BRITISH REGIONAL HEART STUDY

BRHS 40 year follow-up (Q40)

Physical examination protocol

2018-19

British Regional Heart Study:
A follow-up study of cardiovascular risk factors and outcomes in older men

Funded: Dunhill Medical Trust

Lead Investigator: Professor Sheena Ramsay

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BRHS 40 YEAR FOLLOW-UP EXAMINATION

PROTOCOL FOR RESCREEN 2018

Contents

1.0 BACKGROUND

1.1 Who is invited to take part?

The British Regional Heart Study (BRHS) originally included 7735 men, recruited at age 40-59 years in 1978-1980 in 24 British towns. We are now inviting the surviving men in each town (approximately ~70 on average) to attend for re-examination at 77-99 years of age.

Participants who are still living in their original study town will generally be expected to be remeasured in that town. Participants who have migrated from the original town have been invited for remeasurement to another BRHS town which is closer and more convenient for them.

1.2 Focus of re-examination and funding

This re-examination is funded by the Dunhill Medical Trust, and other funds from the British Heart Foundation (BHF). On-going support of the BRHS is from the BHF.
The funding for this re-examination focuses on ageing, particularly loss of muscle mass (sarcopenia), malnutrition and oral health – to understand how these inter-relate and can be prevented. The Principal Investigator (PI) of this project is Sheena Ramsay. Directors if the BRHS are Goya Wannamethee, Peter Whincup and Sheena Ramsay.

Execution of the re-examination:
A 'field team' of three trained researchers will carry out the data collection (Research Nurse, Research Dental Hygienist, Research Phlebotomist).
The field team will be supported by a 'base team' located at the BRHS office at the Royal Free Campus, UCL. Lucy Lennon is the Senior Project Co-ordinator, supported by Patrice and Sarah Ash. Olia Papacosta is the BRHS Data Manager. A couple of other researchers will be trained in case replacement of observers is required.

1.3 Liaison with General Practices

The study will focus on the single General Practice in each town which was originally involved in the study, and where most study subjects are still registered.

By the time the Study Team visits a particular town, the town Practice will have been contacted and informed about the survey. The survey will take place either within the Practice or (where this is not possible) in a local Health Clinic or other community premises.

1.4 Invitations to subjects

The subjects have received a letter inviting them to take part in the study which is sent out six weeks in advance of the survey visit.

The package received by the study subjects will include: -

- the main invitation letter
- an appointment card (with tear-off reply slip)
- a questionnaire
- an information sheet
- a reply paid envelope

The subjects are asked to return: -

- the reply slip confirming, changing or declining their appointment
- the questionnaire

In preparation for the survey visit men are asked: -

- to fast overnight or (in the case of appointments at or after 12.00midday) for 6 hours
- to wear clothing which is easily adjustable

2.0 Framework of assessments being made

The participants will proceed from the Receptionist (identified locally in each town by base team) to Station 1 (Research Nurse 1), then to Station 2 (Dental Hygienist) and then to Station 3 (Research Phlebotomist), returning to the Receptionist before departure. Each of these stations will last approximately 15 minutes: -

With the Receptionist, each participant will: -

- be logged in and have documentation prepared (data sheet and Test Your Memory (TYM) questionnaire for each participant) and check back in at the end of examination.

Receptionist to be briefed by one of the field team, most likely Research Phlebotomist.

Receptionist briefing to include –

- Summary of the study – on-going study (40-year follow-up), older participants attending a physical examination
- Documents to be given to Receptionist - List of participants, data sheets and TYM questionnaires.
- Ask to meet-and-greet participants, check them in (tick on participants list) and direct participants to Station 1.
- At end of Station 3 to receive participants, offer refreshments and show them way out.

At Station 1, each subject will have measurements of anthropometry (except height and weight), blood pressure, and physical function.

At Station 2, each subject will have a dental assessment and lung function measure.

At Station 3, each subject will: -

- provide a fasting blood sample
- have measurements of height, weight and body composition
- be asked about consent for record tracing, result recording, blood storage

Return to Receptionist at the end: -

- Receptionist will offer refreshments.
- 'Test Your Memory' Questionnaire will be given to participant to complete – to be self-completed without assistance and returned to Receptionist before leaving.

3.0 Other general responsibilities

3.1 Travel expenses for participants
If participants request travel costs, one of the Research team will deal with this. The Field team are responsible for the petty cash box.

3.2 Loading and unloading the van
Loading the van – all equipment to be loaded by Field Team.
All equipment should be unloaded at arrival at examination town/ site. And all equipment to be unloaded by the field team on return to the Department in London. Equipment is not to be left in the van – this will not be required in most situations unless moving from one town to next over the weekend and if van parked in a secure car park – to be agreed beforehand with base team.

3.3 Uniform for field team to be worn during examination.

4.0 Core principals of measurements

- Key aim of this project is to obtain standardised, high-quality and complete data.
- All measures will be made as per protocol in this document. This allows standardized measures to be collected in the same way as previous examinations – this is critical in order to obtain valid measures and to investigate changes over time.
- If ever in doubt regarding any measures or situations, please contact the base team or contact Sheena Ramsay.
- Participants attending the examination are study volunteers – they are not patients.
- The examination is purely for research purposes and assessments made are not diagnostic.
- No clinical opinion is to be given to participants. General advice is fine. In case of specific questions, they are to be encouraged to contact their GP. For example, if asked about state of teeth or gums, best to say that this examination is not the same as visiting a dentist, which is the best way of ensuring a thorough dental check-up in a surgery – this is simply a brief check of some measures.
- Also see sections 7.0 and 8.0 on feedback of results and abnormal results.

5.0 STATION 1 (RESEARCH NURSE) PROCEDURES

5.1 On arrival in the morning

Research Nurse 1 will be responsible for switching on all equipment on the station and for calibrating equipment for the station (stadiometer, spirometer).

5.2 CALIBRATION AND CHECKING OF INSTRUMENTS (Research Nurse 1)

5.2.1 MORNING SESSION

The following calibration steps should be undertaken: -

- Skinfold caliper
- Check that gauge is zeroed

5.3 Measurements

These will be taken in order as follows. **Shoes are kept on for these measures: -**

5.3.1 Chair Stand Test (5 stands)

Explain that we will want the participant to stand up from a chair 5 times to see how long it takes. Seek their agreement – if they do not wish to undertake test indicate reason (refusal =1, disability= 2)

Set Up
Use a standard chair without arms and with a seat height of approximately 17 inches for all assessments, regardless of the height of the subject. If possible, place the back of the chair against a wall to prevent movement during the test.

Please ensure that the subject is wearing sensible flat shoes.

Procedure
Instruct and demonstrate the following protocol before asking the subject to perform the test:

Sit as far back as possible in the chair seat. Keep feet firmly planted on the floor, approximately hip width apart and the back of lower legs away from the chair.

Keep knees bent at a 90-degree angle and **arms crossed over the chest.**
(An individual of average or taller height will be able to sit with their upper back against the back of the chair. Individuals of shorter than average height will not be able to touch the chair back while maintaining proper position and are not required to touch the chair back during testing).

Demonstrate the procedure once, returning completely to the correct starting position.

As a trial go, ask the subject to stand from a sitting position with their arms folded, to a straight-legged fully standing position.

The subject should stand to a fully erect position i.e. their knees should not be bent and their back should be upright. This can be assessed on an individual basis i.e. they should stand as upright as they would normally.

After successful completion of the practice go, explain to the subject that on your word "go" you would like them to stand up and sit back down as practiced, five times. Explain that you would like them to do this as quickly as possible and that you will be timing them.

- At the command "Ready, Set, Go" the tester begins timing by starting the stopwatch.
- Count each chair stand out loud when the subject is in the standing position.
- Provide continuous verbal encouragement during the test.
- Stop the stopwatch when the subject is seated back in the chair on the final go, with arms remaining folded and back supported by the chair.

If subjects are unable to stand up one time without assistance than they can use their hands to assist them in rising and returning to the seated position while following all other procedures as described above. Make sure to note that hands were used when recording the assessment data.

If the test is not completed within 30 seconds, record how many completed lifts have been made at that point.

5.3.2 Three metre walking test

General preparation
A 3-metre walkway or 'corridor' is constructed along a wall in a smooth-floored area. Narrow 15-centimetre vertical strips are fixed on the wall at floor level and 3 metres apart within the corridor. We prefer this to sticking a line on the floor which, in our experience, can distract patients. Chairs should be positioned at each end, but at least 0.5 m from the markers to allow for acceleration and deceleration effects. These chairs are of a height to suit the person and facilitate easy standing up.

Explain that we will want the participant to walk a short distance along a corridor at their normal walking pace. Seek their agreement. If they do not wish to undertake test indicate reason (refusal=1, disability=2).

If the subject cannot walk without your assistance they cannot perform the test. Please indicate this in the boxes provided on the data entry sheet.

Subjects sit on a chair wearing their usual comfortable footwear or something suitable which has been provided. Thick-soled trainers are avoided so far as possible.

Avoid doing test while other people are passing close by.

Initial Instructions
I will ask you to stand up and will then say "Go". Then you should walk down to the chair facing you [indicate] at a comfortable pace without rushing. Do not stop until you have reached the other chair. Are you clear about what you are going to do?'

Starting Position
If necessary, subjects are helped to stand up. They may be reminded to walk at a comfortable pace, without rushing and without stopping, until they reach the opposite chair.

Instructions
Once the person is upright and steady the command 'Go' is given calmly, not in a way to imply the need for speed.

Warnings and Encouragement
During the walk no oral encouragement should be given although occasionally the command 'Keep going' is given if subjects seem about to stop or be distracted. Afterwards their efforts are rewarded with 'Well done'.

Feedback about the actual time taken is not given.

