

HUMAN TISSUE AUDIT CHECK-LIST

This checklist is to be used to facilitate audits of consent forms as part of Human Tissue Audits, for compliance with the Human Tissue Act (2004) and for NRES REC approved Research Tissue Banks, the Terms and Conditions of ethical approval.

	Available?	Correct version?	Comments
Blank version of consent form(s)			
Blank version of patient information leaflet			
Signed copy of consent form			
<ul style="list-style-type: none"> • Available? 			
<ul style="list-style-type: none"> • Correct version used 			
<ul style="list-style-type: none"> • Completed correctly 			
<ul style="list-style-type: none"> • Legible 			
<ul style="list-style-type: none"> • References correct PIL version number? 			
Correct version of patient information leaflet used			
Training for staff taking consent			
<ul style="list-style-type: none"> • Informed consent training 			
<ul style="list-style-type: none"> • GCP training 			
<ul style="list-style-type: none"> • HTA training 			
Samples appropriately labelled			
Sample tracking documentation completed			
SOPs <ul style="list-style-type: none"> • Consent procedure • Sample management (collection, labelling, transfer) 			
Samples transfer evidence <ul style="list-style-type: none"> • Service Level Agreement Monitoring Form 			