

UK Biobank

Consent

Version 1.0

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

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This manual details the Consent process at an Assessment Centre of the UK Biobank. Also detailed are aspects of privacy, security of medical information and rights of the participant to withdraw from the UK Biobank project.

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1 Introduction

1.1: This manual details the Consent process at an Assessment Centre of the UK Biobank. Also detailed are aspects of privacy, security of medical information and rights of the participant to withdraw from the UK Biobank project. The Consent procedure takes place at a touch-screen station, after welcome and registration of the participant (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 Refractometry Intraocular pressure Optical Coherence Tomography (Retinal Imaging)

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 Tactus operates the Consent and Touch-screen Questionnaire modules of the assessment visit.

1.4: Consent procedures use the Consent Module of the UK Biobank Assessment Centre Environment (ACE) for the following functions:

- Receipt of Registration Data from the Registration Module
- Presentation of Participant Information and Consent Form text
- Recording consent information, including electronic signature from Participant
- Generating Consent Data, including explicit permission to interact with later ACE Modules

2 The Consent Form

The Consent Form, as with other participant materials (i.e. letters of invitation, information leaflets) have been developed with the advice of the Ethics & Governance Council (EGC) and in accordance with the key principles in the Ethics & Governance Framework EGF

<http://www.ukbiobank.ac.uk/docs/EGF20082.pdf>; <http://www.egcukbiobank.org.uk/>

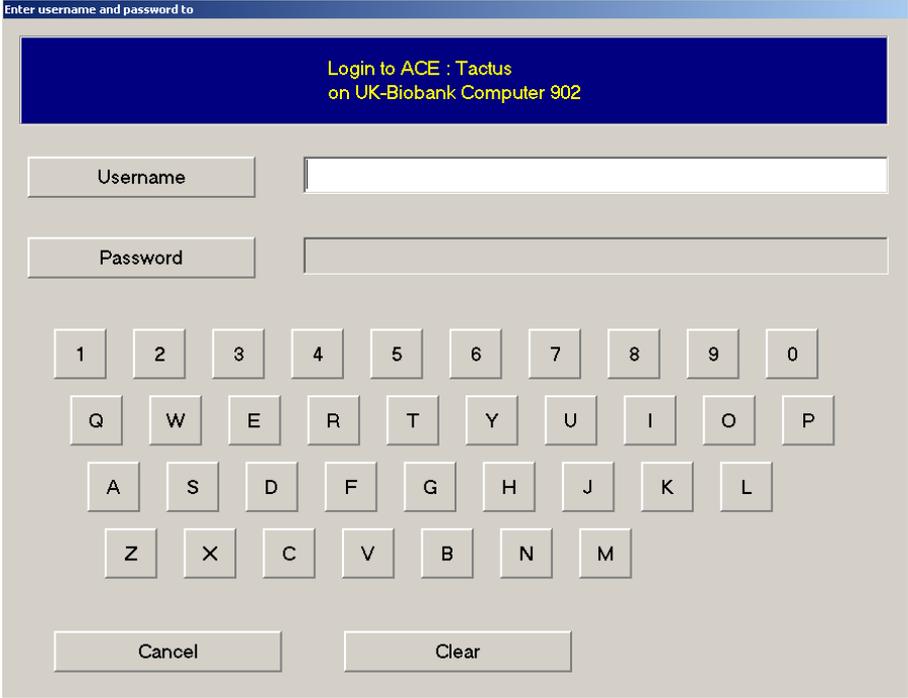
3 Staff

Assessment centre staff typically comprises Duty Manager, Study Interviewer, Phlebotomist, Measurement Technician, Laboratory technician and Receptionist. All Assessment Centre staff are responsible for carrying out the Consent procedure. The Duty Manager oversees that all Assessment Centre staff work in accordance with this procedure.

4 Consent station procedure

4.1: A member of staff introduces the participant to the touch-screen system and offers to answer any questions about UK Biobank. The touch-screen computer area provides each participant with privacy by spacing and partitions. The staff member takes the person through the consent process.

