured on the blood samples: Total/HDL cholesterol, HbA1c, Triglycerides and C-Reactive Protein. In addition, cTn, NT-pro-BNP, DNA, Proteomics and NMR/Metabolomics assays may also be conducted.

If consent is obtained, Total/HDL cholesterol and HbA1c test results will be fed back to respondents and/or their GP.

- The **GOLD** (2.5ml SST) and the **SMALL LILAC** (3ml EDTA) tube will be sent to the RVI-Newcastle lab.
- The **ORANGE** (5ml RST), **WHITE** (5ml PPT) and **BIG PURPLE** (6ml EDTA will be sent to Bristol lab.

5.2 Protocol summary

- **5 tubes of blood** will be collected including 2 tubes which need to be centrifuged in the respondent's home.
- The **centrifugation process** must be followed closely and requires different steps which are interspersed with the other biomeasures. The CAPI programme will prompt you to do each step.
- The blood needs to be sent to **two laboratories** so two **different dispatch notes** are needed.

- The sheets of **barcode labels are NOT preassigned** to a particular respondent before the interview; you will assign a sheet of labels to a respondent when they consent to blood collection and use the barcode scanner to enter this info into CAPI. All labels start with “61”.

5.3 Blood sample COVID-19 protocol

- Centrifuge must be placed at least 2m away from the nurse (ideally in a separate room to where the interview is taking place) to reduce the potential risk related to the possible exposure to aerosol generated from the centrifuge. If this is not possible, then the centrifuge should not be used on that occasion.

5.4 Exclusion criteria

All participants with the following exceptions are not eligible to give blood:

- Pregnant women
- Participants who are HIV positive or who have hepatitis B or C (see section **Error! R eference source not found.**)
- People with clotting or bleeding disorder

  By clotting or bleeding disorders we mean conditions such as haemophilia and low platelets, i.e. thrombocytopenia. There are many different types of bleeding/clotting disorders but they are all quite rare. The reason these participants are excluded from blood sampling is that:

  a) the integrity of their veins is extremely precious

  b) we do not wish to cause prolonged blood loss

  For the purposes of blood sampling, those who have had, for example, a past history of thrombophlebitis, a deep venous thrombosis, a stroke caused by a clot, a myocardial infarction or an embolus are NOT considered to have clotting disorders.
- Those aged 16 and over who have had a fit (e.g. epileptic fit or convulsion) in the **last 5 years** should not be asked to provide a blood sample. Children, those aged 15 and under, who have **ever** had a fit are usually not asked to provide a blood sample. However, if the fit occurred more than 5 years ago, project specific guidance may allow a blood sample to be taken if the participant and parent/guardian consents.
- People who are **currently** on anticoagulant drugs, e.g. Warfarin therapy.

  Check if the participant has a clotting or bleeding disorder or is on anticoagulant drugs, such as Warfarin, and record this in CAPI. These are very uncommon. If you find someone with these problems, do not attempt to take blood, even if the disorder is controlled.

Aspirin or other antiplatelet therapy is **not** a contraindication to blood sampling. If you are uncertain whether a condition constitutes a contraindication to blood sampling, the CAPI programme may have a help screen (press F9) which will guide as to the medications that are antiplatelet medications as opposed to those that are anti-coagulant medications.

- Adults who are not willing or able to give their consent in writing or children whose parent/guardian is unwilling or unable to give consent in writing.

5.5 Consent

As blood sampling is an invasive procedure, we need to ensure that fully informed written consent is obtained from each participant. Information on what they are consenting to is mainly given in the Stage 2 leaflet, and the participant confirms that they have been provided with this information on the consent form.

The cross-project leaflet 'Giving a blood sample' also provides useful information about the risks around giving a sample and after-care. This is information that you should be giving verbally in any case, and you therefore do not need to ensure that the participant has read this leaflet in advance as long as you make sure you have covered all the points yourself.

On **no** account should you ever take blood before you have obtained written consent to do so from the participant.

There are two further written consents we wish to obtain in **most** surveys in respect to blood sampling:

a. Consent to send the results to the GP (verbal consent only is required for results to be sent back to the participant)

b. Consent to store a small amount of the blood, anonymously, for future research purposes

You should seek to obtain all of the required consents before you take any blood.

Small quantities of blood are being stored in special freezers for further analysis in the future. Stored blood will only be analysed in future studies if permission for that particular study is obtained through the relevant Medical Research Ethics Committee (MREC). Any future analysis will be unlinked, which means that the research team doing the analysis will not be able to link it back to the participant. Participants will therefore not receive the results of any tests performed on their blood in the future.

The questions on the CAPI questionnaire will take you step by step through all the procedures for obtaining consents. Make sure you follow these carefully - recording consent codes as instructed and giving reasons for refusals, if applicable.

In summary:

- Ask the participant if they would be willing to have a blood sample taken. Try to reassure participants about the process and be prepared to answer their concerns. You will need to explain the importance of written consent to the participant
- Obtain written consents on the appropriate consent form (including initials **and full signature** where required).
- Remember to enter their name or serial number on each page of the form before asking the participant to sign.
- Remember to enter your name in the qualified nurse space provided on each form.
- Check that you have circled the correct consent codes on the front of the consent booklet, and that this corresponds with the CAPI instructions on screen.

5.6 Equipment

5.5.1 Field documents

- ✓ Nurse consent booklet containing consent forms and dispatch notes
- ✓ Sheet of barcode labels

5.5.2 Blood collection and dispatch equipment

In addition to your standard blood sample equipment, the following are needed **for each respondent**:

- ✓ 5 blood tubes for each respondent (see below)
- ✓ 1 plastic clamshell dispatch pack with 2 slots for blood tubes for RVI lab
- ✓ 1 plastic clamshell dispatch pack with 5 slots for blood tubes for Bristol lab (although only to contain 3 tubes)
- ✓ Test tube holder
- ✓ 1 **PINK** polybag (with tracked 48H labels for RVI lab attached)
- ✓ 1 **BLACK** polybag (with tracked 48H labels for Bristol lab attached)

5.5.3 Centrifuge equipment

- ✓ 1 centrifuge (642 VFD)
- ✓ 1 power lead (approx.140 cm)
- ✓ 6 red tube carriers in a A5 jiffy bag
- ✓ 1 “balancing” tube filled with green water

5.5.4 Tubes for blood collection

You will get a pack of 5 blood tubes for each respondent. The table below summarises the key information about the tubes for blood collection:

Blood tubes summary

Tube Order	Tube Colour	Blood Quantity & Type of Tube	No. Inver-sions	Centri-fuged?	Lab	Analytes
1	**Orange**	5 ml / Rapid Serum tube (RST)	6	Yes	Bristol	Aliquoting and storage for future use
2	**Gold**	2.5 ml / SST tube	6	No	RVI	total/HDL cholesterol/Triglycerides, C-Reactive-Protein
3	**Lilac**	3 ml / K_2 EDTA tube	10	No	RVI	HbA1c
4	**Purple**	6 ml / K_2 EDTA tube	10	No	Bristol	DNA, other analytes
5	**White**	5 ml / PPT EDTA tube	10	Yes	Bristol	Aliquoting and storage for future use

Please Note

- You will also get a balancing tube filled with green water which you might need in some visits to make the centrifuge balanced in case either the White or Orange tube is not (completely) filled.

5.6 Centrifugation

The centrifugation process separates the serum and the plasma from the cells, which is necessary for some of the analyses.

The **TWO** tubes which need to be centrifuged are the **ORANGE** (5ml RST) tube and the **WHITE** (5ml PPT) tube.

The centrifuge (Horizon model 642VFD) will be pre-set so that it spins for 10 minutes at the correct speed. The blood needs to be centrifuged as soon as possible after it is taken so we want you to centrifuge the blood in the respondent's home.

The key elements of the centrifugation procedure are also summarised in your laminated sheet.

5.6.1 Where to place centrifuge during visit

The CAPI will prompt you when to set up the centrifuge. CAPI will prompt you to place the centrifuge at least 2m away from you, ideally in a different room from the one you are carrying out the interview. If this is not possible, then centrifugation should not take place and you will have to code this in CAPI. The centrifuge has four suction feet to keep it in

place whilst spinning (to avoid the risk of it 'walking'). When spinning, the centrifuge will make a low whirring noise.

Please Note
The black rubber suction feet may leave marks on respondent's surfaces, so please be very careful where you put it.

As well as being at least 2m away from the nurse, the set-up location should:

- ✓ ideally be in a separate room, but **NOT** where animals or children can access the machine unseen;
- ✓ be on a **hard, flat and level surface** to allow the stabilizing suction feet to stick down properly;
- ✓ be close to an **electric socket** (e.g. a kitchen work top; on a hard level floor surface). The power lead provided is approx.140 cm long;
- ✓ **allow you to easily reach the power cable** in case you need to turn it off in an emergency;
- ✓ have a **clearance height of 20"** in order to open the lid;
- ✓ allow for space around the centrifuge to **let air circulate around it** - which is required for safety.

5.6.2 Inverting the tubes

It is important to invert the tubes the correct number of times. As shown in the table on the previous page:

- The first 2 tubes: **ORANGE** (5ml RST) **AND GOLD** (2.5ml SST) should be inverted 6 times.
- The second 3 tubes: **SMALL LILAC** (3ml EDTA) **AND BIG PURPLE** (6ml EDTA) **AND WHITE** (5ml PPT) should be inverted 10 times.

5.6.3 Resting the blood to clot

The blood in the **ORANGE** (5ml RST) tube should ideally clot before it can be centrifuged.

- ✓ The orange tube needs to rest for at least 5 minutes - the blood should clot after a maximum of 8 minutes.

The CAPI will tell you when to check the blood to see if it has clotted. When the blood is clotted it will look like photo 2 in Figure 1 below. You should leave the blood to rest in the tube holder in order to clot.

You will record into the CAPI whether the blood is clotted, but you will spin the blood tubes in the centrifuge **whether the blood has clotted or not**.

Appearance of clotted blood in the orange 5ml RST tube

5.6.4 How to place the blood tubes in the centrifuge

Plug the centrifuge in and turn it on at the back. Open the lid and place **all 6** (red) tube carriers into the rotor. The blood tubes should be put - coloured tops upwards - inside the tube holders. Spin the rotator head to check the rotation.

