

UK Biobank

Blood Sample Collection, Processing and Transport

Version 1.0

<http://www.ukbiobank.ac.uk/>

15th April 2011

This manual details the procedure for Blood Sample Collection at an Assessment Centre of the UK Biobank. Also detailed are the methods for sample processing and transport prior to storage.

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1. Introduction

1.1: This manual details the procedure for Blood Sample Collection at an Assessment Centre of the UK Biobank. Also detailed are the methods for sample processing and transport prior to storage. This takes place at the 7th 'station' of the Assessment Centre visit, as listed in Table 1.

Table 1: sequence of assessment visit

	Visit station	Assessments undertaken
1	Reception	<ul style="list-style-type: none"> • Welcome & registration • Generating a USB key for Participants
2	Touch screen Section	<ul style="list-style-type: none"> • Consent • Touch screen questionnaire • Hearing Test • Cognitive function tests (Shape, Pairs, Fluid Intelligence, Snap)
3	Interview & blood pressure	<ul style="list-style-type: none"> • Interviewer questionnaire • Blood pressure measurement • Measurement of arterial stiffness (Pulse Wave Velocity)

4	Eye measurements	<ul style="list-style-type: none"> • Visual acuity • Auto-refraction • Intraocular pressure • Retinal image (OCT Scan)
5	Physical measurements	<ul style="list-style-type: none"> • Height (Standing and Sitting) • Hip & waist measurement • Weight and Bio-impedance (Body Composition) measurement • Hand-grip strength • Ultrasound bone densitometry • Spirometry (Lung function Test)
6	Cardio (Physical fitness)	<ul style="list-style-type: none"> • Exercise ECG (Cycling)
7	Sample collection & exit	<ul style="list-style-type: none"> • Blood samples collected • Urine sample sought • Saliva sample sought • Consent & result summary printed • Travel expense claim provided
8	Web-based diet questionnaire	<ul style="list-style-type: none"> • Dietary assessment

1.2: Throughout this document, the term ‘Participant’ signifies a study participant who is taking part in the Assessment Centre process, regardless of whether they eventually give or withhold consent to take part in the UK Biobank study.

1.3: The collection of data from assessment visits uses the direct data entry system of the Assessment Centre Environment (ACE). This has five components (**Assessment Centre Environment**), of which Porto operates the Sample Collection and Exit station of the assessment visit.

1.4: At the start of their visit, each participant is issued with a USB Key at the Reception station. This USB Key acts as a participant identifier (it contains Participant ID, name, date of birth and gender) and as a temporary storage device for the recorded data. As the participant progresses between stations, the USB key acts as an identifying token and also as a data transfer mechanism. At the Reception & Exit module, all data on the USB key is removed, after it has been backed up to the Assessment Centre head PC.

2. Staff

2.1: The staff member taking blood is a phlebotomist or a nurse with previous experience of blood collection) trained and certified to conduct collection of blood samples. All operational clinical staff may perform sample processing tasks. It is the responsibility of the Assessment Centre manager to oversee and ensure that sample processing is carried out according to protocol and in a safe manner.

3. Health and safety

3.1: The following health and safety measures are adhered to by staff in all cases:

- A white laboratory coat or tunic is worn and fastened to the top.
- Gloves are always worn when handling blood samples, and as an additional precaution, two pairs of gloves could be worn.

- Any member of staff handling blood samples are advised to be vaccinated against Hepatitis B.
- Safety glasses may be worn while handling samples.

Any member of staff handling biological samples must have completed all UK Biobank health and safety documentation in accordance to company policy (See also Appendix 1: Dealing with a needle stick injury (NSI)).

4. Preparation of blood containers

4.1: For each participant the following are prepared and checked to be intact and within expiry date. Each Vacutainer bottle has a barcoded label (Appendix 2: Equipment for blood collection station):

- 21G green Vacutainer needle (Becton, Dickinson and company, USA)
- Vacutainer barrel (Becton, Dickinson and company, USA)
- cotton wool balls or gauze squares
- Micropore tape (3M, USA)
- Plaster

Sets of Vacutainer tubes are placed in the order shown below:

Order of collection	Tube (preservative/contents)	Tube volume	Lid Colour
1	Blood (EDTA)	10 ml	Purple
2	Blood (Li-Hep - PST)	10 ml	Green
3	Blood (Clot activator – SST)	10 ml	Orange
4	Blood (EDTA)	10 ml	Grey
5	Blood (Acid citrate dextrose – 6 ml)	6 ml	Pale Yellow
6	Blood (EDTA – 4 ml)	4 ml	Purple
7	Blood RNA	3 ml	Blue

5. Blood sample collection

5.1: The participant is seated in a curtained blood collection office, is told that this is the final station of the assessment, and asked for a blood sample of about 50ml (2-3 tablespoons) and also to complete the other exit procedures before they leave.

5.2: The participant's USB key is inserted into a computer and the Vox system is used to check their identity. At this point the participant is also asked to update their email address, if they offered to do so during the touch-screen questionnaire and to verify the updated address on-screen.

UK Biobank, Cee Tee : Blood Sampling, Visitor Identity Check

Staff user is Cee Tee Yes No

Participant is Mrs Freida Test Yes No

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UK Biobank, Miss Caron Paterson : Blood Sampling, Email

The participant indicated at the touchscreen that they would like to update their email address.
Please enter the new details below:

Wishes to update email address Yes No

Email address

Has the participant been SHOWN the email address above, and verified it is correct? Yes No

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5.3: At this point the staff member may select 'yes' to print copies of the participant results of the measurements undertaken and the signed Consent Form.

