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[redacted]

By email to [redacted]

Date 27 August 2015

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 3 August 2015. Your email outlined the following request:

"I am seeking information, past and present, relating to fetal tissue / fetal remains / pregnancy remains / pregnancy loss / termination of pregnancy.

The original guidance codes of practice (code 1-consent and code 5-removal initially I believe) and all revised versions over the last 10 years to the current Guidance and FAQs issued March 2015 currently available.

Also details of the information gathering tools used for assessments and inspections by the HTA, specifically the various forms used over the last 10 years as the assessment process has evolved.

In addition I would like details of all reported incidents relating to fetal tissue / fetal remains / pregnancy remains / pregnancy loss / termination of pregnancy from the start of the HTA licenses up to 31 March 2015; I want details of the incidents without the organisations reporting them.

Specific details of my request are:

1. I would like to have all past versions of the HTA's

    a) Code(s) of Practice or Guidance documents covering everything related fetal tissue / fetal remains / pregnancy remains / pregnancy loss / termination of pregnancy;
    b) Disposal of pregnancy remains frequently asked questions (FAQs);
    c) Any 'interim' guidance issued since the start of the HTA in 2005 to those preceding the current documents available on your website dated March 2015.

2. Details of the information gathering tools used for assessments and inspections of the 'post mortem' sector by the HTA over the last 10 years; specifically the various forms used for desktop, onsite or self-assessments.

3. Details of all reported incidents relating to the fetal tissue / fetal remains / pregnancy loss / termination of pregnancy codes of practice and guidance from the beginning of the HTA licences to 31 March 2015 followed by the HTA response to each report. Information to be:

   a) Date of incident;
   b) Classification;
   c) Description of incident;
   d) HTA response."

Response

For the purposes of this response letter we will refer to the material you have specified (fetal tissue, fetal remains and pregnancy remains) as pregnancy remains.

I have broken your request down into the sections outlined below. In the instances where I have included a link to a document on the HTA's website, the information you have requested is exempt from disclosure in response to this request by virtue of section 21 of the FOIA, as it is easily accessible elsewhere. This is an absolute exemption under the FOIA and it does not need to be balanced against the public interest in disclosure.

1. All published versions of the HTA's Codes of Practice that relate to fetal tissue / fetal remains / pregnancy remains / pregnancy loss / termination of pregnancy since the HTA's formation

   Information about pregnancy remains is included in the HTA's Codes of Practice on consent, post-mortem examination and disposal of relevant material. The current versions of these are published on our website at the following links:

   Consent: https://www.hta.gov.uk/code-practice-1-consent
   Post-mortem examination: https://www.hta.gov.uk/code-practice-3-post-mortem-examination
   Disposal of relevant material: https://www.hta.gov.uk/code-practice-5-disposal

   The 2006 and 2009 versions of these Codes, which are superseded by those linked to above, are enclosed with this letter.

2. All published guidance documents that relate to fetal tissue / fetal remains / pregnancy remains / pregnancy loss / termination of pregnancy since the HTA's formation

   We have only published one formal guidance document regarding the disposal of pregnancy remains following pregnancy loss or termination. It was published in March 2015 and is available at the link below:
   https://www.hta.gov.uk/sites/default/files/Guidance_on_the_disposal_of_pregnancy_remains.pdf

This guidance does not apply to stillbirths and neonatal deaths. Nor does it apply to the disposal of embryos created in vitro for fertility treatment or embryo research, as there are separate laws governing each of these areas.

3. All published FAQs regarding the disposal of pregnancy remains since the HTA's formation

   We have only published one set of FAQs regarding the disposal of pregnancy remains, which is the set currently on our website at the following link: https://www.hta.gov.uk/faqs/disposal-pregnancy-remains-faqs

4. Any other 'interim' guidance issued since the start of the HTA in 2005 that precedes the current documents available on our website, dated March 2015

   We published interim guidance on the disposal of pregnancy remains following pregnancy loss or termination in July 2014. A copy of the guidance is enclosed with this response.

5. Details of the information gathering tools used for assessments and inspections of the 'post mortem' sector by the HTA over the last 10 years; specifically the various forms used for desktop, onsite or self-assessments

   We have read this request to mean all versions of the following since our formation:

   a) inspection report and inspection evidence templates used to gather evidence on inspection (for both office and site-visit inspections);
   b) application forms;
   c) self-assessment spreadsheet forms establishments have been or are asked to complete for compliance updates.

   We have enclosed copies of all current and archived documents listed above with this response.

6. Details of all reported incidents relating to fetal tissue / fetal remains / pregnancy loss / termination of pregnancy from the HTA's formation until 31 March 2015 followed by the HTA response to each report. To include:

   a) date of the incident;
   b) classification;
   c) description of incident;
   d) the HTA's response to the incident.

The HTA has required establishments licensed in the Post Mortem sector to report serious incidents since May 2010. These incidents are now known as HTA Reportable Incidents (HTARIs). We initially asked establishments to report any incidents which could fall into one of 11 classifications that, whilst not excluding the reporting of incidents involving pregnancy remains, did not include a classification specifically relating to pregnancy remains. This has

since been extended to 16 classifications, which now includes the following classifications that relate specifically to pregnancy remains:

- disposal or retention of a whole fetus or fetal tissue (gestational age less than 24 weeks) against the express wishes of the family;
- disposal or retention of a whole fetus or fetal tissue (gestational age greater than 24 weeks) against the express wishes of the family.

When an incident is reported to us, we work with the establishment to ensure that the root causes are identified and action is taken to reduce the likelihood of a similar incident happening again. We make sure that the establishment completes agreed actions, or is working to an agreed action plan, before we close the case. I have labelled the final column of the spreadsheet 'action taken to reduce the likelihood of a similar incident happening again' to reflect this.