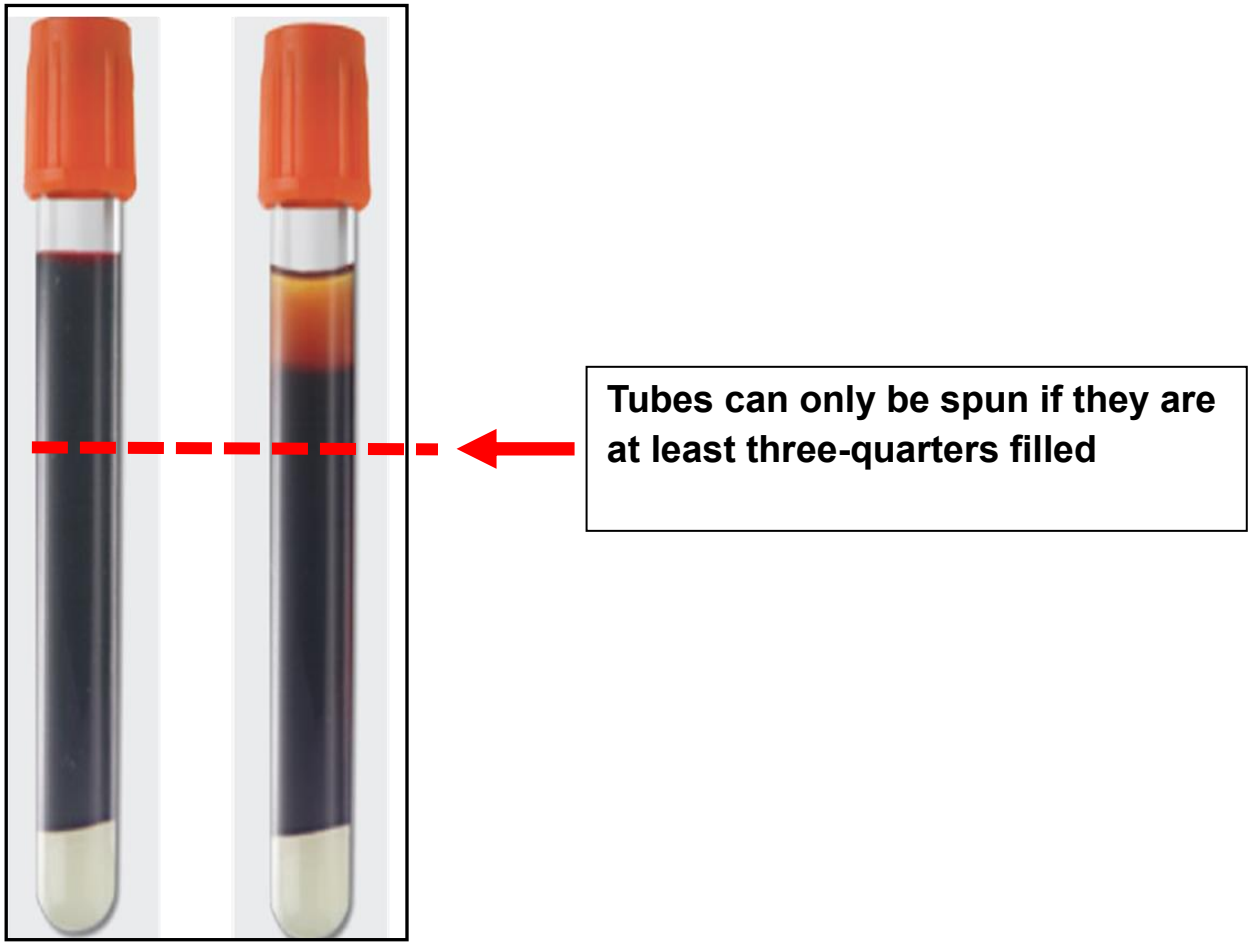
The centrifuge has space for **6 tubes**, but **the maximum number of tubes** you will need to spin is only **2**.

It is very important that the tubes are balanced in the correct way in the centrifuge. If they are not balanced, the **centrifuge could break**. So please follow the instructions for how to place the tubes in the centrifuge below very carefully.

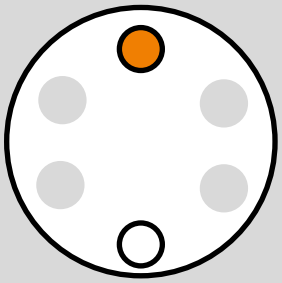
It is vital that the centrifuge contains an **even number** of tubes (i.e. 2). The 2 tubes need to be placed in an **equally weighted pair in opposite** tube holders. So if you fill only 1 of the tubes which need centrifuging you will need to put the balancing tube water-filled SST tube to the centrifuge in order to make sure the centrifuge is balanced. See table on next page.

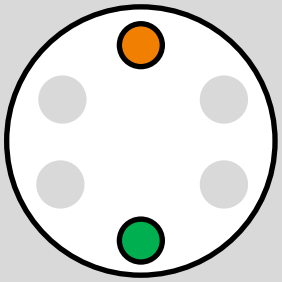
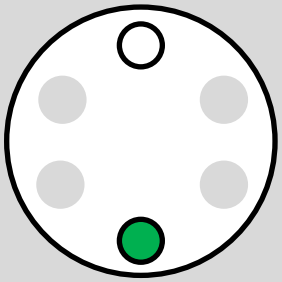
Please Note

Do NOT centrifuge partially filled tubes.



How to place tubes in centrifuge according to how many blood tubes you fill

Tubes filled	Water tube needed?	Total tubes in centrifuge	How to arrange tubes	
2 tubes filled: 1 orange 1 white	No	2	Place orange tube opposite white tube	

If only **orange** tube is filled:	Yes	2	Place **orange** tube opposite **water** tube	
If only white tube is filled:	Yes	2	Place white blood tube opposite **water** tube	

5.6.5 How to operate the centrifuge

Once you have recorded into CAPI whether the blood in the ORANGE tube has clotted you can centrifuge the blood. The CAPI will tell you when to do this.

Before you start the centrifuge, make sure the tubes have been inserted correctly as above then shut the lid. To close and lock the lid, turn the lid knob clockwise to its complete stop position. The LOCKED/UNLOCKED indicator lights show whether the latch is closed properly. If the lid knob is not completely latched, the centrifuge will not operate. When the lid knob is correctly closed, the LOCKED light will turn on. The START button will now operate.

The centrifuge will be pre-set, so you only need to push the START button to operate it.

When the centrifuge is spinning, the RUN indicator light should go on. The RUN indicator light will begin to **flash** when one minute remains.

You will know the centrifuge has finished because it will beep once, the RUN indicator light will go out and the rotor will come to a complete stop.

The UNLOCKED indicator light will illuminate and the locking mechanism will disengage. Turn the dial counterclockwise on the lid to open it and take the blood samples.

Figure *- The 642VFD centrifuge.*

5.6.6 Troubleshooting

If a problem is found during a spin that requires the centrifuge to shut down, press the OPEN/STOP button. The 'RUN' indicator light should go out and the rotor should slow to a stop. The lid will remain locked until the rotor has fully stopped.

5.6.7 Cleaning

ONLY use the standard anti-bacterial wipes or alcohol wipes to clean and disinfect the centrifuge and accessories. All surfaces must be dried immediately after cleaning and disinfecting.

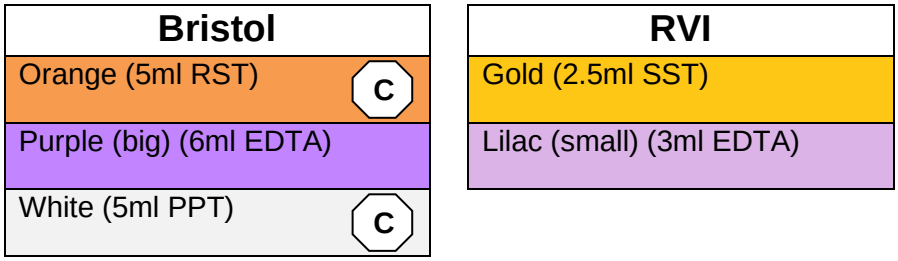
5.6.8 Packing and carriage

The 6 red tubes carriers need to be transported **separately from the centrifuge**. They cannot be left in the centrifuge, otherwise they can get dislodged and fall into the rotor chamber damaging the machine. Please place them in a jiffy bag once you have finished with the centrifuge at the end of the visit.

5.6.9 Practice at home

You should **practice setting up the centrifuge at home** at least once.

5.7 Laboratories – what to send where



C = Centrifuged tubes

Please note: neither of the tubes to be sent to RVI needs centrifuging

5.8 Preparing the participant

The protocol on preparing the participant can be found in the Venepuncture Clinical Procedure Guidelines (CPG) in Chapter 6. Further points to note include:

- Asking the participant to remove any jackets, thick garments and/or roll their sleeves up, so that you can assess which vein in the antecubital fossae may be the most suitable to take the sample from.
- Ensuring they are in a comfortable, safe position and instruct the participant to remain as still and relaxed as possible.

5.9 Procedure

5.9.1 Asking consent

You will need to explain to the participant the need for written consent and how important it is. Please note, **both signature and ticks/initials are needed**. The participant will be asked to give written consent to the following:

- to take the blood sample for analysis
- to inform their GP of the results of the analyses
- to blood being stored for future analysis
- to a sample of blood being taken for DNA extraction, analysis and storage for research purposes

Cohort members may ask why we are asking for samples for DNA extraction again, as many may have given permission to extract DNA from blood samples in the 2002-4 survey. A second DNA sample provides a unique opportunity for research within the new field of 'epigenetics' which investigates how and why genes are expressed and the effect this may have on health and other aspects of life.

Respondents will also be asked for verbal consent to send them the results of their blood tests and you will be prompted to circle the appropriate consent codes on the front of the consent booklet.

Please note that to reduce the passing of documents, you will ask consent for their blood pressure results to be sent to their GP at the same time as the blood sample consent. This will be done in the blood sample module.

5.9.2 What to do step-by-step

Please follow these steps when taking the blood samples for NCDS. The CAPI will prompt you about each step.

STEP 1	Asking Consent
1.1	Ask the participant if they would be willing to have a blood sample taken. Try to reassure participants about the process and be prepared to answer their concerns.
1.2	Complete the consent form obtaining the relevant **signatures and ticks/initials** to take the blood sample and to send the results to the respondent's GP.
1.3	Check that you have all the respondent's ticks/initials and signatures in the appropriate sections of the booklet.
1.4	Check that you have circled the correct consent codes on the front of the consent booklet.
1.5	Assign a sheet of barcode labels to the respondent using the barcode scanner
1.6	You are now ready to take the blood sample. Prepare all the equipment you need and make sure you are using the correct sheet of barcode labels (which you have assigned to this respondent).
STEP 2	**Taking the blood samples, inversion and labelling of the tubes**
2.1	Take the 5 blood samples following this order: 1. Orange (5ml RST) 2. Gold (2.5ml SST) 3. Lilac (small) (3ml EDTA) 4. Purple (big) (6ml EDTA) 5. White (5ml PPT)
2.2	Gently invert the first 2 tubes taken 6 times, and next 3 tubes 10 times: **6 Times** ORANGE (5ml RST) **AND** GOLD (2.5ml SST)

	10 Times SMALL LILAC (3ml EDTA) **AND** BIG PURPLE (6ml EDTA) **AND** WHITE (5ml PPT)
2.3	Put barcode labels on **all** the tubes, place the barcode labels on top of the existing blood tube labels
STEP 4	**Rest tubes for 5 minutes minimum**
4.1	If you have filled the tubes of blood which need centrifuging: • Place the **ORANGE** (5ml RST) and WHITE (5ml PPT) tubes in the test tube holder. • Remember the WHITE (5ml PPT) does not need to clot but it is easier if you keep these tubes together • Leave them there to rest for at least 5 mins. The CAPI will tell you when to check the tubes to see if they have clotted.
STEP 5	**Prepare the small clamshell for RVI (gold and SMALL lilac tubes)**
5.1	Place the **GOLD** (2.5ml SST) and **SMALL LILAC** (3ml EDTA) tubes in the small clamshell.
5.2	Complete the **RVI** dispatch note and the office dispatch note. The CAPI will tell you whether to tick YES or NO for "Consent given to storage for future analysis" based on the consents given earlier.
5.3	Place the small clamshell and RVI dispatch note in the pink polybag for mailing.
5.4	Stick on the 48-hour tracked label **for RVI** on the pink polybag (if not already included).
5.5	Use the barcode scanner to scan the barcode of the 48-hour tracked label that is on the pink polybag for RVI.
STEP 6	**Set up the big clamshell for Bristol**
6.1	Place the remaining **BIG PURPLE** (6ml EDTA) tube in the big clamshell.
6.2	Put the big clamshell and the BLANK dispatch note in a safe place. You will finish packing it at the end of the visit when the other tubes have been centrifuged.
STEP 7	**Centrifuging the blood (if possible)**
7.1	After the Timed Walk, the CAPI will prompt you to check the **ORANGE** (5ml RST) tube resting in the test tube holder to see if it has clotted. Compare the tube against the picture of clotted blood on the laminated sheet, and record in the CAPI.