Timing
Stop-watches, which time to at least 0.01 seconds, should be checked for accuracy regularly. Ordinary wrist watches with second hands are not suitable. The tester, carrying the stopwatch, walks quietly at the side of subjects as they pass the first marker, then continues slightly behind them until close to the final marker when he moves forward opposite it. The tester avoids conveying any sense of pressure on the patient to hurry. Timing begins when the tip of the first foot crosses the first vertical strip and stops when the heel of the last foot crosses the second vertical strip.

If the test is not finished after 30 seconds, mark the data sheet accordingly.

5.3.3 Calf circumference (maximal calf circumference)

Restrictions No restriction, unless participant is unable to stand.

Site Flat surface.

Preparation participant should be sitting with the left leg hanging loosely or standing with their weight evenly distributed on both feet. Ask participant to roll up their trouser leg to uncover the calf.

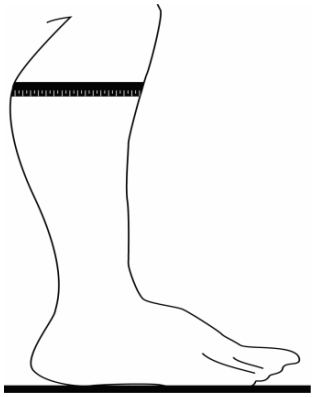
Equipment Circumference tape measure.

Wrap the tape around the calf at the widest part and record the measurement. Slide the tape measure up and down the calf to find the widest point. Take the measure there. Record to the last completed millimetre.

Take additional measurements above and below the point to ensure that the first measurement was the largest.

An accurate measurement can only be obtained if the tape is at a right angle to the length of the calf (see figure below).

Figure: Measuring tape position for maximal calf circumference



5.3.4 Waist circumference

Restrictions No restriction, unless participant is unable to stand to have his weight measured.
Site Flat surface
Preparation Participant wearing light clothing with shirt removed or tucked away – standing.
Equipment Circumference tape measure

Waist and hip measurements should be made with the subject standing with feet one foot apart on a marked template.

The waist should be identified as the mid-point between the iliac crest below and the lower edge of the ribs above, i.e. measured on the right side in the mid-axillary line. Mark the mid-point with a water-soluble marker.

Pass the tape around the waist (for large subjects, ask them to help passing the tape around) and reinsert at front, positioning level at the waist.

Ask subject to breathe out gently and record measurement at the end of expiration to the last completed millimetre.

If you are not satisfied about the accuracy of your measurement, record a 1 in the appropriate coding box `problem'.

Move on to do the first hip circumference, and then repeat the measurement.

5.3.5 Hip circumference

Restrictions No restriction, unless participant is unable to stand to have his weight measured.
Site Flat surface
Preparation Participant wearing light clothing with shirt removed or tucked away – standing.
Equipment Circumference tape measure.

This is measured by placing the tape measure around the hips at the point of maximum circumference.

The tape should be horizontal, and the gluteal muscles not contracted. Record to the last completed millimetre. If you are not satisfied about the accuracy of your measurement, record a 1 in the appropriate coding box.

There is no need to ask the participant to breathe out (or in) for this measurement.

Repeat the measurement.

If you are not satisfied about the accuracy of your measurement, record a 1 in the appropriate coding box `problem'.

5.3.6 Upper Arm circumference (right side)

Restrictions No restriction, unless participant is unable to stand.
Site flat surface
Preparation participant wearing light clothing with shirt removed or tucked away – standing.
Equipment Circumference tape measure

Ask the subject to bend the R arm to 90^{o}.

Identify the acromial process and the lower tip of the olecranon.

Using the tape measure, identify the midpoint of the upper arm, between the acromial process and the lower tip of the olecranon and mark with a felt tip pen.

With the arm hanging down loosely at the side the arm circumference should be measured at this point with the tape measure to the last completed millimetre.

If you are not satisfied about the accuracy of your measurement, record a 1 in the appropriate coding box `problem'.

5.3.7 Skinfold thicknesses (right side)

Restrictions No restriction, unless participant is unable to stand
Site flat surface
Preparation participant wearing light clothing with shirt removed or tucked away – standing.
Equipment Skinfold caliper (Holtain)

Check that calliper reading set to zero before starting measurements.

Explain that you want to measure the thickness of the skin tissue behind the arm and shoulder.

Measure the **triceps skinfold** at the midpoint of the upper arm as marked above.

- Grasp the skin and subcutaneous tissue without muscle immediately above the mark.
- Apply the skinfold caliper, below the fingers holding the skinfold (continue to hold the skinfold throughout the measurements.
- Skinfold calliper dial should be horizontal for the triceps skinfold measurement.
- Place the callipers around the skinfold – count 1,2,3,4,5 and record the reading

Measure the **subscapular skinfold** immediately below the tip of the scapula.

- Scapula tip can be made more prominent by pushing arm forward, or by bringing up behind the back into a (gentle!) half-Nelson position.
- Mark the site at the scapular tip for the reading.
- Grasp the skinfold firmly (not too firmly!) and apply callipers immediately below fingers. Count 1,2,3,4,5 and record the reading.
- Skinfold calliper dial will tend to be oblique for the subscapular skinfold measurement.
- Record first measurements in each of the two sites and then repeat procedure.

5.3.8 Blood Pressure (right arm)

Restrictions	No restriction
Site	Flat surface
Preparation	Participant seated wearing light clothing
Equipment	Omron blood pressure recorder, multiple cuffs

The subject should sit down at the measurement table and rest their right arm on the table. This will ensure that the subject is sitting with their upper arm at chest level.

Apply the appropriate size of cuff on the basis of the information on arm circumference (already measured).

Arm circumference < 22 cm	small cuff
Arm circumference 22 to 32 cm	medium cuff
Arm circumference > 32 cm	large cuff

It should be placed around the upper arm with the bladder centre over the artery. Explain that the cuff will inflate and squeeze the arm during measurement.

Use of the instrument

During initial setting up, the Omron should have been set to take two measurements at one-minute intervals.

This is done by setting the function mode. Do this by pressing on/off button for more than 3 secs while `start' button is also pressed in. To move between function modes F1, F2 and F3, use the start button.

F1 setting = 2 (number of measurements)
F2 setting = 0 (delay to first measurement)
F3 setting = 30 sec (measurement interval)

Machine should then be set to `auto' and `average' ready for the first measurement.

To begin the process of blood pressure measurements, press `start' and start the timer to go off in two minutes. The machine will immediately inflate the cuff and begin the first reading. During the measurement the subject: -

- should not be encouraged to talk
- should be encouraged to keep the right arm still.

The result of the first reading will appear on the screen and should be written down while waiting for the second reading to be completed. The second measurement will be made after a one minute interval on the automatic cycle. While waiting for the second measurement, entries on cuff, instrument, room temperature and ethnic origin can be recorded.

Once the second reading has been made, the `deflate 1^{st} 2^{nd} 3^{rd} ' button should be pressed successively to read off the second reading and reconfirm the first reading (do NOT record the average).

When the 2-minute alarm goes off, the participant should be asked to stand up and the `start' button pressed again to record two further standing blood pressure readings in exactly the same way as the sitting measurements already described.

(NOTE – it is crucial to write down the results of the sitting readings before the start button is pressed, because these readings will be deleted from the instrument).

While these readings are being made, note whether the participant reports faintness on standing or appears breathless and whether a problem with making four consecutive BP measurements.

Items recorded with blood pressure

- Cuff Mark down cuff size used as 1 (small) 2 (medium) and 3 (large).
- Instrument Will generally be 1, but a spare machine will be identified.
- Problem Unable to get 4 consecutive BP readings as in protocol, if this is the case problem = 1
- Faintness Subject reports being faint on standing up for BP measurement Y = 1
- Breathless Subject appears breathless on standing up for BP measurement Y = 1
- Room temperature Reading from digital thermometer

- Ethnicity –Based on the appearance of the individuals
  - Almost all subjects will be white European = 1

  Other codes should be based on the appearance of the individual are: -
  - black African-Caribbean = 2
  - South Asian (Indian, Pakistani, Bangladeshi) = 3
  - Chinese, Japanese, other Eastern = 4
  - Other or unclear = 5

5.3.9 Grip strength

- Sit the participant comfortably in a standard chair with legs, back support and fixed arms. Use the same chair for every measurement.

- Ask them to rest their forearms on the arms of the chair with their wrist just over the end of the arm of the chair – wrist in a neutral position, thumb facing upwards.

- Demonstrate how to use the Jamar handgrip dynamometer to show that gripping very tightly registers the best score.

- **Start with the right hand.**

- Position the hand so that the thumb is round one side of the handle, and the four fingers are around the other side (see picture). The instrument should feel comfortable in the hand. Alter the position of the handle if necessary. One can usually observe if the subject is uncomfortable.

- The observer should rest the base of the dynamometer on the palm of their hand as the subject holds the dynamometer. The aim of this is to support the weight of the dynamometer, but care should be taken not to restrict its movement.

- Encourage the participant to squeeze as long and as tightly as possible or until the needle stops rising. Once the needle stops rising the participant can be instructed to stop squeezing.

- Read grip strength in kilograms from the outside dial and record the result to the nearest 1kg on the data entry form.

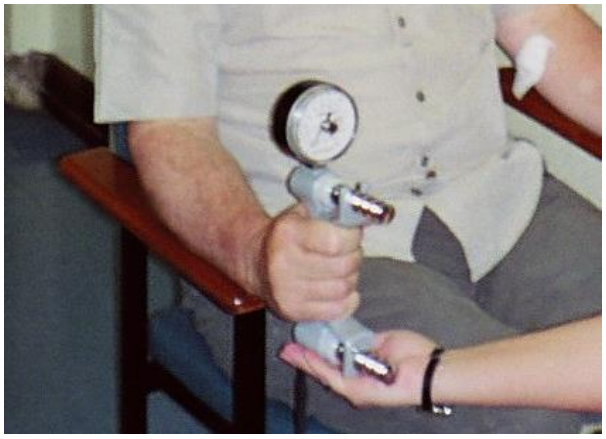
- **Repeat measurement in the left hand.**

- Do two further measurements for each hand alternating sides to give three readings in total for each side.

