

Standard Operating Procedure

Donor consent

SOP: PC001, version ^ 2

Document status: Open

Document active from: 01 May 2008[^]

Document review due: 30 April 2009[^]

Authorisation: This document is authorised and activated by its publication to the G: drive by the Head of Quality and Standards (HQS).

Distribution list:

- Master copy is held by the HQS
- Head of Operations
- CELL database
- onCore UK Website
- CCB Members Portal
- Jocelyn Walters (for upload to EDGE)
- Cathy Warner (for distribution at Addenbrookes)
- Pushpa Patel (for distribution at Pan Birmingham)

Changes to previous version

[^] Changed text is shown in red and deletions shown as [^]. Significant changes are shown under History, below.

Introduction and aim of the procedure

onCore UK aims to consistently provide tissue and data that meets customer and regulatory requirements, whilst working to the highest ethical standards. The start of this procedure is the enrolment of patients prepared to donate their tissue and allow personal data, including their medical history and treatment outcomes, to be made available to researchers. Tissue will not be actively sought from the deceased.

Written consent is not always required for use of tissue for research, however onCore UK will bank only tissue for which written consent to donate to onCore UK has been obtained. Written consent is increasingly recognised as best practice. Written consent is not in itself a substitute for careful face-to-face explanation, hence onCore UK will provide oral and written information to potential donors; listen to their opinions, answer questions and aim to reach a shared understanding. Donors shall be enrolled only if their informed consent is given freely.

The aim of this procedure is to describe the stages needed to obtain consent. It will ensure that potential donors are made aware of the aims of onCore UK, the potential uses of their donated specimens and data, and their right to withdraw consent at any time. Donors shall be made aware of what will happen if they withdraw consent.

The procedure is written to meet the needs of onCore UK, but shall be applied with knowledge of the policies and procedures relating to consent of the hospital Trusts who hold contracts with onCore UK.

Applications and Restrictions

Only designated, trained staff seeking to enrol patients as donors to the onCore UK biobank shall use this procedure. This procedure shall be followed whenever informed consent is sought. It is the responsibility of the person receiving the donor's consent to ensure that the donor fully understands what they are consenting to. Donation is restricted to competent adults as defined in the Human Tissue Authorities' Code of Practice on Consent (current version).

Training

Training to receive donor consent is given according to SOP: TR001 using form: PC001.04. A list of competent staff ^ may be maintained on form PC001.05 ^ at each hospital participating in a biosample donation network if that is useful to the hospital.

Associated procedures and supporting documents

SOP: TR001	General training procedure for onCore UK activities
Form: PC001.01	Patient eligibility flowchart
Form: PC001.03	Tissue bank "screening" log
Form: PC001.04	Training record - onCore UK consent and withdrawal procedures
Form: PC001.05	Record of competence - onCore UK consent and withdrawal procedures
SOP: PC002	Collection of blood at BDN centres
SOP: PC003	^ Enrolment of Donors to the onCore UK CELL database
SOP: PC004	Collection and storage of tissue at BDN centres
SOP: PC005	Withdrawal of tissue and data from the onCore UK biobank
SOP: QS001	Deviations from standard operating procedures
IT001	CELL system manual
Patient information leaflet	Giving tissue and blood samples for cancer research
Consent form	Consent for research using human tissue and blood samples
Donor Forum Card	Donor Forum information leaflet and reply card

The consent procedure

1. Identify patients suitable to become donors using local procedures. Ensure that such patients are suitable to approach for donation to onCore UK using the Patient Eligibility Flowchart, Form: PC001.01. Approach such patients at a time and in a manner that best suits local practices.
2. The stages of consent are:
 - a. Identify patient (see 1 above).
 - b. Make initial approach to patient according to local practices.
 - c. Give patient the onCore UK patient information leaflet (PIL) entitled "Giving tissue and blood samples for cancer research".
 - d. Discuss consent with the patient, covering the points described in the notes below.
 - e. Give the patient time to consider whether or not to donate to onCore UK.
 - f. Note refusal to consent in the patient's case notes and in the screening log (Form: PC001.03), or
 - g. Record consent using the onCore UK consent form and note that consent was received in the patient's case notes and in the screening log (form: PC001.03). The "witness" on the consent form is witnessing only the patient's signature, not the consent process.