7.2	Find a suitable place for the centrifuge and plug it in but do not start it. Open the lid and spin the rotator, place all 6 red tube holders in the rotor, place the ORANGE and WHITE tubes **opposite** each other. If you have only filled 1 of these blood tubes place the green balancing tube opposite it instead. **Shut the lid** and **turn the lid knob clockwise to its complete stop position**. The 'LOCKED' indicator light should turn on to indicate that the latch is closed properly. If the lid knob is not completely latched, the 'LOCKED' indicator light will not turn on and the centrifuge will not operate.
7.3	**Turn on the centrifuge** by pushing the START button on the control panel. The centrifuge will be pre-set to spin for 10 minutes. You don't need to time it. The RUN indicator light should go on. The RUN indicator light will begin to flash when one minute remains. If the centrifuge does not complete the 10 minutes of spinning uninterrupted, do not restart the process.
STEP 8	**End of the centrifugation process**
8.1	After the GP details module the CAPI will tell you to get the blood tubes out of the centrifuge. You will know it has finished because you will hear one loud beep - the RUN indicator light will go out and the rotor will come to a complete stop. The 'UNLOCKED' indicator light will go on and the locking mechanism will disengage.
8.2	When the centrifuge has stopped, turn the lid knob counterclockwise and open the lid. Remove the blood tubes.
8.3	Switch off the centrifuge and unplug it. Remove the red tubes carriers and put them in the jiffy bag.
STEP 9	**Finish packing the blood samples for Bristol**
9.1	Place the remaining tubes in the big clamshell for Bristol. This should now contain (up to) 3 tubes: **ORANGE** (5ml RSTs), WHITE (5ml PPT) and **BIG PURPLE** (6ml EDTA).
9.2	Place the big clamshell in the black striped polybag for Bristol.
9.3	Finish and check the dispatch form for Bristol and put it in the polybag.
9.4	Stick the 48-hour tracked label **for Bristol** on the black striped polybag (if not already included)
9.5	Use the barcode scanner to scan the barcode of the 48-hour tracked label that is on the black striped polybag for Bristol.

5.9.3 Scanning the 48h tracked labels

After filling out the dispatch forms for each lab, CAPI will prompt you to scan the barcode on the Royal Mail tracked 48H label. Please make sure that you scan the barcode (not the QR code), taking care to ensure that the correct label is scanned for each lab.

Below is a picture of what the Royal Mail tracked labels look like (although the image is of a 24h tracked label instead of a 48h tracked label). The barcodes are 13 characters long (circled in red below). If you are unable to scan the barcode with the barcode scanner, you should enter the 13-character barcode number into CAPI by hand, ensuring to remove any spaces.

5.9.4 Postal Strikes

There are a number of planned postal strikes during fieldwork. If you have an appointment on the day of a postal strike and you take a blood sample, you will need to make alternative arrangements to send the samples to the labs.

On the day of a postal strike, you will need to visit a Post Office and ask for a special delivery upgrade (1pm) for each sample to ensure the samples reach the labs in sufficient time. This is an additional cost of £7.65 per sample. Please keep the receipt for reimbursing the cost to INUVI.

5.11 Labelling & packaging the sample(s)

Label the tubes according to your CAPI instructions, using the barcode labels, immediately after completing the venepuncture procedure. Refer to the project specific instructions for further guidance about labelling and packaging the blood samples.

It cannot be stressed enough the importance of correctly labelling each tube correctly and according to the project instructions to link the sample to the person from whom the sample was obtained. Apart from the risk of matching up the blood analyses to the wrong person's data, we will be sending the GP the wrong results which could lead to incorrect treatment decisions, anxiety for the participant and potentially severe harm.

5.12 Other important points

'Giving a blood sample' leaflet

We need to be sure that each participant is left with information about giving a blood sample, including information about who to contact should they experience any side effects as a result of the blood sample.

To provide them with this information, leave the participant with the leaflet **'Giving a blood sample'.** The leaflet includes information on any possible side effects they may

experience such as pain and bruising, and how to care for the puncture site. It is also a useful leaflet to leave behind to reassure the friends and family of the participant of the procedure used should they have any concerns after your visit.

Venepuncture check questions

Always complete the Venepuncture checklist on CAPI for every participant from whom you attempt to and / or take blood from. This shows that you have followed the correct procedure, and noted, where applicable, any abnormalities, and the action you took. The checklist is usually towards the end of the CAPI interview schedule.

Please remember to check the participant's venepuncture site just before you leave and note any obvious bruising seen (if any).

Fainting participants

If a participant looks or feels faint during the venepuncture procedure, it should be discontinued. The participant should be asked to lie down with feet elevated.

If they agree for the sampling to be continued after a suitable length of time, the procedure should be performed with the participant lying down and the circumstances should be recorded in CAPI. **A maximum of two attempts** to gain a blood sample is allowed on any project and the second attempt may only proceed if the participant verbally agrees to the second attempt after a failed first attempt. **Blood samples must only be taken from the ante-cubital fossa, with a maximum of one attempt on each arm.**

If a participant fully faints, then you should apply the principles of first aid by:

- Calling for help / assistance, if there is another adult relative within the house
- Ensure the participant is supported safely and eased into a position lying down on their side, where they can recover. Ensure their airway is clear, so they can continue to breathe unhindered.
- Remain with the participant until they come round and feel able to slowly move to a sitting position.
- Discontinue the interview unless both you and the participant feel it is safe to continue.
- Ensure you submit a Special Report Form to the Field Quality Unit detailing what happened, what course of action you took and how the participant appeared when leaving them.
- **NB: - Should a participant not recover as quickly as expected from a fainting episode then the course of action is to phone the Emergency Services and hand over the situation to them.**

Fitting participants

It is rare for a participant to experience a fit or experience a convulsion during the venepuncture procedure, especially as those with a declared history of fitting or convulsion within the previous 5 years will have been excluded. However, there is always

a possibility of this happening, as a severe vasovagal response to the needle being inserted.

If a participant appears to have an episode of fitting or convulsion during or immediately after venepuncture procedure, then you should apply the principles of first aid by:

- Calling for help / assistance, if there is another adult relative within the house. **If there isn't any other person in the household to support / assist you, then you should call the emergency services.**
- Ensure the participant is supported safely and eased into a position lying down on their side, with their airway supported open and where they can recover safely
- Remain with the participant until they come round, monitor their level of response and breathing. **NB: - Should a participant not recover as quickly as expected, phone the Emergency Services and hand over the situation to them, particularly if there is no other adult household member in attendance.**
- Ensure you submit a Special Report Form to the Field Quality Unit detailing what happened, what course of action you took and how the participant appeared when leaving them.

Handling & disposal of needles and other materials

Safe disposal of needles is required to control the risk of injury from the contaminated sharps. Without the safe disposal of needles there is an increased risk of needle stick injuries and/or psychological trauma due to fear of potential infection from a blood borne virus (BBV). NatCen's policy is that only safety sharps are provided for use on all projects requiring blood sampling. Fieldworkers **must** use them as designed.

Precautions

- Wear gloves at all times when performing the venepuncture procedure to reduce blood 'transmission load' if a needlestick injury occurs
- Sharps should be disposed of at the point of use
- Do not carry sharps unnecessarily
- Sharps handling must be kept to a minimum
- Needles must not be passed directly from hand to hand
- Needles must not be bent or broken prior to use
- Safety Sharps mechanisms should always be engaged at point of use and must never be disengaged or dismantled prior to use.
- Used sharps bins must not be handed to anyone else unless they are to a collection agent for an authorised Sharps and Hazardous Waste Disposal registered service.

Disposal

Do's:

- Continue to wear gloves when disposing of sharps and related contaminated waste
- Dispose of your used sharps in the NatCen provided 1L 'sharps bins' immediately after use
- Have your sharps bin available beside you before opening and using the sharp

- Fully seal the sharps bin when the manufacturer's marked line has been reached or when it is three quarters full (see Sharps Disposal Policy)
- Check to ensure that the sharps bin lid is securely closed and sealed as per Sharps Disposal Policy

Don'ts:

- Fill sharps containers above the manufacturer's marked line
- Dispose of sharps with other clinical waste
- Put your fingers / hands into sharps bins for any reason
- Ever return any used sharps bins by post or courier to the Equipment Unit or to another member of the freelance panel by a postal / courier service for onward disposal.
- Allow non NatCen personnel (e.g. friends / family / colleagues / neighbours) to handle any sealed sharps bins on your behalf.

Any non-sharps venepuncture waste (e.g. gauze swab, gloves, plaster covering etc) should be disposed of by the participant whose sample has been taken, in their own household waste.

Needle stick injury

In the event of a Needlestick injury (by participant or fieldworker) – follow NatCen's specific needlestick injury protocol.

Participants who are HIV or Hepatitis B / C positive

If a participant volunteers that they are HIV, Hepatitis B or Hepatitis C positive, **do not** take a blood sample. Record this as the reason for not taking a blood sample in the CAPI. You should never, as a matter of course, seek this information outright unless it is specified in the Project CAPI questionnaire. Explain that the research protocol does not allow these samples to be sent onward to the lab/s.

Participants who declare they are HIV or Hepatitis B positive during or after venepuncture procedure

If a participant volunteers this information whilst a blood sample is actively being taken – then inform the participant politely that you must stop the procedure, at that point, as any blood taken for research purposes cannot be sent to the laboratory for processing. Dispose of the tubes already filled into the sharps bin and once all sharps are within the bin, the bin should be fully sealed and disposed of according to the current NatCen contaminated waste and sharp disposal procedure.

Record the relevant information into the CAPI – including completion of the venepuncture check questions.

6 NatCen standard clinical procedure guidelines for venepuncture

For the purposes of this Clinical Procedure Guideline (CPG) an adult is considered to be an individual aged 16 yrs and over, who has the 'capacity' to give voluntary, informed verbal and written consent to the taking of venous blood samples, while a participant in a NatCen Nurse/Biomedical Survey.
In order to meet both the legal and ethical requirements for valid consent to this procedure the following elements apply:

- **Capacity to consent** – means that the participant is able to understand the information given to them and can use this information to make an informed decision on whether to give consent to take part or not. For the purposes of NatCen research this requires Nurses/Biomedical Interviewers and Phlebotomists to use their judgement in some situations, as to whether the participant has the capacity to consent. If this is in doubt, then the fieldworker **should not** carry out the procedure and make note of this within the CAPI Schedule and on the Project Consent booklet that is returned to the office (see Appendix 1 for further guidance). When carrying out Nurse/Biomedical Survey work the fieldworker **cannot** accept consent in the following situations:
    - when it is given by another adult in the household, on behalf of an adult participant who is considered to have a reduced capacity to consent. This form of 'consent by proxy' is not acceptable for the giving of a blood sample.
- **Voluntary participation** – means that the decision to give a blood sample or not must be the participant's alone, without pressure from others including the Nurse/Biomedical fieldworker, Phlebotomist or other family members / individuals who may be with the participant at the time (see also 'child assent' above).
- **Informed consent** – means that the participant must be given the full information available, which relates to the blood sample requested for the project / survey. The fieldworker **must** ensure that the participant has had enough time to read this information before making their decision.