- The best of the six grip strength measurements is used in statistical analyses so encourage the subjects to get as high a score as possible.

- Ask `which is your dominant hand? (for writing) and record right, left or ambidextrous (people who can genuinely write with both hands).

- In `dominant' boxes, put 1 in L box or R box to indicate dominance; 1 in both boxes for ambidextrous.



Equipment: Model J00105 JAMAR Hydraulic Hand Dynamometer
Supplier: http://www.lafayetteinstrumenteurope.com/

5.4 Completion of station

- Escort participant to Station 2
- Ensure that any possessions are restored or stored for collection later.
- Records should be taken through to the next station.

5.5 At end of day

- Switch off all instruments; none of station 1 instruments require overnight charging.

5.6 SIMPLICATION OF STATION 1

If a participant cannot be measured completely, key priorities in Station 1 are: -

- Waist circumference
- Hip circumference
- Blood pressure (seated readings only x 2)

6.0 STATION 2 (RESEARCH DENTAL HYGIENIST) PROCEDURES

Includes: - Dental assessment and lung function test (spirometry).

6.1 On arrival

Research Hygienist will be responsible for setting up all relevant equipment on the station and for calibrating equipment for the station (spirometer).

6.1.1 CALIBRATION: Spirometer

Please ensure that spirometer is turned on early and left to warm up before testing.

Check paper supply.

Enter 'set up' mode and go to 1 'accuracy + calibration'. when the machine invites you to blow air through the flowhead to equilibrate temperatures, please blow 3 litres through slowly,
then 'continue'.

Set ambient (room temperature) consulting the electronic thermometer.

Pump 5 litres of air slowly (each litre must take more than 1 second) through the flowhead to calibrate and then 'exit'.

Read in 5.00 as reference volume and enter.

Update calibration if error is 1% or greater.

'Retest' by putting a further 5 litres of air through the flowhead. If error is 1% or greater update calibration again and retest one more time.

If calibration will not settle, raise threshold for correction to 3%.

When you have finished, move to main menu and to FVC test, and when the machine says 'perform blow', blow 1 litre through calibration syringe and record the result.

6.2 CALIBRATION AFTERNOON SESSION

- Recalibrate the Vitalograph as before.

6.3 Procedures for each subject

Research Hygienist will greet the subject, checking his identity on arrival and take the data sheet and Questionnaire.

6.4 Dental examination

Oral health assessment will comprise a tooth count, recording dentures, functional occlusal pairs, brief periodontal examination, soft tissue lesions, dryness score.

Restrictions none unless participant is unable to open mouth wide or refuses dental assessment.
Preparation participant to lie on couch reclining at 45 degrees.
Equipment disposable dental probe, mouth mirror, tray, gloves, head torch, pen.

6.4.1 Briefing subjects

Very briefly explain the dental examination:

- I would like to do a simple dental assessment which will take a few minutes.
- I will do a tooth count and look at the gums of your teeth and will not disturb any existing dental work or fillings.
- If you would like to close your mouth at any time, please indicate by raising your left hand.
- I will use a mirror and a blunt instrument/probe, no sharp instrument; it will not be painful.
- This examination is for only study purposes to specifically examine your gum tissue. I will be calling out numbers that have meaning only for this study.

6.4.1.1 Check if subject has:

Dentures: ask to remove denture(s) and place in disposable tray.
If complete dentures in upper and lower arch, enter tooth count (=0) and occlusal pairs (=0) on data sheet.

Implants: this is a whole tooth replacement not just a crown. Ask subject to point to implant if he has one. **Do not probe gums around implants**. This age group is unlikely to have implants.

Difficulty in opening mouth wide: "do you have any problems opening your mouth wide?". If difficulty in opening or clicking of jaw, ask subject to open only as much as he can. If history of dislocation of jaw on opening mouth wide, do not perform examination.

6.4.2 Examination light (head torch):

Adjust and position the head light while asking the subject to open his mouth.

6.4.3 Dictaphone should be placed on the desk and switched on.

When ready for examination, press 'play' on Dictaphone. All measurements will be spoken out loud to record data on the Dictaphone.

6.4.4 Gloves and examination kit:

- Put on gloves when ready for examination.
- Open the sterile instrument kit which has a mouth mirror and a CPITN probe.
- Mouth mirror is to be held in left hand and probe in the right hand. Mouth mirror is used both for retraction of cheek/lips and for viewing posterior (back) teeth.

Correct grasp of probe "modified pen grasp" – note the corner contact points of middle finger and thumb; handle rests against bony area of knuckle.

6.4.5 Examination

Start with saying the batch number to record on the Dictaphone – "batch number …".

Teeth must be examined in the following order:

Always begin from upper right last (distal most) tooth to upper left last tooth; lower left last (distal most) tooth to lower right.

6.4.5.1 Tooth count:

Use the mouth mirror (left hand) to gently retract the cheek for better visibility of the posterior teeth and use the probe to count the teeth (right hand).

Count teeth in the upper arch starting from the right and call out "Upper arch …teeth".

Lower arch: start counting from the last tooth (distal most) in the lower left arch.
Count teeth in the lower arch and call out "Lower arch …teeth".

Root stumps (without crown) are not to be included in tooth count; broken tooth can be included even if crown is broken.

6.4.5.2 Dentures

Record denture wearing. 1=yes, 2=no if wearing any dentures; complete denture upper or lower; complete overdenture; implant retained denture; and whether denture examined.

Partial upper and/or lower denture – record teeth replaced on data sheet.

6.4.5.3 Functional pairs

- The examination is conducted without dentures.
- This examination is conducted only if there are some natural teeth in both arches.

Posterior occlusal contacts – left and right (premolars and molars)
The assessment of occlusal contacts refers to occlusal contacts between **natural teeth and the pontics of fixed bridges only.**

- A contact is the same as an occlusal stop.
- Ask the subject to close together normally on the back teeth (sometimes the phrase "clench your back teeth together" is the most effective). If they have any difficulty with this, ask them to swallow and keep their teeth closed after swallowing.
- Then using a mirror to hold back the cheek, look at the lower arch from the side and record the distribution of contacts.
- There are potentially eight occlusal units each on right and left sides.
- Coding takes place from the first premolar backwards as this makes it much easier to keep track of the position.
- Just look at each side in turn and work out whether or not there is a NATURAL contact between a lower pre-molar and another natural tooth, then between lower molar and another natural tooth.
- **The presence of a contact is determined by the lower tooth** (i.e. does the natural lower or bridge pontic contact with any natural upper or pontic) and is coded as a "1" even if the area of contact is small.
- A bridge pontic or implant counts as a natural tooth – it is supported by one – but a denture does not).
- There can be no contact if there is no lower tooth in that zone.

- In some cases, it may be difficult to tell whether the teeth actually touch or not, you should assume that they do if you are in doubt.
- An occlusal unit is a single premolar or half a molar (mesial or distal) – record each unit if present as 1 on data sheet; if absent record as 0.

Anterior functional pairs

After the grid for posterior occlusal units is completed, record anterior contacts present.
There are potentially up to three anterior pairs or units of contact each on right and left sides.

- Record functional pair based on lower tooth if in contact with an upper tooth.

Where there is no contact, the subject should be asked to bite edge to edge to see if contact can be obtained.

Where there is a deep overbite, this may be very difficult to assess accurately, so it should just be estimated if there is a problem. Again, actual contact is not strictly necessary if the participant can achieve some sort of contact by protrusion of the mandible. A phrase such as "can you bite on your front teeth like this", with the examiner demonstrating incisal contact may be used if there is any problem.
If any pair of anterior teeth can contact, it is coded as present.

Record two further questions:

1. "How many natural posterior teeth (upper or lower) have no opposing natural tooth?"
2. "How many natural posterior teeth (upper or lower) are opposed only by denture?"

These are self-explanatory and are easily assessed by visual examination with the teeth together, although where there are partial dentures, they will often have to be inserted prior to this part of the examination. This is to identify how many teeth are non-functional.

6.4.5.4 <u>Soft tissue pathology</u>

A brief visual examination of the lips and perioral tissues is conducted. Most intra-oral areas can be easily visualised during the dental examination, however several areas MUST be visualised specifically. These are:

1. Floor of mouth. Mouth mirror used to gently deflect tongue to right and left.
2. Mucosal surface of lips. The upper and lower lips are gently inverted to visualize.
3. Buccal sulci. The mouth is half closed and the cheeks gently retracted.
4. Soft palate - visualise directly or using mouth mirror if needed.

Record Soft tissue lesion(s) as follows –
For each type, tick Yes box if present, tick No box if absent.

1) None
2) Angular cheilitis - inflammation with or without cracking localised to one or both commisures.
3) Denture stomatitis – denture bearing area associated with patchy or localised redness or generalized redness; or multiple small nodular or granular lesions covering denture bearing area with associated inflammation.

4) Denture hyperplasia - is a firm enlargement of the vestibular mucosa, clearly related to the flange of a denture.
5) Ulcer associated with denture trauma - any ulcerated lesion which is believed to be due to trauma alone and not any other pathological process (e.g. malignancy).
6) Other – any lesion other than above.

NOTE: More than one of these lesions can be recorded as these are not mutually exclusive.

6.4.5.5 Clinical dryness score

This is a quick visual assessment using a mouth mirror to assess symptoms associated with dryness of mouth.