- h. Attach a hospital addressograph label to the consent form to ensure sufficient patient identifiers are recorded.
- i. If required by local practices, add an addressograph label to the consent form and add a label such as that shown in Appendix 1 to the patient's case notes to allow easy identification of those patients who have been approached.
- ^ j. Distribute copies of the signed consent form according to local requirements as detailed in appendix ^ 2. Copies may be NCR (no carbon required) forms or photocopies of the form signed by the patient. An original signed form or top copy of the NCR form must be placed in the patient's case notes.

Note that although all of the stages shown above are required, the timing of stages and the way in which the stages are performed will vary according to local practices; for example the patient may receive the PIL either at a hospital appointment or through the post.

onCore UK Donor Forum

onCore UK wishes to invite those individuals who have consented to donate tissue, blood and data to the biobank to become members of the onCore UK Donor Forum. Once an individual has signed the consent form, give them the Donor Forum Card. This card gives information about the Donor Forum and contains a reply slip to be completed by any donor interested in becoming a member of the Forum.

Notes for persons seeking consent

At all times use language that the potential donor can understand and encourage the potential donor to ask questions.

onCore UK will seek to obtain 50ml blood, unwanted tissue and data from each donor. Note that tissue will be sought only if the donor has a tumour resected or biopsied.

Explain the type of data that onCore UK will look for (personal, lifestyle, diagnosis, treatment and outcome data), where it will be obtained from and what will happen when more data becomes available in the future.

After you have described the opportunity to donate to onCore UK, it is essential that the patient is given sufficient time to consider whether to donate (a "cooling off" period) before you seek written consent. Some patients will need longer than others to think about their options; ensure that the patient does not feel under any pressure to make a decision quickly and the time given is sufficient for them.

In most instances, the consent process will take place face-to-face with the patient. If the patient is not expected to attend the hospital in the near future or if a separate appointment is made to receive consent and take blood, then the PIL, consent form and an invitation letter may be sent to the potential donor prior to the hospital appointment. The "cooling off" period then becomes the time between receipt of the invitation letter and leaflet and the time of the appointment.

If an invitation letter is sent out without prior discussion with the patient, or if the period between initial discussion and signing of the consent form is greater than a week, the patient may be reminded of the opportunity to donate by telephone prior to their attendance at the hospital.

When completing the consent form the donor must be given time to consider the options on the form and encouraged to ask questions.

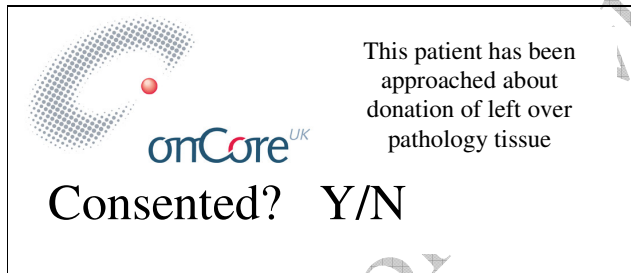
Once the consent form is complete, a date and time for collection of blood and data is arranged according to local practices. This may follow immediately after receiving consent but should be convenient for the donor.

Details of how to enter patient details onto the onCore UK database are given in the onCore UK Software Manual and in SOP: PC003. Details of blood collection, data collection and tissue collection are given in SOPs PC002[^] and PC004 respectively.

Patients who wish to withdraw their donations are advised to contact the individual who took consent if this is possible. Where it is not possible the donor must be put in touch with an individual trained to receive consent for donation as all such individuals will be trained in the withdrawal procedure. The procedure for withdrawal is given in SOP: PC005.

Any deviations from this procedure shall be investigated and recorded according to SOP: QS001.

Appendix 1 Example of label that may be used in patient's case notes.



This patient has been approached about donation of left over pathology tissue

Consented? Y/N

[^]

[^] Appendix [^] 2

Distribute copies of consent forms as appropriate for the hospital shown. In every case the top copy of the consent form must be held in the patient's case notes.

Queen Alexandra Hospital, Portsmouth , [^] Southampton General Hospital and Addenbrookes Hospital:

- a Patient
- b Patient notes
- c Local onCore UK Co-ordinator
- d onCore UK (send to Head of Operations)
- e Histopathology

University Hospital Birmingham:

- a Patient
- b Patient notes
- c Local onCore UK Co-ordinator
- d onCore UK (send to Head of Operations)

^

History

Version	Date active	Changes to previous version
1	30 Jun 2007	None, new procedure
2	01 May 2008	Distribution list amended. Addition of reference to Patient Eligibility Flowchart Addition of option to use onCore UK label in case notes. Addition of instruction to give Donor Forum Card to donors.

END

Uncontrolled when printed