4.2: The UK Biobank staff member inserts the participant's USB key into the computer and logs on securely to ACE:Tactus with username and password using the QUERTY keyboard shown on the touch-screen device:



Enter username and password to

Login to ACE : Tactus
on UK-Biobank Computer 902

Username

Password

1 2 3 4 5 6 7 8 9 0

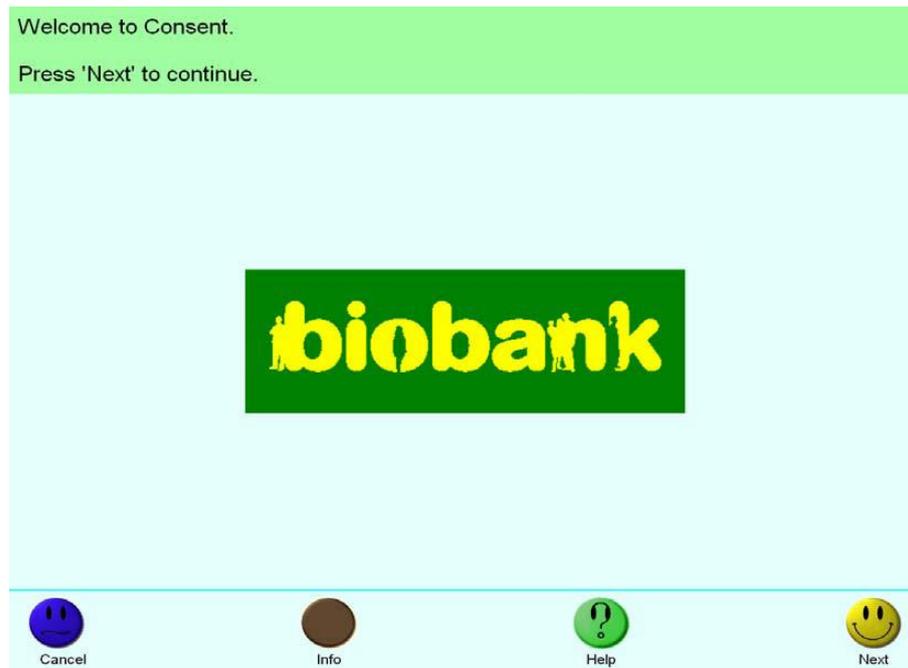
Q W E R T Y U I O P

A S D F G H J K L

Z X C V B N M

Cancel Clear

4.3: The participant is asked to use the 'Next' button to display the next screen and is explained the use of the 'Cancel', 'Next', 'Info' and 'Help' buttons:



Back or Cancel (later versions) allows the participant to move back through the questionnaire and change answers



Info tells the participant how far they have progressed through the touch-screen (and allows adjustment of participant preferences)



Help gives some additional explanation to assist participants to complete the questions where it may be necessary



Next moves the participant to the next screen

The participant is asked to confirm their details by touching the statement “I agree” and then selecting the ‘Next’ button:

Welcome to the UK Biobank Consent Form.

Please confirm that the following details are correct.

Name: Mrs Freida Test
Date of Birth: 12 January 1940
Gender: female

I agree

I disagree

 Back  Info  Help  Next

4.4: If details are incorrect, the participant should select “I disagree”, and receives a pop-up message instructing them to summon a member of staff. The staff member presses ‘Next’, which progresses to the ‘Edit details’ page. On confirmation with the participant the staff member selects which details to edit:

Select which details to edit.
Press Save to sign-off and save changes.
Press Reset to restore the original values from the key.

Title (edited: MRS)
Given name (original: James)
Family name (original: Devlin)
Year of birth (original: 1962)
Month of birth (original: 1)
Day of birth (original: 29)
Gender (original: female)
Reset to original
Save edits

 Back  Info  Help  Next

4.5: If a numerical value requires editing a numerical pad appears on the touch-screen display:

The screenshot shows a mobile application interface. At the top, a green header bar contains the text "Month of birth (original: 1)". Below this is a light blue area with a white input field. To the right of the input field is a "Clear" button. Below the input field is a numeric keypad with buttons for digits 0-9. At the bottom of the screen is a navigation bar with four icons: a blue "Back" button, a brown "Info" button, a green "Help" button, and a yellow "Next" button.

4.6: The staff member enters the correct numerical value with confirmation by the participant, then presses 'Next', which returns the screen to the 'Edit details' page. The 'Save edits' option will enable the user to save and display the changes that have been made.