Record if any of these are present (Yes=present, No=absent)

1) Mirror sticks to buccal mucosa
2) Mirror sticks to tongue
3) Frothy saliva
4) No saliva pooling in floor of mouth
5) Tongue shows loss of papillae
6) Altered/smooth gingival architecture
7) Glassy appearance of other mucosa, especially palate
8) Tongue lobulated/ fissured
9) Active or recently restored (last 6 months) cervical caries >2 teeth
10) Debris on palate (excluding under dentures)

NOTE: More than one of the above can be recorded as these are not mutually exclusive.

6.4.5.6 Periodontal measures

Three periodontal measures assessed:

- Loss of attachment: Two sites to be measured on the buccal side of each tooth (facing the cheek) – mesial and distal.
- Pocket depth: One site (mesial) to be measured for pocket depth.
- Bleeding if in response to probing

Order of assessment: start from upper right 7 (second molar) to upper left 7, then lower left 7 to lower right 7.

Insert the probe gently in the mesial site to measure the depth of the space between the tooth and gum tissue.

Loss of attachment (LoA) is measured from neck of tooth (junction of crown and root) to base of pocket (as far as the probe goes). Neck of tooth can be identified as either a line along the crown of the tooth, or by darker shade of root surface.

Insert the probe in the distal site of tooth 1 and similarly measure loss of attachment.

Pocket depth: Insert probe on mesial site again and measure pocket depth from gingival crest (top of gum) to base of pocket (as far as the probe goes).

IF **DICTAPHONE USED** to record measures: Call out scores for the 3 measures for each tooth as follows –

"Tooth number mesial ..., distal ..., pocket …; Tooth 2 mesial …, distal …., pocket …"**

Similarly, measure LoA and pocket depth in other teeth. If in doubt, record the lower score.

Score to measure loss of attachment and pocket depth:

0 = First probe band - Up to 3.5 mm
1 = First dark band - 4-5.5 mm
2 = Between two dark bands - 6-8.5 mm
3 = Second dark band - 9+ mm
8 = Unscorable
9 = Missing tooth in sextant

(Score 8 should only be used if the pocket cannot be probed either because of discomfort or because there is a physical barrier e.g. a large shelf of calculus or filling).

When probing lower anterior tooth, retract lower lip gently with left hand if needed – tense muscles of lower lip maybe difficult to retract with mouth mirror.

Adequate lighting is crucial for reliable measurements – adjust light and headlight as needed during examination.

Bleeding on probing:

Upper arch:

After measuring loss of attachment and pocket depth in the upper arch, go back to visually check all teeth starting from upper right to see if bleeding in response to probing at the 2 sites (mesial and distal). Retract the cheek to observe posterior teeth.
There may be a delay of approx. 20 seconds for bleeding to occur after probing.

Record bleeding on probing as:

Score:
0 – no visible bleeding
1 – evidence of bleeding
9 – missing tooth in sextant

Call out bleeding scores as:
"Measure 2; tooth 1 mesial…; distal…;Tooth 2 mesial…; distal …Tooth 2 mesial …; distal …"

The subject may close his mouth for a couple of seconds before probing teeth in lower arch.

Lower arch:

After recording LoA and pocket depth in lower arch, look for bleeding in the same way as upper arch starting from lower right 7.

Call out bleeding scores as:
"Measure 2; tooth 4 mesial…; distal…;Tooth 5 mesial…; distal …Tooth 6 mesial …; distal …"

Press the 'stop' button on the Dictaphone to stop recording.

6.4.6 After examination

Ask the subject to put on dentures if removed.

6.4.7 Disposal of gloves, probe, mirror:

Gloves should be removed inside out and disposed with clinical wastes. Mouth mirror and probe are to be disposed in sharps bin.

6.4.8 Transcribe data from Dictaphone to data entry sheet:

At the end of Station play back the recording to transcribe data recorded to the data entry sheet.

NOTES for Probe grasp:

The probe is to point toward the apex of the tooth, parallel to the long axis of the tooth. If tooth is tilted the probe should be aligned according to the position of the tooth.

The probe is to be held with a light grasp not to exceed 20 grams – it should be possible to remove the probe from the examiner's hand without resistance.

Do not exert force greater than 20 grams. Probing should not cause pain or blanching of the gum tissue, if it does, too much pressure is being exerted. As an indication of the force required when probing, place the probe below your fingernail, this should not be painful if the appropriate pressure is used.

Possible concerns that might be raised by subjects and appropriate responses:

- Treatment: Assure him that the exam will not include any treatment or procedure. Only a mirror and a blunt-ended hand instrument will be used to examine the gums of few teeth.
- Qualifications of the examiner/advice on dental health: The examiner is a dental hygienist but cannot comment on state of gums as this is not a proper check of gums.
- Existing dental work: The exam will not interfere with any existing dental work such as fillings, crowns or bridges.
- Pre-existing medical conditions: If subjects raise the issue of pre-existing medical conditions the following statement may be helpful "In the past there was a policy not to examine the gums of some patients with some heart problems or joint replacements. However, the National Institute for Clinical Excellence (NICE) has recently reviewed the evidence in this area and concluded that there is no significant risk from the examination of teeth and gums. Our policy is in line with this, but if you prefer not to have the gum examination, please let me know." In this case, ask for permission to do only a tooth count or measures other than periodontal measures.

6.5 SPIROMETRY

Equipment: **Instrument 1:** Vitalograph Compact II (used in BRHS Town 21 (Bedford) for 36 subjects)
Instrument 2: Vitalograph Compact II (used in BRHS Town 21 (Bedford) for 11 subjects)
Instrument 3: Vitalograph Alpha Touch device **– used in all other towns**

Note: There was instrument failure during the fieldwork in BRHS town 21 at the very start of the study. A back-up instrument 2 was used which subsequently also failed. A 3rd instrument was purchased and used for the fieldwork of the remaining 23 BRHS towns.

Preliminary explanation to subject. "We would like to measure the size of your lungs by asking you to blow into this machine".

Contraindications - There are no absolute contraindications to spirometry, but common sense should be exercised. Defer spirometry until about six weeks in patients who have had: -

- pneumothorax
- eye, ear chest or abdominal surgery
- myocardial infarction or stroke

Then proceed with instructions:

"What I want you to do is to take a very big breath in and to blow out as hard and as long as you can, until your lungs are empty. Watch me."

(Demonstration by nurse using mouthpiece)

Subject then practices once: ensure that: -

full breath in
lips tightly around mouthpiece
long hard blow right to the end

Before measurements are made, check about use of inhaler use within last 24 hours, and record the time of last inhaler use.

Before starting the test enter the subject's 3-digit batch number and press the 'enter' key in order to proceed.

On the main menu press 'FVC test'. The machine will then say 'perform test', indicating that it is ready for the first blow.

We want to record three definitive blows. Encourage the subject with the first blow `big breath in….and out…. blow, blow, blow…right to the end'.

After each blow, press 'end test' to expedite results and then 'retest' to go on to the next test.

The machine takes a short period to calculate results, after which FVC, FEVI and PEF figures will then be displayed on the screen. Once the results of each of the first two blows are displayed press 'retest' and the machine will display 'perform test' to indicate readiness for the next reading.

Once the result of the third reading is recorded, check the `best test variation' which is recorded on the screen. If best test variation is more than 5% after 3 readings, please take an additional reading by pressing 'retest' again.

If you are not satisfied that subject has done an adequate blow on at least one reading, please enter 1 in the `problem' box.

Once the 3 (4) readings are complete, press 'end test' to return to the main menu. Press 'print' and then 'selected' to print out the results. The printed output should be stapled onto the front of the data sheet in the space provided. Then press the 'new patient' category and agree to delete old patient's results. This will leave the machine waiting for the next subject's serial number to be entered in due course.

Changing printer paper

Open the printer slot.

Feed the paper in from R side from the lower side of the roll with the printer release switch pushed or held over to L side. The paper may slide through or can use `paper feed' on lower L panel of main menu to drive paper through – this will only function when the printer release switch is pushed to the L side.

In the event of Vitalograph printer failure

Please record the number of readings and the best test variation directly from the screen before leaving the test screen. Then on main menu press option 5, display results, and write down the other parameters on the data sheet.

6.6 End of Station

Escort participant to Station 3.

6.7 Research Hygienist tasks at the end of day

- Check data sheets are complete and transcribe any data recorded on Dictaphone.
- Switch off spirometer.

6.8 SIMPLICATION OF STATION 2

If a participant cannot be measured completely, key priorities in Station 2 are: -

- Tooth count if time permits

7.0 STATION 3 (RESEARCH PHLEBOTOMIST) PROCEDURES

Blood test, height, weight and body composition

7.1 On arrival

Research Phlebotomist will be responsible for switching on all equipment on the station and for calibrating equipment for the station (stadiometer).

- Set up relevant equipment
- Prepare blood syringes and collection tubes for the morning and (if possible) afternoon session, following the appointment list for the day

7.2 CALIBRATION AND CHECKING OF INSTRUMENTS

The following calibration steps should be undertaken: -

7.2.1.1 Stadiometer

Please check recorded height of standard 1 metre rule once instrument set up, and record result. (This ensures that recorder has not become displaced)

7.2.2 Tanita body composition

- Check paper supply.
- Calibrate the Tanita Viscan, following the manual instructions: -
    - stand the instrument on a flat surface
    - make sure nothing stands between the distance sensors
    - turn on the unit
    - press the `O over 130 cm' key for about 2 seconds, using a pen tip
    - `CAL' will be displayed
    - press the `start' button to begin the calibration
    - (NEVER switch instrument off during calibration, when oooo symbols appear!)
    - Once finished the instrument will display `CAL End' and it will turn itself off.

7.3 Procedures for each subject

Research Phlebotomist will greet the subject, checking his identity on arrival and take the data sheet and Questionnaire.

