

### **SOP for consenting 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.

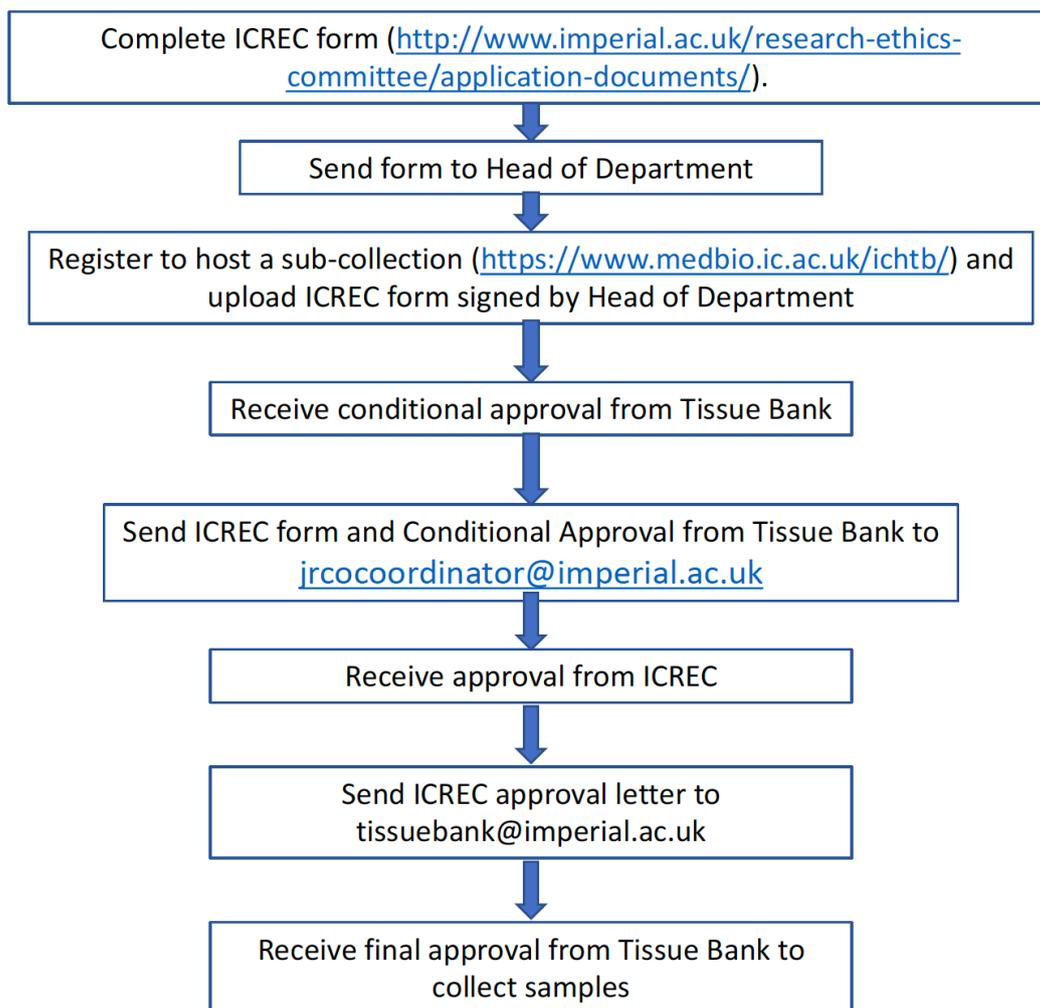
If you wish to collect samples from healthy volunteers you must first make an application to Imperial College Research Ethics Committee (ICREC) via the [ICREC application form](#). Projects that collect samples from Imperial staff and students using Tissue Bank approved consent materials go through an expedited review with ICREC. Prior to sending the application to ICREC please send the completed form to your Head of Department and ask him/her to complete the relevant box. The Head of Department has the right to approve the proposal or to ask ICREC to consider the proposal at their next meeting. Once the Head of Department has approved your project, you can then apply to host a sub-collection with the Tissue Bank. The ICREC form with the Head of Department approval must be uploaded as part of your application to host the sub-collection. Tissue Bank will then provide you with a letter of conditional approval that can be submitted with your application, signed by your Head of Department to [jrcocoordinator@imperial.ac.uk](mailto:jrcocoordinator@imperial.ac.uk).

In order to finally approve your sub-collection your approval letter from JRCO must be sent to [tissuebank@imperial.ac.uk](mailto:tissuebank@imperial.ac.uk). Tissue Bank will then issue a formal approval letter and you can then start collecting your samples. Remember that you must also register a project, using the Application to Access Samples form (available to download from the Tissue Bank webpages), before your samples can be used for research. The flowchart in Figure 1 below summarises the procedure.

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-PI3v4 – attached to this document). Copies of the consent form, the patient information sheet and barcode labels for samples by the Tissue Bank Secretariat.

Figure 1: Flowchart for Healthy Volunteer sub-collection registration



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.