

Ref. No: 505020222
From: Commercial
Date: 02/02/22

REQUEST & RESPONSE

Having reviewed your website and policies, I am unable to obtain the relevant documents, which is why I have made this request. I would like to know which documents are used for the review and approval of new medical devices within your NHS Trust/entity.

The exact naming of the documents may differ, but the context is the same, so we ask for judgement to be used, and please let us know if you require further clarification.

1. Could you please provide a copy of the Trusts/entity "New Medical Device policy?"

Please see attached- Management of Medical Devices Policy, Version 4, approved by the Patient Safety Council on 8th December 2021

2. Could you please provide a copy of the Trusts/entity "Medical Devices and Procurement Review Group policy?"

Please see attached -Procurement Manual, Version 1, approved by the Procurement Steering Council on 4th September 2020.

3. Could you please provide a copy of the Trusts/entity "Business case template for new medical devices or technology" for new medical/diagnostic device approval?

Please see attached - Business Case template for St Helens and Knowsley Teaching Hospitals NHS Trust.

4. Could you please provide a list of all approved medical devices in your Trusts/entity? Excel format, word or PDF is fine.

The Trust does not have a list of approved medical devices

5. Could you please provide a copy of the policy which supports "medical devices on trial requirements".

Please see attached -Management of Medical Devices Policy, Version 4 Section 6.2.5 and 6.2.6 Page 20

6. Could you please provide the policy for including a new pathology test within the Trusts/entity?

- a. **5.5 Examination Process**
- b. **CHANGE CONTROL: Change Control Checklist**
- c. **Pathology Change Control**
- d. **Pathology Equipment Acceptance Testing**
- e. **Pathology Examination Procedure Verification and Review**

7. Could you please provide the policy for the “New medical Product Selection Group”

Terms of Reference for Medical Devices Group

8. Could you please confirm how often new medical device review meetings take place?

Bi-monthly Medical Devices Group meetings

9. Could you please provide me the name of the staff member responsible for finances of new medical devices and their email address.

Head of Capital and Treasury Services Simon.Collins@sthk.nhs.uk

10. Could you please provide me the name of the staff member responsible for procurement of new medical devices and their email address.

Head of Procurement Chris.McNamara@sthk.nhs.uk

11. Lastly, could you please supply a copy of the last 3 ‘New Medical Device meeting’ minutes and also the location of where they are published on your website?

Yes –

- **September 7th 2021**
- **November 19th 2021**
- **January 12th 2022**