

Dear

FREEDOM OF INFORMATION – MEDICAL DEVICES POLICY

I write in response to your request for information in relation to NHS Lothian's Medical Devices Policy.

Question:

1. Please provide the date when your medical device (as defined by MHRA, i.e. also including relevant software) procurement policy (or policies, if you e.g. have a separate one for medical software) was/were last updated.

Answer:

The last approval date of the Medical Devices Policy was 7 June 2022. The policy is publicly available on NHS Lothian's Policy Online website here: https://policyonline.nhslothian.scot/wp-content/uploads/2023/03/Medical_Devices_Policy.pdf

This information is exempt under Section 25 of the Freedom of Information (Scotland) Act 2002 - Information otherwise accessible

- (1) Information which the applicant can reasonably obtain other than by requesting it under section 1(1) is exempt information.

Question:

2. Please state whether the policy (mentioned in point 1 above) requires that a clinical ethicist should be consulted during purchase decisions (if a clinical ethicist is only needs to be consulted under certain conditions, please list these). A clinical ethicist is defined as a member of your clinical ethics committee (under whatever name it operates in your organisation, but this does not include research ethics committees) or an academic with a dedicated post in ethics or a permanent staff members explicitly employed to provide clinical ethics support.

Answer:

No, the policy does not require this.

Question:

3. If the policy requires ethical issues to be considered during such device purchase decisions, but not via input of a clinical ethicist as defined above, please state the mechanisms in place for fulfilling that requirement.

Answer:

The policy does not require this.

Question:

4. Please state whether you had clinical ethicist (as defined above) involvement in the purchase of any clinical artificial intelligence applications irrespective of whether this is mandated by your policy.

Answer:

No, there has not been clinical ethicist involvement in any purchases.

I hope the information provided helps with your request.

If you are unhappy with our response to your request, you do have the right to request us to review it. Your request should be made within 40 working days of receipt of this letter, and we will reply within 20 working days of receipt. If our decision is unchanged following a review and you remain dissatisfied with this, you then have the right to make a formal complaint to the Scottish Information Commissioner within 6 months of receipt of our review response. You can do this by using the Scottish Information Commissioner's Office online appeals service at <https://www.foi.scot/appeal>. If you remain dissatisfied with the Commissioner's response you then have the option to appeal to the Court of Session on a point of law.

If you require a review of our decision to be carried out, please write to the reviewer at the address at the top of this letter. The review will be undertaken by a Reviewer who was not involved in the original decision-making process.

FOI responses (subject to redaction of personal information) may appear on NHS Lothian's Freedom of Information website at: <https://org.nhsllothian.scot/FOI>

Yours sincerely

ALISON MACDONALD

Executive Director of Nursing Midwifery and AHPs

Cc: Chief Executive