4.7: The participant is then asked to read the text on the next two screens, which summarise the UK Biobank Patient Information Leaflet <http://www.ukbiobank.ac.uk/docs/BIOINFORBK14920410.pdf>.

4.8: At this point the participant is told that this is an ideal opportunity to ask any questions they may have about participation.

4.9: If the participant wishes to take part they are asked to read the statements on the consent screen, and to touch "I agree" or "I disagree". If the participant selects "I agree" to all statements displayed on the consent form then, after selecting the 'Next' button the completed consent form is displayed:

Consent Form: UK Biobank**Assessment centre number:** [INSERT CENTRE NUMBER]**Participant identifier:** [INSERT PARTICIPANT IDENTIFIER]

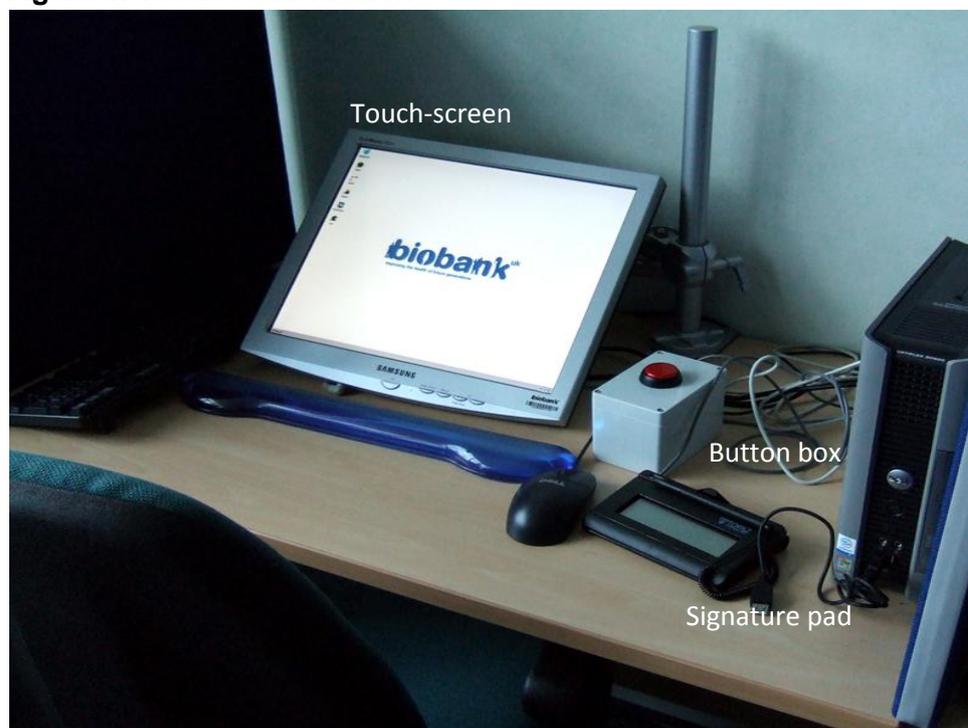
The purpose of UK Biobank is to set up a resource that can support a diverse range of research intended to improve the prevention, diagnosis and treatment of illness, and the promotion of health throughout society.

Thank you for reading the Information Leaflet, and asking any questions that you might have had. If you would like to participate, please respond to each of the following questions on the touch-screen and then sign the computer pad.

I have read and understand the Information Leaflet, and have had the opportunity to ask questions.	I agree
I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.	I agree
I understand that I may be re-contacted by UK Biobank (e.g. to answer some more questions and/or attend another assessment visit), but this is optional.	I agree
I give permission 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).	I agree
I give permission for long-term storage and use of my blood and urine samples for health-related research purposes (even after my incapacity or death), and relinquish all rights to these samples which I am donating to UK Biobank.	I agree
I understand that <i>none of my results will be given to me (except for some measurements during this visit) and that I will not benefit financially from taking part (e.g. if research leads to commercial development of a new treatment).</i>	I agree
I agree to take part in UK Biobank.	I agree

4.10: The participant is shown how to sign the consent form using the electronic signature pad (figure 1) and is informed that a copy of the form will be provided at the end of the visit.

