NHS REC Approved Research Tissue Banks – Audit Check-List

The following checklist is to be used in addition to the Human Tissue Act audit checklist, to facilitate audits relating to NHS REC approved research tissue banks which store material under the Human Tissue Act.

Date audit undertaken:
Audit undertaken by:

	Y,N, N/A	Comments
Research Tissue Bank Site File		
• Site fil available for the audit?		
• Local structure populated and complete?		
○ Copy of HTA licence for premises		
○ Local structure/organograms		
○ Local Staff List – including PD role acceptance, job descriptions/CVs		
○ Copies of HTA and GCP training certificates		
• Ethics documentation populated and complete?		
○ Protocol		
○ Blank Consent form and patient information leaflets		
i. Consent forms include reference to DNA, use in animals, export, and commercial use and cost-recovery (where appropriate)?		
ii. References correct version of PIL?		

	Y,N, N/A	Comments
○ Tissue Request Policy and formalised Ethics / tissue request committee committee?		
○ IRAS application form(s), substantial amendments, approval letter(s), NHS Permissions, and other study correspondence		
○ Copy of RS approval		
○ Annual reports		
i. Submitted on time & complete?		
ii. Copy provided to RS?		
• SOPs, Policies and Risk Assessments populated and complete?		
○ List of Human Tissue Act General Quality Documents		
○ List of Local Quality Documents (including approval & revision dates)		
i. SOPs in place documenting the banks activities?		
ii. Evidence of having read RTB specific SOPs?		
iii. Evidence of having read Biorepsoitory SOPs? (where relevant)		
• Research tissue dispensation applications		
○ Applications & review		
○ List of approved studies and tissue collection centres		
• Sample Supply Agreements) populated and complete?		
○ Internal sample supply agreements		

	Y,N, N/A	Comments
○ External researcher supply agreements (e.g. MTAs/SLAs) & courier records		
• RTB specific Meetings populated and complete?		
• Adverse Events – Reports and Actions populated and complete?		
○ Clinical team using correct consent form and patient information leaflet		
○ Samples collected in line with banks SOPs?		
○ Samples requiring HTA storage are stored in an approved storage location, with the knowledge/consent of the local PD?		