

Standard Operating Procedure

CBE/HTA-XX-SOPXXX

Title: <CAPITALS>

Location: [Insert CBE Laboratory Unit (room number if it needs to be specified) OR CBE Tissue Engineering Laboratory (T208B) OR CBE Laboratories {i.e. if applies to all CBE labs}]

1. PURPOSE

The intent of this SOP is to [Insert the primary objective of SOP here]

<Ensure that the equipment or procedure and the purpose for which it is to be used is described precisely; i.e. less than 20 words>

2. SCOPE

This SOP applies to [Insert to who (e.g. location where task is carried out) and what this SOP applies, insert any restrictions where they may apply]

<e.g. This SOP applies to the Containment Level 2 Laboratory Unit of the CBE and its personnel> <e.g. This SOP applies to production and control of SOPs>

3. RESPONSIBILITIES

[Insert specific applicable responsibilities; if relevant clarify specific steps in process the person holding the title is accountable for].

[Insert what personnel should do in the event of a deviation – could be to initiate a CAPA, contact their supervisor, notify a member of the lab management team, etc]

4. REFERENCES

[Insert list of documents used to write this SOP]

5. PROCEDURE

<Identify the sequence of steps required to perform the procedure - consider using a process map to identify critical steps; identify where/what checks should be made and where/what records should be generated. Describe clearly and concisely each of the steps required to perform the required tasks. Identify any safety or cautionary notes, cross references to SOPs/Operators manual. Where necessary refer to supplementary documentation (i.e. when there are a large number of steps) to reference sub processes e.g. buffer preparation>

Version 001

Effective Date: dd.mm.yyyy

Review dd.mm.yyyy

Written by: Date:	Reviewed by: Date:	Approved by: Date:
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Step 1: [Insert title of step]

[Insert details of the process step here – instruction should be adequate to perform the task].

[Insert secondary details or clarification here as necessary; for referenced SOPs or other documents, use “see Title of Other SOP”; or for further details, use “ see Operators Manual”].

Step 2: [Insert title of step]

[Insert details of the process step here – instruction should be adequate to perform the task].

[Insert secondary details or clarification here as necessary; for referenced SOPs or other documents, use “see Title of Other SOP”; or for further details, use “ see Operators Manual”].

Step 3 etc.....

6. DOCUMENTATION

<Identify the document(s) required to be completed for the purpose of becoming a record (e.g. log sheets) or for the purpose of creating other documentation (e.g. form to be used as a template). Provide record sheets or templates where required to the document controller i.e. requirements for recording output such as monitoring and maintenance log sheets, training records or training certification templates etc.>

The following records are outputs of this SOP:

- 6.1. [Insert name of form, record, document, or log;
- 6.2. [insert name of form, record, document, or log]

These records will be filed in [Insert where filed, stored, or otherwise archived for future review or retrieval]. [Insert any record retention requirements]

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SOP Version History

Version Reviewed	Date Revised/ Reviewed	DCN No	Revision Summary	New Version Number

SOP Withdrawal Date:	
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Document Control

The Master Copy of all SOPs is filed by the dQM. The latest version is maintained on the CBE network. This document is not a controlled copy once printed from the network. If this SOP appears inadequate or outdated it is the responsibility of all staff to bring this to the attention of the dQM or their Supervisor immediately.

Security Statement

This SOP is the intellectual property of the CBE within Loughborough University, and as such, must not be circulated outside of the University without the written approval from the dQM and the author.

Acknowledgements

<include if appropriate>

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