Figure 1: Touch-screen station



4.11: If the electronic signature pad does not work, the staff member prints two copies of the completed consent form on a network printer and asks the participant to

sign both copies. To do this the staff member presses the 'Next' button to open the 'Consent (Paper)' page and selects the 'Print Consent' button. One copy of the form is retained by the duty manager in a locked filing cabinet; the other copy is given to the participant ([Appendix 1: Consent Form: UK Biobank](#)).

4.12: If the participant is physically unable to provide a signature, two paper copies of the consent form are signed by two members of staff: the one witnessing consent and another, one of whom must be a qualified nurse. One copy is retained by the duty manager in a locked filing cabinet; the other copy is given to the participant;

4.13: Once consent has been given, the UK Biobank staff member selects the 'Next' button, enters their username and password using the touch-screen password and again selects the 'Next' button:

4.14: During the consent process, the UK Biobank staff member determines whether the participant has the mental capacity to provide informed consent ([Appendix 2: Procedures for assessment of mental capacity](#)). If concerns arise these are reported to the centre manager/deputy. In cases of uncertainty the manager or deputy should suggest the person does not participate.

4.15: If the participant selects "I disagree" for any of the consent questions, a message is displayed to contact a member of staff who will then provide further information and clarification on any issues. More senior staff are also available and, should it be required, senior members of the central UK Biobank team can be contacted by telephone at any time during Assessment Centre operation.

4.16: The computer system does not allow any subsequent stations to be undertaken unless the consent process has been completed by the participant signing the consent form and a member of staff verifies that this has been done.

4.17: Participants who have given consent are asked to remain at the touch-screen station so they can complete the questionnaire. Participants who do not give consent have their USB key returned to the reception station for data removal, and are thanked for their time before leaving.

5 Participant withdrawal process

5.1: Participants are advised at enrolment that they have the right to withdraw at any time without giving a reason and without penalty. This is essential to preserve and demonstrate the voluntary nature of participation.

5.2: There are three levels of withdrawal from the study;

1. “No further contact”: This means that UK Biobank would no longer contact the participant directly, but would still have permission to use information and samples provided previously and to obtain further information from their health-relevant records]
2. “No further access”: This means that UK Biobank would no longer contact the participant or obtain information from their health-relevant records, but would still have permission to use the information and samples provide previously
3. “No further use”: This means that, in addition to no longer contacting or obtaining further information about the participant, any information and samples collected previously would no longer be available to researchers. UK Biobank would destroy the participant’s samples (although it may not be possible to trace all distributed sample remnants) and would only hold their information for archival audit purposes. The participant’s signed consent and withdrawal would be kept as a record of their wishes. Such a withdrawal would prevent information about the participant from contributing to further analyses, but it would not be possible to remove their data from analyses that had already been done.

6 Participant withdrawal process within the Assessment Centre

6.2: This is the procedure for UK Biobank staff to process a participant who wishes to leave an Assessment Centre at any time throughout their visit. All Assessment Centre staff are responsible for carrying out this procedure. The Assessment centre Manager oversees that all staff work in accordance with it.

6.3: When a participant would like to withdraw from the study they ideally go through the Exit station, although this might not always be the case. Assessment centre staff always record reasons why the participant can not/does not continue (e.g. participant fainted). The staff member checks that the participant definitely wants to conclude the visit, since they cannot re-enter the Assessment Centre once this is done. The

staff member explains that the system will not allow them to book a new appointment or attend the Assessment Centre at a later date.

6.4: The participant's USB key is retrieved and inserted into a computer operating the Porto program ([Assessment Centre Environment](#)), where the staff member can sign off the appointment as having been abandoned. If the participant has not completed the Consent section of the assessment, this is all that is required.

6.5: If the participant has completed the Consent section of the assessment and would like to withdraw, the USB is taken to a station and the Exit module is run: the staff member records the reason for abandonment of the visit next to each module that has not been completed:

Screenshot 8: Exit procedure

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			

6.6: The participant completes all sections of the Assessment Centre Participant Withdrawal Form ([Appendix 3: Withdrawal Form](#)), and is asked to confirm which of the three levels ([Section 5.2](#)) they wish to withdraw to.

6.7: The participant is advised by the staff member that their samples and data will be withdrawn by the UK Biobank Co-ordinating Centre and they will be contacted in writing to confirm their withdrawal from the study. All withdrawal forms are forwarded promptly to the administration team at the UK Biobank Coordinating Centre.