7.3.1 HEIGHT

Restrictions none unless participant is unable to stand to have his/her height measured
Site flat surface
Preparation participant not wearing shoes
Equipment Harpendon stadiometer

The participant is asked to stand on the stadiometer facing forwards, and as tall as he can. The Research Nurse should check for the following points: -

- FEET: ankles should be together and resting on the bar at the back,
- ARMS: should be resting by sides, not behind or in front,
- BACK: should be as straight as possible
- HEAD: subject should look straight ahead (i.e. lower edge of orbit is in line with external auditory meatus [earhole]) – this is the Frankfort plane, should be horizontal.

The index fingers of both hands should then be placed below the mastoid process on each side. During inspiration the increase in height should be maintained and during expiration a gentle stretch should be applied.

Then bring down headplate gently, record height to last completed millimetre.

Particular care is needed to ensure that the participant does not stand on tiptoe.

Record any problems which the patient has which may lead to underestimation of height in the `problem with height' box.

Any problem = yes = 1

CHECK – Make sure can set up and take down the stadiometer.

7.3.1.1

NOTE

Corrections to Height Measurements
Due to issues with the stadiometer—specifically, a displacement of the height recorder—in two of the towns, height measurements were systematically underestimated. To address this, the field team conducted calibration checks using a one-meter ruler before the morning and afternoon examination sessions each day. The discrepancies were recorded by date and session. These data were then used to correct the height measurements accordingly.

7.3.2 WEIGHT AND TANITA MA418BC BODY COMPOSITION

Ask participant if he has a pacemaker, which also includes a defibrillator.

If he HAS a pacemaker or defibrillator, he should NOT have measurements with the Tanita body composition monitor but should be weighed with the simple Tanita scales.

If he does NOT have a pacemaker or defibrillator, he should have measurements with the Tanita body composition monitor and should not be weighed with the simple Tanita scales.

7.3.2.1 PARTICIPANT HAS PACEMAKER/DEFIBRILLATOR

Site - flat surface

Preparation – participant wearing light clothing and not wearing shoes, all heavy items removed from pockets.

Equipment – Tanita scales (NOT the Tanita body composition monitor)

Use of Tanita scales (pacemaker cases): -

Participant should stand straight if possible - leaning to one side (or forwards) can affect the weight recorded. If the weight registered is between two 0.1 kg marks, take the lower one.

7.3.2.2 PARTICIPANT DOES NOT HAVE PACEMAKER/DEFIBRILLATOR

Use of body composition analyser: **Tanita BC-418 (non-pacemaker cases)**

Enter information on the following: -

- clothing weight (1 kg)
- age (whole years) from data sheet label
- gender
- height (cm)
- fitness designated as normal.

Participant stands on scales for weighing and then grasps handles for body composition measurements when instructed to do so.

Printout is automatically produced and stapled to the datasheet (minimum 2 staples)

7.3.2.2.1 Body composition measurements

NOTE – Body composition measurements

Due to issues with data inputs into the Tanita machine, the integrity of the body composition measurements/outputs has been compromised. As a result, the data is not being made available.

7.3.2.3 Derived weight variable

WEIGHT (q40weight)

Weight measurements taken either using the Tanita Body Composition machine or ordinary digital scales (for individuals with a pacemaker) have been combined into a single (derived) variable, q40weight.

Blood sampling

The blood sample will be taken at the end of the examination. The blood sample should be taken with the subject lying down.

We would like to ask you to give us a blood sample for the measurement of factors related to the heart and circulation – would that be OK?

Check whether the subject has had previous problems with blood sampling.

Alcohol swabs will be provided for skin cleaning where needed - allow to dry after use.

A tourniquet may be used throughout. Wear the rubber gloves provided for taking the sample. A 21-gauge butterfly needle (or Sarsted needle) should generally be used; a supply of 23 gauge needles will also be supplied for more exceptional use.

A maximum of three attempts may be made in the different arms if the subject consents. No further attempt to obtain blood should be made.

There are nine collection tubes which will be prepared in advance. They should be taken in the order specified on the separate protocol, with citrate tubes (x2) taken first followed by serum tubes (x3), followed by EDTA tubes (x3) followed by fluoride-oxalate (x1).

After venepuncture, raise subject's arm and encourage subject to press firmly on cotton wool pad to avoid bruising. Plasters are provided. Please check for elastoplast allergy - if present, use cotton wool and tape.

After venepuncture the tubes should be gently agitated and placed in a rack. Please label the tubes with the appropriate serial number labels, sticking an extra label copy in the space provided on the data sheet. Please record: -

- the full success/partial success/failure of sampling
- the reason for failure if appropriate
- the time of venepuncture
- the time when the participant last ate
- if partial success, which of the `primary' collection tubes have blood in them

Bloods should be sorted by individual subject. The serum tubes will be taken apart for centrifugation at least 30 minutes after collection (see below) and then restored to the main sample base collection.

7.4 Consent

- Participants' consent needs to be obtained for data storage.
- Take them through the 'BRHS consent form'. They need to write their initials to say if they agree to participate – left-hand column to 'agree'; right-hand column if 'do not agree'.
- Point out that initials are needed for each question on consent sheet.
- Observer/ research phlebotomist to sign and date the consent form too.

7.5 End of Station

- Escort participant to Receptionist where Test Your Memory questionnaire and refreshments will be given.

7.6 Research Phlebotomist tasks at the end of day

- The 3 serum tubes should stand for a minimum of 30 minutes and then centrifuged for 10 minutes at 4200 rpm. These will either be shipped overnight or refrigerated and then despatched the following day.
- Switch off all instruments

7.7 SIMPLICATION OF STATION 3

If a participant cannot be measured completely, key priorities in Station 3 are: -

- Height
- Weight
- Blood test

8.0 FEEDBACK OF RESULTS

When the subject agrees, results will be fed back to the subject's G.P. including: -

Height

Weight

Body mass index with cutoffs as a comment, viz: -

20 or less	= underweight
>20-25	= acceptable
>25-30	= overweight
>30	= obese

Systolic BP (mean of 2 readings)

Diastolic BP (mean of 2 readings)

Blood results

From **biochemistry**

Include:

Total LDL, HDL cholesterol and triglycerides

Blood glucose

urea k na creatinine urate

tprotein alb bili alk phos ast = aspart transam alt = alanin transam ggt = gamma gt

(exclude: mg ca corr ca po4)

From **haematology**

Include: wbc, hb, platelets, rbc, hct, mcv, mch, mchc only

Abnormal values as defined by the laboratory will be indicated with a star next to the abnormal parameter. Abnormal values requiring more urgent attention are summarized on the next page.

9.0 MARKEDLY ABNORMAL RESULTS

9.1 During study measurements

The only abnormalities which are likely to be identified during the study measurements are a high blood pressure reading or any serious soft tissue pathology in the mouth.

9.1.1 Action for high blood pressure readings

Comparability issue

Diastolic pressure readings

Average 120mm Hg or more: severely raised

Average 100-119mm Hg: moderately raised

Systolic blood pressure readings

Average 210mm Hg or more: severely raised

Average 180-209mm Hg: moderately raised

If either systolic or diastolic pressure is **severely** raised, should tell the patient: -

`Your blood pressure is **high** today. Has your blood pressure been high before, or have you received treatment for high blood pressure?'

(If no), `Blood pressure can vary from day to day, so that one high reading does not necessarily mean that you have high blood pressure.'

(All) `You would be well advised to arrange to see your doctor **within a week** to have a further check on your blood pressure. I will give you a card with a note of your blood readings today to give to your doctor'.

If either systolic or diastolic pressure is **moderately** raised, should tell the patient: -

`Your blood pressure is **on the high side** today. Has your blood pressure been high before, or have you received treatment for high blood pressure?'

(If no), `Blood pressure can vary from day to day, so that one high reading does not necessarily mean that you have high blood pressure.'

(All) `You would be well advised to arrange to see your doctor **during the next two or three weeks** to have a further check on your blood pressure. I will give you a card with a note of your blood readings today to give to your doctor'.

Direct notification of GP - to be discussed **

9.2 Pathology in the mouth (Station 2)

Reporting serious pathology:

If the examiner notices a lesion which he /she considers may be serious and potentially life threatening (such as a suspected malignancy) – examiners are very unlikely to encounter such potentially serious pathology, the incidence of these lesions is very low, the examination is not a screening exercise. However, it is possible that such a lesion may be noticed and, as the implications are serious, a protocol to deal with this eventuality is in place.

In the extremely unlikely event that such a lesion is noted, the examiner can make sure that the participant's GP is informed, whilst ensuring not to cause the participant unnecessary worry.

The following wording is suggested

"In this survey it is our policy to inform your doctor of any ulcers or inflamed areas we see. As there is an area like this in your mouth I would like to inform your doctor, who should contact you to arrange a check-up. If you do not hear from them in the near future, please arrange your own appointment.

It is most unlikely that any such lesions will be found, and it is also unlikely that, even those which are reported, will turn out to be serious. It is the responsibility of the examiner not to alarm the participant unduly.

If the participant asks what the examiner thinks the lesion is, the examiner should answer honestly that they do not know, before re-iterating standard survey policy as above.

9.3 Abnormalities on biochemical/haematological tests

Results which should be phoned through to the General Practitioner directly would include: -

- blood glucose above 15 mmol/L (provide urea and electrolytes also)
- blood urea above 20 mmol/L
- serum potassium below 2.5 mmol/L or above 6.0 mmol/L
- serum sodium below 120 mmol/L
- Haemoglobin below 8.0 g/dl; acute leukemia

Reporting serious pathology: If the examiner notices a lesion which he /she considers may be serious and potentially life threatening (such as a suspected malignancy) – examiners are very unlikely to encounter such potentially serious pathology, the incidence of these lesions is very low, the examination is not a screening exercise and does not involve examination of the oral soft tissues (except for gums of some teeth). However, it is possible that such a lesion may be noticed and, as the implications are serious, a protocol to deal with this eventuality is in place.

In the extremely unlikely event that such a lesion is noted, the examiner can make sure that the participant's GP is informed, whilst ensuring not to cause the participant unnecessary worry.

