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1. Scope

- 1.1 Restore Bioservices (a division of Harrow Green Limited) is a provider of low temperature off site storage of the 'Customer' Samples ('Services').
- 1.2 The Parties have entered into a 'Commercial Agreement' ('Agreement') for the supply of the Services on the date of this agreement, a condition of which is that the parties must enter into a separate 'Quality Technical Agreement' ('QTA') setting out quality control and regulatory requirements for the supply of the Services.
- 1.3 The 'Customer' will send Restore Bioservices the 'Customer' samples ('Samples')
 - 1.3.1 Restore Bioservices will receive the Samples.
 - 1.3.2 The Samples within will be relocated to an Restore Bioservices owned Storage Vessel and continuous temperature controlled and monitored for the duration of the Agreement as per the Fees in Schedule 2 of this QTA
 - 1.3.3 The 'Customer' will arrange all couriers to, and from Restore Bioservices or contract Restore Bioservices to provide logistical support ('Logistics').
 - 1.3.4 The 'Customer' will retain responsibility for the insurance pertaining to the Samples though included in the Agreement is a liability which can be extended as per the Fees in Schedule 2 of this QTA.
- 1.4 The parties wish to enter into this Quality Technical Agreement In relation to the Obligations and Description of Services.

2. Obligations

- 2.1 This Quality Technical Agreement forms an addition to the Agreement in place between Restore Bioservices and the Customer that details terms and conditions of supply.

2.2 This Quality Technical Agreement shall terminate automatically on termination or expiry of the Agreement.

2.3 Both parties will inform the other of any updates or changes to controlled documentation (where applicable) allowing more than 1 week prior to their use for time to review.

2.4 Both Parties will supply the other with all details of any serious adverse events and/or reactions (SAEAR) observed during procurement/manufacture/storage/transportation within 24 hours of being made aware of the SAEAR.

2.5 The storage of tissue for human application or research is an HTA regulated activity.

Restore Bioservices affirms that storage will take place in an HTA licensed facility under the Agreement.

2.6 Restore Bioservices affirms that it will keep up to date with relevant regulatory changes and inform The Customer of any changes in licences affecting the Customers samples

1. Description of Services

	Description	Restore	Customer
3.1. Prior to Transportation of Samples to Restore			
3.1.2	Prior to the transport of the Storage Vessels to Restore Bioservices, provide a full inventory of the Storage Vessels and Samples contained within being transported.		x
3.1.3	On subsequent deliveries of Samples, provide a list of Samples contained in the consignment for inventory update (within the Restore Bioservices Portal)		x
3.1.4	Ensure that all sample data is uploaded to the Restore Bioservices Portal	x	
3.1.5	Ensure that samples are stored in suitable storage vessels	x	
3.1.6	Ensure that samples are labelled appropriately using labels suitable for ultra-low temperature storage		x
3.1.7	Provides Restore Bioservices with full information of the infectious status of the Samples (where applicable)		x
3.1.8	Pre-arrange the delivery of the samples with Restore Bioservices, giving at least 48 hours' notice.		x
3.1.9	Ensure any consent or ethical approval for storage is obtained and stored in accordance with GDPR and /or relevant legislation/regulations for the duration of storage or for two years (which ever is shorter)	x	x
3.1.10	Complete the Authorised User List, New Customer Form, Prospective Biorepository User Questionnaire are complete prior to the Agreement starting and are notified of updates.		x

