Licence application assessment report on compliance with HTA licensing standards
Licence assessment date: **29 October 2020**

TJ Smith & Nephew Ltd

Proposed HTA licensing number 12703

Application for a licence under the Human Tissue Act 2004

Activities applied to be licensed

Area	Storage of relevant material which has come from a human body for use for a scheduled purpose	Removal from the body of a deceased person (otherwise than in the course of an anatomical examination or post-mortem examination) of relevant material of which the body consists or which it contains, for use for a scheduled purpose other than transplantation
Hub site **TJ Smith & Nephew Ltd**	Applied to be licensed	Not applied to be licensed

Summary of visit findings

The HTA found the proposed Designated Individual (DI) and the proposed Licence Holder (LH) to be suitable in accordance with the requirements of the legislation.

TJ Smith & Nephew Ltd (the 'establishment') was found to have met all HTA standards.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Compliance with HTA standards

All applicable HTA standards have been assessed as fully met.

Advice

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

Number	Standard	Advice
1.	C1(c)	The proposed DI is advised to clarify, in establishment documentation, that the DI is responsible for supervising licensed activities and ensuring suitable practices are taking place. This includes ensuring that there are processes in place to provide an assurance that imported material has been sourced with suitable consent. In addition, imported material should be procured, used, handled, stored, transported and disposed of in accordance with the consent which has been obtained.
2.	GQ3(a)	The establishment intends to develop a programme of HTA-specific training. The proposed DI is advised to consider including this as part of the establishment's induction programme for all staff working with, or having access to, relevant material. This will help to provide an assurance that all staff are aware of the need to store and use human material appropriately.
3.	T2(b)	While the establishment has processes to ensure that the date, reason and method of disposal of relevant material are recorded, the proposed DI is advised to consider consolidating this information for all relevant material in a central location, rather than in study specific documents.

Background

TJ Smith & Nephew Ltd (the 'establishment') is a global medical technology company. The Preclinical Sciences department has applied for an HTA licence to store relevant material which has come from a human body for use for scheduled purposes. Working in compliance with several regulators and accrediting bodies, including working to Good Laboratory Practice and ISO 9001 standards, the establishment undertakes preclinical studies in

support of Smith & Nephew's global research efforts. The establishment will only receive relevant material that has been imported from suppliers within the Smith & Nephew network.

Description of activities undertaken during visit

The HTA's regulatory requirements are set out in Appendix 1. Due to the national response to the COVID-19 pandemic, no site visit was undertaken. The Regulation Manager covered the following areas during a remote (desk-based) assessment.

Standards assessed against during visit

There are 47 standards in the Research sector, of which 37 were assessed. Standards C1(a), C1(b), C1(d), C1(e), C1(f), C2(a), C2(b), C2(c), T1(g) and PFE2(b) could not be assessed as the establishment does not intend to directly seek consent, distribute relevant material, or to store material from the deceased (standards published 3 April 2017).

Review of governance documentation

Policies and procedural documents relating to all licensable activities, including the establishment's Quality Manual, standard operating procedures, risk assessments and those pertaining to traceability systems were reviewed. Documents detailing the plans for adverse events, incident management, governance meetings and audits were also reviewed.

Visual inspection

No site visit was undertaken as part of the licence application assessment.

Meetings with establishment staff

The assessment included remote meetings with the proposed DI, proposed LH contact, and proposed Persons Designated.

Report sent to proposed DI for factual accuracy: 17 October 2020

Report returned from proposed DI: No factual accuracy or request for redaction comments were made by the DI

Final report issued: 18 October 2020

Appendix 1: The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the DI is a suitable person to supervise the activity authorised by the licence and that the premises are suitable for the activity.

The statutory duties of the DI are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity, and;
- the conditions of the licence are complied with.

Its programme of site visit inspections to assess compliance with HTA licensing standards is one of the assurance mechanisms used by the HTA.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. They are grouped under four headings:

- consent;
- governance and quality systems;
- traceability, and;
- premises facilities and equipment.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that there has been a shortfall against a standard, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is provided.

HTA inspection reports are published on the HTA's website.

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 Human Tissue Act 2004 (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 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:

   - A notice of proposal being issued to revoke the licence;
   - 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;
   - A notice of suspension of licensable activities;
   - Additional conditions being proposed, or;
   - 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 Codes of Practice, 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 review or at the time of the next 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 the final inspection report. Establishments 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, or;
- follow up at next routine site visit inspection.

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