Human Tissue Authority
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London
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Tel 020 7269 1900
Web www.hta.gov.uk
Email enquiries@hta.gov.uk
Date 28 March 2018

[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 5 March 2018. I have arranged for a Regulation Manager to contact you to discuss your enquiry and to see if we can be of any further assistance in this matter. In the meantime, I have set out the HTA's response below.

Your email outlined the following request:

> Dear Sir/Madam,
>
> I understand there are several centres in the UK that are licensed to perform ovarian tissue preservation and transplantation with the purpose of fertility preservation for patients who undergoing cancer treatment. Under freedom of information act could you please provide me with information about what quality indicators are used to ensure the process can result in meaningful for patient results. And which ongoing quality checks of post-cryopreservation tissues are undertaken to ensure the outcomes following processing meets the criteria of set quality indicators.
>
> Thank you very much for your information.

Response

It is a requirement of Annex II of EU Directive 2006/86/EC that establishments that process tissues or cells intended for human application must ensure that critical processing procedures are validated and do not render the tissues or cells clinically ineffective or harmful to the recipient. It is also a requirement of the legislation that

the processing procedures must undergo regular critical evaluation to ensure that they continue to achieve the intended results.

These requirements are reproduced in the HTA's 'Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment' (the Guide) which forms the Annex to HTA Directions 003/2010. The Guide also sets out that the critical quality attributes of the given tissues or cells must be defined and described, as well as the methodologies required to achieve those specifications. Reagents and materials required to achieve or maintain the critical quality attributes (CQAs) of the tissues and cells must be listed and subject to acceptance controls. All critical equipment should be identified and be subject to appropriate controls.

The legislation does not, however, define the acceptance criteria for specific types of tissue or cells. In light of this, prior to processing a new tissue or cell type, establishments must provide the HTA with evidence that the above quality control measures and validation requirements have been met. Validation may be based on studies performed by the establishment itself, or on data from published studies or, for well-established processing procedures, by retrospective evaluation of the clinical results for tissues supplied by the establishment. The HTA has issued further guidance on the validation of preparation processes here .

The validation report should specify the CQAs and critical process parameters (CPPs) and include evidence that demonstrates that their use will ensure that tissues or cells are not rendered clinically ineffective or harmful by the preparation process. For ovarian tissue, such CQAs and CPPs can include, for example, follicle numbers, viability and morphology both pre-and post-cryopreservation, absence of histological evidence of malignancy within the tissue, lack of microbial contamination, and the time and temperature in transit prior to processing. However, the establishment must define these acceptance criteria and provide evidence to support their use.

Establishments must also have a documented process for the regular critical evaluation of its processing methodologies to ensure that they continue to achieve the intended results. As above, the establishment must define the tests that will be performed to meet this requirement and have evidence to support their use. For novel therapies, the tests performed, and the processing methodologies being followed, should be reviewed frequently to ensure that they take into account developments in the field. In the event that significant changes need to be made to the processing methodology being used, the modified process must first be validated and documented. There should also be regular review and evaluation of the cumulative effects of minor changes to the processing method. A documented risk assessment must be carried out to decide the fate of any tissue and or cells stored prior to the introduction of a new processing step, which affects the quality and safety of the tissue or cells.

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

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