Note: Printing off the Consent form and physical measurement results may be delayed until after the venepuncture procedure.

5.4: The staff member records the number of hours since the participant ate or drank anything (except plain water) and whether they are able to give a blood sample, recording the reason if not.

Note: Participants with haemophilia do not undergo blood sampling.

UK Biobank, Miss Caron Paterson : Blood Sampling, Blood Sample * TRAINING/DEMONSTRATION VISIT *

Time since last meal or drink (except plain water) 5 hours

Participants with haemophilia should not have bloods taken

Able to take blood sample Yes No

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5.5: For participants able to provide a blood sample, a screen appears, with data entry fields for the blood tubes.

UK Biobank, Dr Alan Young : Blood Sampling, Blood Sample * TRAINING/DEMONSTRATION VISIT *

Time since last meal or drink (except plain water) 5 hours

Participants with haemophilia should not have bloods taken

Able to take blood sample Yes No

Samples

Please take sample EDTA1 next

EDTA1	1	
PLASMA1	4	
SERUM1	5	
EDTA2	2	
ACD B 1	7	
EDTA3	3	
RNA	8	

Manual Click on cap-colour to clear corresponding bar-code entry

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5.6: Blood is taken using a good aseptic technique. The phlebotomist washes their hands in a dedicated sink at the start of each session before collecting blood, and uses a new pair of disposable gloves for each participant. A disposable apron can also be worn.

Note: Participants are asked whether they could have a latex allergy. If the answer is yes or they are not sure, latex free gloves are worn during the procedure.

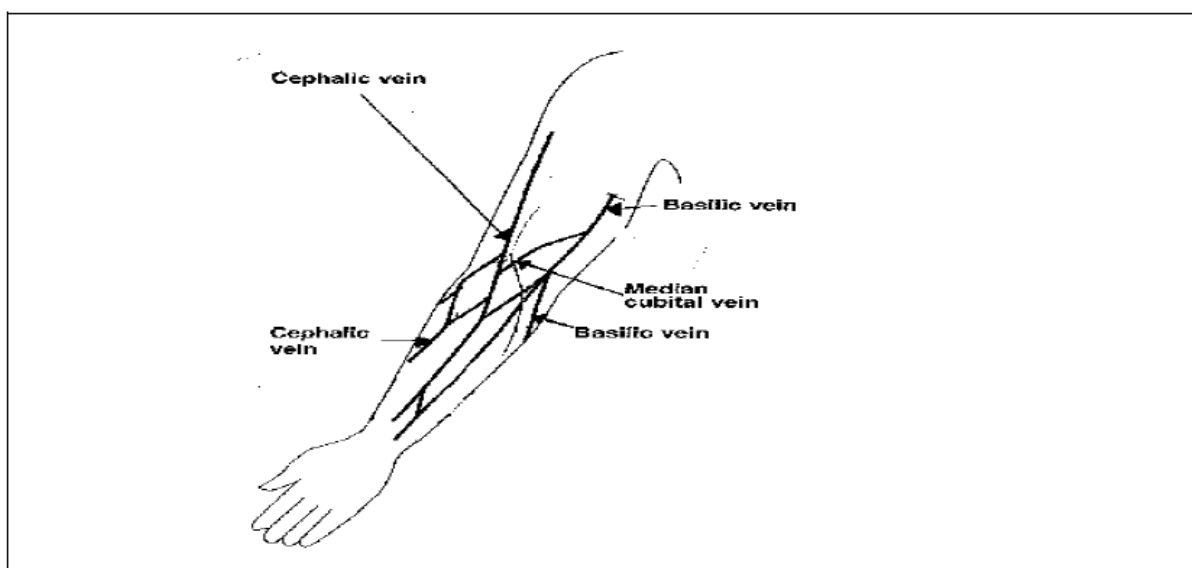
5.7: The participant is asked whether they have ever had any previous problems giving a blood sample and, if so, what the difficulty was. If they report previous difficulties then a butterfly needle may be used in veins on the back of hand (**section 7**). The Duty Manager is consulted before continuing if there are any doubts about this procedure.

5.7: The phlebotomist listens to the participant and checks they are well, especially if they inform them they are prone to fainting.

6. Venepuncture using vacutainer needle (Standard method)

6.1: If the participant reports no previous problems, they are asked to remove any clothing from their forearm to allow assessment and selection of a suitable vein.

6.1: The phlebotomist looks for a suitable vein in front of the elbow: surface veins in the inner elbow (e.g. cephalic, or cubital veins: see below) are preferred for venepuncture, as they lie just below the skin and there are few nerve endings. The participant is asked for their preferred site for the procedure based on their experience.



6.2: The participant is seated comfortably in a special phlebotomy chair, which has arm rests and is designed to accommodate a person should they faint during the venepuncture process. The participant's arm is placed in a downwards position supported on the arm rest.

6.3: The phlebotomist gently palpates the selected vein to assess suitability, such as being bouncy, soft, straight, refills when compressed, with a large lumen and well supported. Avoided are veins that are bruised, thin, hard, mobile or near a bony prominence.

6.4: A tourniquet is applied to the upper arm on the chosen side (approximately 7 – 10 cm above the intended venepuncture site). The tourniquet is moderately tight, with the radial pulse at wrist still palpable. The tourniquet is in place no longer than one and a half minutes.

6.5: If veins are not very visible, the phlebotomist taps the skin lightly over the expected place of the vein, and instructs the participant to clench and unclench their fist or allow the arm to hang down at their side. The other arm is also considered, with tourniquet in place. Failing this, a vein lower down their arm may be used (although such veins are usually smaller, more mobile and more painful to take blood from).