Venepuncture remains one of the most common invasive procedures performed within Health Care services. As such, it is often seen as a 'routine' type of procedure by those who perform venepuncture. However, for those undergoing venepuncture – this procedure may not be 'routine' for them, and equally exposes them to potential health related side effects that they would not be exposed to if they were not a participant in the study. It must also be remembered that participants if consenting to the giving of a blood sample, will be doing so for research data collection purposes and not because they are having a 'health check'. Therefore, there are ethically guided restrictions on how many attempts can be made to obtain a blood sample and from which venepuncture site the sample may be taken from. However, it must be remembered that the motivation for many participants to consent to a blood sample, will be because they view the results of any blood sample they may receive from their participation in the project, to be useful to them, from a health point of view.

This CPG therefore follows 'best practice' principles for venepuncture, to protect both the volunteering participants and the fieldworker carrying out the venepuncture. This CPG

therefore applies to all projects requiring venous blood samples within NatCen Survey work and should be read in conjunction with the specific Project Instructions regarding the requirements for the blood sample (number and type of blood tubes, order of draw, labelling and dispatch procedures etc.).

6.1 Exclusions from this CPG:

A participant will be excluded from this CPG if:

- Venepuncture is not a requirement of the Project they are taking part in
- The participant has a known clotting or bleeding disorder
- The participant is taking any prescribed anticoagulant medication
- The participant (of any age) has had a fit or convulsion (including an epileptic fit) in the previous 5yrs
- The participant will not, or is unable to give written consent for the venepuncture to be carried out, or in the case of a child / young person under the age of 16yrs, the parent / legal guardian is unable to, or unwilling to, give written consent for the venepuncture to be carried out.

Arrangements for excluded participants – consent to having a blood sample taken is entirely voluntary and so no alternative arrangements are required or available for excluded participants.

Equipment required:
Nurses/Biomedical fieldworkers should always ensure that they have the required equipment to hand, along with spare capacity of consumables to cover any potential second attempt of venepuncture required. All equipment should be regularly checked for expiry dates and stock control maintained appropriately.

Equipment required:	Rationale:
✓ Antibacterial/viral hand gel or wipes	➢ To reduce risk of cross infection to respondent from practitioner
✓ Clean small wipeable plastic or disposable tray to lay out equipment on and provide a clean work area	➢ To reduce the risk of introducing infection from respondent's surrounds
✓ Well-fitting disposable vinyl gloves	➢ To reduce the risk of cross infection ➢ To reduce the impact of potential inoculation of a blood borne virus should a Needlestick injury occur to the fieldworker
✓ 70% alcohol impregnated skin cleansing swab (or non- alcohol water-based swab supplied for those participants who do not wish alcohol on their skin)	➢ To reduce risk of cross infection into venepuncture wound from respondent's own skin surface flora (e.g. *Staphylococcus aureus*)
✓ Disposable Tourniquet	➢ To reduce risk of cross infection associated with reusable, material-based tourniquets.

✓ 21g, 23g straight and / or 'butterfly' safety needles (appropriate to the blood sampling system being used – Vacutainer or Monovette)	➢ To enable the right needle to bore for the respondent's anatomy to be chosen, thus reducing the risks of potential side effects (e.g. haematoma). ➢ To reduce the risk of Needlestick injury to the fieldworker
✓ Appropriate 'in date' sample tubes (according to the blood sampling system being used for the Project)	➢ To ensure that the research data gained through the blood sample is useable.
✓ Disposable gauze swabs	➢ To provide immediate short term wound cover following removal of the needle from the vein and skin layers.
✓ Hypoallergenic spot plaster or gauze swab and micropore (for those who may be allergic to plaster adhesive).	➢ To provide longer term wound cover and reduce the risk of infection following the procedure.
✓ 1L sharps bin with semi & full closure mechanism.	➢ To comply with COSHH regulations for disposal of hazardous waste.
✓ 'After you've had a blood sample' NatCen participant leaflet	➢ To provide follow up information to the participant in the event of any side effects felt once the fieldworker has left the household.

Procedure for Venepuncture:
*Written consent **must** have been gained, according to the specific project instructions, **before** these steps are followed.*

Action	Rationale
1. Ensure that you and the participant are in a comfortable, suitable and well-lit position to commence the procedure and cope with any potential fainting or fitting. a. If taking blood from a child, gain the parent / legal guardian's assistance and make sure that undue restraint is not to be used. If children are non-compliant the procedure should be abandoned.	➢ To optimise participant and own comfort and minimise risk of harm to participant and yourself, through good musculoskeletal positioning. ➢ To provide appropriate recovery space should the participant feel faint or starts to fit. ➢ To ensure children are feeling safe and secure during the procedure and that we or parents are not inappropriately restraining them.
2. Ask the participant to remove any jackets, thick garments and/or roll their sleeves up.	➢ To gain visibility of both antecubital fossae. No other potential sites for venepuncture can be used for NatCen blood sampling.

3. Enquire as to whether the participant has had any previous problems having a blood sample taken.	➢ To assess the risk of potential side effects of venepuncture. ➢ To plan alternative actions to manage any increased risk present.
4. Inspect the antecubital fossa on each arm to decide, with the participant, which vein is most suitable, (either visually or through palpation).	➢ To assess the state of the veins and optimise participant comfort and best attainment of the sample on the first attempt. ➢ To identify and distinguish between the veins, arteries and tendons.
5. Cleanse your hands by appropriate washing or with antibacterial/viral hand gel or wipes prior to laying out your equipment.	➢ To reduce risk of cross infection.
6. Ensure your equipment is close to hand. Along with spare blood bottles in case a bottle has lost its vacuum.	➢ To ensure a smooth venepuncture procedure, optimise participant comfort and reduce risk of needlestick injury. ➢ To ensure a full sample draw can be obtained.
7. Identify with the participant if they have any known allergies to alcohol swabs, plaster or micropore.	➢ To ensure that an allergic reaction is avoided in a known situation. ➢ To plan for use of water-based skin prep method and alternative would closure following venepuncture.
8. Cleanse the selected site for min 30 secs with an Alcohol swab (or water-based swab if necessary), working from the centre outwards in concentric circles and allow to air dry for minimum of 30 secs.	➢ To enable the alcohol to reduce the level of surface microbes that might be drawn into the venepuncture wound site. ➢ To reduce the alcohol contamination of the first sample drawn along with reducing pain from any alcohol pushed into the skin layers upon needle entry.
9. Prepare the needle and lay bottles in the correct order of draw (as per relevant project instructions).	➢ To ensure the sample is taken in the right order to draw and minimise cross contamination of blood tube additives, which may then affect the analysis of the samples later.
10. Put on gloves.	➢ To reduce risk of cross infection for participant and reduce level of inoculation of participant serum in the event of a needlestick injury to the fieldworker.

11. Instruct the participant to remain as relaxed and still as possible through the procedure (i.e. no 'fist pumping'; patting of the antecubital fossae etc).	➢ To minimise the risk of injury to participant and fieldworker. ➢ To reduce the effect of any pre-analytical variables (e.g. haemostasis; haemoconcentration etc.)
12. Apply the disposable tourniquet	➢ To provide partial occlusion of the venous system and enable the selected vein to become fuller for the sample to be taken.
13. Stabilise the vein if required and insert the needle smoothly, bevel up, into the vein	➢ To reduce the risk of harm to the participant and maximise the gaining of a sample at first attempt.
14. If using a multiway (butterfly') needle, secure the needle on one wing with micropore tape, especially for a 'long draw'.	➢ To reduce the risk of accidental withdrawal of the needle and thus potential harm to the participant and fieldworker.
15. Loosen the tourniquet within 60 seconds of application, usually after the first tube is drawn once the flow of the sample is established.	➢ To reduce the effect of haemoconcentration and haemolysis on the blood sample analysis.
16. Continue to draw the remaining sample, in the correct project specific order of draw, inverting the blood tubes as per manufacturer's instructions.	➢ To ensure the tube additives mix with the blood sample as appropriate to the tube used and maximise the analysis.
17. Continue to monitor the venepuncture site and participant's reaction throughout sample collection.	➢ To identify any potential side effect (e.g. haematoma formation; nerve implication; misplacement of the needle). ➢ To enable the procedure to be stopped at the earliest opportunity to reduce any further harm.
18. Once the draw is finished, remove the needle (engaging the safety feature), while ensuring pressure is applied to the venepuncture site with a gauze swab. The participant should continue to provide gentle pressure on the wound site, with their affected arm extended not bent.	➢ To ensure the participant's clotting cascade commences at the wound site and minimize risk of haematoma at the venepuncture site. ➢ Ensuring the participant's affected arm remains extended at the elbow will minimise internal blood leakage into interstitial spaces and a haematoma formation.
19. Dispose of the used needle immediately into the sharps bin and	➢ To comply with COSHH regulations and minimise risk of needlestick injury to participant and fieldworker.

ensure the lid is in the 'semi close' position.	
20. Inspect the venepuncture site and cover with a spot plaster (or clean gauze and micropore if participant is allergic to plaster).	➢ To ensure any abnormalities are noted, about which the participant can be advised. ➢ To prevent cross infection
21. Provide the 'After You've Had A Blood Sample' NatCen participant leaflet and advise on not carrying heavy loads or undertaking sporting activities (using their affected arm) for the immediate 2 hrs following the venepuncture.	➢ To promote healing of the venepuncture wound and the clotting process at the needle entry point within the vein. ➢ To comply with the Project's ethical approval for provision of information.
22. Ask the participant to dispose of the consumable waste in their household waste (keeping the Sharps Bin in your equipment bag).	➢ To comply with Environmental Agency regulations for disposal of household waste. **NB:** any part used blood bottles that are not being sent to the lab in the sample pack must be placed into the Sharps Bin for disposal as per NatCen protocol for hazardous waste disposal.
23. Label, pack and dispatch the samples according to the Project instructions.	➢ To ensure the samples arrive in the lab in a fit state to be analysed. ➢ To comply with the Environmental Agency regulations on the posting of biological samples.
24. Remove gloves and cleanse your hands by appropriate washing or with antibacterial/viral hand gel or wipes.	➢ To reduce risk of cross infection.
25. Record the outcome and any abnormalities noted in the CAPI schedule and on the consent booklet where applicable.	➢ To comply with the Project instructions and enable NatCen Field quality team to follow up on any participant or lab concerns if raised.
26. Thank participant for their time and donation, provide the appropriate Project Specific incentive if applicable and Project Specific leaflet called "After you've had a blood sample".	➢ To value their sample as part of the data collection. ➢ To ensure that they receive their specific incentive (if applicable), as per the MREC approval for the Project they are participating in. ➢ To ensure that they have a point of reference should they experience any delayed side effects from the venepuncture process once the fieldworker has left the Participant's home.

