Loughborough University **The Centre for Biological Engineering**	**Self-inspection Audit Report**			
Document Ref: HTA-MI-FORM/010	Version N^{o}:	1.0	Issue Date:	

SAR No: CBE-HTA/SAR/000

Inspection Date:		
Facility/Area inspected:		
Quality Standards inspected:	☐ **Consent** ☐ **Governance & Quality Systems** ☐ **Premises, Facilities & Equipment** ☐ **Disposal**	☐ **Sample traceability test** ☐ **Other** *(give details)*
Reason for inspection:		

Inspection Personnel:			
Name	**Position/Role**	**Signature**	**Date**

This core checklist is provided as a framework for conducting a self-inspection audit of the CBE facilities, practices and processes involving work with HTA licensable material. It should not be considered exhaustive and may be expanded to address specific circumstances, as required.

Once the inspection is completed, those audit points which have been assigned a 'NO' response will normally require remedial attention and/or corrective/preventative action.

Date of next inspection:	

AUDIT CHECKLIST

Audit Point	Compliance? (Yes/ N/A or No) If No, state level of non-compliance minor/major/critical)	Actions/Comments	CAPA Reference Action Status at next inspection
Part 1: Consent			
C1	**Consent is obtained in accordance with the requirements of the Human Tissue Act (2004) and as set out in the code of practice**		
Are consent forms compliant with HTA Code of Practice?	☐Yes ☐N/A ☐No		
Are copies of blank or completed consent forms made available for that using/releasing relevant material? (*Consent forms may be requested*).	☐Yes ☐N/A ☐No		
Where a 3rd party takes consent, is there a procedure to ensure consent is appropriate & evidence provided?	☐Yes ☐N/A ☐No		
C2	**Information about the consent process is provided and in a variety of formats**		
Is a SOP covering the consent process in place (including procedure for providing information on consent for those taking consent themselves)?	☐Yes ☐N/A ☐No		
Are interpreters made available, where appropriate?	☐Yes ☐N/A ☐No		
Are consent/patient information leaflets ethically reviewed? (*Copies and REC numbers available?)*	☐Yes ☐N/A ☐No		
Are consent forms regularly reviewed? (*to ensure content is suitable, and forms are complete and available*)	☐Yes ☐N/A ☐No		
Do agreements with 3rd parties contain appropriate consent	☐Yes		

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information?	☐N/A ☐No		
How is sample consent linked to tissue databases (including wishes/exceptions)?	☐Yes ☐N/A ☐No		
C3	**Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent**		
For staff taking consent, is there evidence of training (dates & competencies)?	☐Yes ☐N/A ☐No		
Part 2: Governance & Quality System Standards			
GQ1	**All aspects of the CBEs work are supported by ratified documented policies/procedures as part of the governance process**		
Is a list of SOPs available? Are SOPs in place to cover all licensable activities?	☐Yes ☐N/A ☐No		
Are risk management systems in place?	☐Yes ☐N/A ☐No		
Are regular governance meetings held with minutes/agenda?	☐Yes ☐N/A ☐No		
Does an internal complaints system exist?	☐Yes ☐N/A ☐No		
GQ2	**There is a documented system of quality management and audit**		
Are SOPs numbered, version controlled, regularly reviewed, have an update history?	☐Yes ☐N/A ☐No		

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Is there a change control mechanism for implementation, change of operational systems and processes?	☐Yes ☐N/A ☐No		
Is there evidence of a schedule of self-inspections of the facility?	☐Yes ☐N/A ☐No		
Are document databases secure and information confidential?	☐Yes ☐N/A ☐No		
GQ3	**Staff are appropriately trained in techniques relevant to their work and are continuously updating their skills**		
Are qualifications and job descriptions of staff available?	☐Yes ☐N/A ☐No		
Are training records including dates, competencies and training plans available?	☐Yes ☐N/A ☐No		
Are induction programmes available & documented? Is there a documented training programme?	☐Yes ☐N/A ☐No		
GQ4	**There is a systematic and planned approach to the management of records**		
Are there documented procedures for the creation, amendment, retention and destruction of records	☐Yes ☐N/A ☐No		
Is there a regular audit of record content to check for completeness, legibility and accuracy?	☐Yes ☐N/A ☐No		

