

Standard Operating Procedure

Withdrawal of donor consent

SOP: PC005, version 2

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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. Such donors may decide to withdraw their consent; this document describes the procedure to be followed if this happens.

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

Applications and Restrictions

Only designated, trained staff shall use this procedure. All persons trained to seek and receive consent shall be trained to use part 1 of this procedure. In addition, some staff of onCore UK may be trained to discuss withdrawal and shall be trained to remove and dispose of all undistributed tissue and data. The procedure shall be followed whenever a donor wishes to revoke consent to donate tissue and data to the onCore UK biobank. onCore UK has set a target completion time for this procedure of seven working days after receipt of a signed request for withdrawal.

Training

Training in the procedure to follow when a donor withdraws is given according to SOP: TR001 using form: PC001.04 for hospital staff and form PC005.01 for onCore UK staff.

Associated procedures and supporting documents

Consent form	Consent for research using human tissue and blood samples
Form: PC001.03	Screening log
Form: PC001.04	Training record - onCore UK consent and withdrawal procedures
Form: PC005.01*	Training record - withdrawal of tissue and data
Form: PC005.03	Record of withdrawal by donor.
SOP: TR001*	General training procedure for onCore UK activities
SOP: PC001	Donor consent
SOP: QS001	Recording and investigation of deviations from standard operating procedures
SOP: OP024*	Sample retrieval
SOP: OP025*	Sample destruction

* Applicable only to onCore UK staff

Part 1.

The withdrawal procedure - communicating with the donor

1. The onCore UK Patient Information Leaflet describes what will happen if a donor decides to withdraw consent. The leaflet advises the donor to contact either the hospital where consent was given or onCore UK.
2. A donor may indicate that they wish to withdraw consent verbally or in writing; by telephone, face-to-face, in an e-mail, text or letter.

Face-to-face withdrawal

3. If possible, any donor who wishes to withdraw consent is referred to the individual who received consent; it is essential, however, that the donor does not feel that there are any barriers to withdrawal. If the person who received consent is unavailable, it is acceptable for any trained and competent individual to discuss withdrawal with a donor.
4. At all times language shall be used that the donor can understand and the donor encouraged to ask questions.
5. No attempt to change the donor's mind shall be made if they have decided to withdraw.
6. The donor shall be told that his or her data will be deleted from the onCore UK database so that it cannot be used again and that samples in storage will be destroyed in the way human tissues and blood from hospitals are normally destroyed.
7. The donor shall be told that it is not possible to retrieve and destroy samples and data that have been distributed to researchers and used in research, nor is it possible to withdraw the results of such research or prevent their publication. onCore UK shall contact researchers and ask for any unused samples to be destroyed so that they cannot be used in any further research. The donor shall be reassured that onCore UK never gives the researcher access to any personal data that will allow the donor to be identified.
8. The donor shall be allowed to ask questions and all questions answered honestly. onCore UK shall provide help in answering any questions if local staff are unsure of the answers.
9. The donor shall be asked to sign form: PC005.03. This is necessary so that we can demonstrate that the person withdrawing consent is the same person who gave consent. The completed form shall be sent to the Head of Operations at onCore UK; a copy may be held locally if required.

Remote withdrawal

10. If withdrawal is requested by telephone, e-mail, text or fax then form PC005.03 shall be sent to the donor for completion and return to onCore UK. Alternatively the donor can download the form from the onCore UK website, www.oncoreuk.org in the section "About us" under "Policies and practices". The donor shall be told that samples and data will be put into quarantine until the form is received and samples will be sent for destruction within 7 days of receipt of the form. The Head of Operations at onCore UK (see 13 below) shall be notified of the request to withdraw samples.
11. The Head of Operations shall ensure that samples and data are quarantined according to SOPs: OP024 and OP025. If the completed form PC005.05 is not received within one month the Head of Operations shall send a letter to the donor warning them that samples are going to be destroyed. This letter shall give the donor the opportunity to indicate that he or she no longer wishes to withdraw as shown in appendix 1.
12. If the request for withdrawal is received in a signed letter, or once the signed form PC005.03 is received, the signature shall be checked against that on the consent form and the withdrawal of consent recorded in the donor's case notes. A comment shall be added to the donor's record on the screening log (form: PC001.03) stating that consent is withdrawn; this addition shall be dated and signed. The copy of the consent form (Form: PC001.01) held in the donor's case notes shall be scored through with a single line, "WITHDRAWN" written and the form dated and signed. Copies of the amended consent form shall be sent to everyone who received copies of the original (as shown in SOP: PC001).
13. The Head of Operations shall be informed by telephone (020 8731 4595) that the donor has withdrawn consent, quoting the donor's name, address, date of birth, hospital number and, if available, NHS and onCore UK numbers. This phone call must be made as soon as possible and always within two working days. Alternatively an e-mail can be sent to operations@oncoreuk.org, a template for this e-mail is shown in appendix 2. Please do not use a donor's name, address or date of birth in any e-mail or fax.
14. onCore UK has set a target of seven working days from receipt of a signed form to completion of sample destruction and data deletion.
15. When confirmation of sample destruction and record deletion is received from onCore UK, the donor shall be notified that their withdrawal is complete. A template for this notification is given in appendix 3. This notification must be sent as soon as possible and always within two working days of receipt of confirmation from onCore UK.