Trouble shooting:
Below are some problems or issues that may arise as a result of the venepuncture process:

Problem / Issue:	Action & Rationale:
A. No visible or palpable veins in either antecubital fossae.	➢ A tourniquet can be applied for a short period of time to see what suitable veins become visible and / or palpable. This must be released fully again, prior to preparation of the targeted venepuncture site and the blood flow allowed to return to normal for a few minutes, before undertaking venepuncture. ➢ If still no visible or palpable veins - **do not** attempt venepuncture and code as appropriate in the CAPI schedule. MREC approval does not currently allow NatCen nurses/biomedical interviewers / phlebotomists to undertake venepuncture at any other site (e.g. back of hand).
B. The participant experiences pain and / or tingling in their arm / hand when the needle is inserted (with no flash back of blood into needle or bottle).	➢ Remove the needle immediately and discontinue the procedure. The needle may have hit a tendon or nerve rather than entering the vein. Code as appropriate in the CAPI Schedule. ➢ Monitor participant's pain / tingling and advise accordingly. ➢ After the visit, complete a Special Report Form to submit to the Field Quality Unit.
C. The participant experiences more than slight pain when the needle is inserted, **and** the blood bottle fills very quickly with bright red blood.	➢ Most likely an arterial puncture has occurred. ➢ Remove the needle immediately and discontinue the procedure. ➢ Apply immediate pressure to the site and elevate the participant's arm for **at least** 5 minutes to aid the clotting cascade and reduce effect of injury. ➢ Monitor participant's pain and whether there are any signs of haematoma formation. ➢ Code as appropriate in the CAPI Schedule. ➢ Advise participant regarding any further pain or side effects that might be experienced, once you have left the house.

	➢ Contact the Project specific Survey Doctor and Biomedical Centre to inform them of the situation and actions you've taken. ➢ After the visit, complete a Special Report Form to submit to the Field Quality Unit.
D. There is no flow of sample, once needle is inserted into the vein and the evacuated blood bottle attached (i.e. BD Vacutainer® blood bottle or pre evacuated Monovette® blood syringe).	➢ Bevel of needle may have moved within the vein and be 'sucking' at the vein wall. Rotate the needle laterally slightly to release the bevel. ➢ Needle tip may have advanced through the posterior vein wall. Withdraw the needle slightly to bring bevel back into vein lumen. ➢ Vacuum of blood bottle may be lost. Use a replacement tube in the same order of draw.
E. The blood flow reduces once the tourniquet is released.	➢ Retighten the tourniquet if it has not been in place for the full minute. Venous flow may be reduced in the elderly and in those with fragile veins; therefore, some further occlusion of vein may be required.
F. A haematoma is seen developing at the site of the venepuncture during the process.	➢ Remove the needle immediately and discontinue the procedure. The needle may have gone directly through the anterior and posterior vein wall. ➢ Code as appropriate in the CAPI Schedule. ➢ Apply pressure to the wound site to facilitate the clotting cascade. ➢ Monitor participant's haematoma and advise accordingly. ➢ After the visit, complete a Special Report Form to submit to the Field Quality Unit.
G. The participant becomes / feels faint during the process.	➢ Remove the needle immediately and discontinue the procedure. ➢ Call from assistance from another household member if available. ➢ Assist the participant to a position in which they can recover (ideally laying down with legs raised). ➢ Monitor their recovery and advise accordingly regarding any further side effects of venepuncture they may

	experience after you have left the house. ➢ Code as appropriate in the CAPI Schedule.
H. The participant fully faints (i.e. has a loss of consciousness)	➢ **As above steps (in G)** ➢ Summon the Emergency Services if the participant does not appear to be recovering as quickly as you would expect, **or** if you feel you need urgent medical assistance for the situation. ➢ If the Emergency Services are called, then contact the Project specific Survey Doctor and Biomedical Centre to inform them of the situation and actions you've taken. ➢ After the visit, complete a Special Report Form to submit to the Field Quality Unit.
I. The participant experiences a fit during the process.	➢ Remove the needle immediately and discontinue the procedure. ➢ Call from assistance from another household member if available. ➢ Assist the participant to a position (if necessary) which can allow the fit to pass without them injuring themselves and which keeps their airway open throughout. ➢ Summon the Emergency Services if the participant does not appear to be recovering as quickly as you would expect **or** if you feel you need urgent medical assistance for the situation. ➢ Monitor their recovery and advise accordingly regarding any further side effects of venepuncture they may experience after you have left the house. ➢ Code as appropriate in the CAPI Schedule ➢ If the Emergency Services are called, then contact the Project specific Survey Doctor and Biomedical Centre to inform them of the situation and actions you've taken. ➢ Complete a Special Report Form to submit to the Field Quality Unit.

6.2 Mental Capacity to Consent for Venepuncture – Guidelines for Assessment

A participant's mental capacity must be assessed at the time the decision to allow a blood sample to be taken needs to be made. In the case of children and young people (under 16yrs), this will also apply to the parent or legal guardian of that child / young person.

The Nurse/Biomedical fieldworker / Phlebotomist must assume that the participant has the capacity to consent, rather than assuming that they do not have this capacity, based on their age; appearance; health condition; or behaviour displayed at the time of the visit. The Nurse/Biomedical fieldworker / Phlebotomist must also not assume any lack of capacity to consent based on any reports given by an interviewer, who has previously visited the participant. Although this information might provide some background to the situation, the Nurse/Biomedical fieldworker / Phlebotomist must make their own judgement when they see the participant themselves.

In order to assess if the participant can make the decision to consent to a Blood Sample being taken or not, then the Nurse/Biomedical fieldworker / Phlebotomist must be satisfied that the participant:

- understands what the blood sample is for; how it will be used by the research team/s; how the sample is to be taken; whether there are any side effects of the procedure; whether they have the opportunity to receive results or not; whether NatCen is able to inform their GP of their results or not.

- understands and can weigh up this information to help them make their decision.
- understands that they may decline at any point with no repercussions (even if they initially give consent and then change their mind while the procedure is taking / or about to take place).
- can communicate their decision (verbally or by sign language and in writing*)

* **Notes:**
- For participants who are blind or partially sighted a Project specific MREC approved text may be written for the participant by the Nurse/Biomedical fieldworker / Phlebotomist to conform to Ethical Approval for consent to venepuncture.
- For participants who cannot read or understand written English, there is no Ethical Approval for another member of the household to translate the Project Specific Consent Document. Any participant in this situation will therefore become ineligible for the blood sampling data collection element, as they will not be able to give an informed consent, as per the ethical approval for that Project.

7 NatCen NCDS protocol for anthropometric measurements

7.1 Overview

The anthropometric measurements included are:

- weight and body-fat percentage,
- waist and hip circumference.

In NCDS we are using an extra-long EasyCheck tape (200cm) for the waist and hip measurement. You will be taking 1 waist measurement and 1 hip measurement.

All the measures will be fed back to the respondent via the Measurement Record Card if they wish.

7.1.1 Weight

Respondents who self-report their weight to be over 130kg or 20.5st in the interview will be excluded from the weight and body-fat measurements. If this is the case, the CAPI will ask you whether you think that this weight is **clearly** incorrect. If you think that this weight is **clearly** incorrect and their weight is below that, you will proceed with the weight and body-fat measurements. If you do not think that this weight is **clearly** incorrect, then the respondent will be excluded from the weight and body-fat measurements.

Respondents who have pacemakers will be excluded from taking part in the body-fat measurement.

If the respondent does not want their body fat percentage measured, or is excluded from this measurement, we would like you to take their weight only.

7.1.2 Body-fat

Measuring body-fat requires a height measurement. You will not be measuring respondents' height in this NCDS survey. Instead, the CAPI will tell you the respondent's height as which was measured in an earlier sweep of the study, or if their height has never been measured as part of NCDS then you will be told their self-reported height from the interview at this wave. Again, you will be asked by the CAPI whether you think this value is **clearly** incorrect. If you do think it is **clearly** incorrect then the CAPI will prompt you to enter an estimate of the respondent's height which you will then use for the body-fat measurement.

7.1.3 Waist and hip

You will only need to take 1 waist measurement and 1 hip measurement in this survey. You should also use the extra-long EasyCheck tape (200cm) to take these measurements.

7.2 Anthropometry COVID-19 protocols

- For weight and body-fat, nurses should stand at the maximum distance the handset lead will allow them to. The weighing scale should be placed next to a stable surface, such as a wall or table.
- For waist and hip, the respondent will place the tape measure around themselves and the nurse will take the measurements from behind the respondent to reduce face-to-face proximity.

7.3 Weight and body fat measurement

A person's body fat percentage is the total weight of the person's fat divided by the person's weight. Some regard the body fat percentage as the better measure of an individual's fitness level, as it is the only body measurement which directly calculates the particular individual's body composition without regard to the individual's height or weight. Body fat is measured by sending a weak electrical current around the body from one foot to the other.

7.3.1 Exclusion criteria

Participants are excluded from this measurement if they are:

- Pregnant
- Too frail or unable to stand upright
  If you are concerned that being on the scales may cause them to be too unsteady on their feet then do not weigh them. Alternatively you can place the scales next to something that they can steady themselves on.
- Over 130kg (20 ½ stone) in weight
  The maximum weight registering accurately on the scales is 130kg. If you think that they exceed this limit then code it appropriately in CAPI and follow the prompts. Do not attempt to weigh them.
- Participant is fitted with a pace-maker.

7.3.2 Equipment

You will need:

- Tanita BF - 522W scales
- AA batteries (x4)
- Antibacterial wipes

These scales measure weight and body fat percentage sequentially.

Calibrating the scales

These scales **do not** need recalibration as they are manufactured to maintain their calibration. However, on each set of scales there is a label with a date that they need to be re-inspected by for wear and tear. If your scales are close to inspection date, please contact the INUVI office.

7.3.3 Procedure

Place scales on a flat firm floor surface, with room for the participant to step on safely. Wipe the footplate surface of the scales with an antibacterial wipe and allow drying (min 30 secs). Ideally the participant should be bare footed for the bio-impedance to be effective, however it can be done through light or thin material e.g. socks, tights and stockings.

Before asking the participant to step on the scales, it is necessary to enter the participant's age, gender, body type and height in whole centimetres into the scales. These details will be displayed in CAPI. This is in order that body fat percentage can be correctly calculated. We do not take a height measurement on NCDS and ask the cohort member to give self-reported height.

1. Switch the scales on by pressing the yellow ON/SET button on the right hand side of the hand-held console. The console will beep and the display screen will flash with the default age (30).

2. Enter the participant's age in years by using the yellow arrow keys to scroll up or down to the desired age. Holding down the arrow buttons will enable you to do this quickly. Press the 'SET' key to confirm the selection. The console will beep.

3. Select the appropriate gender and body type by using the yellow arrow keys. There are four options: 'standard male, 'standard female', 'athletic male', 'athletic female'. **Always select standard body type**. Press the up or down arrow to scroll though the four different options. Then press the 'SET' key to confirm the selection. The console will beep.

4. Next enter the participant's height in whole centimetres. The console will display the default height (170). Use the arrow keys to scroll up or down to the desired height. Holding down the arrow buttons will enable you to do this quickly Press the 'SET' key to confirm the selection.

NOTE: If you **make a mistake** when entering these numbers, turn off the scales (using the red OFF button) and start again.

5. The console will beep twice and the display will show '0.0'. Ask the participant to step onto the scales.

6. The participant should stand with both feet flat on the surface of the foot pads. Make sure their feet are positioned touching the front and back foot pads. This is essential in order for the current to be passed through the body. The participant should face forward with their legs straight and should stand still.

7. Once stabilised, the weight measurement will appear in the display and the scales will beep. You should not attempt to note the weight at this point.

8. The participant should remain on the scales while their body fat is measured. Five zeros (00000) will appear on the display. They will disappear one by one from left to right. After they have all disappeared, the scales will beep twice to indicate that body fat has been measured. The participant may then step-off the scales. This should take about 10 seconds.

