

DIRECTIONS TO LICENSED ESTABLISHMENTS IN THE RESEARCH SECTOR, GIVEN UNDER THE HUMAN TISSUE ACT 2004

Directions requiring establishments in the Research sector to submit a compliance update to the Human Tissue Authority (HTA)

	Ref: 006/2019
These Directions are:	General Directions
Sections of the Human Tissue Act 2004 providing for these Direction	Sections 23 and 37
These Directions come into force on:	02 September 2019
These Directions remain in force:	Until the Directions are revoked

- 1. These Directions are given in relation to licences issued to Research sector establishments under Sections 16(2)(c) and 16(2)(e) of the Human Tissue Act 2004.
- 2. The Directions require licensed Research establishments to submit information about licensable activities being undertaken.
- 3. Submissions must be made to the HTA no later than 18 October 2019.
- 4. Detailed instructions for completing the submission are provided in a separate document, which is available on the HTA website at: https://www.hta.gov.uk/policies/guide-submitting-compliance-updates-using-hta-portal
- 5. The information required by these Directions will be used to:
 - a. Ensure each establishment's continued suitability to be licensed
 - b. Inform the scheduling of site-visit inspections
 - c. Inform the HTA's regulatory approach to each sector

Dated 05 August 2019

Signed

A.N.Hansal

Nicolette Harrison Director of Regulatory Delivery