

Risk Assessment of activities relating to the CAPA plan for
HTA licence 12217

HAZARDS	PERSONS AFFECTED	RISKS	CONTROL MEASURES
Breach of directions issued to the University of Oxford by the Human Tissue Authority	University of Oxford, researchers working under licence 12217	Failure to comply with HTA directions to report all new collections discovered to be in breach of the HT Act, or in breach of the licensing requirements, or failure to report all collections disposed of. HIGH	<ul style="list-style-type: none"> * Report all samples of relevant material found to be in breach of HTA standards of the licensing requirements of the HT Act to the Designated Individual (DI) for licence 12217 and the Human tissue Governance Team (HGT). * Report all samples disposed of and forward disposal logs to the DI and HGT.
Failure to declare sample holdings of relevant material	University of Oxford, researchers working under licence 12217	Failure to comply with HTA directions to report all new collections discovered to be in breach of the HT Act, or in breach of the licensing requirements HIGH	<ul style="list-style-type: none"> * Mandatory training programme issued to all users of relevant material * Full draw-by-draw search for relevant material prior to the end of the CAPA plan
Lack of consent for material held	University of Oxford, researchers working with relevant material	Breach of HT Act or breach of the licensing requirements. Reputational damage to the institution HIGH	<ul style="list-style-type: none"> * Mandatory training programme issued to all users of relevant material * Full draw-by-draw search for relevant material prior to the end of the CAPA plan * Examination of material found for consent records and the creation of an acceptable inventory

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Lack of ethical approval	University of Oxford, researchers working with relevant material	Breach of HT Act or breach of the licensing requirements. Reputational damage to the institution HIGH	<ul style="list-style-type: none"> * Mandatory training programme issued to all users of relevant material * Full draw-by-draw search for relevant material prior to the end of the CAPA plan * Examination of material found for relevant approvals under REC or similar
Lack of suitable training	University of Oxford, researchers working with relevant material	Breach of HT Act or breach of the licensing requirements. Reputational damage to the institution HIGH	<ul style="list-style-type: none"> * Mandatory training programme issued to all users of relevant material
Lack of suitable traceability	University of Oxford, researchers working with relevant material	Breach of HT Act or breach of the licensing requirements. Reputational damage to the institution. Loss of samples MED	<ul style="list-style-type: none"> * Mandatory training programme issued to all users of relevant material * Full draw-by-draw search for relevant material prior to the end of the CAPA plan * Examination of material found for relevant traceability standards
Breach of confidentiality	University of Oxford, sample donors	Dissemination of patient / donor identifiers to researchers or unauthorised staff / students. LOW	<ul style="list-style-type: none"> * Keep any documents (e.g. consent forms) or samples carrying patient identifiers in security-controlled premises where the information cannot be seen by unauthorised staff. * Do not include patient identifiers in email communication unless using specifically designated email addresses. * Where possible, over-label samples showing patient identifiers with a unique sample code.
Breach of security	University of Oxford, researchers working with relevant material	Unauthorised access to samples LOW	<ul style="list-style-type: none"> * Conduct cataloguing of samples in security-controlled areas to avoid access by unauthorised staff. * Avoid leaving sample collections (e.g. boxes of slides or blocks) unattended. * Avoid large concentrations of multiple sample collections in a single area pending cataloguing.
Damage to premises leading to damage to relevant material	University of Oxford, researchers working with relevant material	Breach of HT Act or breach of the licensing requirements. Reputational damage to the institution. Loss of samples LOW	<ul style="list-style-type: none"> * Maintain good working relationships with the OUHT. * Report all concerns regarding the estate to OUHT as soon as possible * Safety inspections of areas

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Equipment failure	University of Oxford, researchers working with relevant material	Breach of HT Act or breach of the licensing requirements. Reputational damage to the institution. Loss of samples MED	<ul style="list-style-type: none"> * All key equipment maintained and inspected regularly * Acknowledgment of the expected life span of the equipment, with funding applications made to replace items at the end of their normal useable life * Safety inspections of areas * Redundancies built into storage systems where available * Key equipment remotely monitored
Loss of sample	University of Oxford, researchers working with relevant material	Contamination, degradation or loss of sample during handling. MODERATE	<ul style="list-style-type: none"> * Handle samples in accordance with SOPs. * Handle small numbers of samples at once to limit the risk of thawing for frozen samples, the risk of falling / breakage for sample containers and microscope slides. * Minimise time that frozen samples are taken out of freezers or liquid nitrogen storage. Keep on dry ice if possible / appropriate. * Keep containers of frozen / fresh tissue closed to avoid external contamination and cross-contamination. * Handle labels with care to avoid smudging or removing labels; immediately replace fallen labels where possible, re-label with permanent ink to avoid smudging if necessary. * Where removing lids or caps is unavoidable, only have one container open at a time to limit the risk of accidentally swapping lids or caps.
Incorrect storage of sample	University of Oxford, researchers working with relevant material	Storage of samples in the wrong storage location or in a place which is not consistent with the inventory. LOW	<ul style="list-style-type: none"> * Receive instruction from sample custodians as to any coding systems for storage locations (e.g. rack numbers, box numbers, coding of locations within boxes). * Double check storage locations before final placing.

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