Note: If a suitable vein cannot be found in the forearm, the difficulties are explained to the participant and permission asked to collect a sample from veins in the back of hand using a Safety Lok butterfly needle ([section 7](#)).

6.6: Only if skin is visibly dirty, the area around identified vein is cleaned with a Mediswab alcohol impregnated wipe. When alcohol wipe is used, the skin is allowed to dry for least 30 seconds, since alcohol may cause pain on venepuncture and/or contaminate the blood sample.

6.7: The Vacutainer needle is inspected and the expiry date and paper seal are checked. The 21G green Vacutainer needle is screwed into a Vacutainer barrel, and the needle cover is removed.

6.8: The phlebotomist uses one hand to draw skin towards the participant's hand so that it is tight over the vein. With the Vacutainer barrel held between thumb and index finger, and needle along the line of the vein at an approximately 15-30 degree angle to skin, the phlebotomist ensures the bevel of the needle is in the upwards position and inserts the needle through skin into the vein.

7. Venepuncture using Safety Lok butterfly needle (Alternative method)

Note: This method is only used either if the participant reports previous problems with blood collection from the elbow or if the standard method has failed and the participant has given permission. It is also used if the participant volunteers the information that they carry a blood-borne viral infection.

7.1: The participant's hands are placed palm down on the desk and a suitable vein is located in the back of their hand, ideally on their non-dominant side.

7.2: The participant is asked to remove clothing from the forearm to allow a tourniquet to be applied. This is applied to the forearm approximately 7-10 cm above the intended venepuncture site, moderately tight, with the radial pulse at the wrist still palpable. The tourniquet is in place no longer than one and a half minutes,

7.3: If veins are not very visible, the skin is lightly tapped over their expected location and the participant is instructed to clench and unclench their fist or allow the arm to hang down at their side. The other hand is considered, with tourniquet in place.

7.4: Only if skin is visibly dirty, the area around identified vein is cleaned with a Mediswab alcohol impregnated wipe. When an alcohol wipe is used, the skin is allowed to dry for least

30 seconds, since alcohol may cause pain on venepuncture and/or contaminate blood sample.

7.5: The Safety Lok pack is opened and the rubber tipped needle is screwed into the Vacutainer barrel if not already pre-attached. The plastic wings of a 21G or 23G needle are held together between thumb and index finger and the end sheath is removed. The tubing is pinched closed between the third and fourth finger.

7.6: Using one hand to draw skin tight over vein, the phlebotomist slides the needle into the vein with needle bevel upwards, initially at about 45 degrees and then reducing to almost parallel with skin when in vein. Blood should flash into the tubing when the vein is entered. Stability of the needle in the vein is maintained either by using gentle digital pressure or by securing the butterfly needle by taping the wings onto the skin using Micropore tape. Samples are collected as described below.

Note: If micropore tape is used to secure wings, two pieces of tape are placed in line with the needle, since placing tape directly across the butterfly wings may impede the action of the safety device.

8. Collection of blood samples into Vacutainers

8.1: The Vacutainer barrel is held steady with one hand while with the other hand the phlebotomist selects the first Vacutainer tube in sequence (purple cap 10 ml EDTA tube) from the pre-prepared rack. The Vacutainer tube is pushed into the barrel until the sharp end of the needle within the barrel pierces the rubber bung of the tube.

8.2: The tourniquet is released as blood begins to flow into the Vacutainer tube but some pressure/tightness is kept on tourniquet if flow is slow.

8.3: When Vacutainer 1 is full, the blood flow stops. The Vacutainer tube is removed from the barrel and Vacutainer 2 inserted. Vacutainer 1 is gently inverted ten times then returned to rack while the second tube is filling.

Note: If not able to invert the Vacutainer while the other bottle is filling then the phlebotomist inverts all tubes immediately upon completion of blood sampling.

8.4: This step is repeated to fill Vacutainers 2-7 according to order in rack: with particular attention to the gentle inversion of the tubes (1 to 6) after each is filled with blood. The Blue RNA bottle is shaken vigorously for 20 seconds immediately after the sample is obtained:

1. Purple (10 ml)
2. Green (10 ml)
3. Orange (10 ml)
4. Grey (10 ml)
5. Pale yellow (6 ml)
6. Purple (4 ml)
7. Blue (3 ml)

8.5: If blood flow slows during collection, the tourniquet is re-applied and the participant is asked to clench and unclench their fist while keeping their arm still. When blood flow starts again, the tourniquet is released and collection is continued.

Note: If blood flow does not re-start, the phlebotomist explains the difficulties to the participant and asks permission to repeat venepuncture in the other forearm or, failing that, to collect the sample from veins in back of their hand using a Safety Lok butterfly needle (as described in Section 7).

8.6: After blood collection is complete (with either all required Vacutainers filled or as many as possible), a clean cotton wool dressing is applied over skin at insertion of needle. The needle is removed and pressure applied on puncture site.

8.7: The participant is asked to maintain pressure on the cotton wool long enough to stop bleeding, and to elevate their arm slightly in order to help minimise bruising. The participant is not allowed to bend their arm in case this causes a haematoma.

8.8: Vacutainer barrel and needle are disposed of as a single unit into a sharps bin immediately upon removal from vein. The needle is not re-sheathed.

Note: The participant is asked whether they have an allergy to elastoplast. If so, a hypoallergenic dressing is used in the following step:

8.9: Once bleeding has ceased, the cotton wool dressing is removed from the participant's arm and an elastoplast or hypoallergenic dressing applied to cover the puncture site. If bleeding persists, pressure is re-applied with dressing and repeated a few minutes later.

