NDMRB-RA-120

Risk Assessment: Human Tissue Act (HTA) in the NDMRB

Scope

The Human Tissue Authority (HTA) was set up to regulate the removal, storage, use and disposal of human bodies, organs and tissue for a number of Scheduled Purposes – such as research, transplantation, and education and training – set out in the Human Tissue Act 2004 (HT Act). The HT Act covers England, Wales and Northern Ireland and came into force on 1 September 2006.

The NDMRB is currently registered under HTA licence number 12217, this satellite licence covers the storage of human tissue for research purposes under the Act.

The NDMRB management policy is to ensure compliance with the Human Tissue Act and with the standards and guidance set by the Human Tissue Authority. The level of quality required is achieved through adoption of a system of procedures that reflect the regulatory standards and guidelines and the documents contained within various SOP's.

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Risk Matrix:

Risk Matrix		Likelihood			
		High	Medium	Low	Negligible
Consequence	Severe	High	High	Medium	Effectively Zero
	Moderate	High	Medium	Medium/low	Effectively Zero
	Insignificant	Medium/Low	Low	Low	Effectively Zero
	Negligible	Effectively Zero	Effectively Zero	Effectively Zero	Effectively Zero

Risk Assessment:

Hazard (Cause and consequence)	Risk if no control in place	Affected Groups	Existing controls	Risk if control in place (target)	Further Action
Failure to declare collections and cohorts which are being stored under licence 12217. Failure to declare holdings and cohorts will be reported as adverse events. This may result in holdings being put into quarantine and potentially having to be destroyed.	HIGH	Groups holding and working with HTA relevant material	The PD for the NDMRB sends out an annual call for groups to declare their holdings in the building under licence 12217. This information is then sent on to the university HTA governance team to be declared to the HTA. It is the responsibility of the PI to declare holdings and new holdings that may be brought into the building throughout the year must be declared BEFORE being held under licence 12217 in the NDMRB All staff working with HTA relevant material must be suitably trained, use all resource available and maintain a training record.	Medium/Low	Regular, at least annual, internal audits to be carried out of each groups holdings. Follow up audits must be carried out and corrective actions completed in a timely manner. Any new undeclared holdings must be reported to the governance team ASAP.
Failure to carry out at least annual internal audits and follow up audits Failure to monitor compliance with the HTA may result in suspension of the licence	HIGH		An audit schedule is to be held by the PD and regular audits to be carried out. Where non-conformance is highlighted follow up audits must be carried out and actions to be closed in a timely manner. Failure of groups to ensure compliance with the HTA must be reported as an adverse event to the university HTA governance team.	Medium/Low	The PD is to also ensure that audits are carried out with the university governance team in attendance.

Consent obtained when samples are collected not sufficient or non-existent. This may result in the quarantine of samples and if consent cannot be obtained then samples may be destroyed	HIGH	Groups holding and working with HTA relevant material	Detailed training must be given to all staff who are obtaining consent for samples being donated for research purposes. All staff taking blood from healthy volunteers in the NDMRB must read NDMRB-SOP-016 Taking Blood in the NDMRB and sign off in their training records If the consent is non-existent or has expired then the samples must not be used and must be quarantined. If consent cannot be obtained or is withdrawn then the samples must be destroyed. If a group is working with HTA relevant material of which they were not involved in the gaining of consent, a blank consent form should be requested so that it can be seen how consent has been sought. Samples must also have an MTA in place and an outline of the project and REC reference must be provided.	Medium/Low	None
Key members of staff working with HTA relevant material not suitably trained	HIGH		All staff working with HTA relevant material must be suitably trained, use all resource available and maintain a training record. It is imperative that staff are trained before they commence working with HTA relevant material which is being held under licence 12217. Staff must understand all elements of working with HTA relevant material. All staff working with HTA relevant material must read the university overarching SOP which are available on the Research services website. Staff must also complete the online training course which is also available on the research services website.	Medium/Low	None

Insufficient and/or incomplete record keeping – the HTA calls for complete and fully auditable records with regards to: Sample tracking Equipment servicing Premises maintenance	HIGH		Groups working with and holding HTA relevant material must ensure that they keep full and up to date records for all cohorts and holdings. This includes full traceability for samples and destruction or transfer logs. This includes samples that may come into the NDMRB but be shipped or rendered acellular within 7 days of receipt. Core facility equipment is serviced annually and group specialist equipment is managed by the groups. Service sheets should be kept on file and ready for audit when requested.	Medium/Low	Regular, at least annual, internal audits to be carried out of each groups holdings. Follow up audits must be carried out and corrective actions completed in a timely manner
Non-conformance to HTA requirements – potential quarantine of samples and/or suspension of licence	HIGH		Any non-conformance to the HTA must be reported to the PD. This will be reported as an adverse event and an investigation launched. Practices may need to be amended to improve performance moving forward.	Medium/Low	Regular, at least annual, internal audits to be carried out of each groups holdings. Follow up audits must be carried out and corrective actions completed in a timely manner
Failure to report adverse events in a timely manner or at all This is a failure to comply with HTA requirements and therefore is a non-conformance. May result in quarantine of samples or suspension of licence.	HIGH	Groups holding and working with HTA relevant material	Adverse events must be reported in order to ensure an investigation can be launched into the reasons why it may have occurred. This will aid the NDMRB to improve quality systems and hopefully avoid similar events from reoccurring. Adverse events also identify training needs and whether staff are working within the remit of the HTA.	Medium/Low	Ensure staff know to report adverse events to the PD so that the university HTA governance team can be informed.
Failure of liquid nitrogen storage facilities or -80 storage facilities Either resulting in the loss of HTA samples	HIGH		The NDMRB has a monitoring system in place for both -80 and LN2 storage systems (Comark). This is covered in NDMRB-SOP-030 Ultra Low Temperature (ULT) storage monitoring system There is an emergency protocol in place that should help prevent the loss of HTA material – NDMRB-SOP-031 NDMRB Liquid Nitrogen and -80 Freezer Emergency procedures and failure protocol. These areas are managed by the buildings and facilities team.	Medium/Low	Users of these facilities must make themselves aware of the systems in place that ensure the protection and monitoring of the ULT storage in the NDMRB.

Relevant H&S procedures, security and controls are not in place. This would result in an unsafe and unsecure working environment.	HIGH		All local H&S and protocols are created using university lead guidance. All staff working in the NDMRB are expected to familiarise themselves with the H&S guidance available on the internal pages of the NDMRB website as well as university policy. All COSHH is supplied via the website. All equipment which is supplied by the building, for example biological safety cabinets (BSC), fume hoods, fire safety appliances, Cat 3 etc will be maintained by the NDMRB facilities team. Centrifuges and incubator servicing is arranged by the lab manager - annually All PPE is supplied by the NDMRB. All local equipment is managed by individual groups. The indecent book is held by reception – all accidents and incidents are reported using this book, the USO is informed and all are investigated and procedures amended if required.	Medium/Low	Each member of staff must complete a building safety induction, lab safety induction and complete a training record – a copy of which is held by the lab manager. Staff cannot gain access to the building without attending the safety sessions and further training is applicable for further restricted areas within the NDMRB

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