	Title: Procedure in the event of withdrawal of consent to store human tissue.	Author: G. Cockerill	Date: 2/Oct/2012
	No: SOP_R7	New Author: P. Madhou	Date: 1/Sept/2024
	Version: 5		Review Date March 2026

SOP_R7 : PROCEDURE IN THE EVENT OF WITHDRAWAL OF CONSENT TO STORE HUMAN TISSUE.

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Out of date documents must not be relied upon and should be destroyed.

Rev	Date	Amendment	Approved by	Authorised by
5	Sept 2024	City merge, review & formatting	AS/PM	HTLRG
4	Sept 2023	New DI, updated contacts & formatting	AS	HTLRG
4	Sept 2022	New DI, Add PD & Review	AS	HTLRG
4	August 2020	Review	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	New DI details	AS	MF
2	March 2016	Issued for use	GC	HTLRG
1	Oct 2013		HTLRG	HTLRG
1	Nov 2012	Issued for use	GC	HTLRG
0	Oct 2012	Draft issued for comments		

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1. Purpose/Background

1.1 This SOP outlines the procedures to be followed when a donor withdraws consent for the further storage of human tissue.

1.2 This procedure has been developed to comply with the Human Tissue Authority (HTA) Code of Practice E (Research).

2. Scope

2.1 This SOP applies to all activities covered under the Human Tissue Act Licence 12335, which governs the storage of relevant material that has come from a human body for a scheduled purpose.

3. Responsibilities

3.1 The responsibility for ensuring that immediate and appropriate actions are taken in response to the withdrawal of consent lies with the Principal Investigator (PI), the Designated Individual (DI), and the Persons Designated (PDs). They must ensure that the wishes of the individual withdrawing consent are fully respected and implemented.

4. Procedures

4.1 Consent Withdrawal Notification: The donor (or their guardian) must sign a Consent Withdrawal Notification, which should then be distributed to all members of the Human Tissue Licence Review Group (HTLRG). In cases where tissues have already been used in research (and are partially unlinked), the donor must acknowledge that these data cannot be retrieved, and the tissues already utilized will not be tracked or reclaimed.

4.2 Action Upon Notification: The DI, PI, and RPs must ensure that any remaining tissue samples are disposed of, and all associated data are deleted within 24 hours of receiving the withdrawal notification.

5. Related Documents

- **SOP_R8**: Procedure for Disposal of Human Tissue.
- **SHEP_20**: Policy and Procedure for Disposal of Clinical Waste.

6. Amendment of SOPs

6.1 If, during the application of this document, the user identifies a modification that could improve the SOP, they should inform the Person Designated (PD) so that the suggested changes can be reviewed and, if appropriate, implemented.

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7. Contacts DIs and PDs

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