The following wording is suggested –

"In this survey it is our policy to inform your doctor of any ulcers or inflamed areas we see. As there is an area like this in your mouth I would like to inform your doctor, who should contact you to arrange a check-up. If you do not hear from them in the near future, please arrange your own appointment.

It is most unlikely that any such lesions will be found, and it is also unlikely that, even those which are reported, will turn out to be serious. It is the responsibility of the examiner not to alarm the participant unduly.

If the participant asks what the examiner thinks the lesion is, the examiner should answer honestly that they do not know, before re-iterating standard survey policy as above.

10.0 PROTOCOL VIOLATIONS/DEPARTURES FROM PLAN

These will need to be dealt with as they arise. Details should be recorded in the study log book.

If a member of staff is ill:-

- please phone base so that a replacement can be found as soon as possible, and any other arrangements made.

IF ONE OBSERVER IS UNAVAILABLE WITHOUT REPLACEMENT, THE OTHER OBSERVER SHOULD PRIORITISE THE FOLLOWING:

- Height
- Weight and bioimpedance
- Waist circumference
- Hip circumference
- Blood pressure (seated readings only x 2)
- Spirometry
- Blood test
- Tooth count

11.0 ANSWERING QUESTIONS ABOUT THE STUDY

What is the study for?

To research health conditions in older age, particularly related to cardiovascular diseases, such as disability, frailty, loss of muscle, nutrition and dental health.
To understand how these conditions are interrelated and how these could be prevented in the future.

What has the study shown so far?

Over the last 40 years, the study has contributed to a variety of research findings. These include: a better understanding of factors leading to heart disease (such as smoking, obesity); patterns of how heart disease is distributed in Britain; role of physical activity in heart disease.

Will you want to see me again?

We are in contact with periodically with questionnaires and we are very grateful for participation in that. These face-to-face visits are less frequent, but we will contact if any plans in the future.

Will these results be seen by my doctor?

If they agree, results can be shared with their GP.

What happens if my tests are abnormal?
GP will be informed if any abnormal results.

12.0 Appendix 1: GP referral letter for high blood pressure

APPENDIX 1

Dear Doctor_____,

British Regional Heart Study

Your patient_____ attended our survey examination. His sitting blood pressure readings were: -

SBP*_____DBP_____

SBP*_____DBP_____

We recommended that he should attend your surgery for a further blood pressure measurement within a week/within two-three weeks.

Thank you for your attention.

British Regional Heart Study

* These measurements were made with a Dinamap instrument, which overestimates systolic blood pressure by about 8 mmHg compared with a mercury sphygmomanometer.

For attention of study receptionist

This study participant has kindly agreed to return for a further set of survey measurements during the next few days. Please book him another appointment to attend at his convenience.

13.0 Appendix 2: Data sheets (Physical examination data collection form)

14.0 Appendix 3: Blood separation plan

BRITISH REGIONAL HEART STUDY

BRHS 40 year follow-up physical examination (Q40)

Datasheet 2018 Assessment

NAME:
STUDY ID:
DOB:
AGE
GP Details:

Please amend details if incorrect

British Regional Heart Study, Department of Primary Care & Population Health, UCL Medical School, Royal Free Campus, Rowland Hill Street, London NW3 2PF Tel: 0207 7830 2335

STATION 1

Affix Label: Serno/batch

Observer Initials ☐☐ Time ☐☐:☐☐ (24 hr)

Chair rise (5 times)
If No – : 1= refused 2= disability ☐ Secs: ☐☐.☐☐ N at 30 sec? ☐ Used hands? (Yes=1) ☐

Gait speed (walk 3 meters)
If No – : 1= refused 2= disability ☐ Secs: ☐☐.☐☐ Used w/aid ☐ Incomplete at 30 secs (Yes=1) ☐

MEASUREMENTS

				Problem P=person T=technical
Calf circ 1(cm)	☐☐☐.☐			Problem ☐ P/T
Waist circ 1	☐☐☐.☐	waist circ2	☐☐☐.☐	Problem ☐ P/T
Hip circ 1	☐☐☐.☐	Hip circ 2	☐☐☐.☐	Problem ☐ P/T
Arm circumf	☐☐☐.☐			Problem ☐ P/T
Triceps 1	☐☐.☐	Triceps 2	☐☐.☐	Problem ☐ P/T
Subscapular 1	☐☐.☐	Subscap 2	☐☐.☐	Problem ☐ P/T

BLOOD PRESSURE

Cuff size : Arm circ < 22 cm = **1** (small) 22-32 cm = **2** (medium) >32 cm = **3** (large)

Cuff used ☐ Instrument ☐ Problem ☐ P/T

Blood pressure	Sitting 1	Sitting 2
Systolic (mmHg)	☐☐☐	☐☐☐
Diastolic (mmHg)	☐☐☐	☐☐☐
Heart Rate (per min)	☐☐☐	☐☐☐

Room temp(^{0}C) ☐☐.☐ Ethnicity ☐ **1**=WE **2**=BAC **3**=SA **4**= Ch/J/O **5**= Other

Grip Instrument ☐

	1	2	3		
Grip strength (Right hand) kg	☐☐	☐☐	☐☐	R Dominant (Yes=1) ☐	Problem ☐ P/T
Grip strength (Left hand) kg	☐☐	☐☐	☐☐	L Dominant (Yes=1) ☐	Problem ☐ P/T

STATION 2: ORAL HEALTH

Observer initials ☐☐ No examination ☐ REASON: 1=Refusal, **2**= unable to open mouth, **3**=other

	UPPER			LOWER		
Dentures	Yes	No	Yes/Not worn	Yes	No	Yes/Not worn
(please tick)	1	2	3	1	2	3
Wears a denture?						
Full denture ?						
Partial denture ?						
Implant retained denture ?						
Complete overdenture?						
Denture/s examined?						

PARTIAL DENTURE(S) PRESENCE OF TEETH ON

	18	17	16	15	14	13	12	11	21	22	23	24	25	26	27	28
UPPER																
	48	**47**	**46**	**45**	**44**	**43**	**42**	**41**	**31**	**32**	**33**	**34**	**35**	**36**	**37**	**38**
LOWER																

1 = Tooth replaced on partial denture Blank = Teeth not replaced by partial denture

FUNCTIONAL PAIRS	RIGHT							
Posterior	**8D**	**8M**	**7D**	**7M**	**6D**	**6M**	**5**	**4**

LEFT							
4	**5**	**6M**	**6D**	**7M**	**7D**	**8M**	**8D**

	RIGHT		
Anterior	**13**	**12**	**11**

LEFT		
21	**22**	**23**

1=Contact present 9=Absent

☐☐ **Number of natural posterior teeth (upper or lower) with no opposing natural tooth**

☐☐ **Number of natural posterior teeth (upper or lower) opposed only by denture**

NATURAL TEETH

TOTAL UPPER

TOTAL LOWER

PRESENCE OF NATURAL TEETH

18	17	16	15	14	13	12	11	21	22	23	24	25	26	27	28
48	**47**	**46**	**45**	**44**	**43**	**42**	**41**	**31**	**32**	**33**	**34**	**35**	**36**	**37**	**38**

Reference
9=Missing; 1=Present; 2=Implant; 3=rootstump

PERIODONTAL MEASURES

	17	17	16	16	15	15	14	14	13	13	12	12	11	11
	D	M	D	M	D	M	D	M	D	M	D	M	D	M
LA														
PD														
GB														

	21	21	22	22	23	23	24	24	25	25	26	26	27	27
	M	D	M	D	M	D	M	D	M	D	M	D	M	D
LA														
PD														
GB														

	47	47	46	46	45	45	44	44	43	43	42	42	41	41
	D	M	D	M	D	M	D	M	D	M	D	M	D	M
LA														
PD														
GB														

	31	31	32	32	33	33	34	34	35	35	36	36	37	37
	M	D	M	D	M	D	M	D	M	D	M	D	M	D
LA														
PD														
GB														

LA=Loss of attachment **PD**=pocket depth **GB**=Gingival bleeding

GB score: **0**=No **1**=yes **8**=unscorable **9**=Missing tooth

Clinical oral dryness score (please tick)		**Yes**	**No**
		1	2
1	Mirror sticks to buccal mucosa		
2	Mirror sticks to tongue		
3	Frothy saliva		
4	Saliva pooling in floor of mouth		
5	Tongue shows loss of papillae		
6	Altered/smooth gingival architecture		
7	Glassy appearance of other mucosa, especially palate		
8	Tongue lobulated/ fissured		
9	Active or recently restored (last 6 months) cervical caries >2 teeth		
10	Debris on palate (excluding under dentures)		

Soft tissue lesion(s) (please tick)		**Yes**	**No**
		1	2
1	None		
2	Angular cheilitis		
3	Denture stomatitis		
4	Denture hyperplasia		
5	Ulcer associated with denture trauma		
6	Other		

Reference
LA/PD score
0 = 0 to 0.5 mm
1 = 0.6 to 3.5 mm
2 = 3.6 to 5.5 mm
3 = 5.6 to 8.5 mm
4 = 8.6 to 11.5 mm
8=Unscorable
9 = Missing tooth

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STATION 2 : SPIROMETRY

Observer Initials ☐☐

Contraindications:

	YES
Collapsed lung/pneumothorax in last 6 weeks?	☐
Heart attack or Stroke in last 6 weeks?	☐
Ear, Eye, chest or abdominal surgery in last 6 weeks	☐

Do <u>not</u> proceed to spirometry if YES to ANY of the above.

