Licence application visit on compliance with HTA minimum standards

RxCelerate Ltd, Babraham Research Campus, Cambridge

HTA licensing number 12665

To be licensed under the Human Tissue Act 2004 for the

- **Storage of relevant material which has come from a human body for use for a scheduled purpose**

27 February 2017

Background

A site visit of RxCelerate, Babraham Research Campus, Cambridge ('the establishment') was carried out as part of the licence application assessment. The establishment consists only of the site at Babraham Research Campus.

This report summarises the visit and provides advice to the establishment to support post-licensing compliance.

RxCelerate is a contract research organisation that works together with the University of Cambridge. The establishment undertakes pre-clinical research on behalf of pharmaceutical companies. The primary reason for the licence application is for storage of human tissue received from pharmaceutical companies, other suppliers of human tissue and blood from volunteers. At the time of the inspection, there were five colon biopsies from the living being stored for a project which has received ethical approval from a recognised (NHS) research ethics committee (REC); these samples are therefore exempted from the licensing requirements of the Human Tissue Act 2004 (HT Act).

A visual inspection of the establishment was undertaken and included areas where human tissue will be stored for the purpose of research under the HT Act. This relevant material will include blood samples taken from volunteers based at the Babraham Research Campus. Consent for these samples will be sought by trained RxCelerate staff.

Tissue will be stored in one -80°C freezer and in two -20°C freezers located in two laboratories. Slides of human tissue are kept within the microscope room in the category 2 laboratory. The freezers are under a maintenance contract with the Babraham Estate.

There is CCTV monitoring of the building and an electronic swipe entry system to the building where RxCelerate laboratories are located. Access to the laboratory is restricted and doors are locked when not in use. The temperatures of the freezers are monitored by a proprietary temperature monitoring system and staff are alerted by email and phone if temperatures are outside of the defined ranges. There is a contingency procedure in place for equipment breakdown. The establishment uses a web-based laboratory management system to track samples of human tissue. A separate secure database for HTA samples will soon be implemented. An audit of stored material demonstrated traceability of samples.

A round-table discussion with the proposed Designated Individual (DI) and the Project Coordinator was held. The discussion covered: consent; premises; facilities and equipment; governance and quality management systems and traceability systems.

Advice

During and following the site visit, the inspection team advised the proposed DI on several issues to ensure compliance with the HTA's licensing standards before the licence was offered. These included ensuring that:

- Agreements with suppliers include documented assurances about donor consent;
- Expiry dates of tissue samples stored under NHS Ethics approval are documented and consent will be sought for any further work with these tissues;
- Regular, minuted HTA-related governance meetings are implemented;
- Audits cover compliance with HTA standards;
- Receipt of all samples delivered by courier is documented;
- Procedures to report incidents involving human tissue are documented to record events, monitor trends and enable future learning;
- The disposal policy is extended to cover human tissue;
- Risk assessments are performed for all practices and processes requiring compliance with the HTA's Code of Practice E, including a premises risk assessment;
- Stored HTA relevant material will be clearly labelled as human tissue to ensure staff are aware that these tissues have to be handled accordingly;
- In the event that it is necessary to store material at -80°C, another freezer will be purchased to ensure human tissue is stored securely on RxCelerate licensed premises;
- Human and animal tissue will be stored separately;
- Material transfer agreements are in place before any material is sent from or returned to another establishment;
- Contingency arrangements for the storage of samples will be formalized.

These matters were addressed prior to the licence offer.

The HTA also advises the proposed DI to consider the following to further improve practices:

No.	Standard	Advice
1.	C3	The proposed DI is advised to ensure that appropriate consent is obtained by suitably trained staff, evidence of consent training will be documented and competence of staff will be assessed and maintained.
2.	GQ3	The proposed DI is advised to ensure that all new staff working with human tissue undertake an induction programme, which includes information on the HTA and licensing to ensure compliance with human tissue legislation and the regulatory framework.
3.	GQ6	The proposed DI is advised that staff should be aware of expiry dates for studies that have received ethical approvals from recognised RECs. This is because the storage of samples will then fall under the authority of the licence.

Following the licensing application visit and subsequent amendments to documentation made by the establishment, the HTA assessed the establishment as suitable to be licensed for storage of relevant material for a scheduled purpose (research in connection with disorders, or the functioning, of the human body).

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Individual standards which are not applicable to this establishment have been excluded.