8.10: Each filled Vacutainer is scanned using a barcode reader, then it is checked on the computer that each tube has been properly scanned, as this links these samples to the participant. If the scanner fails to recognise a barcode, the tube ID is manually entered by selecting the 'Manual' button and carefully entering the 13-digit tube ID.

UK Biobank, Dr Alan Young : Blood Sampling, Blood Sample * TRAINING/DEMONSTRATION VISIT *

Time since last meal or drink (except plain water) hours

Participants with haemophilia should not have bloods taken

Able to take blood sample Yes No

Samples

Please take sample EDTA1 next

EDTA1	<input type="text"/>	1	<input type="text"/>
PLASMA1	<input type="text"/>	4	<input type="text"/>
SERUM1	<input type="text"/>	5	<input type="text"/>
EDTA2	<input type="text"/>	2	<input type="text"/>
ACD B 1	<input type="text"/>	7	<input type="text"/>
EDTA3	<input type="text"/>	3	<input type="text"/>
RNA	<input type="text"/>	8	<input type="text"/>

Click on cap-colour to clear corresponding bar-code entry

< Prev Help Lock Next >

8.11: If one or more tubes are not collected the reasons why not are recorded using drop-down menus for each specific tube; empty blood tubes are not scanned.

UK Biobank, Gen Every Where : Blood Sampling, Blood Sample

Time since last meal hours

Able to take blood sample Yes No

Samples

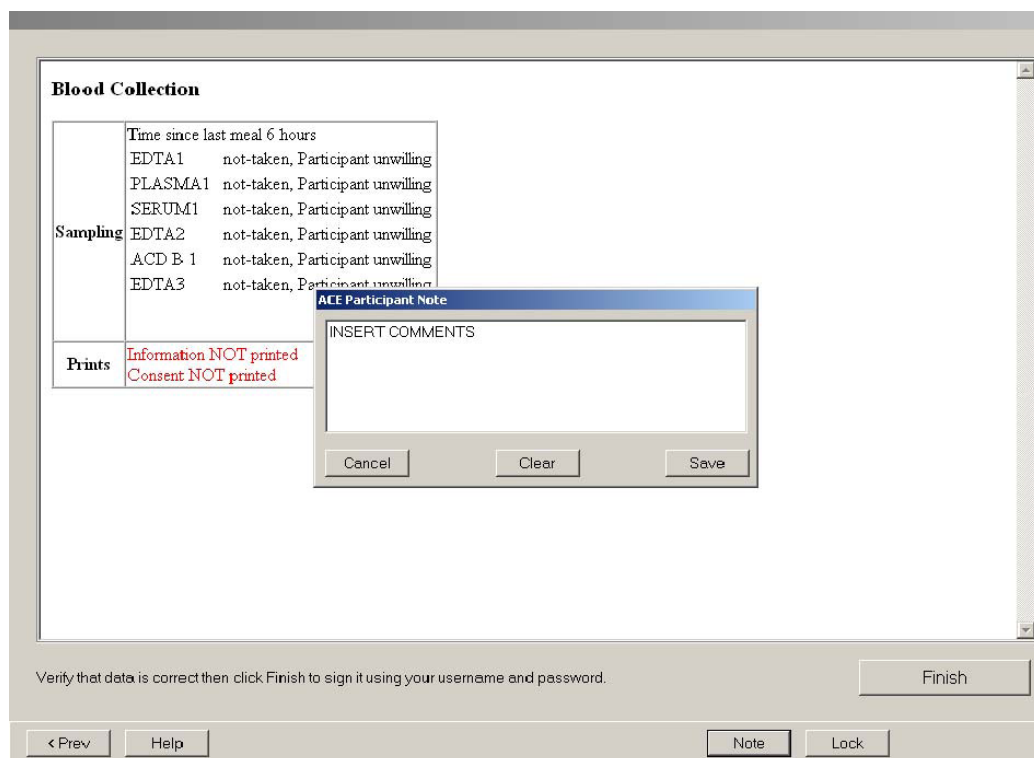
Please take sample EDTA1 next

EDTA1	<input type="text"/>	1	<input type="text" value="Participant unwilling"/> <input type="text" value="Insufficient sample"/> <input type="text" value="Tube breakage"/> <input type="text" value="Other equipment failure"/>
PLASMA1	<input type="text"/>	4	<input type="text"/>
SERUM1	<input type="text"/>	5	<input type="text"/>
EDTA2	<input type="text"/>	2	<input type="text"/>
ACD B 1	<input type="text"/>	7	<input type="text"/>
EDTA3	<input type="text"/>	3	<input type="text"/>

Click on cap-colour to clear corresponding bar-code entry

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8.12: When all filled tubes have been scanned, selecting 'Next' sends a message to the sample processing station and activates a timer that ensures that tube 3 (orange cap) is allowed to stand for 30 minutes prior to centrifuging.



Blood Collection	
Time since last meal 6 hours	
EDTA1	not-taken, Participant unwilling
PLASMA1	not-taken, Participant unwilling
SERUM1	not-taken, Participant unwilling
Sampling EDTA2	not-taken, Participant unwilling
ACD B 1	not-taken, Participant unwilling
EDTA3	not-taken, Participant unwilling
Prints	Information NOT printed Consent NOT printed

ACE Participant Note

INSERT COMMENTS

Cancel Clear Save

Verify that data is correct then click Finish to sign it using your username and password.

Finish

< Prev Help Note Lock

8.13: Selecting the 'Finish' button automatically opens the 'Conclude' stage to complete the visit. On the next screen the identity of participant and phlebotomist are confirmed.