3.1.11	Liaise solely with staff identified on the Authorised User List	x	
3.2. Prior to Transportation of Samples to Restore Bioservices			
3.2.1	Arrange the transportation of the Storage Vessels and/or Samples from the Customer to Restore Bioservices.		x
3.2.2	Where Logistic services are provided, ensure continuous and real-time temperature monitoring of Customer's Storage Vessels/ subsequent Samples throughout transport. Where the customer chooses their own logistical solutions, to download data (or retrieve from transport company) and store appropriately (if applicable).	x	x
3.2.3	Upon receipt of the Storage Vessels/Samples at Restore Bioservices, carry out a visual integrity inspection of the Storage Vessels.	x	
3.2.3	Provision of suitable barcodes for Box level storage management	x	
3.3. Transportation & Receipting of Samples			
3.3.1	Inform the Customer within 4 hours following the receipt of the Storage Vessels/subsequent Samples at Restore Bioservices (as the barcodes are scanned).	x	
3.3.2	Condition check and reject any damaged/perished or any otherwise unsuitable Storage Vessel/Sample. This will be managed according to the 'Rejection Process'.	x	
3.3.3	Report SAEs related to the receipt of the Storage Vessels/ subsequent Samples to the Customer and relevant authorities within 24 hours of discovery.	x	
3.3.4	Following relevant SOPs, and update inventory on the Restore Bioservices Portal	x	
3.3. Release of Samples & Transportation			
3.3.1	Prior to the release of any Samples from Restore Bioservices, provide, in writing, a full inventory request (via the Restore Bioservices Portal) of the Samples being requested for transport.		x
3.3.2	Give Restore Bioservices at least 48 hours' notice prior to the requirement to ship samples		x
3.3.3	Identification, pick and pack the requested Samples into required transport vessel following relevant SOPs, and update inventory	x	
3.3.4	Where Logistic services are provided, ensure continuous and real-time temperature monitoring of Customer's Storage Vessels/ subsequent Samples throughout transport. Where the customer chooses their own logistical solutions, to download data (or retrieve from transport company) and store appropriately (if applicable).	x	x
3.3.5	Upon receipt of the transport vessel transfer the Samples to the secure custody of the Customer following the Customer's SOPs		x

3.3.6	Report to Restore Bioservices and any relevant authorities any SAEs related to the transport of the Samples to the Customer within 24 hours of discovery.	x	
3.3.7	Complete and retain documentation regarding the storage of the Sample at Restore Bioservices, including the Sample storage record, and documentation regarding the release of the Samples from Restore Bioservices.	x	
3.3.8	Contact Restore Bioservices to organise the repatriation of any stored Samples at its own expense giving no less than 90 days' written notice as per Commercial Contract.		x
3.3.9	Request in writing the requirement of disposal services. Provide such services pursuant to applicable regulations.		x
3.4. Quality Management			
3.4.1	Ensure that any relevant local, statutory, or regulatory updates relevant to the cryogenic storage of the Samples are communicated immediately.	x	
3.4.2	Ensure availability of a documented Quality Management System with designated personnel and assure that all activities under this agreement are carried out in line with the current best practice guidelines to always safeguard the quality of the Samples.	x	
3.4.3	Accountability for data accuracy & administration as low as box level	x	
3.4.4	Accountability for data accuracy & administration as low as vial level		x
3.4.5	For every critical activity, the equipment and personnel involved must be trained, identified, and documented. Maintain records of all actions relating to the equipment use, storage and retrieval of the Samples.	x	
3.4.6	Ensure availability of a documented system to ensure traceability including inventory management and labelling. Ensure that the Samples can be identified at all stages from transport from the Customer, to release from Restore Bioservices or Sample disposal.	x	
3.4.7	Provide a monthly report of the temperature of the Storage Vessel holding the Samples (where the Customer does not require integration into Restore Bioservices Portal)	x	
3.4.8	Communicate with the other Party the discovery of any quality defects and supply any relevant information regarding any discovered quality defects. Inform the other Party before notifying a regulatory body on any recalls, returns or critical deviations that may impact the Samples	x	
3.4.9	Restore Bioservices shall allow the Customer, or its authorised representative, to perform audits of Restore Bioservices' facilities, quality management system, technical documentation and other requirements related to this agreement. Audits shall be conducted on a Business Day prior to each anniversary of this agreement at mutually agreed times. The Customer will communicate to Restore Bioservices in writing the date of any audits at least 4 weeks prior to the date of the Audit.	x	
3.4.10	Notify other Party about delegation of activities to Third Parties.	x	
3.4.11	Approve delegation of activities to Third Parties.	x	

3.4.12	Maintain all relevant documentation relating to the Services for 5 years (if under HTA). Records will then be destroyed unless the Customer informs Restore Bioservices otherwise.	x	x
3.4.13	Inform the Customer, as soon as reasonably practicable, if the storage facility is to be inspected by any regulatory body who may wish to audit the storage vessel. Where reasonably practicable, the Customer will be given the opportunity to have a representative present during an inspection by regulatory body that is directly related to the Samples	x	
3.4.14	Allow pre-arranged, accompanied access to the Samples	x	