6.8: The procedure followed by Assessment Centre staff when dealing with enquiries and complaints in the Assessment Centre is outlined in [Appendix 4: Procedure for dealing with enquiries and complaints in the Assessment Centre](#)

7 Dealing with “Removal of Contact Details” requests from invitees

Requests from invitees to have their contact details removed are received by the Participant Resource Centre (PRC) by telephone, postal reply form or email, or by

the Coordinating Centre by letter. Telephone callers are told that their details will normally be removed within 21 days, which is in accordance with the Data Protection Act. Requests for removal of contact details are flagged appropriately within the Coordinating Centre database.

8 Appendices

8.1 Appendix 1: Consent Form: UK Biobank

Assessment centre number: [INSERT CENTRE NUMBER]

Participant identifier: [INSERT PARTICIPANT IDENTIFIER]

The purpose of UK Biobank is to set up a resource that can support a diverse range of research intended to improve the prevention, diagnosis and treatment of illness, and the promotion of health throughout society. Thank you for reading the UK Biobank Information Leaflet, and asking any questions that you might have had. If you would like to participate, please respond to each of the following questions on the touch-screen and then sign the computer pad.

I have read and understand the Information Leaflet, and have had the opportunity to ask questions.	I agree
I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.	I agree
I understand that I may be re-contacted by UK Biobank (e.g. to answer some more questions and/or attend another assessment visit), but this is optional.	I agree
I give permission 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).	I agree
I give permission for long-term storage and use of my blood and urine samples for health-related research purposes (even after my incapacity or death), and relinquish all rights to these samples which I am donating to UK Biobank.	I agree
I understand that none of my results will be given to me (except for some measurements during this visit) and that I will not benefit financially from taking part (e.g. if research leads to commercial development of a new treatment).	I agree
I agree to take part in UK Biobank.	I agree

[INSERT PARTICIPANT NAME]	[INSERT DATE]	[INSERT PARTICIPANT SIGNATURE]
Volunteer name	Date	Signature

[INSERT STAFF MEMBER NAME]	[INSERT DATE]
Staff member name	Date

For further information about UK Biobank, please call free of charge on 0800-0-276-276 or look at the project website at www.ukbiobank.ac.uk

8.2 Appendix 2: Procedures for assessment of mental capacity

8.2.1: At the start of the consent/touch-screen station, supervising staff are to determine whether each potential participant has the mental capacity needed to provide consent. **It should generally be assumed that the person has the required capacity unless there is evidence to suggest otherwise.**

8.2.2: Evidence for lack of capacity might include signs of confusion or anxiety as to the purpose of their attendance at the Assessment Centre. Alternatively, the person might show a lack of understanding of the information leaflet sent with their invitation letter (e.g. thinking participation is compulsory rather than voluntary; not realising what participation involves), although this could be due to not reading the information leaflet sufficiently carefully. A person who is unable to make a decision for themselves is unable:

- To understand the information relevant to their decision;
- To retain that information;
- To use or weigh that information as part of the process of making their decision, or;
- To communicate their decision (whether by talking, using sign language or any other means).

8.2.3: Where uncertainty exists, staff should determine whether the person has read the information leaflet, and aim to provide a full understanding of what participation involves. If it is thought that there is a lack of mental capacity then the Assessment Centre manager (or their deputy) should be involved. It may be appropriate to move to a private area for this discussion.

8.3 Appendix 3: Withdrawal Form



Assessment Centre Participant Withdrawal Form

All boxes MUST be completed in order to withdraw from the study PLEASE NOTE THAT IF WE ARE UNABLE TO VERIFY YOUR DETAILS, WE MAY BE UNABLE TO WITHDRAW YOU.	
Participant identifier : □ □ □ □ □ □ □ □ □ □	Name of Participant : PLEASE WRITE IN BLOCK CAPITALS
Date of Birth :	Signature :
Telephone Number :	
Address and <u>Post Code</u> :	Date :

I wish to withdraw my participation in UK Biobank with immediate effect. The withdrawal options have been discussed with me and I have selected the withdrawal option as indicated below.

PLEASE PUT A CROSS IN ONE BOX ONLY.

