Recording consent for healthy volunteers TB-SOP-004CD

LOCATION OF AUTHORISED COPIES

- SharePoint > SOPs > Current > ICHTB > Consent and Documentation
- ICHTB Secretariat.

Documents related to this SOP:

TB-DOC-SCM11-v3-19_6_18. Sub-collection management

TB-DOC-PIS3v4. PIS for Healthy Volunteers

TB-DOC-CF3v4. Consent form for Healthy Volunteers

SOP for recording consent for healthy volunteers

Researchers often need samples from a control population. In some cases, these samples can be obtained from patients with a different type of disease from the one the researcher is studying, but sometimes a fluid sample (usually blood) or non-invasive sample (sweat, breath, urine, saliva or faeces) from a healthy person is required. Where the individual is not currently a patient treated by the NHS Trust, consent for acquisition of the sample must be recorded in an appropriate manner. Approval for the collection must also be approved by Imperial College Research Ethics Committee (ICREC http://www.imperial.ac.uk/media/imperial-college-Research-ethics-committee/public/Imperial-College-Research-Ethics-Committee-TOR-2017.pdf).

Researchers wishing to collect fluid or non-invasive samples for research purposes from staff and students at Imperial College/ICHT must firstly register their subcollection with the Tissue Bank. This can now be done on-line via the Tissue Bank database (www.medbio.ic.ac.uk/ichtb). If you are a Principal Investigator who already holds a sub-collection, just log on to the database using your College username and password and click apply to hold a sub-collection. If you wish to open your first sub-collection please contact the Tissue Bank so that we can register you appropriately.

Information on what is required to set up and run a sub-collection can be found in the <u>Sub-collection Management for Persons Designated and Principal Investigators</u> document (available from the Tissue Bank website: https://www.imperial.ac.uk/media/imperial-college/medicine/tissue-bank/TB-DOC-SCM11-v3-19_6_18-SC-management-for-PDs-and-Pls.pdf).

The Tissue Bank Secretariat must be assured that the samples will be collected by appropriately qualified individuals (e.g. blood samples obtained either by a registered phlebotomist, qualified doctor or nurse). Applications to register the sub-collection must also state how donors will be recruited.

Volunteers must be provided with the information sheet entitled "Donating Biological Samples for Research – Information for Donors" and must be asked to sign the Donor Consent Form (TB-DOC-CF3v4: https://www.imperial.ac.uk/media/imperial-college/medicine/tissue-bank/TB-DOC-PI3-v4-10-5-18-doc-H.pdf). Copies of the consent form, the patient information sheet and barcode labels for samples can be obtained by contacting the Tissue Bank Secretariat.

Medical records of healthy donors cannot be accessed, and all samples must be anonymised. Feedback of individual results to donors is also not permitted.

In order to use the collected samples in research, individual projects must be approved by the Tissue Management Committee. Information on the process for doing this can be accessed here: www.imperial.ac.uk/imperial-college-healthcare-tissue-bank/using-human-samples/accessing-material-taken-specifically-for-use-in-research

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