NDM Research Building

The Nuffield Department of Medicine Research Building

HTA Licence 12217

CONTROLLED DOCUMENT

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DOCUMENT TITLE: NDMRB-POL-018 MANAGEMENT OF HUMAN SAMPLES AT THE NDMRB

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1. INTRODUCTION

1.1. The Nuffield Department of Clinical Medicine Research Building (NDMRB) is a new medical research building on the Old Road Campus. The NDMRB is part of the Nuffield Department of Medicine and allow development of the Target Discovery Institute and expansion of existing research groups of NDM with research synergies such as Viral Immunology. The building is also home to one of two sites for the Centre for Tropical Medicine and Global Health.

1.2. The TDI is directed by Sir Professor Peter Ratcliffe. The NDMRB houses approximately 250 researchers, support staff and students. The institute has 20 research groups working in the areas of target and drug discovery, cancer research, Alzheimer's research, viral immunology, tropical medicine and global health.

1.3. Each group within the NDMRB works independently on a set of projects; the scientists within the group report directly to the Principal Investigator (PI) leading the group.

2. PURPOSE

2.1. This Policy gives an overview of how human material work is managed within the NDMRB. It defines collections stored under the HTA licence 12217 and HTA recognised Research Ethics Committee (REC) approvals.

2.2. This Policy also covers imported samples, inventory, adverse events and its procedure and gives reference to other SOPs for disposal of human tissue and internal audits.

3. RESPONSIBILITY

3.1. It is the responsibility of the University Principal Investigator (PI) to ensure that all routine operations and procedures performed at the NDMRB under their group have suitable SOPs.

3.2. It is the responsibility of the PI to maintain oversight of tasks which they have delegated.

3.3. It is the responsibility of all NDMRB personnel to follow the policies for each procedure.

3.4. It is the responsibility of the PI to ensure compliance of personnel and to ensure that only trained individuals perform study tasks.

3.5. It is the responsibility of the PI to make sure all projects are covered under REC approval and are registered under HTA Licence 12217 where required.

3.6. It is the responsibility of the PI to declare all new collections to the Human Tissue Collection Responsible Officer (CRO) and the Human Tissue Person Designated (PD), both based in the NDMRB.

4. HUMAN TISSUE TRAINING

4.1. All new students/staff/visitors working in the laboratory complete the building and laboratory inductions where they are informed about requirements for work with the

human tissue. They are given the NDMRB Registration RA form (1) to complete, in order to determine whether they will be working with human material or not.

4.2. Once the form is returned to the NDMRB Laboratory Manager/CRO, the individuals which declared to be working with human material, will be given a link to complete the HTA Training (2).

4.3. It is a requirement for all students/staff/visitors working with human tissue to complete the training (2).

4.4. Following successful completion of the training, a certificate will be released and should be retained in the group's lab folder or similar. It is responsibility of the PI to make sure staff has the Training Record HTA of completion to maintain oversight and ensure compliance within the NDMRB. Retraining is to be undertaken every two years.

4.5. All staff/students will be given access to iPassport (3) by the HT CRO and must read and acknowledge the SOPs required depending on their duties. iPassport is where all Human Tissue SOPs for the NDMRB are currently stored and updated. Staff will receive emails prompting them when a new SOP has been added or a new version created.

5. GOVERNANCE OF HUMAN TISSUE USE

5.1. The NDMRB Tissue Holdings Spreadsheet lists all the studies at the NDMRB and indicates whether they are under REC or covered under HTA Licence 12217. This list also states, but not limited to, the study/project title, REC reference or HTA licence number, REC end date, sample type, location, consent forms location, labelling of samples and any MTAs in place (4). Samples under HTA Licence 12217 are identified in the table (in the freezer room) which details the exact location of those samples in the freezer, the custodian of the samples and the collection name (4).

5.2. Samples stored under HTA Licence 12217 should only be stored in rooms that display a licence certificate.

5.3. The CRO supply the Human Tissue Governance Team (HTGT) with a comprehensive annual return that details all collections held at the NDMRB under the HTA Licence 12217.

5.4. NDMRB collections registered under HTA Licence 12217 will be subject to an annual audit by the HTGT. This will be performed in accordance with Core SOP HTA006 Audit (5).

5.5. The CRO will coordinate with the HTGT and collection PIs and their collections custodians.

5.6. The CRO will also perform NDMRB audits on collections under HTA Licence 12217 on a 12 months basis in accordance with NDMRB-SOP-059 Internal Audit (6).