9. The body fat percentage will appear in the display. The display will rotate between body fat percentage, body water percentage and the weight for about 30 seconds. You should record the weight, body-fat percentage and the body water percentage in the participant's measurement record card.

10. Record the measurement in CAPI.

11. In order to take the measurement again, you should turn the scales off and back on again. Note that the scales will turn off automatically after about 30 seconds.

The kg/lb key can be pressed when the scales are turned off to change the measurement settings. There are 3 possible options: kilograms (kg), pounds (lb) and stones and pounds (st-lb). However, **you should always use the scales in 'kg mode'** as we want to enter height in centimetres and measure weight in kilograms. If you are asked to enter height in feet and inches or the weight is displayed in stones and/or pounds, this means that the measurement settings are incorrect and should be changed. Once the scales are in 'kg mode', they should stay in this mode unless the kg/lb button is pressed.

7.4 Waist and hip circumference

There has been increasing interest in the distribution of body fat as an important indicator of increased risk of cardiovascular disease. The waist and hip circumferences are measures of the distribution of body fat (both subcutaneous and intra-abdominal). Analyses suggest that waist circumference and waist-hip ratio are predictors of health risk like the body mass index (weight relative to height).

7.4.1 Equipment

You will need:

- An 'Easy-Check Circumference Measurement' tape calibrated in millimetres
- Antibacterial wipes

7.4.2 Exclusion

Participants are excluded from the waist and hip circumference measurement if they:

- Are pregnant
- Are chair bound
- Have a colostomy / ileostomy

7.4.3 Using the Circumference Measurement Tape

The tape is passed around the circumference and click the press button in place at the back of the plastic slider. To check the tape is horizontal you have to position the tape on the right flank and look round the participant's back from his/her left flank to check that it is level. When taking the reading, be sure not to lift the tape, hold it flat against the body otherwise you will get an inaccurate measurement.

7.4.4 Preparing the participant

The Participant needs to be wearing light clothing. Explain to the participant the importance of this measurement and that clothing can substantially affect the reading. If possible the participant needs to remove:

- All outer layers of clothing, such as jackets, heavy or baggy jumpers, cardigans and waistcoats
- Shoes with heels
- Tight garments intended to alter the shape of the body, such as corsets, Lycra body suits and support tights/underwear
- Belts

Pockets should be emptied and if possible ask the participant to empty their bladder before taking the measurement.

Explain to the participant that the waist and hip measurements taken on NCDS are taken at different points to where the participant might think their waist and hips are. Therefore measurements may differ to those taken for clothing purposes.

Some participants may be wearing religious or other symbols which they cannot remove and which may affect the measurement. Do not embarrass or offend the participant by asking them to remove such items. Record in CAPI if the measurement is likely to be affected by this.

Steps 1-3 apply to both waist measurement and hip measurement.

1. Ensure that the participant is standing erect in a relaxed manner and breathing normally. Weight should be evenly balanced on both feet and the feet should be about 25-30cm (1 foot) apart. The arms should be hanging loosely at their sides. This position will provide the most accurate measurement of both the waist and the hip, and will allow for them to be measured easily.
2. You should be standing behind the participant.

3. With assistance from the participant pass the tape around the participant's body, or if they are able to, get them to pass the tape around themselves and check that it is not twisted. Click the press button in place at the back of the plastic slider.

Measuring waist circumference

4. The participant's waist is located midway between the iliac crest and the costal margin (lower rib). To locate the levels of the costal margin and the iliac crest, ask the Participant if you can touch them, and use the fingers of your right hand held straight and pointing in front of the participant to slide upward over the iliac crest.
5. Position the tape at the participant's waist, ensuring that it is horizontal.
6. Ask the participant to breathe out gently and to look straight ahead. This is to prevent the Participant from contracting their muscles or holding their breath.
7. Take the measurement at the end of a normal expiration by holding the slider flat against the body and read the measurement from the red line.
8. Record the measurement in CAPI in centimetres and millimetres. Always record to a one decimal place. If the result falls between two millimetres, record to the **nearest even millimetre**.

Measuring hip circumference

9. The participant's hip circumference is the widest circumference over the buttocks and below the iliac crest.
10. Position the tape in this area ensuring that the participant is looking straight ahead and not contracting their gluteal muscles. Ensure the tape is horizontal.
11. Measure the circumference at several positions over the participant's buttocks, by holding the slider flat against the body and read the measurement from the red line.
12. Record the widest circumference in CAPI. Always record to one decimal place. Report in centimetres and millimetres. If the result falls between two millimetres, record to the **nearest even millimetre**.
13. If the participant wishes, record the waist and hip measurement, as given in CAPI, on their measurement record card.

7.4.5 Additional points

- If you have problems palpating the rib, ask the participant to breathe in very deeply. Locate the rib and as the participant breathes out, follow the rib as it moves down with your finger.
- The tape should be tight enough so that it doesn't slip but not tight enough to indent clothing.
- If the participant is large, ask him/her to pass the tape around rather than 'hug' them. Remember to check that the tape is correctly placed to take the measurement and horizontal all the way around.
- Some participants will be wearing clothing where the waistband of the trousers/skirt sits on the waist. Do not attempt to move the clothing or take the measurement at a different position. Measure the waist circumference over the waistband and make a note of this in CAPI. If the waistband is not horizontal all the way around the body i.e. it may be lower at the front, always ensure that the tape is horizontal which may mean that it passes over the waist band in some places and not in others. If there are belt loops, thread the tape through the loops so that they don't add to the measurement.

- We only want to record problems that will affect the measurement by more than would be expected when measuring over light clothing. As a rough guide only record a problem if you feel it affected the measurements by more than 0.5cm. We particularly want to know if waist and hip are affected differently.
- Before packing the tape away ensure the length of tape is wiped with an antibacterial wiped and allowed to dry (min 30 secs) to reduce potential cross infection between households.

8 NatCen NCDS protocol for timed walk measurement

8.1 Overview

The timed walk involves recording the time taken by the respondent to walk a distance of 8 feet (244cm) at their ***usual walking pace***.

The purpose of the timed walk is to objectively measure the overall health and level of disability of NCDS respondents.

Walking speeds in people aged 60 and over have been shown to predict

- level of disability,
- future use of health care; and
- mortality.

8.2 Timed walk COVID-19 protocol

- The nurse should stand at the end of the course, perpendicular to the walking course whilst maintaining social distancing if possible

8.3 Exclusion criteria

To be eligible to do the timed walk respondents need to meet the following criteria:

- ✓ Able to walk without assistance from another person. They **are** allowed to do the test using a walking aid (such a stick or Zimmer frame)

You will have a laminate card to remind you of the key points to remember when performing the test.

8.4 The equipment

8.4.1 The tools

You will use the following equipment to conduct the timed walk:

- Tape measure (to measure out 8 ft)
- Card to put at end of tape
- Stopwatch

8.4.2 Tape measure instructions

The tape measure is easy to operate and has a lock on it to keep it open while it is being used. Please release this lock **very carefully** as it can easily hurt you or someone else. Please also ensure that it does not become an obstacle that could trip up someone.

8.4.3 Stopwatch instructions

The make and model of stopwatches in the field may vary so it is important to ensure you are familiar with the type you will be using.

8.4.4 Script Card

You will have a laminate card to remind you of the key points to remember when performing the test

8.4.5 Recording the walk properly

When you record the timed walk, it is very important that you do so **accurately**.

The last four digits of the stopwatch will display the time in hundredths of a second, e.g. 02.34.

Please enter this carefully into the CAPI after each of the 2 walks.

8.5 Introducing the test

As closely as possible, follow the instructions in the CAPI program and this protocol to describe the test and how to perform it correctly.

Do not provide any additional encouragement beyond the script provided in the CAPI programme and this protocol.

The detailed instructions and demonstration may seem unnecessary to some respondents. Say that you are going to explain the test in detail since this is the best way to make sure that everyone does the test in a similar manner.

8.5.1 Ask permission to conduct the test

Once the respondent has consented to perform the test then check that it will be safe to conduct.

8.6 Safety precautions

We hope that most respondents will do the timed walk but there are some questions in the CAPI which ensure that it is safe to carry out the test.

8.6.1 Safety assessment

Before the respondent performs the test, you will have the chance to assess the safety and the respondent's willingness to perform the test.

 If you believe it is **not safe** for the respondent then **do not** conduct the test.

8.6.2 Check floor surface

 It is strongly preferable to conduct the timed walk on a floor that is:

- level,
- not carpeted
- and not slippery (e.g. highly polished).

If all the available space is carpeted, choose a floor with the thinnest and hardest carpet.

8.6.3 Respondents' footwear

 Respondents should have appropriate footwear which does not risk them slipping or tripping during the test. The respondent should ideally conduct the test in:

- low-heeled shoes,
- trainers,
- or bare feet (if they do not have a suitable pair of shoes).

 The respondent should **NOT** wear:

- slippers,
- high-heeled shoes
- or be in just socks or tights.

8.6.4 Other things to check

Make sure that there are no barriers to safety such as:

- poor lighting;
- loose rugs;
- furniture in the way: or
- pets/children who might get in the way.

8.6.5 Assess whether there is enough space to conduct the test

You will need space of around **12 feet** to conduct the test in a straight line.

The test may be performed in a hallway or sheltered corridor if there is no suitable space elsewhere. Make sure that:

- the surface is good
- lighting is good
- location is safe
- location is reasonably private.

In rare instances where these criteria are not met, it could be conducted outside; however it is vital that you avoid dark spaces or uneven floor surfaces.

 If you cannot find a suitable space or the space is not safe, **do not conduct the test**

 Walking aids (such a stick or Zimmer frame) may be used on this test.

 The respondent should **not** rely on the support of another person.

8.6.6 Removing obstacles

If possible, and with the respondent's permission, remove any barriers to safety as appropriate.

 Do not risk harming yourself by moving heavy furniture.

8.7 Safety during the test

✗ DO NOT do the test if the respondent appears to be in danger of falling.

8.7.1 How to support the respondent

The nurse should stand at the end of the course, perpendicular to the walking course whilst maintaining social distancing if possible. You will then be able keep a close eye on the respondent as they turn to start the second test. This is the time when an individual is most likely to need to check their balance. Standing at the end of the course will also enable you to see the respondent complete the test clearly.

8.7.2 If the respondent falls

If the respondent does fall:

- call for help if appropriate.

If the respondent is NOT injured, help them by:

- first having them get on their knees or on all fours.
- place a chair next to the respondent and have them support themselves onto the chair.
- If assistance is needed:
  - lift under the shoulders;
  - **do not** hold their arm,
  - hold around their body.

✗ Do not try to lift the respondent alone from the floor or put yourself at risk.

✓ Remember to seek help if it is needed. Complete a report for any incident of this kind.

✗ If the respondent loses their balance or falls, do not attempt to complete the walking test.

8.8 Demonstration

Demonstrate the walk for the respondent. Remind the respondent not to begin to do the walk until after you have demonstrated it. It is very important that the nurse demonstrates each step correctly. Experience has shown that respondents follow more closely what the nurse does rather than what they say. If the respondent indicates that they do not understand how to do the test, demonstrate it again rather than relying on repeating

verbal instructions. Repeat the demonstration only once. If the respondent still does not understand, skip the test. Do not 'coach' the respondent.