8.17: Copies are printed of the results provided to the participant, and signed consent. Any incidental findings are recorded at this stage (Appendix 3: Procedures for dealing with potentially serious results and incidental findings).

8.18: The results information sheet contains the Diet Questionnaire PIN and log-in details. The participant's attention is drawn to this and it is explained that on completion of the visit they have the option of completing a self administered Web Based Diet Questionnaire http://www.ukbiobank.ac.uk/docs/quaire_v3.pdf.

UK Biobank, Gen Every Where : Conclusion, Thankyou from UK Biobank

967 550 674 Mr Micheal Morris Consented

Visit Stage	Time completed	Authorisation	Status
Welcome	2007-03-08T17:53:06	TESTGREET	complete
Consent	2007-03-09T12:37:22	TESTYESNO	complete
Touchscreen	2007-03-09T13:02:37	TESTTOUCH	complete
Interview+BP	2007-03-09T13:23:46	TESTINTBP	complete
Biometrics	2007-03-12T10:28:13	TESTSUPER	complete
Blood sample	2007-03-14T13:58:57	TESTDRAC	complete
Conclusion			

Participant Printouts

Print Consent

Print Information

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8.19: If the participant has any questions about their results, it is explained that UK Biobank are unable to provide any interpretation of these results and it is suggested they contact either NHS Direct (0845 4647 available 24 hours/ www.nhsdirect.nhs.uk) or their own GP.

8.20: On-screen it is checked that the participant has completed all of the stations. The status column shows successfully completed stations are indicated in green, whereas incomplete or missed stations are shown in red. If any stations are showing red on-screen, the participant is asked if they have visited that station. If not, and if the participant is willing, they and their USB key are taken to that station. If a participant was unable to complete a station, the reason for this is entered in the status column below.

8.21: On the screen below, once data is correct, 'finish' is selected and the phlebotomist's user name and password are entered.

Visit Conclusion

Urine	Urine not-taken, Participant not present
Missed Stages	Marking 1 stages as Missed 1. Blood sample, no arms okkkkkkkkkkkkkkk

Verify that data is correct then click Finish to sign it using your username and password.

Finish

< Prev Help Lock

8.22: The participant is thanked and checked that they are feeling well and fit to leave the Assessment Centre. They are directed to the toilet and asked to return the urine and saliva samples to the sample specimen fridge before they leave. If required, the participant is given a travel expense claim form which is completed at home and returned in the pre-paid envelope. The participant is given a Comments Card, which, once completed can be placed in the Comments Box at Reception area.

8.23: The participant is directed to the Web Based Diet Questionnaire Area. They are reminded that the log-in details and PIN number are shown on the results information sheet and that log-in assistance can be provided by any member of staff supervising the Reception and Touchscreen areas.

8.25: The participant is invited to help themselves to a hot drink and biscuits before or after completion of Web Based Diet Questionnaire. Blood samples are taken through to the sample processing area by the phlebotomist and handed directly to the person responsible for processing the blood samples.

8.26: The surfaces in the blood station are cleaned with Azowipes after each participant. Any spillages in the blood station are cleaned immediately using Virkon.

9. End of Day Procedure

The VOX programme is left running for at least 30 minutes after the last participant leaves the booth, to allow data transmission.

10. Sample processing and storage

10.1: This section details the methodology of processing blood, urine and saliva samples collected from participants in the Assessment Centre from the point after the samples have been logged into the centre's application system. This method is used by UK Biobank clinical staff to process the clinical samples taken from participants, safely and to required quality standards. The samples are packed according to protocol and are transported by a dedicated TNT courier, according to a schedule that ensures they remain at the correct temperature.

10.2: Sample processing software

The Sample Collection system is operated by Spectare, one of the five components in the direct data entry system of the Assessment Centre Environment (ACE) (**Assessment Centre Environment**).

10.3: The Spectare system will indicate that a blood sample needs to be collected from the blood sampling station and the system assigns tube IDs to participant IDs. Blood samples are scanned immediately after sampling so the system can time blood samples for centrifugation. This is essential in the case of Serum Separator Tubes, which require a 30 minute delay. The system then indicates when a sample should be taken out of the centrifuge and separated. It can be used to indicate if a sample has been lost or damaged. The system is also used to log urine samples.

10.4: Abbreviations

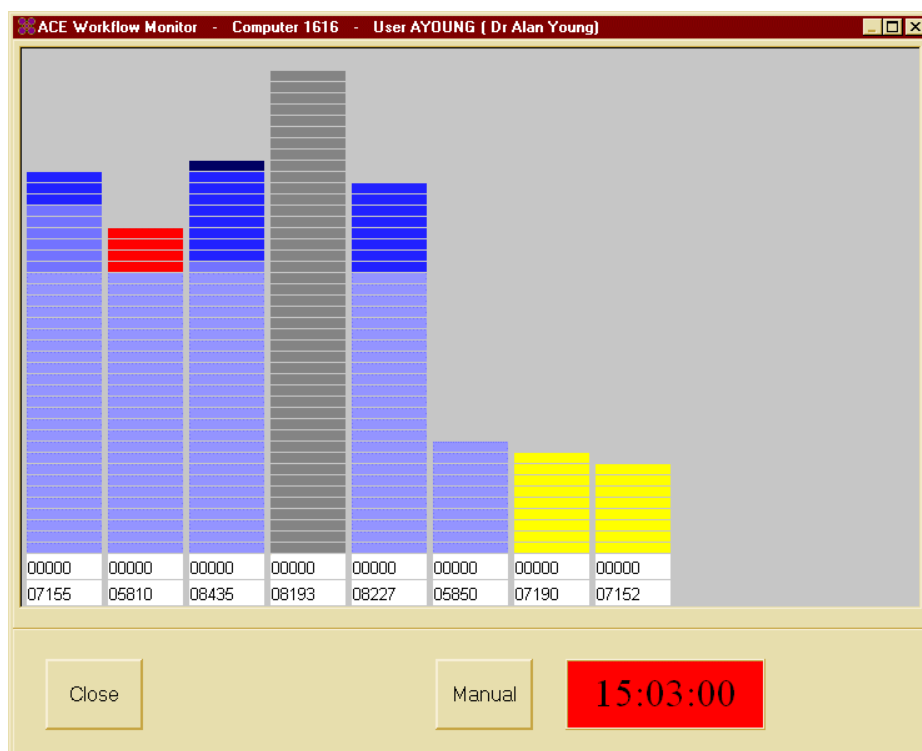
Terminology	Definition
SST	Serum Separator Tube
PST	Plasma Separator Tube
ACD	Acid Citrate Dextrose
EDTA	Ethylenediaminetetraacetic acid
RNA	Ribonucleic acid
RCF	Relative centrifugal force