SPIROMETRY **Instrument** ☐ **Time 24h** ☐☐:☐☐

	YES
Chest Infection in last 6 weeks	☐
Inhaler used in last 24 hours	☐

BTV % ☐☐·☐

Problem ☐ **P/T**

P= participant performance
T= instrument problem

SPIROMETRY DATA **Please staple printout HERE**	
⬇	Ref number ☐☐☐ N blows ☐☐ BTV % ☐☐☐ FVC ☐☐☐ FEV1 ☐☐☐ FEV0.5 ☐☐☐ PEF ☐☐☐ FEF25-75% ☐☐☐ FEF75-85% ☐☐☐ FEF25% ☐☐☐ FEF50% ☐☐☐ FEF75% ☐☐☐

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STATION 3

Observer Initials ☐☐

Problem
P=person T=technical

Height (cm) ☐☐☐.☐ Problem? ☐ P/T

Weight
TBC weight – set to automatically subtract 1kg for clothes

Pacemaker? No ➡ TANITA BODY COMPOSITION ☐☐☐.☐ **(kg)** Problem? ☐ P/T

Yes ➡ SCALES ☐☐☐.☐ **(kg)** Problem? ☐ P/T

BLOODS

Time (blood test) ☐☐:☐☐ (24hour)

Fasting instructions followed? ☐ **1**=YES **2**=NO **3**=DIABETIC

Time last eaten? ☐☐:☐☐ (24hour)

Day last eaten? ☐ **1**=TODAY **2**= YESTERDAY

ID AFFIX BLOOD LABEL HERE

Blood Test Success? ☐ FULL=**2** PART=**1** NONE=**0** Problem? ☐ **1**=REFUSAL **2**=TECHNICAL

IF blood sample is incomplete (ie "PART" sample) – mark complete tubes with **1**

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

A B C DE FJ K LN PS T

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Station 3: **BIOIMPEDANCE DATA**

Please staple BIOIMPEDANCE printout here	**BIOIMPEDANCE DATA** TANITA BODY COMPOSITION ANALYSER – (Print out stapled)
⇩ **Staple here** **NOTE** **Due to issues with data inputs into the Tanita machine, the integrity of the body composition outputs has been compromised. As a result, the data is not being made available.** **Staple here**	Date DD MM YYYY Time (24hr) □□□□ Body type Standard=1/Athletic=2 □ Gender Female=1/Male=2 □ Age □□ Height □□□ cm Weight □□□ □ kg BMI □□ □ kg/m2 BMR □□□□ kJ □□□□ Kcal Fat % □□ □ % Fat mass □□ □ kg FFM □□ □ kg TBW □□ □ kg Visceral fat rating □□ --- IMPEDANCE Whole Body □□□□ Right leg □□□□ Left leg □□□□ Right arm □□□□ Left arm □□□□ Segmental Analysis Right leg Fat % □□ □ % Fat mass □□ □ kg FFM □□ □ kg Predicted Muscle Mass □□ □ kg Left leg Fat % □□ □ % Fat mass □□ □ kg FFM □□ □ kg Predicted Muscle Mass □□ □ kg Right arm Fat % □□ □ % Fat mass □□ □ kg FFM □□ □ kg Predicted Muscle Mass □□ □ kg Left arm Fat % □□ □ % Fat mass □□ □ kg FFM □□ □ kg Predicted Muscle Mass □□ □ kg Trunk Fat % □□ □ % Fat mass □□ □ kg FFM □□ □ kg Predicted Muscle Mass □□ □ kg

Station 3: BRHS CONSENT FORM

Affix Label: Serno/batch

BRITISH REGIONAL HEART STUDY ASSESSMENT 2018

Please write your initials inside the box to indicate if you agree with each statement, or leave blank if you disagree.

	AGREE
1. I have read and understand the Information Leaflet, and have had the opportunity to ask questions**.**	
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.	
3. I give permission for the results of the blood tests and the clinical measurements made today to be available to my doctor.	
4. I give permission for long-term storage and use of my blood samples for health-related research purposes (even after my incapacity or death).	
5. I am willing to continue with existing permissions for access to my medical and other health-related records*, and for long-term storage and use of this and other information about me, for **health-related research purposes** (even after my incapacity or death).	
6. I give permissions for linkage to my dental care records	

I agree to allow the Research Team to continue to study my health in accordance with the criteria above. I understand that any details recorded will be treated in complete confidence.

Signed _____

Print name _____ Date: _____

Researcher: Initials _____ Date: _____

*Medical and other health-related records from agencies related to the National Health Service: NHS Digital Hospital Episode Statistics (HES), Minimum Mental Health Dataset (MMHDS)- Diagnostic Imaging Dataset (DIDS)-, the General Register Office, Cancer Registry, Primary Care Patient Registration Service.

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14.0 Appendix 3: Blood separation plan

BRHS BLOOD SEPARATION PROTOCOL BRHS RE-SCREENING STUDY- 2018

LABS USED

ROYAL FREE HOSPITAL
HSL, Health Services Laboratories LLP (HSL), Project Number: P565

Glasgow Lab Paul Welsh
BHF Glasgow Cardiovascular Research centre
University of Glasgow

BRHS RE-SCREENING STUDY- 2018

A: INTRODUCTION

The study will start in Mid August 2018, with a two-day pre-pilot of around 8 individuals. This will be followed by the pilot survey where we aim to see 40 men and women. The main study will take place from September 2018 through to February 2019 and cover around 1,000 male participants for 24 UK sites.

The British Regional Heart Study (BRHS) are running a 40-year follow up study. Blood samples are listed in Appendix A.

Samples will be sent to two laboratories:

Royal Free Hospital: Blood samples will be delivered to the laboratory by Royal Mail (around 20 samples per day) from Tuesday to Thursday with accompanying paperwork. Samples taken on Friday will either be sent by courier to arrive at the lab on Saturday morning or will be hand delivered by the field team.

Requested tests: Full Blood Count, HbA1c, Basic biochemistry, Glucose, Glycated Hb

Glasgow: Blood samples will be delivered to the laboratory by Royal Mail (around 20 samples per day) from Tuesday to Thursday with no accompanying paperwork.
Samples taken on Friday will be kept in the cooler and delivered to the lab on Tuesday.

Requested tests: Preparation of sub-aliquots and storage of the samples at -70^{O}C.
(No analysis will be conducted, preparation of aliquots for storage/ future analysis).

All Serum gel samples will be pre-spun the before shipping.

The schedule will be:

Month	Week Commencing	Towns
August	13	Training
	20	Pilot
	27	Bedford
Sept	3	Dunfermline - Falkirk
	10	Ayr- Carlisle
	17	Exeter
	24	BREAK
Oct	1	Burnley, Harrogate,
	8	Hartlepool, Darlington
	15	Maidstone- Gloucester
	22	Newcastle- U- Lyme- Mansfield
	29	Merthyr- Shrewsbury
Nov	5	BREAK
	12	Southport- Wigan
	19	Dewsbury
	26	Grimsby- Scunthorpe
Dec	3	Lowestoft
	10	Ipswich
	17	BREAK
	24	BREAK
	31	BREAK
Jan	7	Guildford

B: STUDY PATHWAY

The study will follow the pathway indicated below:

1. AT THE SITE:

- The following blood tubes will be taken from each subject.

Tubes	Quantity	Size	BD Vacutainer Reference	Purpose
*Citrate	2	2.7ml	363095	Aliquot (to give up to 2, 1ml aliquots)
**Serum gel	1	5ml	367954	Basic automated clinical biochemistry[$]- RFH
*Serum gel	1	5ml	367954	Aliquot (to give up to 3, 1ml aliquots from both tubes)
*Serum gel	1	8.5ml	367958	Aliquot (to give up to 3, 1ml aliquots from both tubes)
**EDTA	1	4ml	367839	Full blood count- RFH
**EDTA	1	4ml	367839	HbA1c- RFH
*EDTA K2EDTA	2	6ml	367873	Aliquot (to give up to 6, 1ml aliquots)
**Fluoride oxalate	1	2ml	367934	Glucose Glycated Hb- RFH

* Glasgow Laboratory
** RFH Laboratory –

$Components of the basic automated clinical biochemistry

To include:

Urea, Urate, Creatinine, Sodium Potassium, Magnesium, Calcium, Corrected Calcium, Phosphate, Total Protein, Albumin, Total Bilirubin, Alk.Phos., AST, ALT, Gamma-GT, Total Cholesterol, LDL-Cholesterol, HDL-Cholesterol, Triglycerides

1.1 ORDER OF DRAW

- **There are 10 Blood collection tubes, to be taken in the following order:**

  Citrate tubes (x2)

  Serum tubes (x3),

  EDTA tubes (x4)

  Fluoride-oxalate (x1).

- All samples must be collected in the correct sequence and gently mixed by inversion according to BD (and ISO) recommendations.

- In particular note that citrate tubes must be fully filled – any under filled citrate tubes should be discarded and a replacement tube taken.

Order of draw	Tube type	Colour	Invert gently through 180^{O}	Clot time
1	Sodium citrate	Blue	3 to 4 times	n/a
2	Serum gel	Gold	5 to 6 times	minimum 30 minutes
3	Potassium EDTA	Purple	8 to 10 times	n/a
4	Fluoride Oxalate	Grey	8 to 10 times	n/a

- Serum gel tubes must be allowed to clot for a minimum of 30 minutes before being centrifuged on site to preserve the sample during transit.

- Serum gel tubes only should be centrifuged at 1300 to 2000g for 10 minutes at 25^{O}C room temperature.

- Each tube will be labelled with the following details:
  - Study Number (a unique identifier in the format A/nnnnnn/AAA)

- Pre-printed labels must be used for blood tubes.

- Blood tubes will be sent in Bio-bottles and conform to the requirements for transport of biological samples.

- Transport will be via Royal Mail with a guaranteed following day delivery.