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Is there a back-up/recover facility in the event of loss of records?	☐Yes ☐N/A ☐No		
Are there systems ensure data protection, confidentiality and public disclosure (whistle-blowing)?	☐Yes ☐N/A ☐No		
GQ5	**There are documented procedures for distribution of Relevant Material?**		
Is there a process for reviewing and recording the release of relevant material to other organisations eg SOPs?	☐Yes ☐N/A ☐No		
Are agreements in place between the CBE and the organisation to whom the relevant material is supplied re the (eg Universities, NHS, Tissue banks) re the tracking and use of material and eventual disposal?	☐Yes ☐N/A ☐No		
GQ6	**A coding and records system facilitate traceability of Relevant Material, ensuring a robust audit trail**		
Is there an ID system which assigns a unique code to each donation and to each of the products associated with it?	☐Yes ☐N/A ☐No		
Is an audit trail is maintained which includes details of when and where the relevant material was acquired, the consent obtained, the use to which the material was put, when the material was transferred and to whom?	☐Yes ☐N/A ☐No		
GQ7	**There are systems to ensure that all adverse events are investigated promptly**		
Is there a system for recording Adverse Event Reporting and Corrective/Preventative Actions (CAPAs)?	☐Yes ☐N/A ☐No		
Is there a system for communicating HTA related issues to staff?	☐Yes ☐N/A ☐No		

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GQ8	**Risk assessments of CBE's practices and processes are completed regularly and are recorded and monitored appropriately**		
Are risk assessments available for practices and processes relating to risk to integrity of relevant material and H%S of staff working with/handling the material?	☐Yes ☐N/A ☐No		
Are risk assessments reviewed when appropriate?	☐Yes ☐N/A ☐No		
Can staff access risk assessments and are made aware of local hazards and training?	☐Yes ☐N/A ☐No		
Part 3: Facilities, Equipment, Premises			
PFE1	**The premises are fit for purpose**		
Has a risk assessment been carried out of the premises to ensure that they are appropriate for the purpose?	☐Yes ☐N/A ☐No		
Are policies are in place to review and maintain the safety of staff, authorised visitors and students?	☐Yes ☐N/A ☐No		
Do the premises have sufficient space for procedures to be carried out safely and efficiently?	☐Yes ☐N/A ☐No		
PFE2	**Environmental controls are in place to avoid potential contamination**		
Is there appropriate separation of relevant material?	☐Yes ☐N/A ☐No		
Is there an air classification system and maintenance of air quality	☐Yes		

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including control and monitoring of environmental conditions?	☐N/A ☐No		
Is there a documented cleaning & decontamination procedure?	☐Yes ☐N/A ☐No		
Are policies in place to ensure that premises are secure and confidentiality is maintained?	☐Yes ☐N/A ☐No		
Are appropriate H&S controls in place for staff, students and visitors?	☐Yes ☐N/A ☐No		
PFE3	**There are appropriate facilities for the storage of Relevant Material, consumables and records**		
Are relevant material, consumables and records stored in suitable environments and precautions are taken to minimise risk of damage or theft and ensure the security of holdings?	☐Yes ☐N/A ☐No		
Are contingency plans in place in case of failure in storage areas?	☐Yes ☐N/A ☐No		
Are critical storage conditions monitored, controlled and recorded?	☐Yes ☐N/A ☐No		
Are there systems to deal with emergencies on a 24 hour basis	☐Yes ☐N/A ☐No		
Is there a record indicating where material is stored in the premises?	☐Yes ☐N/A ☐No		

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PFE4	**Systems are in place to protect the quality/integrity of Relevant Material during transport and delivery to a destination**		
Are there documented policies and procedures for the appropriate transport of relevant material, including a risk assessment for transportation?	☐Yes ☐N/A ☐No		
Is there a system in place to ensure the traceability of material is maintained during transport?	☐Yes ☐N/A ☐No		
Are there records of transportation and delivery?	☐Yes ☐N/A ☐No		
Are agreements with recipients or providers of material recorded?	☐Yes ☐N/A ☐No		
PFE5	**Equipment is appropriate for use, maintained, quality assured, validated and where appropriate, monitored**		
Are there records of calibration, validation and maintenance, including agreements with maintenance companies?	☐Yes ☐N/A ☐No		
Do users have access to instructions and/or SOPs for equipment and receive training in use and maintenance where appropriate?	☐Yes ☐N/A ☐No		
Are staff aware of how to report an equipment failure/malfunction?	☐Yes ☐N/A ☐No		
Contingency planning in place in event of Premises/Facilities/Equipment failure & staff trained?	☐Yes ☐N/A ☐No		

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Part 4: Disposal			
D1 **There is a clear and sensitive policy for disposing of human organs and tissue**			
Is there a documented disposal policy and does it consider H&S requirements?	☐Yes ☐N/A ☐No		
D2 **Disposal is documented**			
Are there procedures for the safe disposal of material? Are records of disposal available?	☐Yes ☐N/A ☐No		
Is there a process to link disposal back to donor wishes?	☐Yes ☐N/A ☐No		
Is disposal recorded in tracking software including reason, date, method and route of disposal?	☐Yes ☐N/A ☐No		
Is the policy made available to the public?	☐Yes ☐N/A ☐No		
Part 5: Additional Inspection/Tests			
	Describe each additional inspection or test carried out and its outcome		