10.5: Operating the sample refrigeration.

Refrigerators used for storing the blood, urine and saliva samples are kept between 2 to 8°C. Frequent openings of the refrigerator door may require the temperature to be turned down during the clinic operating times. Temperature of the fridges and freezers are recorded each day before opening the doors.

10.6: Operating the Spectare software.

When the sample processing PC is turned on, the Biobank screen opens. Spectare software is opened by double clicking the icon. The operator logs in, gives their username and password and presses enter/start, then clicks 'the sample button' under operation. The operator logs out of the system when leaving the lab area.



10.7: Shutting down the software and PC after use.

This is done after processing, when the last sample has disappeared from the screen, by pressing Close, then Exit, then shutting down the computer.

10.8: Processing blood samples

10.8.1: Every time a new serum separator tube (SST) pops up on the screen, new blood samples will be ready to process and are brought over to the laboratory by the staff member taking the blood samples.

10.8.2: All the EDTA tubes (purple and grey cap) are immediately placed in their dedicated rack within the fridge. Racks are loaded in order from first participant.

10.8.3: The ACD samples (yellow cap) are placed in the corresponding rack stored at room temperature on the bench top. Racks are loaded in order from first participant.

10.8.4: All the RNA tubes (blue cap) are placed immediately in their dedicated rack within the fridge. Racks are loaded in order from first participant.

10.8.5: The green capped tubes (PST) are moved to the centrifuge pending rack and are spun in a centrifuge immediately (see below for centrifugation). PST tubes are placed in the corresponding rack within the refrigerator after centrifugation. Racks are loaded in order from first participant.

10.8.6: To process the SST (orange cap), the tube is scanned then the number block on-screen changes from white to green to highlight the selected sample. On pressing 'received' the yellow counting blocks change to pale blue.

10.8.7: The SST is placed in the dedicated rack under the computer while positioning correctly with the sample order on the screen. The SST need to stand to clot for 30 minutes until centrifugation. The Spectare software counts up the minutes until centrifugation is needed by placing a blue block on the screen for every minute passed. After 30 minutes a red block appears and centrifugation then needs to be done immediately. Therefore:

10.8.8: The tube that needs centrifugation is scanned; 'spin' on the Spectare software is pressed (the timer will pop-up dark blue blocks) and centrifugation is started immediately (see below for centrifugation).

10.8.9: After spinning, the tube is scanned again while keeping the spun tube upright. A black time block now appears on-screen.

10.8.10: 'Completed' is pressed, and the processed tube disappears from the screen after 4 minutes. The tube is kept upright and placed in the dedicated rack in the fridge. Racks are loaded in order from first participant.

NOTE: - the operator can scan each tube any time to check the tube number. The number block changes from white to green to highlight the selected sample. When scanning the tubes 2 options are offered:

- UN-DO: when pressed the blocks will turn yellow again.
- DISCARD: when pressed the sample will get greyed out and will disappear completely after 4 minutes.

10.9: Centrifugation

10.9.1: There are three centrifuges (figure 1) each with four buckets, which can hold up to four sample tubes each.

Figure 1: Centrifuge



10.9.2: Each bucket is balanced with its opposite partner in terms of its contents, either containing none or 4 tubes. The tube contents of each bucket is balanced & counter balanced, e.g. full tubes are counter balanced with full tubes and empty tubes are counter balanced with empty tubes. Lids are correctly attached to the buckets before starting the centrifuge (Figure 2).

Figure 2: Correctly balanced buckets



10.9.3: The centrifuge is set with brakes on. With the lid open, pressing the 'short' button shows the current status of the brakes. If this needs changing, the short button is kept depressed until 'brake on' is displayed.

10.9.4: The centrifuge is set to spin for 10 minutes at 2000 RCF as shown in figure 3. Both the green PST and orange SST tubes are spun under the same conditions within the centrifuge.

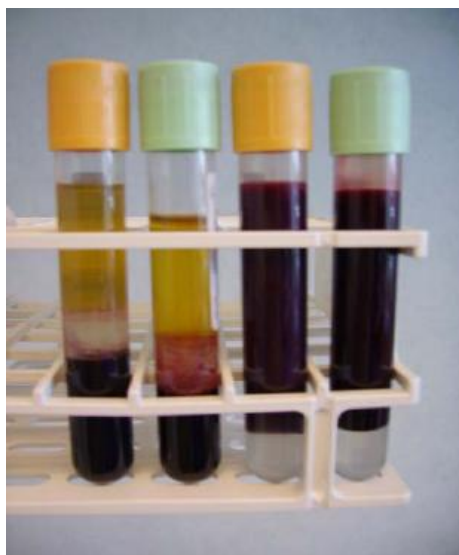
Figure 3: Centrifuge timing and speed



10.9.4: Once the centrifuge has finished each tube is checked immediately to ensure the spinning was effective and their contents have separated as shown in figure 4. The tubes are immediately removed and placed in their corresponding rack within the refrigerator. Racks are loaded in order from first participant.

