

Human Tissue Authority
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Date 22 September 2014

[REDACTED]

By email to [REDACTED]

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 21 August 2014. Your email outlined the following request:

“Please provide any information held by the Human Tissue Authority about:

1. The alleged sale/misuse of human tissues at The Christie Hospital and/or the Manchester Cancer Research Biobank.
2. Any Whistleblowing allegations at The Christie Hospital and/or the Manchester Cancer Research Biobank.

I make this request under the Freedom of Information Act.”

Background

The Christie NHS Foundation Trust is licensed by the HTA to store relevant material which has come from a human body for use for a Scheduled Purpose. This is a licensable activity under the Human Tissue Act 2004. Their licence number is 30004.

The Christie Pathology Partnership, which forms part of the Christie NHS Foundation Trust, is also licensed by the HTA to undertake activities in the post mortem and human application sectors at the same site. The HTA has taken your request to refer only to the research sector licence, licensing number 30004, in its response. The HTA has not received any information about allegations made regarding the Christie Pathology Partnership.

The HTA became aware of allegations made about The Christie NHS Foundation Trust, licence number 30004, on 8 July 2014. The allegations came to the HTA’s notice following communication from the Department of Health which informed us that Ms Rosie Cooper, a Member of Parliament, intended to put forward Parliamentary Questions on 10 July 2014.

We were told that the Parliamentary Questions would ask for information held by the Secretary of State for Health and/or the Department of Health regarding the following:

- a) allegations that tissue samples were sold by The Christie NHS Foundation Trust to pharmaceutical companies without the knowledge of the donors concerned;
- b) whether the Secretary of State for Health's attention was drawn to any such allegations;
- c) what investigation the Secretary of State for Health and/or the Department of Health had conducted and/or planned to conduct into such allegations.

Whilst the questions were mainly focussed on matters outside the HTA's remit, one of the questions related specifically to allegations around the sale of human tissue samples to pharmaceutical companies without the knowledge of the patients concerned.

As a result of the allegations in the Parliamentary Question relating to the sale of human tissue, the HTA initiated discussions and information gathering with The Christie NHS Foundation Trust, licence number 30004.

The Human Tissue Act 2004 does not prevent the sale of human tissue for research. Research tissue banks may charge for providing human tissue samples to researchers, including those working for private companies, so that their running costs are recovered.

Where cost recovery, or any other charging mechanism, is in place it is important that research tissue banks are able to satisfy themselves that the information provided to potential donors is sufficient to ensure they understand that their tissue may be shared with researchers, subject to a fee being charged. We also recommend that research tissue banks improve transparency by providing easily-accessible information about how and why they charge, and to whom they will supply tissue samples. Consistent with our [Code of Practice on Consent](#), potential donors should be informed if their samples could be used for research involving the commercial sector.

The HTA understands that Manchester Cancer Research Biobank (of which The Christie NHS Foundation Trust is a member) operates a cost recovery system when exchanging tissue with researchers. Thus, the HTA's focus with regard to the allegations has been on consent processes.

The HTA has reviewed the consent processes in place at The Christie NHS Foundation Trust and the Manchester Cancer Research Biobank and we are satisfied that they provide the information that tissue donors need to provide informed consent.

The HTA worked closely with all regulators who were initially involved in this matter throughout our investigation: namely the Care Quality Commission, Monitor, the Medicines and Healthcare products Regulatory Agency and the Health Research Authority. The HTA also maintained contact with The Christie NHS Foundation Trust to facilitate information sharing and ensure we undertook a robust and transparent investigation into these allegations.

The remaining allegations are a matter for the appropriate regulators (the Care Quality Commission and Monitor) to consider and take regulatory action where appropriate. Their

investigations are ongoing and the findings will be published for public reference upon completion.

Response

The HTA's investigation of these allegations was kept to a very small number of staff for operational reasons. In order to respond to your request a search of the Outlook accounts of these staff members was undertaken. We searched for all emails from the period 8 July 2014 until 21 August 2014 which contained the following terms:

- Christie
- Manchester Cancer Research Centre
- Manchester Cancer BioBank

We also conducted a search of the personal folders of these staff members and of our internal information management systems, CRM and IMPACT.

