
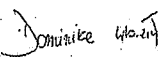


SOP Management of Histological samples

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Version	Date	Reason for Change
1.1	16 th September 2014	
2	26 th April 2016	Update of process

1.0 PURPOSE

This Standard Operating Procedure (SOP) describes the process for requesting, tracking, storage and transport of histological samples to and from the Clinical Investigation and Research Unit (CIRU) laboratory.

2.0 INTRODUCTION

Histological samples are often required for central analysis in clinical trials. Patients will either have consented for archival tissue to be retrieved or for a biopsy to be undertaken. Samples will then be requested as per protocol from the relevant histological departments (either at BSUH or external) and after sample anonymisation will be sent to CIRU laboratory for transportation to central laboratories.

The purpose of this SOP is to ensure the tissue is tracked throughout this process to ensure safety of the samples and to minimise delays.

3.0 RESPONSIBILITIES

All research staff involved in the process of requesting, anonymising and transporting histological tissue samples will be responsible for ensuring that their practice is in accordance with the information set out in this SOP.

The main personnel that this will apply to will be the Research Nurses, Research Practitioner, the CIRU portering staff, CIRU laboratory staff and the CIRU lab administrators.

4.0 PROCEDURE

4.1 Where possible, the research nurse will document on the R&D feasibility form, whether central analysis of the histological samples is required, along with the urgency of sample shipment.

4.2 The research nurse/practitioner will request the release of the tissue, in writing, using the R&D Histological Sample Request Letter, enclosing a copy of the patient's trial informed consent documentation. Where the trial has specific guidance regarding amount tissue, (volume/slides/blocks), the research nurse will add this information to the requesting letter. The request letter will be faxed, scanned or posted to the relevant histology department, as indicated in the specific study protocol/laboratory manual. The research nurse, research practitioner will inform the CIRU Lab administrator of the request.

4.3 The Histology department will release the sample, including the relevant documentation, for transportation to CIRU. If the sample is from the BSUH histology department, the histology secretary will inform the requesting research nurse/practitioner or CIRU lab administrator that the sample is ready for collection.

4.4 The CIRU lab administrator will receive all external samples and will log the samples on the CIRU laboratory tissue tracking database. They will then inform the research nurse/practitioner that the sample requires anonymisation. For internal samples the research nurse/practitioner or CIRU lab administrator will collect the sample from BSUH histology. If it is the research nurse/practitioner collecting the sample they will also anonymise the sample at this point. If the person collecting the sample is the CIRU lab administrator they will log the sample on the CIRU laboratory Tissue Tracking Database, place the sample in the designated draw and inform the research nurse/practitioner that the sample requires anonymisation.

Link to the password protected CIRU Laboratory 'Tissue Tracking Database'
:T:\Research & Development\CIRU\Labs\Lab Admin\CIRU Lab - Tissue Tracking/Tissue Tracking Database

4.6 On completion of the anonymisation process the research nurse/practitioner will log the process on the CIRU laboratory tissue tracking database.

4.7 The histology sample and relevant paperwork will then be placed in the designated drawer within the CIRU laboratory and the CIRU laboratory staff will be informed either in writing or verbally that the sample is ready for transportation.

4.8 The sample will be stored in the CIRU lab until transportation can take place but, where possible, it will be transported to the external lab on the same day of receipt in CIRU lab in accordance with the protocol/laboratory manual.

4.9 The CIRU lab technician or lab administrator will update the tissue tracking database and relevant sample logs in the study lab folder once the sample has been shipped.

5.0 RETURNING HISTOLOGICAL SAMPLES TO HISTOLOGY

5.1 When the sample is returned from the trial central laboratory to CIRU, it will immediately be transferred to the CIRU lab administrator.

5.2 The CIRU lab administrator will update the CIRU tissue tracking database, documenting that the sample has been returned and inform the CIRU laboratory staff that the sample has returned.

5.3 The sample will be stored temporarily in the CIRU lab.

5.4 The CIRU lab technician or lab administrator will package the sample appropriately and arrange transportation of the tissue back to the relevant histology department.

The samples from the BSUH Histology Lab can be taken directly to the histology secretary's office by the CIRU lab technician or lab administrator.

Sample repatriation to its original histology lab must be recorded on the Tissue Tracking Database and in study lab folder.

5.5 All samples sent from CIRU lab will be sent with paperwork that requests that the laboratory in receipt of the sample confirms receipt by fax or email.

If the sample is returned to the BSUH Histology Lab, the name of secretary accepting the sample back must be recorded.

5.5 The CIRU lab technician or CIRU lab administrator will update the tissue tracking database.