Figure 4: Serum and Plasma separation tubes

Tube order shown: SST spun, PST spun, SST unspun and PST unspun



10.12: Equipment maintenance

10.12.1: Breakages and spillages

Spillages in the centrifuges are cleaned immediately using Virkon (Du Pont, UK)

10.12.2: Daily Maintenance

Before the centrifuge is switched on the rotor is rotated by hand to ensure there is no stiffness and that it can rotate freely

10.12.3: Weekly Maintenance

All of the removable parts are taken out and cleaned with Virkon; the inside of the centrifuge is wiped with Virkon.

10.12.4: Monthly Maintenance

The rotor is removed and grease applied to contacting parts within the rotor and buckets. Buckets and lids are washed.

10.12.5: Fridges and freezers

Each fridge has its own digital thermometer with the display positioned outside the fridge. Temperature is recorded daily and documents maintained for all fridges and freezers. Freezers are defrosted every three months. Only one freezer is defrosted at a time. Fridges are kept clean and undergo a deep clean every six months.

10.12.6: Waste disposal

The laboratory area is kept clean, and documents are maintained for each cleaning routine undertaken. All hazardous waste bins are emptied and the secured bags taken to the hazardous waste collection bin. Documents are maintained describing whether they are sharps, bags or urine containers. The documents describing the clinical waste totals are sent to the co-ordinating centre support team on the last working day of each month.

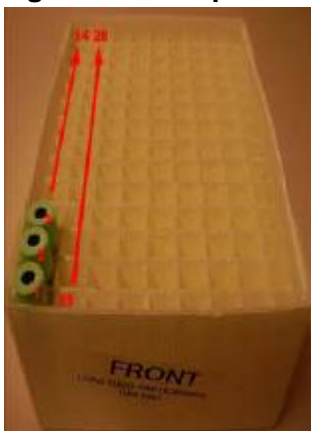
11. Transporting of samples

11.1: This section details the correct method of packing the blood, urine and saliva samples so they reach the UK Biobank laboratory undamaged and within acceptable temperature limits. Also detailed are the correct method for dealing with courier pick ups, any delays in pick up and the return of sample boxes from UK Biobank Coordinating Centre.

11.2: Preparing samples for transport

At the beginning of each day the lab processing staff member prepares 12 transport racks: 8 for the blood and urine tubes and 4 for the saliva tubes. These are stored in the Assessment Centre holding fridge, except for the ACD blood sample tubes – yellow cap. During the day the sample tubes are loaded into the specific transport rack from the first participant to the last participant (Figure 5). The ACD blood sample tubes are kept AND transported at room temperature in a rack.

Figure 5: Transport rack



11.3: The EDTA 4ml (small) tube (purple cap) and the ACD tubes have a smaller inner rack within the transport rack to ensure the smaller tubes are transported safely.

11.4: 45 minutes prior to the courier arriving, lids are placed on the racks and each rack is individually placed inside a plastic bag. Three sheets of absorbent paper are placed inside the bag. The plastic bag is sealed with a cable tie (figure 6).

Figure 6: Sealing racks for transport

11.5: On the two short sides of the transport box are placed a cool pack and a spacer (see figure 7). The cool packs are kept in the freezer for at least 24 hours before use and are taken out 30 minutes before being used each day.

Figure 7: Mediporter transport box with cool packs

11.6: The bagged racks (except the ACD tubes) are placed into the large transport box (figure 8).

Figure 8: Racks in Mediporter

11.7: A third spacer is placed on top once the sample racks are all loaded and the

third cool pack is placed on top of the spacer (figure 9).

Figure 9: Mediporter with cool pack



11.8: The polystyrene lid is placed on top of the box. The lid of the plastic outer box is closed. Every Tuesday a datalogger is placed in both the large transport box and the Mediporter (**Section 13**).

11.9: The ACD samples are placed inside a Mediporter without a cool pack

11.10: The lids of both transport boxes are closed and sealed with plain cable ties (figure 10) and they are moved to the designated pick up area.

Figure 10: Sealing the transport boxes



12. Courier collection

12.1: All Assessment Centres use TNT to return the sample transport boxes to the Coordinating Centre Laboratory. Collections from all Assessment Centres occur at 8:30pm, Monday to Saturday (excluding Bank Holidays).

12.2: The sample transport boxes are packed (Section 11) and placed ready for collection in a designated area. TNT provide all UK Biobank Assessment Centres with pre-addressed consignment notes. Assessment Centre Staff complete a TNT Consignment note by inserting the date, and then attaching a barcode from the consignment note on to each individual transport box, prior to collection. Transport boxes are made ready for collection before 8:30pm.

12.3: The TNT courier signs the consignment note and leaves a copy as proof of collection, collects all transport boxes and delivers them to the UK Biobank Co-ordinating Centre for 07:30am the following morning.

12.4: Late Courier Pick Up

If the TNT courier has not arrived by 8:45pm the Assessment Centre Manager is informed. The Assessment Centre Manager telephones the TNT Emergency Contact telephone number immediately. Arrangements are then made with TNT for a separate pick up that same evening, transporting the samples to UK Biobank Coordinating Centre for the following morning.

12.5: Return of sample boxes from UK Biobank coordinating centre.