5.7. An Internal Audit schedule exists for the NDMRB (7). Dates and audit reports are available on the iPassport.

6. REC APPROVAL AND EXPIRY

6.1. Prior to the set-up of Material Transfer Agreements (MTAs) or agreements with Research Tissue Banks (RTB), groups are to make the NDMRB CRO aware of any new potential collections so correct procedures can be followed.

6.2. For collaborations, PIs must obtain REC approval letter and date of REC approval expiry and provide this information to the NDMRB CRO and to the HTGT (8) , before a MTA can be drawn up.

6.3. The CRO and HTGT will keep track of end dates (9) and prompt the PI when the end of REC is approaching. PIs storing/using samples under REC usually have one calendar year to either (this will also depend on what was arranged when the MTA was drawn):

- Return the samples to the provider
- Or to dispose of their samples accordingly

6.4. If the original REC approval allows (and the MTA, if applicable) for the samples to be kept for further research, your options are the following (please contact the CRO or HTGT if you are unsure on what you can do with your samples once REC ends):

- For samples that are of relevant material (human samples that contain cells) options are to either apply for a new NHS REC approval or apply for a Central University Research Ethics Committee (CUREC) approval (10). However as CUREC is not a HTA recognised REC (has not been approved by the NHS), samples will also need to be stored under the HTA licence 12217. If the samples are adopted under the HTA licence, HTA FRM001 Registration Form for Licence 12217I12 needs to be filled in firstly and sent to the HTGT. Sufficient notice should be given to the HTGT to allow for registration.
- For samples of non-relevant material (acellular), there is no need to store them under the licence, however in most cases a CUREC approval (10) will be required.

7. IMPORTED SAMPLES

7.1. Before any samples are imported into the NDMRB, PIs need to discuss this with the CRO, so correct procedures can be taken to make sure the samples enter the building ethically.

7.2. Researchers must normally declare imports (and exports) of human tissue to HM Revenue and Customs (HMRC). Further advice can be obtained from the HM Revenue Customs National Advice Service (0845 0109000).

7.3. Where samples are imported as part of a collaboration which is not covered by a valid UK REC approval and the samples are relevant material, the collection will need to be adopted under HTA licence 12217.

7.4. It needs to be noted that the HTA licence only allows storage of samples and not its use. Therefore if samples were to be used in research, a REC approval would be required (CUREC or NHS).

7.5. A suitable MTA must be in place prior to importing samples. MTAs can only be signed off by authorised signatories, who are based in Research Services (11).

7.6. It must clearly define where the responsibility of consent lies and where consent is stored. All versions of a blank template consent form and of Patient Information Sheet (PIS) must be obtained and stored in the appropriate group's HTA subfolder and with the CRO (8).

7.7. Samples must be traceable at all time and it is advised to retain the original identifier of the sample in order to facilitate traceability.

7.8. Samples must only be used, stored and disposed as per the agreed MTA, no deviation is authorized without amendment of the MTA. Unauthorized deviation may warrant an Adverse Event (AE) (please see section 10 below on adverse events).

7.9. It is the responsibility of the PI to ensure all work is carried out in accordance with the MTA.

8. INVENTORY

8.1. Each group is responsible for keeping an inventory of the samples stored whether in the cryofreezers, -80°C freezers, cold rooms or at room temperature.

8.2. Groups are also responsible for ensuring that the inventory is kept up-to-date and that it is fully traceable. Please refer to SOP-045 Human tissue samples records, inventory and traceability for correct procedure (12).

8.3. For samples under HTA Licence 12217, core SOP HTA002 Traceability (13) or should be followed. Where samples traceability under Licence 12217 is lost, an AE must be reported.

8.4. Inventories should be password protected if any identifiable information is present.

9. DISPOSAL

9.1. For disposal of material under HTA Licence 12217, HTA TEMP002 Disposal Log (14) or adapted NDMRB Destruction log (15) must be completed. A copy of the completed form should be given to the CRO, who will assign a unique identifier to the form, file it and then will pass it on to the HTGT. For more details please refer to core SOP HTA005 Disposal (16).

9.2. For disposal procedures for samples please refer to NDMRB-SOP-045 Sample Traceability, Labelling and Disposal at the NDMRB (12). Inventories should be updated for the purpose of traceability when samples are disposed of. Date of disposal, reason, by whom and how should be recorded. No records should ever be deleted.

10. ADVERSE EVENTS and NON-COMPLIANCE

10.1. Adverse events that occur at the NDMRB are recorded, reported and dealt with according to Core SOP HTA003 Reporting and Managing Adverse Events (17). An action plan will be developed to resolve and prevent any potential recurrence.

