HUMAN TISSUE ACT – BIOREPOSITORY AUDIT CHECK-LIST

This checklist is to be used to facilitate Biorepository audits to assess compliance against HTA research sector licensing standards. For audit checklists for NHS REC approved research tissue banks and clinical audits.

	Yes/No	Comments
• Organisation structure populated and complete?		
○ Copy of HTA licence for premises		
○ Copy of signed PD role acceptance form		
○ Local staff List & HTA/GCP Training certificates		
○ List of local tissue collections and key contacts (Biobanks, Studies conducted under REC approved Research Tissue Banks, Research Tissue Banks)		
• SOPs, Policies and Risk Assessments populated and complete?		
○ List of Human Tissue Act General Quality Documents		
○ Quality Document (including approval & revision dates)		
• Evidence of having read SOPs? ○ Local? ○ HTA?		
• Section 4 (Facilities and equipment) populated and complete?		
○ Premises, Facilities and Equipment – Storage locations		
○ Sample tracking system & IT		

	Yes/No	Comments
• Material Transfer Agreements. populated and complete?		
○ Internal sample supply agreements		
○ External researcher supply agreements (e.g. MTAs/SLAs) & courier records		
• HTA Committee Meetings Minutes populated and complete?		
• Adverse Events – Reports and Actions populated and complete?		
• Audits & HTA Risk Assessments populated and complete?		

	Yes/No	Comments
CONSENT		
Where are signed consent forms stored?		
If no, evidence that consent is in place?		
Consent procedure documented?		
Includes:		
• Procedure for managing consent forms/		
• Procedure for communicating donor wishes e.g. consent opt outs?		
• Consent withdrawal procedure?		
Evidence of staff training & competency assessment for staff taking consent? • GCP Training up to date. • HTA Training up to date.		
GOVERNANCE AND QUALITY SYSTEMS		
Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities?		
• Consent procedure (answered above)		

	Yes/No	Comments
• Sample management: Collection, labelling tracking, specimen preparation/preservation, receipt, storage and tracking, including unique sample identification numbers		
• Sample transfer/transport arrangements		
• Document management – systematic and planned approach to the management of records, local procedures for creation, review, amendment, retention and destruction of records.		
• Equipment management (including maintenance contracts & temperature monitoring)		
• Cleaning & decontamination procedure		
• Contingency planning		
• Disposal		
• Staff training and induction (including provisions for visiting staff?		
Document control system in place?		
• Revision history and version number		
• Effective from and to date		
• Review date		
• Regularly reviewed?		
• Pagination		
• Author and reviewer names		
Risk assessments in place, including HTA Risk assessment?		
Documents secure and backed-up?		
Self-inspections conducted?		
Regular governance meetings held?		

	Yes/No	Comments
TRACEABILITY		
Identification system which assigns a unique code to each donation and to each of the products associated with it.		
A register of donated material, and the associated products where relevant, is maintained.		
An audit trail maintained, which includes: when and where tissue were acquired and received; consent obtained; sample storage locations; the uses to which any material was put; when and where the material was transferred, and to whom.		
Sample tracking solution		
• System validated/secure?		
• Patient identifiable data stored?		
• Tracks consent: type, opt outs & location of forms		
• Tracks each sample individually		
• Includes disposal (reason, route, date, person responsible)		
• Tracks REC numbers & expiry dates		
• Audit trail/Sample history		
A system is in place to ensure that traceability of relevant material is maintained during transport.		
Records of transportation and delivery and any agreements with courier or transport companies, or recipients of relevant material are kept.		
Sample transfer agreements in place with external organisations?		
Sample supply agreements in place with internal academics?		
Disposal records in place?		
• Disposal tracks reason, route, date, person responsible		
• Donor wishes considered		

	Yes/No	Comments
PREMISES/FACILIES/EQUIPMENT		
Premises/equipment secure?		
Freezers appropriately labelled to maintain quality, safety and security of staff		
HTA licence displayed		
Staff aware of how to report a problem.		
Safe staff working areas		
Maintenance contracts for equipment		
Maintenance and monitoring records available		
Cleaning/decontamination records available.		
Critical storage conditions monitored 24h, controlled & recorded?		
Records available?		
Temperature ranges added to door		
Call out rotas?		
Testing of alarms?		
Contingency planning & staff aware of procedures?		
Checks & filling of liquid nitrogen Dewar's documented?		
Compliance with institutional policies and procedures? E.g. Health & Safety.		