

Standard Operating Procedure

Enrolment of donors to the onCore UK CELL database

SOP: PC003, version 1

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Changes to previous version

Changed text is shown in red and deletions are shown as ^. Details of significant changes are shown under History, below.

Introduction and aim of the procedure

This standard operating procedure defines the procedure for enrolling new donors onto onCore UK's CELL database. Patients are enrolled after they have consented to donate tissues and data for research.

Applications and restrictions

Only designated, trained staff shall use this procedure to enrol donors to the onCore UK CELL database. Donor enrolment is limited to those patients who satisfy the onCore UK recruitment criteria, defined in contracts with hospitals and in form: PC001.01 "Patient eligibility flowchart". In addition, only those patients who have given informed consent, as described in SOP: PC001, shall be enrolled into the database.

Donors shall be enrolled to the database only once.

Training

Instructions on the use of the database are given in the CELL System Manual, IT001. Training in use of the CELL system to enrol a donor shall be given according to SOP:TR001 and recorded using form: PC003.01. A list of competent staff may be held at the hospital site using form: PC003.02 if that is helpful locally.

Associated procedures and supporting documents

SOP: TR001	General training procedure for onCore UK activities
Form: PC003.01	Training record - Enrolment of donors to the onCore UK CELL database
Form: PC003.02	Record of competence - Enrolment of donors to the onCore UK CELL database
SOP: QS001	Deviations from standard operating procedures
IT001	CELL system manual

Procedure

- 1 Ensure that patient has consented to donate tissue and data to onCore UK according to SOP: PC001, Donor consent.
- 2 Log on to the CELL database as shown in the CELL system manual, IT001.
- 3 Check that the patient has not been enrolled into the database previously as follows:
 - from the sitemap, select "patients"
 - choose "Patients by surname" from the list of search options
 - type the patient's surname into the search box and press "OK"
 - details of all donors with that surname will be shown as a list
 - check the list to see if the patient has been enrolled previously
 - if patient has been enrolled, proceed as shown in section 6 below.
- 4 If the patient has not been enrolled previously:
 - press "Add patient"
 - enter all available details. The following fields must be completed or you will not be able to proceed:
 - Surname
 - First name
 - Date of birth
 - Sex
 - Hospital
 - Consent
 - Consent updated on
- 5 Once you have filled in all of the available details, press "Save" and wait for the "Operation successful" message to appear.
- 6 Return to the "Sitemap" and proceed to log samples or data as necessary. Once finished, log off from the CELL database as described in the CELL system manual, IT001.
- 7 Any deviations from this procedure shall be recorded and investigated according to SOP: QS001.

History

Version	Date active	Changes to previous version
1	01 May 2008	None, new procedure

END

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