10.2. Serious Adverse Incidents could occur to samples, such as freezer failure, use of a sample without consent, non-compliance with ethical approval, undertaking licensable activities without a licence or disposal of wrong sample.

10.3. Whether an adverse event has occurred or was just near-missed, involved personnel have a duty to report the event promptly to the CRO. The CRO will liaise with the PD and HTGT.

10.4. Adverse Event or non-compliance must be reported using the iPAssport non-compliance tab (3) by the individuals who witnessed the event, with the help of the CRO if required.

10.5. The HTGT, Person Designated and CRO will agree on an action plan. The CRO will coordinate the implementation of the action plan and provide updates to the HTGT, when required.

10.6. The task associated with the non-compliance, progress of the action plan will be recorded and updated via iPassport.

10.7. In the case of a catastrophic AE, for example in instances where staff safety is affected, the NDMRB Departmental Safety Officer will make sure this accident or incident is reported.

10.8. If the AE did not involve samples under HTA Licence 12217, the same process applies, but the HTGT and PD will most likely not be involved.

11. ARCHIVING AND DESTRUCTION OF DOCUMENTS

11.1. All essential documents for a study must be retained by the PI for at least 5 years after the completion of study-related activities. This includes; SOPs, training records, sample inventory, equipment records, etc.

11.2. In certain cases there might be a legal requirement to retain document/records for a longer period of time. If this is the case, the reason for is should be known to the relevant persons, such as NDMRB IT, CRO and PD.

11.3. The data both paper and electronic should be archived appropriately (consider space, security, fire protection, water protection, humid conditions, etc.).

11.4. Electronic records are to be archived on the University server in a distinct folder.

11.5. Records should be destroyed with the level of security required by the confidentiality of their contents.

11.6. Paper records at the NDMRB should be disposed of via the confidential bin.

11.7. Putting records in a normal recycling bin is not an acceptable method of destruction as it remains accessible to anyone who finds them.

11.8. With digital records, it is important to remember that deletion from a server may not be sufficient. Therefore, when the retention period has ended, electronic records should be destroyed in accordance with all legal and ethical requirements and should involve the Information Governance Manager and the NDMRB IT Manager.

12. DATA PROTECTION AND RESEARCH

12.1. For the University policy on the General Data Protection Regulation please refer to https://researchsupport.admin.ox.ac.uk/policy/data

13. INFORMATION SECURITY POLICY

13.1. For the University policy on Information Security please refer to: https://www.ndorms.ox.ac.uk/information-security-policy

14. BIBLIOGRAPHY

1. NDMRB-FRM-008 New starter registration risk assesment can be found on . : s.n.

2. HTA Training can be accessed here: https://researchsupport.admin.ox.ac.uk/governance/human-tissue/training.

3. iPassport can be accessed via this link: https://htg.ipassportqms.com.

4. NDMRB Tissue Holdings Spreadsheet can be found here R:\Administration and Facilities\Lab Management\HTA.

5. Core SOP HTA006 Audit can be found on iPassport: https://htg.ipassportqms.com.

6. NDMRB-SOP-059 Internal HTA audit guidance.

7. NDMRB Audit Schedule can be found here: R:\Administration and Facilities\Lab Management\HTA\HTA inspections and audits.

8. REC information, MTAs, consents and PIS are kept in group specific folder which is located here: R:\Administration and Facilities\Lab Management\HTA\NDMRB Ethical Approvals and consent templates.

9. End of REC dates spreadsheet can be found here: R:\Administration and Facilities\Lab Management\HTA .

10. Information on CUREC applications can be found here: https://researchsupport.admin.ox.ac.uk/governance/ethics.

11. NDMRB-SOP-073 Material Transfer Agreements (MTA) guidance for human tissue samples transfer.

12. NDMRB-SOP-045 Human tissue samples records, inventory and traceability.

13. HTA002 Traceability (Core document on https://htg.ipassportqms.com).

14. HTA_TEMP002 Template disposal log (core document on https://htg.ipassportqms.com).

15. NDMRB-FRM-018 Human material destruction log.

16. HTA005 Disposal (Core document on https://htg.ipassportqms.com).

17. HTA003 Adverse event reporting and impact assessment (Core document on https://htg.ipassportqms.com).

18. NDMRB Tissue Holdings Spreadsheet can be found here R:\Administration and Facilities\Lab Management\HTA.