Consent standards
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice
• Consent forms comply with the HTA's Code of Practice • Consent forms are in records and are made accessible to those using or releasing relevant material for a scheduled purpose • If the establishment obtains consent, a process is in place for acquiring consent in accordance with the requirements of the HT Act 2004 and the HTA's Codes of Practice • Where applicable, there are agreements with third parties to ensure that consent is obtained in accordance with the requirements of the HT Act 2004 and the HTA's Codes of Practice • Consent procedures have been ethically approved
C2 Information about the consent process is provided and in a variety of formats
• Standard operating procedures (SOPs) detail the procedure for providing information on consent • Agreements with third parties contain appropriate information • Independent interpreters are available when appropriate • Information is available in suitable formats, appropriate to the situation • Consent procedures have been ethically approved
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent
• Standard operating procedures (SOPs) detail the consent process • Evidence of suitable training of staff involved in seeking consent • Records demonstrate up-to-date staff training • Competency is assessed and maintained

Governance and quality system standards
GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process
• Policies and procedures are in place, covering all activities related to the storage of relevant material for research in connection with disorders, or the functioning, of the human body

- Appropriate risk management systems are in place
- Regular governance meetings are held; for example, health and safety and risk management committees, agendas and minutes
- Complaints system

GQ2 There is a documented system of quality management and audit

- A document control system, covering all documented policies and standard operating procedures (SOPs).
- Schedule of audits
- Change control mechanisms for the implementation of new operational procedures

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

- Qualifications of staff and training are recorded, records showing attendance at training
- Orientation and induction programmes
- Documented training programme, (e.g. health and safety, fire, risk management, infection control), including developmental training
- Training and reference manuals
- Staff appraisal / review records and personal development plans are in place

GQ4 There is a systematic and planned approach to the management of records

- Documented procedures for the creation, amendment, retention and destruction of records
- Regular audit of record content to check for completeness, legibility and accuracy
- Back-up / recovery facility in the event of loss of records
- Systems ensure data protection, confidentiality and public disclosure (whistle-blowing)

GQ5 There are documented procedures for distribution of body parts, tissues or cells

- A process is in place to review the release of relevant material to other organisations
- An agreement is in place between the establishment and the organisation to whom relevant material is supplied regarding the tracking and use of material and eventual disposal or return

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail

- There is an identification system which assigns a unique code to each donation and to each of the products associated with it
- An audit trail is maintained, which includes details of when and where the relevant material was acquired, the consent obtained, the uses to which the material was put, when the material was transferred and to whom

GQ7 There are systems to ensure that all adverse events are investigated promptly

- Corrective and preventive actions are taken where necessary and improvements in practice are made
- System to receive and distribute national and local information (e.g. HTA communications)

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately

- Documented risk assessments for all practices and processes
- Risk assessments are reviewed when appropriate
- Staff can access risk assessments and are made aware of local hazards at training

Premises, facilities and equipment standards

PFE1 The premises are fit for purpose

- A risk assessment has been carried out of the premises to ensure that they are appropriate for the purpose
- Policies in place to review and maintain the safety of staff, authorised visitors and students
- The premises have sufficient space for procedures to be carried out safely and efficiently
- Policies are in place to ensure that the premises are secure and confidentiality is maintained

PFE 2 Environmental controls are in place to avoid potential contamination

- Documented cleaning and decontamination procedures
- Staff are provided with appropriate protective equipment and facilities that minimise risks from contamination
- Appropriate health and safety controls are in place

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.

- Relevant material, consumables and records are stored in suitable secure environments and precautions are taken to minimise risk of damage, theft or contamination
- Contingency plans are in place in case of failure in storage area
- Critical storage conditions are monitored and recorded
- System to deal with emergencies on 24 hour basis
- Records indicating where the material is stored in the premises

PFE 4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination

- Documented policies and procedures for the appropriate transport of relevant material, including a risk assessment of transportation
- A system is in place to ensure that traceability of relevant material is maintained during transport
- Records of transportation and delivery
- Records are kept of any agreements with recipients of relevant material
- Records are kept of any agreements with courier or transport companies

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored

- Records of calibration, validation and maintenance, including any agreements with maintenance companies
- Users have access to instructions for equipment and receive training in use and maintenance where appropriate
- Staff aware of how to report an equipment problem
- Contingency plan for equipment failure

Disposal Standards

D1 There is a clear and sensitive policy for disposing of human organs and tissue

- Documented disposal policy
- Policy is made available to the public
- Compliance with health and safety recommendations

D2 The reason for disposal and the methods used are carefully documented

- Standard operating procedures (SOPs) for tracking the disposal of relevant material detail the method and reason for disposal
- Where applicable, disposal arrangements reflect specified wishes

Appendix 2: Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the Human Tissue Act 2004 (HT Act) or associated Directions

   or

   A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

   A critical shortfall may result in one or more of the following:

   (1) A notice of proposal being issued to revoke the licence

   (2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.

   (3) A notice of suspension of licensable activities

   (4) Additional conditions being proposed

   (5) Directions being issued requiring specific action to be taken straightaway

2. **Major shortfall:**

   A non-critical shortfall that:

   - poses a risk to human safety and/or dignity, or
   - indicates a failure to carry out satisfactory procedures, or
   - indicates a breach of the relevant CoPs, the HT Act and other relevant professional and statutory guidelines, or
   - has the potential to become a critical shortfall unless addressed

   or

   A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

   In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. **Minor shortfall:**

A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based or site visit.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. You must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.