All information that we consider can be disclosed under FOIA in response to this request can be found at the following link, which will provide a folder of documents when clicked on:

http://www.hta.gov.uk/db/downloads/CHRISTIE_FOI.zip

The password you will need to open each document is 'nearlychristmas'.

If you have a Windows system which is older than Windows 7 you will require ZIP file software to view these documents. If you do not have this software please contact me so I can arrange an alternative viewing method.

We have worked through the documents to ensure duplicate information is not provided where possible.

We consider that the remainder of the information you requested is exempt under the FOIA and it is therefore withheld from this response. We have set out the exemptions we have applied when considering your request below.

Section 31 FOIA

Section 31 provides an exemption which protects a variety of law enforcement interests. In particular, we have considered section 31 (1)(g) and section 31(2)(c), which state that information is exempt from disclosure if such disclosure would prejudice the exercise by any public authority of its functions to ascertain whether circumstances, which would justify regulatory action in pursuance of any enactment, exist or may arise.

The HTA has been working with a number of regulators on the matter you have requested information about. We consider that some information we hold may impact on the ability of these regulators to undertake their functions.

There is strong public interest in allowing regulators to conduct their regulatory activities. We are satisfied that, at the time of your request, disclosing this information would prejudice the

exercise of regulatory functions and therefore this exemption applies; on that basis, the information is withheld.

Section 40 FOIA

In reviewing the information you have requested, we have noted some of the documents contain information which is exempt by virtue of the fact that it is personal data, disclosure of which would be unfair to the individuals concerned.

Section 40(3)(a)(i) FOIA states that information is absolutely exempt from disclosure if its disclosure would breach any of the Data Protection Act's data protection principles. Insofar as the documents contain information relating to identifiable HTA staff members¹ and others, we have concluded that disclosure under FOIA would breach the first data protection principle. This is because disclosure of this personal data is not necessary in the public interest and, further, it would be unfair to the individuals concerned, who could have no expectation that relevant information relating to them would be made public.

In accordance with section 40 FOIA, the documents enclosed in this response have been redacted so they do not include personal information, such as names of staff (other than those in senior positions), patients, dates of birth and death and causes of death.

Section 41 FOIA

In reviewing the information you have requested, we have noted some of the documents contain information which the HTA has received in confidence from other regulators under our Memorandum of Understanding (MoU), disclosure of which would result in an actionable breach of confidence.

Section 41 FOIA is also an absolute exemption. It applies to information supplied to the HTA by a third party, disclosure of which would amount to a breach of confidence actionable by any person.

We have applied the common law test of confidentiality to this information and our findings are outlined below:

- a) The information we hold which was sent to us in confidence by third parties with whom we have MoUs, a statement agreed between two organisations that outlines what they intend to achieve and their commitment to work together, in accordance with our regulatory function and to ensure we investigate allegations where there could be a breach of the Human Tissue Act. This information is not in the public domain. Where applicable, some of this information was provided to these third parties in confidence and is not in the public domain.
- b) The HTA gave assurances to these third parties, both when the MoUs were drafted and before when the information in question was shared, that any information shared would be treated in confidence; the information was therefore shared with the expectation of both the HTA as receiver and the third parties as providers that it would be treated confidentially. Where applicable, information provided to the third parties

¹ Who are not in the Senior Management Team.

was given in the expectation of both the provider and receiver that the information would be treated confidentially. The HTA believes this information would not have been shared unless there was an expectation of all parties that the information would be treated confidentially.

- c) The HTA believe that disclosure of the information provided to us in confidence would cause detriment to the third parties who provided it to us and the parties who provided it to them.
- d) The HTA believe it would not be in the public interest to disclose this information, as it was shared with the HTA in confidence and there is strong public interest in allowing concerns and allegations to be raised and investigated through the whistleblowing process. These concerns and allegations of wrongdoing are made in the public interest and in the aim of protecting patients and staff. If the public felt that concerns could no longer be raised anonymously and confidentially through the whistleblowing process, it would deter people from doing this and could prevent potential wrongdoing from being investigated and resolved.

In accordance with section 41 FOIA, any document in this response which contains information supplied to the HTA in confidence has been redacted so this information is not released. Any document which the HTA believe was provided in confidence in its entirety has been excluded from this response by virtue of section 41 FOIA.

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

Yours sincerely,

