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|  | Title : Procedure for management and records of human tissue collection. | Author: G. Cockerill  | Date: 2/Oct/2012          |
|   | No: SOP_R13  | New Author: P. Madhou | Date: 1/Sept/2024         |
|   | Version: 6   |                       | Review Date<br>March 2026 |




**SOP\_R13 : PROCEDURE FOR MANAGEMENT AND RECORDS OF HUMAN TISSUE COLLECTION.**

**Disclaimer**

When using this document, please ensure that the version you are using is the most up to date either by checking on the City St George's /PORTAL/HTA website for any new versions or contact the HTA coordinator to confirm the current version.

**Out of date documents must not be relied upon and should be destroyed.**

|            |             |   |                    |                      |
|------------|-------------|---|--------------------|----------------------|
| 6          | Sept 2024   | City merge, review & formatting         | AS/PM              | HTLRG                |
| 5          | Sept 2023   | New DI, updated contacts & formatting   | AS                 | HTLRG                |
| 5          | Sept 2022   | New DI, Add PD & Review                 | AS                 | HTLRG                |
| 4          | August 2020 | Review (Section 5 references added)     | AS/PL              | HTLRG                |
| 3          | March 2018  | Reviewed & Amended (New Author)         | AS                 | PL                   |
| 3          | July 2017   | Reviewed and PD contact details updated | AS                 | PL                   |
| 3          | July 2017   | Reference to HTA codes updated          | PL                 | HTLRG                |
| 3          | July 2017   | Reviewed and PD contact details         | PL                 | HTLRG                |
| 2          | Dec 2016    | Update contact list                     | AS                 | PL                   |
| 2          | Oct 2016    | DI change details                       | AS                 | MF                   |
| 2          | March 2016  | Issued for use                          | GC                 | HTLRG                |
| 1          | Nov 2012    | Issued for use                          | GC                 | HTLRG                |
| 0          | Oct 2012    | Issued for discussion                   | GC                 |                      |
| <b>Rev</b> | <b>Date</b> | <b>Amendment</b>                        | <b>Approved by</b> | <b>Authorised by</b> |

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## 1. Purpose

1.1 This SOP outlines the management processes and record-keeping requirements for all tissue collections and holdings maintained at CSGUL under the HTA License 12335. The purpose is to ensure compliance with the Human Tissue Authority (HTA) regulations and to safeguard the ethical use, storage, and disposal of human tissue.

## 2. Scope

2.1 This SOP applies exclusively to activities covered by HTA License 12335, which includes the storage of relevant material obtained from human bodies for scheduled purposes.

2.2 The SOP does not cover the addition of new specimens to existing collections. Any proposal for new additions will require separate ethical approval and licensing arrangements.

2.3 This SOP encompasses all major activities related to the management of human tissue collections, including record-keeping, controlling access, and the proper disposal of specimens.

## 3. Responsibilities

3.1 The overall responsibility for implementing this SOP lies with the R&D Manager, acting under the direction of the License Holder (LH) or the Designated Individual (DI). The DI is responsible for ensuring that all activities covered by this SOP are properly investigated and reported.


3.2 The SOP also outlines the responsibilities of the individuals in charge of each tissue collection held at CSGUL, including ensuring compliance with HTA regulations and CSGUL policies.

## 4. Procedure

4.1 The DI will receive HTA Registration of Collection documents following provision of Host Site Approval, and will establish which tissue collections/holdings held at SGUL will be subject to the terms of the HTA License. 12335, and will be responsible for ensuring that the list is reviewed and checked on an annual basis by the HTLRG (see SOP-GEN2).

4.2 For each tissue collection identified, the PI in conjunction with the R&D Manager will ensure that a Responsible Person (RP) is nominated with the following responsibilities:

- a. Managing and maintaining the collection to an appropriate standard to ensure the long-term availability of the collection as a resource for SGUL.
- b. Ensuring that access to specimens for teaching and research is properly controlled, approved and recorded.
- c. Ensuring that proposals for access to specimens for research are properly covered by the correct authorisation and where appropriate, ethical approval.

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d. Managing a record of all specimens in the collection, ensuring that appropriate authorisation is granted and that the disposals are handled in accordance with SGUL procedures for disposal of clinical material.

e. Maintaining a record of all specimens in the collection, together with, where appropriate, consent forms and other relevant records, ensuring that there is a complete match between specimens and records.

4.3 Records may be maintained in an electronic or paper format. If records are maintained in an electronic format, they must be saved on drives that are securely backed up at least daily. If records are maintained in a paper format, with access being available to both RP, and the R&D Manager in the absence of the RP.

## 5. Related Documents

5.1 HTA License 12335: Collection and Storage of Relevant Material for Scheduled Purposes

5.2 HTA License 12330: Conducting Anatomical Examinations

5.3 SOP-GEN1: Creating Standard Operating Procedures

5.4 SOP-GEN2: Human Tissue License Review Group

5.5 SOP-HTA-4: Dissection Room Audit of Records

5.6 SOP-HTA-5: Dissection Room Records

5.7 HTA Registration Collection Form

5.8 SOP-R6: Use of Itemtracker for Logging Samples

5.9 SOP-R5: Management and Use of Freezers for Storing Tissue Samples

## 6. References

6.1 HTA Codes of Practice:


- Code A: Guiding Principles and the Fundamental Principle of Consent
- Code C: Anatomical Examination

6.2 Directions under the Human Tissue Act 2004:

- 001/2006 and 002/2007

## 7. Amendment of SOPs

7.1 If, during the application of this SOP, any user identifies a potential improvement, they should notify the Person Designated (PD) for review and possible amendment.

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### 15. Contacts DIs and PDs

|                             |    |                                     |          |  |
|-----------------------------|----|-------------------------------------|----------|--|
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