8.9 Criteria for an acceptable test

Please note the following criteria must be met for a measurement to be considered acceptable. If they are not met, the walk should be repeated:

- Respondent begins with both feet together at the beginning of the course.
- The nurse starts timing when either foot is placed down on the floor across the start line. The **whole foot** must be across the line before the test is started, so if the respondent is shuffling, or puts their foot down so that it straddles the line, start the stopwatch when the whole foot has crossed the line.
- **If respondent is using a walking aid:** Start the stopwatch when the whole **foot** crosses the line. **Do not** start counting from the time the walking aid crosses the line.
- The respondent walks and does not race. The respondent should walk at their **usual walking pace**.
- The respondent walks all the way past the end of the tape measure.
- Stop timing when either foot is placed down on the floor across the finish line. The whole foot must be across the line before the test is complete, so if the respondent is shuffling, or puts their foot down so that it straddles the line, stop the stopwatch when the whole foot has crossed the line.

8.10 Nurse Script

The following description provides an appropriate script for you to follow for the test.

 Please try to **use the same wording every time you** administer the Timed Walk **so that all tests are administered consistently** between interviewers/nurses, over time, and between studies.

(A) First, follow the CAPI screens which will help you exclude individuals for whom it would not be appropriate to carry out the Timed Walk.

(B) If appropriate, begin to set up and introduce the Timed Walk

Nurse (N): "OK, we'll proceed then. I'd like to find a space we can use to do the walk. We'll ideally need 12 feet of space."

If you cannot find a suitable space or do not feel the space is safe, tell them "It would be safest to skip this test and move on to the next set of questions."

Ensure that the respondent is wearing appropriate footwear at this point. If not, ask them to change their shoes or to put shoes on.

N: "I'm going to place the measuring tape alongside the space where the walk will take place. This is our walking course. I want you to walk to the other end of the course at your usual speed, just as if you were walking down the street to go to the shops. Walk all the way past the other end of the tape before you stop.

If there is space, ask "Do you feel this would be safe?"

If they answer "No" tell them "It would be safest to skip this test and move on to the next set of questions."

N: "Now I'd like to demonstrate how to do the test. Please don't get up until after I demonstrate the test. You will start by lining your feet up at the starting point."

"For the test I'll say "Ready? Begin" Are you ready to go now?"

Then get the stopwatch ready. Place a piece of card at the end of the walking course and stand at the end.

N: "Now, I am going to time you as you walk the course. I will be asking you to walk the course two times. I'd like you to stand here with your feet lined up. Start walking when I say "Begin". "Ready, begin".

Enter the results in the CAPI of the first trial in hundredths of a second, exactly as it is shown on the stopwatch. If the respondent was unable to complete the test or you stopped them because of safety reasons, do not attempt to complete the test. Tell them "It would be safest to skip this test and move on to the next set of questions." Otherwise, continue.

N: "Now I want you to repeat the walk. Remember to walk at your usual pace and go all the way past the other end of the course. I'd like you to stand here with your feet lined up. Start walking when I say "Begin". "Ready, begin".

For the second trial, ensure that the respondent walks back along the course they have already covered. Move the card to the other end and stand there before you say "Ready, begin". Enter the results of the second trial in hundredths of a second into the CAPI.

In instances where the respondent did not complete the test, the CAPI programme will prompt you to briefly describe why. In all instances, follow the protocol.

9 NatCen NCDS protocol for leg raise measurement

9.1 Overview

Balance and coordination are necessary to carry out successfully every day locomotor functions at reasonable speeds and to prevent falls. The 'Leg Raise' balance test is one of a series of these performance measurements. This test will enable an objective measurement of the overall health and level of ability of a large population of people in regard to balance.

Balance and coordination are necessary to carry out successfully every day locomotor functions at reasonable speeds and to prevent falls. They are also related to general health and balance declines with age.

- The respondent should hold the position with their arms folded across their chest.
- The leg raise with eyes closed should be attempted by all participants, regardless of whether they could do it with their eyes open, as long as it is safe.

9.2 Leg raise COVID-19 protocol

- The nurse should maintain 2 metre social distancing if possible.
  If the respondent wishes for the nurse to stand closer for comfort then they may do so, trying to stand to the side of the person.

9.3 The measures

Participants in NCDS 2020-23 Survey will be asked to stand on their preferred leg and raise the other foot off the ground a few inches to try to balance on the one leg. They need to try to stay balanced for as long as possible (up to 30 seconds) with their arms folded. They will be asked to hold two positions:

1. Leg raise eyes open (see Section **Error! Reference source not found.** - Stage1)
2. Leg raise eyes closed (see Section **Error! Reference source not found.** - Stage 2)

9.4 Exclusion criteria

All sample members are eligible for the leg rise measure with the following exceptions:

- Participants who are chair bound or wheelchair bound
- Participants who need to use an aid for walking or standing
- Participants who find it too painful to stand or balance on one leg, due to surgery or longstanding or current short-term illness or injury

- ✘ After discussion with the participant it becomes clear that they are too unsteady on their feet for the measurement, and thus consider it too unsafe to conduct the measurement.

If the participant is unwilling or unable to do this test please record the reason for this.

9.5 Equipment

9.5.1 Equipment needed

The following are needed:

- ✓ a stopwatch

9.5.2 Script Card

You will have a laminate card to remind you of the key points to remember when performing the test.

9.5.3 How to use a stopwatch

The make and model of stopwatches in the field may vary so it is important to ensure you are familiar with the type you will be using.

9.5.4 Safety precautions

What to check

It is important to check and put in practice the following:

- ✓ **Footwear** - It is strongly suggested that this activity is performed in shoes with very low or no heels. It is hard to perform normally with shoes with heels on. Ask the participant if the footwear they are wearing is what they wear most of the time around the house. Soft soled, heel-less slippers, or just socks/tights should not be worn, since they may cause the participant to slip. The participant can do the measure in bare feet if they do not have appropriate shoes.

- ✓ **Floor surface** - it is strongly preferable to do the test on a floor which is level/even, not carpeted (e.g. be aware of loose rugs or carpets) and not slippery (e.g. highly polished).

- ✓ **Area** - Make sure there is still a firm support nearby for the participant to steady themselves with, when getting into position. Stand by the side of the respondent. If necessary, provide gentle support to the respondent's arm to help them into position.

- ✓ **Participant self-reliance** - If a participant is uncomfortable performing the test or if it is felt that the leg raise is not safe for a given individual, the test should not be performed.
- ✓ **Nurse position** - When the participant is performing the test, stand off to the side whilst maintaining social distancing. The participant should ideally be positioned next to a stable surface, such as a wall or table.

9.5.5 In the event of accident

If the participant does fall:

- ✓ call for help if appropriate OR, if respondent is NOT injured, help him/her as explained below;
- ✓ complete a report (SRF – Special Report form) for any incident of this kind.
- ✓ do not attempt to complete the test again (either with eyes open or closed).

If respondent is NOT injured help them by:

- ✓ first having them get on their knees or on all fours.
- ✓ placing a chair next to the respondent and having them support themselves onto the chair.

If assistance is needed:

- ✓ lift under the shoulders;
- ✓ hold around their body (remember: do not hold their arm);
- ✗ do not try to lift the respondent alone from the floor or put yourself at risk.

9.6 What to do step-by-step

9.6.1 Stage 1 – Leg raise eyes open

STEP 1	Explain the procedure: a. You will ask them to stand on their preferred leg and raise the other foot off the ground a few inches to try to balance on the one leg keeping the arms folded; b. They need to try to stay balanced for as long as possible up to 30 seconds; c. While balancing:

	✓ They may bend their knee or move their body to maintain their balance, ✓ They must *try to keep their standing foot still* ✓ *They must keep their arms folded* ✓ Respondent's raised leg should not be touching their standing leg ✓ Make sure there is a firm support close to the respondent d. All the procedure will be performed with eyes open.
STEP 2	Demonstrate the test.
STEP 3	Allow respondent to practice the test in order to decide which leg to use.
STEP 4	Ask the respondent if they feel safe to do the test (*verbal consent*).
STEP 5	Explain to start the test you will say "*Ready*, *begin*".
STEP 6	Ask the participant to decide which leg they are going to balance on. Enable them to have one practice only, on each leg, if they need to, to decide.
STEP 7	Start the stopwatch timing as soon as the participant raises one leg off the ground, and has the arms folded.
STEP 8	Stop the stopwatch when: a. They lose balance and / or touch their free foot on the floor; b. They move their arms away from their chest. c. They lose balance and / or their balancing foot moves position on the floor (including raising their heel from the floor); d. **Or** after 30 seconds, whichever happens first.
STEP 9	Record the outcome in CAPI (in seconds to 2 decimal points).
STEP 10	Thank the participant and proceed to stage 2.

9.6.2 Stage 2 – Leg raise eyes closed

The respondent should be asked to do the balance test with their eyes closed **even if they could not** do the balance test with their eyes open. However, do not attempt the leg raise with eyes closed if you or the respondent thinks it would not be safe.

STEP 1	Explain the procedure: a. You will ask them to stand on their preferred leg again and raise the other foot off the ground a few inches to try to balance on one leg - this time with their eyes closed. b. They need to try to stay balanced for as long as possible up to 30 seconds. c. While balancing, the same conditions apply as previously performed.

	d. When in the position - as soon as one leg is raised off the ground and the arms are folded - the eyes must be closed.
STEP 2	Demonstrate the test.
STEP 3	Allow the respondent to practice in order to decide which leg to use.
STEP 4	Ask the respondent if they feel safe to do the test (with eyes closed).
STEP 5	Explain to start the test you will say "*Ready*, *begin*".
STEP 6	Ask the participant to decide which leg they are going to balance on. Enable them to have one practice only, on each leg, if they need to, to decide.
STEP 7	Start the test, observing the stopping criteria at step 7 above. You should also stop the stopwatch if the participant opens their eyes before 30 seconds.
STEP 8	Record the outcome in CAPI (in seconds to 2 decimal points).
STEP 9	Thank the participant.

9.7 Feedback to respondents

The CAPI program will guide you through the leg raise procedure. Introduce and explain the two stages of the test, as outlined below.

In general:

- Do not provide additional encouragement beyond the language provided by the detailed instructions
- After the measure, acknowledge the participant's efforts but do not give feedback. Neutral phrases such as "Thank you" or "That's fine" are examples of the kinds of things you could say.

Please Note

Results will be analysed on a population level not on an individual performance level as there may be specific issues that may affect the participant's performance on the day the measurement is taken. As with other bio measure protocols, if you feel that anything has made the measurement unreliable then you should make a note in CAPI.

Balance and coordination are necessary to carry out successfully every day locomotor functions at reasonable speeds and to prevent falls. The 'Leg Raise' balance test is one of a series of these performance measurements. This test will enable an objective measurement of the overall health and level of ability of a large population of people in regard to balance.

10 NCDS protocol for timed walk measurement

10.1 Overview

The timed walk involves recording the time taken by the respondent to walk a distance of 8 feet (244cm) at their ***usual walking pace***.
The purpose of the timed walk is to objectively measure the overall health and level of disability of NCDS respondents.

Walking speeds in people aged 60 and over have been shown to predict

- level of disability,
- future use of health care; and
- mortality.

10.1.1 Comparison to other studies

We can compare the results we gather with the English Longitudinal Study of Ageing (ELSA) as well as the Health and Retirement Study which is conducted in the United States.

10.2 Changes to protocol due to COVID-19

The nurse should stand at the end of the course, perpendicular to the walking course whilst maintaining social distancing if possible

10.3 Exclusion criteria

To be eligible to do the timed walk respondents need to meet the following criteria:

- ✓ Able to walk without assistance from another person. They **are** allowed to do the test using a walking aid (such a stick or Zimmer frame)

You will have a laminate card to remind you of the key points to remember when performing the test.