Initially each Assessment Centre is provided with a supply of sample transport boxes. From the start of the centre the sample boxes are returned to the Assessment Centre via TNT on a daily basis. The cool packs are kept in freezers so they are ready for use. All delivery notes are stored in the Assessment Centre filing in the Data Collection Section.

13. Temperature monitoring

13.1: On a weekly basis a temperature monitor (datalogger), TempTale 4 (figure 11), is placed inside both large transport boxes (blood /urine and saliva) and the mediporter.

Figure 11 Temptale 4



13.2: The co-ordinating centre configures the dataloggers to automatically begin recording, this is done before they are sent out to the assessment centre. Therefore the assessment centre does not need to press the start button. A symbol of a sun will be present on the datalogger screen to indicate it is set to automatically begin recording (figure 12).

Fig 12 Temptale 4 set to record



13.3: The datalogger is placed on top of the rack within the plastic bag, with this rack at the top of the large transport boxes or mediporter. This will stop the datalogger being inadvertently switched off in transit.

14. Appendices

14.1 Appendix 1: Dealing with a needle stick injury (NSI)

14.1.1: In the event of a NSI the staff member should encourage bleeding of puncture wound by gentle squeezing, not sucking of the area. Wash the affected area with soap and clean, warm running water, do not scrub. Dry and protect the injury site with appropriate dressings.

14.1.2: The incident is reported to the Assessment Centre Manager, stating clearly whether the needle stick injury occurred pre or post venepuncture. If the injury occurred post venepuncture it is immediately reported to the nearest Local Accident & Emergency department for further advice. Details of the incident are accurately recorded in the Incident File on SharePoint as soon as possible after the event.

14.2 Appendix 2: Equipment for blood collection station

Equipment list
Furniture 1 desk 1 chair 1 adjustable desk lamp
Computing 1 desktop personal computer 1 monitor 1 bar code reader
Other Equipment 1 tourniquet 1 test tube rack

Consumables 21G green Vacutainer needle 21G Safety Lok butterfly needle 23G Safety Lok butterfly needle Vacutainer barrel Mediswab alcohol impregnated skin wipe Pre labelled Becton-Dickinson vacutainer blood tubes Micropore/hypoallergenic tape Disposable materials tray Disposable gloves Disposable apron Cotton wool balls or gauze squares Plasters Sharps bin Clinical waste bag Urine collection pots Vacutainer urine tubes Opaque plastic bags (for urine sample) Printing paper Travel expense claim forms Pre- paid envelopes
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14.3 Appendix 3: Procedures for dealing with potentially serious results and incidental findings

14.3.1: Background

14.3.1.1: The Information Leaflet advises participants that the baseline assessment visit is not a health check. With the exception of the feedback of a limited range of measures (e.g. blood pressure, weight, lung function and bone density) at the end of the assessment visit, participants will not receive any feedback of their individual results. (The overall findings from research based on UK Biobank will, however, be made available to participants.)

14.3.1.2: Staff do not have the same duty of care that they would have in a clinical setting. Rather, their legal duty of care is determined by the research context, and relates to safe and competent collection of consent, questionnaire data, physical measurements, and blood and urine samples.

14.3.1.3: Assessment centre staff are trained not to provide interpretation of results. There may, however, be occasions when it is appropriate to draw attention to results (e.g. very high blood pressure) or incidental findings (e.g. suspected melanoma) that may be potentially serious (i.e. life-threatening).

14.3.2 Dealing with potentially serious results

14.3.2.1: At the end of the assessment visit, participants receive a printed summary of the results of a limited number of physical measurements made during the visit. This summary indicates whether any of these results fall outside defined desirable ranges depending on age, sex and weight (as relevant).

14.3.2.2: Staff may draw these findings to the attention of the participant, but should not attempt to interpret them. Instead, the person should be directed for relevant advice (e.g. stopping smoking; reducing dietary fat and salt) to leaflets available in the Assessment Centre and to NHS Direct (telephone 0845-4647 or www.nhsdirect.nhs.uk).

14.3.2.3: Participants found to have high blood pressure levels at the assessment visit are to be asked whether this is already being managed by their own doctor. If not, the person should be advised to discuss the result with their GP at the earliest opportunity.

14.3.3 Dealing with potentially serious incidental findings

14.3.3.1: An incidental finding is defined as an unexpected finding which is not part of the research assessment and may have clinical significance. Incidental findings may be identified at any stage of the assessment visit.

14.3.3.2: Incidental findings can be divided into two main types:

- *Observational findings:* Staff may identify observational findings that range from physical evidence (e.g. skin discolouration suggestive of melanoma) through to comments made by participants (e.g. threatened suicide); and
- *Disclosed findings:* Participants may voluntarily raise health concerns with staff during the course of the assessment visit (e.g. severe chest pain on exercise).

14.3.3.2: Potentially serious incidental findings identified during the Assessment Centre visit by any member of staff should be reported immediately to the Assessment Centre manager or their deputy. This senior member of staff should use their professional judgement to decide what action to take.

14.3.3.3: This may involve discussing the finding with the participant in a neutral manner (e.g. "Are you aware of changes in this mole?") and, if it remains a serious concern, enquiring about any action already taken (e.g. "Have you asked your GP to look at this mole?"). Where no action has been taken regarding a potentially serious incidental finding, the participant should be advised to discuss it with their GP at the earliest opportunity. [Note: In an emergency, it would be appropriate to call for an ambulance or other appropriate assistance.]

14.3.3.4: A record is to be made in the comments section of the ACE IT system of actions taken for potentially serious incidental findings that are identified. These records will be monitored by the Coordinating Centre on a regular basis.