Part 2.

The withdrawal procedure - onCore UK operations

1. onCore UK Operations staff shall be made aware of the withdrawal of consent by a telephone call to the Head of Operations or an e-mail to the Operations e-mail account.
2. Within one working day of receipt of this information, the location of all of the donor's samples or their derivatives shall be determined.
3. Samples and derivatives shall be retrieved from storage according to SOP: OP024 and destroyed according to SOP: OP025.
4. Researchers who have received samples from the donor shall be contacted and notified that consent has been withdrawn; ask them to destroy any remaining material. A template for this notification is given in

- appendix 4. Operations staff shall ensure that the researcher does not receive any of the donor's personal identifiable information during this process.
5. All of the donor's records shall be deleted from the CELL system. The records to be deleted include all personal data such as demographics, treatment and outcomes as well as sample related data such as sample identifiers, processing data and inventory details. Note that system audit records are not destroyed, as the audit trail must be preserved.
 6. The person who notified Operations of the withdrawal of consent shall be notified that samples have been destroyed and records deleted, either by telephone or using the e-mail template shown in appendix 5.
 7. Deviations from this procedure shall be investigated and recorded according to SOP: QS001.

History

Version	Date active	Changes to previous version
1	30 June 2007	None, new procedure
2	31 Jan 2008	Removal of requirement to complete separate record of competence (now part of training record form). Part 1 sections 10, 11 and 14 - updated to give increased information on the use of form PC005.03 Record of withdrawal by donor. Introduction of template letter to patient who has not confirmed in writing that he/she wishes to withdraw. Grammatical corrections to all sections.

Appendix 1 Template letter to donor

(DATE)

Dear (donor),

Thank you for notifying (individual, unit or hospital name) that you wish to withdraw consent for your samples and data to be banked by onCore UK and used by researchers. Before we destroy samples and data we normally ask the donor to sign a form to confirm their wishes in writing. As we have not yet received this form from you would like to check whether you still wish to withdraw consent or if you have changed your mind and no longer wish to withdraw. We are very happy to discuss any questions or concerns that you may have; please be assured that will not attempt to influence your decision. Our contact details are given at the end of this email.

If you do still wish to withdraw your samples and data, you do not have to do anything. We will destroy all of your unused samples and remove data from the database **unless you tell us not** to within fourteen days of the date at the top of this letter. You can contact us as follows:

Post:

(Address)

Telephone: (Number)

e-mail: (Address)

Yours sincerely,

(Signature)

(Printed name)
Head of Operations

Appendix 2 Template e-mail to onCore UK Operations staff

From:
Hospital:

The donor identified below has withdrawn consent for their samples and data to be banked by onCore UK and used by researchers. Please destroy all unused samples and remove data from the database.

Hospital number:
NHS number*:
onCore UK number*:

* if known

Date on which withdrawal form was signed:

Send e-mail to: operations@oncoreuk.org

Appendix 3 Template notification of sample destruction and data deletion

To: (donor)

We have acted upon your request to withdraw your tissue and information from the onCore UK tissue bank and are pleased to confirm that your request has been carried out. All tissue and blood samples held by the bank have been destroyed and all information about you has been deleted. All researchers who have received any of your samples have been informed of your decision to withdraw and asked to destroy any samples that remain.

Thank you for your interest in the use of tissue in cancer research.

From: (BDN)

Appendix 4 Template notification to researcher of donor withdrawal

To; (Researcher)

The donor of the samples identified below has withdrawn consent for their use by researchers. Please destroy all unused samples and delete any data held.

Sample type	Sample identifier	Date dispatched from onCore UK

From: Operations, onCore UK

Appendix 5 Template e-mail to confirm successful donor withdrawal

To: (*person requesting destruction of samples and inactivation of data*)

The samples from the donor identified below have been destroyed and the associated donor and sample data have been deleted from onCore UK's records.

Hospital number:

NHS number*:

onCore UK number*:

* if known

Date on which withdrawal form was signed:

From: Operations, onCore UK

END