1.2 DELIVERY ADDRESSES AND CONTACT DETAILS

ROYAL FREE LAB DELIVERY ADDRESS

'SAMPLES FOR PROCESSING'
Clinical Biochemistry Laboratory
Level 1 - Rapid Response Lab
Pond Street
London NW3 2QG
RRL Lab Manager: Saida Solkar
RFL Haematology Contact Number: 02077940500 (ext.33662)
RFL Contact Email Address: saida.solkar@nhs.net or bree.james@nhs.net

GLASGOW DELIVERY ADDRESS

Elaine Butler/Josephine Cooney/Paul Welsh
BHF Glasgow Cardiovascular Research centre
University of Glasgow
126 University Place
Glasgow
G12 8TA

In the event that the site team needs to contact the laboratory the appropriate numbers are:
Designated MLA (Elaine Butler) 0141 330 4344
Paul Welsh 0141 330 2569

2. AT THE LABORATORY - PRE-ANALYSIS

- Samples will be received Tuesday through Friday having been sent via Royal Mail in Bio-bottles to arrive the following day in the laboratory.
- **FRIDAY SAMPLES WILL ARRIVE ON TUESDAY - GLASGOW LABORATORY ONLY**
- The designated MLA (or nominated deputy) will unpack, check and verify the contents of all delivered samples.
- Any discrepancies / anomalies in the samples received will be reported to Lucy Lennon 02078302335 l.lennon@ucl.ac.uk
- GLASGOW ONLY: Aliquots will be prepared as described in the Post-analysis section.

3. AT THE LABORATORY – ANALYSIS

ROYAL FREE LAB

- Blood tubes will be sent along with request forms in Bio-bottles and conform to the requirements for transport of biological samples.
- Transport will be via Royal Mail or Courier with a guaranteed following day delivery.
- An independent listing of samples sent will be forwarded with each Bio-bottle by the on-site team.
- Two 4ml EDTA tube for FBC, one SST tube for biochemistry, one fluoride oxalate tube for random glucose per participant will be labelled with the following details:

- Request Form must have the following information:

  RFH –4 blood collection tubes (max)

Site						**Royal Free Hospital LAB USE ONLY**		
Patient ID	Tube Type			Tubes Taken		**Tubes Rec'd**		
	C	**Serum**	**5.0ml**	**0**	**1**	**0**	**1**	**Basic biochemistry:**
Source Code: BRHS								
	K1	**EDTA**	**4.0ml**	0	1	**0**	**1**	**FBC**
Study Number/ Batch Number	**K2**	**EDTA**	**4.0ml**	0	1	**0**	**1**	**HbA1c**
	T	**Flu.Ox.**	**2.0ml**	**0**	**1**	**0**	**1**	**Glucose/ Glycated Hb**
Date of Birth								
Sex:								

Requested Tests:

- Full Blood Count
- HbA1c
- Basic automated clinical biochemistry:
  Urea, Urate, Creatinine, Sodium Potassium, Magnesium, Calcium, Corrected Calcium, Phosphate, Total Protein, Albumin, Total Bilirubin, Alk.Phos., AST, ALT, Gamma-GT, Total Cholesterol, LDL-Cholesterol, HDL-Cholesterol, Triglycerides
- Glucose
- Glycated Hb

Booking samples on Winpath:

EDTA samples will arrive via Royal Mail, labelled with a unique number, patient initial, surname, and date of birth. There will be an accompanying form, which should be used for capturing the demographics onto Winpath.

Enter the patient details onto Winpath as follows:

Surname: as provided
Forename: Patient initial (the unique patient number)
Sex: Male
Clinician: WHIN
Source: BRHS
Category: Trial

Test:

Please ensure that the sample collection date is entered as per request form.

Once the request is complete, give the forms to the BMS authorising and load the samples for analysis. NB If the samples arrive out of hours keep the forms together and forward them to diagnostic haematology the following working day.

Authorisation should be followed as instructed in **LP-HAE-ResAuth** SOP, all abnormal results must be treated as any other sample i.e. sample checks, urgent film, microscopy and then notify the Haem registrar if

required. *Also phone abnormal results to the BRHS Office: 02078302335 and the contact names are: Lucy Lennon and Sarah Ash. If it's out of hours the contact person is Dr Sheena Ramsay on xxxxxxxxxx*

Once the results are authorised, to be sent to Olia Papacosta- o.papacosta@ucl.ac.uk in an excel document in an encrypted email on a monthly basis. Please note the results which will be sent will not include the DOB.

4. AT THE LABORATORY – POST-ANALYSIS - GLASGOW LABORATORY

(NO ANALYSIS CONDUCTED, PREPARTION OF ALIQUOTS FOR STORAGE/ FUTURE ANALYSIS)

- Sample aliquots will be prepared off-line, on the day samples are received in the laboratory and following centrifugation of the samples by the designated MLA.
- The Serum gels tube will have been pre-spun and **must not** be re-spun.
- Screw cap aliquot tubes, labels and storage containers will be supplied by BRHS together with an agreed coding system uniquely identifying the subject and type of aliquot (serum, EDTA plasma, citrated plasma)
- A system of colour coded caps has been suggested for the three types of aliquots. For example:
    - CITRATED PLASMA CLEAR
    - SERUM GEL RED
    - EDTA PLASMA PURPLE
- **Glasgow will purchase aliquot tubes, caps and storage boxes and labels**
- **BRHS will send and electronic list of participants IDs** (confirmed and non-confirmed)- **to**
- **Paul.Welsh@glasgow.ac.uk**
- Aliquot Labelling : Aliquot letter / Participant # / Batch #:
  A / 123456 / 001

- Sample aliquots from all other tubes will be created according to the table below:
- After centrifugation the plasma from tubes of the same sample type will be pooled and gently mixed before creating sub-aliquots.

<table>
<tr><td>Tubes</td><td>Primary Tubes</td><td>Expected Pooled Volume (mL)</td><td>Cap colour</td><td>Possible Maximum Sub-Aliquots Made</td></tr>
<tr><td></td><td></td><td></td><td></td><td>6</td></tr>
<tr><td>Citrate</td><td>A</td><td>4mL Citrated plasma</td><td rowspan="2">Clear</td><td rowspan="2">2 Aliquots</td></tr>
<tr><td>Citrate</td><td>B</td><td>4mL Citrated plasma</td></tr>
<tr><td rowspan="3">Serum gel</td><td>*C</td><td>1mL serum</td><td></td><td>RFH - Basic Biochemistry</td></tr>
<tr><td>DE</td><td>2mL serum</td><td rowspan="2">RED</td><td rowspan="2">6 Aliquots</td></tr>
<tr><td>FJ</td><td>4mL serum</td></tr>
<tr><td>EDTA</td><td>*K1</td><td colspan="3">RFH Sample lost to Haematology- FBC</td></tr>
<tr><td>EDTA</td><td>*K2</td><td colspan="3">RFH Sample lost to Haematology – HbA1c</td></tr>
<tr><td>EDTA</td><td>LN</td><td>6mL EDTA plasma</td><td rowspan="2">Purple</td><td rowspan="2">6 Aliquots</td></tr>
<tr><td>EDTA</td><td>PS</td><td>6mL EDTA plasma</td></tr>
<tr><td>Fluoride oxalate</td><td>*T</td><td colspan="3">RFH - Sample lost to Protein Section – Clinical Biochemistry</td></tr>
</table>

- Each aliquot tube will be uniquely identified with the Study Number only.
- The type of sample contained within is identified by the Cap colour
- All additional information sample information is available from the printed documentation.
- Aliquots will be stored at -70^{O}C boxed and racked, categorised by Project Name, site, subject and sample type.

APPENDIX 3

Appendix A: **BRHS Re-examination 2018 Blood Aliquoting Schedule**

IN THE FIELD				IN THE LAB						
VACUTAINER TUBES	**SIZE**	**TUBE LABEL**	**BD VACUTAINER REFERENCE**	**CENTRIFUGE?**	**ALIQUOTTING**			**TUBE LABELS**	**CAP COLOUR**	**RESIDUE**
					No.	**Vol.**	**Type**			
*Citrate	2.7 ml	A	363095	Yes	1	~1.4ml	Plasma	A	Clear	Retain
*Citrate	2.7 ml	B	363095	Yes	1	~1.4ml	Plasma	B	Clear	Retain
$Serum gel	5.0 ml	C	367954	No - Prespun in field RFH - Biochemistry	1	1ml				Discard
*Serum gel	5.0 ml	DE	367954	No - Prespun in field	2	1ml ~1.3ml	Serum	D, E	Red	Discard
*Serum gel	8.5 ml	FJ	367958	No - Prespun in field	4	1ml 1ml Rest	Serum	F, G, H, J (No I, avoid confusion)	Red	Discard
$EDTA $EDTA	4ml 4ml	K1 K2	367838 367838	RFH - Haematology	0	0	0	NA	NA	Discard
*EDTA	6 ml	LN	367873	Yes	3	1ml 1ml Rest	Plasma	L, M, N	Purple	Retain
*EDTA	6 ml	PS	367873	Yes	3	1ml 1ml Rest	Plasma	P, R, S	Purple	Retain
$Fluoride oxalate	2 ml	T	367934	Yes - RFH Biochemistry	0	0	0	NA	NA	Discard
TOTAL VACUTAINERS PER SUBJECT			**10**	**TOTAL ALIQUOTS PER SUBJECT**				**14**		

* Glasgow Laboratory $ Royal Free Hospital Laboratory

APPENDIX 3

Aliquot storage

- Each tube type A to S stored in separate series of 100 space storage boxes.
- Each tube type to be packed from front of box in rows left to right.
- Allow one row empty between each town.
- Each box to be labelled with letter, town (x of y), town (x of y) and study details e.g.

BRHS RESCREEN 2018 **A** **Harrogate 1 of 2**	**BRHS RESCREEN 2018** **A** **Harrogate 2 of 2** **Shrewsbury 1 of 2**	**BRHS RESCREEN 2018** **A** **Shrewsbury 2 of 2** **Lowestoft 1 of 2**