10.4 Equipment

10.4.1 The tools

You will use the following equipment to conduct the timed walk:

- Tape measure (to measure out 8 ft)

- Card to put at end of tape
- Stopwatch

10.4.2 Tape measure instructions

The tape measure is easy to operate and has a lock on it to keep it open while it is being used. Please release this lock **very carefully** as it can easily hurt you or someone else. Please also ensure that it does not become an obstacle that could trip up someone.

10.4.3 Stopwatch instructions

The make and model of stopwatches in the field may vary so it is important to ensure you are familiar with the type you will be using.

10.4.4 Script Card

You will have a laminate card to remind you of the key points to remember when performing the test

10.4.5 Recording the walk properly

When you record the timed walk, it is very important that you do so **accurately**.

The last four digits of the stopwatch will display the time in hundredths of a second, e.g. 02.34.

Please enter this carefully into the CAPI after each of the 2 walks.

10.5 Introducing the test

As closely as possible, follow the instructions in the CAPI program and this protocol to describe the test and how to perform it correctly.

✗ **Do not** provide any additional encouragement beyond the script provided in the CAPI programme and this protocol.

The detailed instructions and demonstration may seem unnecessary to some respondents. Say that you are going to explain the test in detail since this is the best way to make sure that everyone does the test in a similar manner.

10.5.1 Ask permission to conduct the test

Once the respondent has consented to perform the test then check that it will be safe to conduct.

10.6 Safety precautions

We hope that most respondents will do the timed walk but there are some questions in the CAPI which ensure that it is safe to carry out the test.

10.6.1 Safety assessment

Before the respondent performs the test, you will have the chance to assess the safety and the respondent's willingness to perform the test.

 If you believe it is **not safe** for the respondent then **do not** conduct the test.

10.6.2 Check floor surface

 It is strongly preferable to conduct the timed walk on a floor that is:

- level,
- not carpeted
- and not slippery (e.g. highly polished).

If all the available space is carpeted, choose a floor with the thinnest and hardest carpet.

10.6.3 Respondents' footwear

 Respondents should have appropriate footwear which does not risk them slipping or tripping during the test. The respondent should ideally conduct the test in:

- low-heeled shoes,
- trainers,
- or bare feet (if they do not have a suitable pair of shoes).

 The respondent should **NOT** wear:

- slippers,
- high-heeled shoes
- or be in just socks or tights.

10.6.4 Other things to check

Make sure that there are no barriers to safety such as:

- poor lighting;
- loose rugs;
- furniture in the way: or
- pets/children who might get in the way.

10.6.5 Assess whether there is enough space to conduct the test

You will need space of around **12 feet** to conduct the test in a straight line.

The test may be performed in a hallway or sheltered corridor if there is no suitable space elsewhere. Make sure that:

- the surface is good
- lighting is good
- location is safe
- location is reasonably private.

In rare instances where these criteria are not met, it could be conducted outside; however it is vital that you avoid dark spaces or uneven floor surfaces.

 If you cannot find a suitable space or the space is not safe, **do not conduct the test**

 Walking aids (such a stick or Zimmer frame) may be used on this test.

 The respondent should **not** rely on the support of another person.

10.6.6 Removing obstacles

If possible, and with the respondent's permission, remove any barriers to safety as appropriate.

 Do not risk harming yourself by moving heavy furniture.

10.7 Safety during the test

✗ DO NOT do the test if the respondent appears to be in danger of falling.

10.7.1 How to support the respondent

The nurse should stand at the end of the course, perpendicular to the walking course whilst maintaining social distancing if possible. You will then be able keep a close eye on the respondent as they turn to start the second test. This is the time when an individual is most likely to need to check their balance. Standing at the end of the course will also enable you to see the respondent complete the test clearly.

10.7.2 If the respondent falls

If the respondent does fall:

- call for help if appropriate.

If the respondent is NOT injured, help them by:

- first having them get on their knees or on all fours.
- place a chair next to the respondent and have them support themselves onto the chair.
- If assistance is needed:
  - lift under the shoulders;
  - **do not** hold their arm,
  - hold around their body.

✗ Do not try to lift the respondent alone from the floor or put yourself at risk.

✓ Remember to seek help if it is needed. Complete a report for any incident of this kind.

✗ If the respondent loses their balance or falls, do not attempt to complete the walking test.

10.8 Demonstration

Demonstrate the walk for the respondent. Remind the respondent not to begin to do the walk until after you have demonstrated it. It is very important that the nurse demonstrates each step correctly. Experience has shown that respondents follow more closely what the nurse does rather than what they say. If the respondent indicates that they do not

understand how to do the test, demonstrate it again rather than relying on repeating verbal instructions. Repeat the demonstration only once. If the respondent still does not understand, skip the test. Do not 'coach' the respondent.

10.9 Criteria for an acceptable test

Please note the following criteria must be met for a measurement to be considered acceptable. If they are not met, the walk should be repeated:

- Respondent begins with both feet together at the beginning of the course.
- The nurse starts timing when either foot is placed down on the floor across the start line. The **whole foot** must be across the line before the test is started, so if the respondent is shuffling, or puts their foot down so that it straddles the line, start the stopwatch when the whole foot has crossed the line.
- **If respondent is using a walking aid:** Start the stopwatch when the whole **foot** crosses the line. **Do not** start counting from the time the walking aid crosses the line.
- The respondent walks and does not race. The respondent should walk at their **usual walking pace**.
- The respondent walks all the way past the end of the tape measure.
- Stop timing when either foot is placed down on the floor across the finish line. The whole foot must be across the line before the test is complete, so if the respondent is shuffling, or puts their foot down so that it straddles the line, stop the stopwatch when the whole foot has crossed the line.

10.10 Nurse Script

The following description provides an appropriate script for you to follow for the test.

 Please try to **use the same wording every time you** administer the Timed Walk **so that all tests are administered consistently** between interviewers/nurses, over time, and between studies.

(A) First, follow the CAPI screens which will help you exclude individuals for whom it would not be appropriate to carry out the Timed Walk.

(B) If appropriate, begin to set up and introduce the Timed Walk

Nurse (N): "OK, we'll proceed then. I'd like to find a space we can use to do the walk. We'll ideally need 12 feet of space."

If you cannot find a suitable space or do not feel the space is safe, tell them "It would be safest to skip this test and move on to the next set of questions."

Ensure that the respondent is wearing appropriate footwear at this point. If not, ask them to change their shoes or to put shoes on.

N: "I'm going to place the measuring tape alongside the space where the walk will take place. This is our walking course. I want you to walk to the other end of the course at your usual speed, just as if you were walking down the street to go to the shops. Walk all the way past the other end of the tape before you stop.

If there is space, ask "Do you feel this would be safe?"

If they answer "No" tell them "It would be safest to skip this test and move on to the next set of questions."

N: "Now I'd like to demonstrate how to do the test. Please don't get up until after I demonstrate the test. You will start by lining your feet up at the starting point."

"For the test I'll say "Ready? Begin" Are you ready to go now?"

Then get the stopwatch ready. Place a piece of card at the end of the walking course and stand at the end.

N: "Now, I am going to time you as you walk the course. I will be asking you to walk the course two times. I'd like you to stand here with your feet lined up. Start walking when I say "Begin". "Ready, begin".

Enter the results in the CAPI of the first trial in hundredths of a second, exactly as it is shown on the stopwatch. If the respondent was unable to complete the test or you stopped them because of safety reasons, do not attempt to complete the test. Tell them "It would be safest to skip this test and move on to the next set of questions." Otherwise, continue.

N: "Now I want you to repeat the walk. Remember to walk at your usual pace and go all the way past the other end of the course. I'd like you to stand here with your feet lined up. Start walking when I say "Begin". "Ready, begin".

For the second trial, ensure that the respondent walks back along the course they have already covered. Move the card to the other end and stand there before you say "Ready, begin". Enter the results of the second trial in hundredths of a second into the CAPI.

In instances where the respondent did not complete the test, the CAPI programme will prompt you to briefly describe why. In all instances, follow the protocol.

11 Online Dietary Questionnaire (ODQ)

The Online Dietary Questionnaire is to be completed by the respondent on two days in the week after the nurse visit. The two days will be selected at random in CAPI.

11.1 Exclusion criteria

Participants are excluded from the Online Dietary Questionnaire if they:

- Do not have access to the internet.

11.2 Equipment

For each cohort member you will need:

- 'Online Dietary Questionnaire' leaflet
- Login sticker (from the labels page assigned to this respondent)

Respondents will be asked to complete the dietary questionnaire for two days after your visit.

In order to access the questionnaire, respondents will need to type **www.ncdssurvey.co.uk** into their web browser (e.g. Internet Explorer) and log in using the details you will give them. Cohort members can complete the questionnaire on a computer, or on a tablet or smartphone. The questionnaire then asks them to report everything they had to eat and drink during a 24- hour period. The online questionnaire will take about 10-20 minutes to complete on each day.

11.3 Procedure

The online dietary questionnaire placement should occur at the end of your visit. We have changed the protocol so you fill in the leaflet before you give it to the respondent to read in order to minimise the transfer of you passing the leaflet back and forth with the respondent:

1. Record the dietary questionnaire login code in CAPI. It is an 8-digit code found on the labels page which you have assigned to the respondent in the blood sample module. Please make sure you use the ODQ label from the same sheet as the barcode labels you have used for this particular participant. If you did not take a blood sample then you should use a new sheet of labels for the respondent just for the ODQ login code label. If the login code does not match the barcode label for a particular respondent, please explain why in the CAPI. This will allow the office to resolve any data issues back in the office.
2. CAPI will automatically select two days on which we want the respondent to complete the questionnaire.

3. Write the day (Mon-Sun) and date of each of the two days onto the ‘Online Dietary questionnaire’ leaflet.
4. Stick the dietary questionnaire login label onto the ‘Online Dietary questionnaire’ leaflet.
5. Ask the respondent to read the ‘Online Dietary Questionnaire’ leaflet. If the respondent is unable to do this, go through it with them. Please refer to NatCen COVID-19 secure protocols on handling documents.
6. Read out the explanation of the task to the cohort member from CAPI.

11.4 Additional points

11.4.1 Selection of days

CAPI will select two random days from the seven-day period following your visit (it will not select the day immediately following the nurse visit). The cohort member must complete the dietary questionnaire on both selected days, answering about what they ate the day before. The selected days are chosen at random and cannot be changed. New days cannot be assigned because they are ‘atypical’, for instance because the cohort member is busy, on holiday, travelling etc., or because they would prefer different days.

11.4.2 When should the respondent complete their dietary questionnaire?

The questionnaire should be completed by the respondent on each of the selected days. The questionnaire itself asks respondents to report what they ate the previous day.

All the questions in the questionnaire ask about ‘yesterday’, so if they miss their allocated day they should answer about the day before the day on which they are completing it. If they miss their first allocated day it would be good if they can try to complete the questionnaire before their second allocated day. They cannot complete the questionnaire more than once on any one day.

11.4.3 Addressing concerns regarding data security

Note that:

- All data is held and transferred securely, in line with UK Data Protection legislation.
- The online questionnaire will not collect any information from the device which might allow the cohort member to be located or identified, such as location data,

GPS data or internet usage data.

11.4.4 Text and email reminders

The participants will be sent texts and emails to remind them to complete the ODQ. They can choose not to receive these, and you can code this in the CAPI.