We have undertaken a thorough search of our systems to find all incidents involving pregnancy remains that were reported to us between our formation in 2005 and 31 March 2015. The search found 36 incidents, of which two were reported prior to the introduction of the incident reporting requirement in May 2010. The information you requested about these incidents is provided in the enclosed spreadsheet.

You will note that we have provided the quarter of the business year that each incident was reported in and summaries of the incidents and HTA actions. Our reasons for this are set out below.

Section 31 FOIA

Section 31(1)(g) FOIA provides an exemption for 'the exercise by any public authority of its functions for any of certain specified purposes'. Those specified purposes include 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 (the Act), include superintending compliance with requirements imposed by, or under, Part 1 of the Act and with Codes of Practice made under the Act.

All establishments licensed in the Post Mortem sector are required to report HTARIs to the HTA, partly so that we can identify trends and share learning across the sector, but also so that we can identify establishments that may require additional oversight by the HTA. Whilst it is a regulatory requirement that licensed establishments must report HTARIs, we rely on establishments to supply detailed, frank and full accounts of incidents rather than adopting a 'tick box' approach to reporting HTARIs. Establishments are encouraged to supply all relevant information at an appropriate level of detail so that the HTA can consider what action to take on a case-by-case basis..

Our view is that the disclosure of the full incident description provided in HTARI reports in response to FOIA requests would have an adverse impact on the quality of HTARI reports supplied to us by licensed establishments, and in particular the level of detail supplied in the body of HTARI reports. Licensed establishments are currently very open with us when

completing HTARI reports, but the prospect of full disclosure under FOIA would be likely to result in a cautious and restrictive approach to HTARI reporting because of fear of adverse publicity on the part of establishments.

Our assessment is that if establishments were deterred from providing us with detailed and frank reports because of the prospect of disclosure, our supervisory functions would clearly be prejudiced in relation to licensed establishments, and it would be more difficult for us to assess the risk of reoccurrence and determine the appropriate regulatory response.

We are satisfied that full disclosure of the descriptions in the HTARI reports is information which, if disclosed, would prejudice our ability to exercise our regulatory functions insofar as they relate to the supervision of licensed centres and that section 31(1)(g) therefore applies.

Public interest test

Section 31 FOIA is a conditional or qualified exemption. This means that, even where it is considered to apply, it may be relied on only if the public interest in applying the exemption outweighs the public interest in disclosure.

We acknowledge that there is a significant public interest in accessing information regarding untoward incidents that take place in HTA licensed mortuaries and that there is also real public interest in access to information that relates to our effectiveness as a regulator. We also appreciate there is a public interest in openness and transparency generally. We are mindful that we are already providing summary information regarding HTARIs reported to the HTA between its formation in 2005 until 31 March 2015. This information gives a sufficiently full and fair indication of the nature of reported incidents and we are not satisfied that disclosure of the full descriptions provided in the reports would be likely to add significantly to public understanding of the issues.

There are a number of reasons why it would be contrary to the public interest for the full descriptions included in the initial reports to be disclosed. There is a very strong public interest in ensuring that licensed establishments are regulated effectively. As indicated above, the prospect of publication is likely to have an adverse effect on the quality of future HTARI reporting and there is a real risk that this in turn would have an adverse impact on our ability to scrutinise reported incidents and adherence to licence conditions and to identify cases where regulatory action is required.

Furthermore, we rely on the submission of full and frank HTARI reports from licensed establishments to enable us to identify trends or sector specific risks in order to issue alerts or guidance. The provision of frank and suitably detailed reports makes a very important contribution to our ability to raise standards and take appropriate action to prevent similar incidents happening elsewhere. In order to carry out this work, we need access to detailed information about incidents and the events which lead to them. It is clearly in the public interest that establishments should not be inhibited from supplying us with information at the necessary level of detail.

In view of the very considerable public interest in ensuring that licensed establishments should not be deterred from supplying us with the information we require in order to discharge our regulatory functions and promote safe practice, we have concluded that the

public interest test in this case favours the application of the section 31(g) exemption to justify the summary disclosure rather than the full incident report. We do not believe that the public interest would be served by providing a further level of detail which may jeopardise the effectiveness of the HTARI notification system, which in turn would reduce the effectiveness of our regulatory activity in this area.

Section 40 FOIA

The incident descriptions have been summarised to remove all personal data and dates which could be used to identify mothers of fetuses of less than 24 weeks gestation, the families of fetuses of more than 24 weeks gestation and any establishment staff members involved in the incident. This is because this data is exempt from disclosure by virtue of the fact that it is personal data, disclosure of which would be unfair to the individuals concerned, or which is confidential information relating to fetuses of more than 24 weeks gestation which could amount to personal data relating to the families involved. Please note that pregnancy remains of less than 24 weeks gestation are regarded as tissue of the mother under current legislation.

Section 40(3)(a)(i) FOIA provides that information is absolutely exempt if its disclosure would breach any of the Data Protection Act's data protection principles. Insofar as the descriptions contain information relating to identifiable staff members, the mothers and the families involved, we have concluded that disclosure under FOIA would breach the first data protection principle. This is because it would be unfair to the individuals referred to in the incident descriptions, who could have no expectation that information relating to them in the incident report descriptions would be made public.

In accordance with section 40 of the FOIA the descriptions provided in this response have been summarised so that they do not include any information which could lead to a person or fetus being identified, such as the names of staff and patients. We are releasing only the quarter of the business year the incidents took place in so to not provide personal information in relation to the date of miscarriages and terminations of pregnancy.

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

There is no charge for making an appeal.

Yours sincerely

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