Work Instruction	**Tissue Sampling - Histopathology**
Version	Work Instruction 025 v1.0
Date	08th November 2019
Review Date	2 years
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CONTENTS:

1.0	**Purpose, Scope & Objectives**
	This instruction describes the process for obtaining tissue samples from histopathology for a clinical trial and ensuring all paperwork is completed correctly
2.0	**Personnel & Responsibilities**
	All Oncology Clinical Trial Staff and Histopathology department staff
3.0	**Background**
	Pathology departments routinely collect and store tissue samples from patients. The samples are used to diagnose the type of cancer present, grade and responsiveness to certain types of treatment. Only a small amount of the tissue samples is used up during this initial diagnostic process therefore what isn't used is preserved and stored. Clinical trials centres often require confirmation of histopathological diagnosis and may request that the additional saved tissue samples be sent to their labs. On occasions there may not be enough saved sample and further biopsies may be required.
4.0	**Definitions**

	SIV – Site Initiation Visit
5.0	**Health & Safety**
6.0	**Equipment & Documentation**
7.0	**Procedure**
	- Ensure Histopathology staff are invited to all SIVs where tissue sampling is a requirement of the trial. - On receipt of tissue boxes from trial centre, the trials team must store the boxes in the lab and email Histopathology to inform them of equipment arrival. This allows the histopathology team the opportunity to go through the paperwork, check the boxes and familiarise themselves with any trial specifics. - As soon as a potential patient has been identified for the trial, the trial team must email the histopathology trials team (Alison.green18@nhs.net / Louisekeers@nhs.net and plh-tr.cellularclinicaltrial@nhs.net) with the following information: Potential Trial Name Potential Patient Name, Hospital Number & Date of Birth *(NB please only email one patient per email to avoid any confusion)* - Once patient has consented to the trial and to tissue sampling, send the trial ID number to the histopathology trials team (Alison.green18@nhs.net / Louisekeers@nhs.net and plh-tr.cellularclinicaltrial@nhs.net) - Histopathology will check tissue availability and viability and email the trials team back with information as to whether or not there is enough tissue to send, where it is located (on or off site) and the histopathology number. If the sample is not sufficient histopathology will inform the trials team. - If a re-biopsy is required it is the clinical trial team and PI who are responsible for talking to the patient and booking another biopsy, if the patient agrees. - Once date has been arranged the clinical trial team inform the histopathology trials team (Alison.green18@nhs.net / Louisekeers@nhs.net and plh-tr.cellularclinicaltrial@nhs.net) of the date and time so that histopathology can ensure correct management of the sample. - Once sample has been obtained, either archive or fresh, histopathology and trials team HCA's collect samples boxes and paperwork from the lab to send of the sample. - Histopathology photocopy and scan relevant paperwork and send to all members of the trial team. Histopathology will also keep a copy of all paperwork in their department. - If the trials team become aware of any change in patient status the team must inform histopathology straight away.
8.0	**References**
9.0	**List of Appendices**

	N/A
10.0	**Document Control**
	All Work Instructions are stored on the shared research drive: G/Research Common/Training & Education/How To work instructions/ Printed copies are not controlled and therefore may not be the current version of the document.
11.0	**Training Record & Competency Assessment**
	Records of the training and competency assessment for this work instruction shall be retained by the nominated educator for the staff group involved. All staff members have a responsibility to retain their own training records for continuing personal & professional development.
12.0	**Monitoring Compliance and Effectiveness**
	The Oncology Trials Team Leader and Histopathology trials lead will meet monthly to discuss effectiveness of this process and any risks or issues that arise. Risks and Issues will be recorded on the Supporting Services register held by the Oncology Trials team leader.
13.0	**Revision History**
	Issue 1 – First issue
14.0	**Managerial Approval**

Name	**Signature**		**Date**
Author			
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