

Human Tissue Authority  
151 Buckingham Palace Road  
London  
SW1W 9SZ

[REDACTED]  
  
By email to [REDACTED]

**Tel** 020 7269 1900  
**Web** [www.hta.gov.uk](http://www.hta.gov.uk)  
**Email** [enquiries@hta.gov.uk](mailto:enquiries@hta.gov.uk)  
**Date** 8 March 2019

Dear [REDACTED]

### Freedom of Information request

Thank you for your request for information under the Freedom of Information Act (FOIA), which was received by the Human Tissue Authority (HTA) on 28 February 2018. Your email outlined the following request:

Dear FOI Officer,

I am sending this request under the Freedom of Information Act.

Please send me this information by e-mail to [REDACTED] in a machine readable format such as .csv or .xlsx where appropriate.

- 1) Please provide a copy of all communications between the HTA and the Institute concerning problems with the handling and storage of human tissue at the institute.
- 2) Please provide a copy of all complaints received by the HTA concerning the handling and storage of human tissue at the Wellcome Sanger Institute
- 3) Please provide any reports held on the compliance of the Wellcome Sanger Institute with HTA guidelines on the handling and storage of human tissue.

Please provide information from the period 1st January 2017 to 28th February 2019.

If you have any queries about this request please contact me on [REDACTED]

If you are encountering practical difficulties complying with this request, please contact me so that we can discuss the matter and if necessary I can modify the request.

Please acknowledge receipt of this request.

Many thanks for your assistance.

Kind regards,

## **Response**

Under section 1(1) (a) of the FOIA, you are entitled to be told whether or not the HTA holds information within the scope of your request, unless an exemption applies. In this case, the HTA can neither confirm nor deny that it holds the requested information, for the reasons set out below.

Section 31(1) (g) of the FOIA, read together with section 31(2) (c), provides that the HTA does not need to inform you whether or not it holds the requested information if doing so would be likely to prejudice the functions of the HTA exercised for the purpose of “ascertaining whether circumstances which would justify regulatory action in pursuance of any enactment exist or may arise”.

The HTA’s functions, which are set out in general terms at section 15 of the Human Tissue Act 2004, include superintending compliance with requirements imposed by, or under, Part 1 of the Human Tissue Act 2004 and with Codes of Practice made under the Human Tissue Act 2004 (see section 15 (c) of the Human Tissue Act 2004).

Section 31 of the FOIA is a ‘qualified’ exemption. This means that, even where the exemption applies, we can rely on it only if the public interest in applying the exemption outweighs the public interest in disclosing whether or not the information is held.

In considering the public interest test, we acknowledge that there is a significant public interest in understanding whether or not concerns have been raised to the HTA about the compliance with the Human Tissue Act 2004 of particular named institutions, and that there is a public interest in our activities relating to our remit as a regulator. We also appreciate there is a public interest in the HTA maintaining openness and transparency generally.

On the other hand, there is a strong public interest in ensuring that the HTA's regulatory functions are carried out without being prejudiced. Disclosing whether or not concerns have been raised about the compliance or otherwise of individual

named institutions is likely to cause such prejudice and, in some cases, could result in evidence being suppressed.

On balance, therefore, we have concluded that to confirm or deny that we hold the information described in your request would pose a realistic risk that it would prejudice our ability to ascertain “whether circumstances which would justify regulatory action in pursuance of any enactment exist or may arise”, and that the exemption at section 31(1) (g) applies.

As a related assurance for your future reference, I can confirm that the HTA does routinely report quarterly on the serious incidents and/or investigations in its Regulatory Delivery Report to Members of the Human Tissue Authority. This information is held within the public domain of the HTA website via the following hyperlink:

<https://www.hta.gov.uk/about-us/how-we-do-it/authority-meetings-topic-listings>

### **Further information**

If you are unhappy with the way the HTA has handled your request for information in this case, you may in the first instance ask us for an internal review by writing to us at the above postal or email address.

If you remain dissatisfied with the handling of your request or complaint, you have the right to appeal directly to the Information Commissioner for a decision, at the address below. There is no charge for making an appeal.

Information Commissioner’s Office  
Wycliffe House  
Water Lane  
Wilmslow  
Cheshire SK9 5AF

Telephone: 08456 30 60 60 or 01625 54 57 45

Website: [www.ico.gov.uk](http://www.ico.gov.uk)

Yours sincerely