- **No further contact:** This means that UK Biobank would no longer contact you directly, but would still have your permission to retain and use information and samples provided previously and to obtain and use further information from your health records.
- **No further access:** This means that UK Biobank would no longer contact you or obtain further information from your health records in the future, but would still have your permission to use the information and samples provided previously.
- **No further use:** This means that, in addition to no longer contacting you or obtaining further information about you, any information and samples collected previously would no longer be available to researchers. UK Biobank would destroy your samples (although it may not be possible to trace all distributed sample remnants) and would only hold your information for archival audit purposes. Your signed consent and withdrawal would be kept as a record of your wishes. Such a withdrawal would prevent information about you from contributing to further analyses, but it would not be possible to remove your data from analyses that had already been done.

Please return to the freepost address below:

UK Biobank, **Freepost** RRKZ-YAXH-ZYSR, 1-2 Spectrum Way, Adswood, Stockport, Cheshire, SK3 0SA

For official use only – WMS ID No: _____ **Assessment centre location:** _____

We are constantly trying to improve the experience we give participants at UK Biobank and would appreciate it if you would outline your reason for withdrawal in the box below.

Reason for withdrawal:

8.4 Appendix 4: Procedure for dealing with enquiries and complaints in the Assessment Centre

8.4.1: The procedure

8.4.1.1: This procedure details the method that Assessment Centre staff reports any issues, enquiries or complaints to the co-ordinating centre support team. This facilitates a structured approach to resolution of the issue.

8.4.1.2: All Assessment Centre staff are responsible for reporting any issues, enquiries or complaints which arise to the Assessment Centre manager. The manager decides whether or not the issue needs escalating to the co-ordinating centre support team. It is then the responsibility of the co-ordinating centre support team to resolve the issue. The Quality Assurance Manager oversees that all Assessment Centre, and co-ordinating centre staff work in accordance to the procedure

8.4.2: Reporting general issues

8.4.2.1: All non-urgent issues, enquiries or complaints are reported by filling out the Assessment Centre issue log.

8.4.2.2: All urgent issues, enquiries or complaints are reported by calling the Assessment Centre Helpline Number. If the Co-ordinating Centre receives a call from an Assessment Centre, this will still be entered on the issue log and assigned an Issue ID number by a member of the Co-ordinating Centre Support Team - usually the person receiving the call. The issue ID number will be relayed to the Assessment Centre. All issues, complaints and enquiries are recorded on the Assessment Centre Issue Log; this provides a record of all issues and the action taken to resolve them.

8.4.3: Guidelines for dealing with enquiries and complaints in the Assessment Centre

8.4.3.1: All enquiries and complaints from people attending the Assessment Centre are acknowledged immediately and discussed with the person by a member of staff. The member of staff should decide whether they can adequately address the issue raised and, if so, should then check that they have dealt with it to the satisfaction of the person concerned.

8.4.3.2: All enquiries or complaints which cannot be addressed adequately by a member of staff are, in the first instance, referred to one of the senior nurses on duty. All serious concerns or complaints are also referred to the Assessment Centre manager or their deputy.

8.4.3.3: As a general principle, staff refer people with enquiries about the project aims and procedures to the relevant sections of the Participant Information Leaflet <http://www.ukbiobank.ac.uk/docs/BIOINFOBK14920410.pdf> or Further Information Leaflet <http://www.ukbiobank.ac.uk/docs/Furtherinformationleaflet.pdf> (copies available in the Assessment Centre). Any additional information provided should be consistent with these Information Leaflets and presented in a neutral manner (i.e. without any coercion to take part). The person is given the opportunity to reflect upon this information and to discuss it with a more senior member of the Assessment Centre team (e.g. the manager or deputy).

8.4.3.4: Enquiries or complaints that cannot be addressed adequately by the Assessment Centre manager or their deputy are referred immediately to the Co-ordinating Centre both in and outside of office hours using either the Assessment Centre Issue Log or by calling the Assessment Centre Helpline number. The enquiry or complaint will either be dealt with directly or referred to a more senior member of the UK Biobank team. As required, the person involved can discuss their enquiry or complaint directly with central staff via the telephone in the dedicated Assessment Centre office.

8.4.3.5: If the person involved has any residual concerns, Assessment Centre staff provides them with a copy of the Participant Information Leaflet and indicate the section at the end entitled "*Who do I contact if I have any concerns?*"