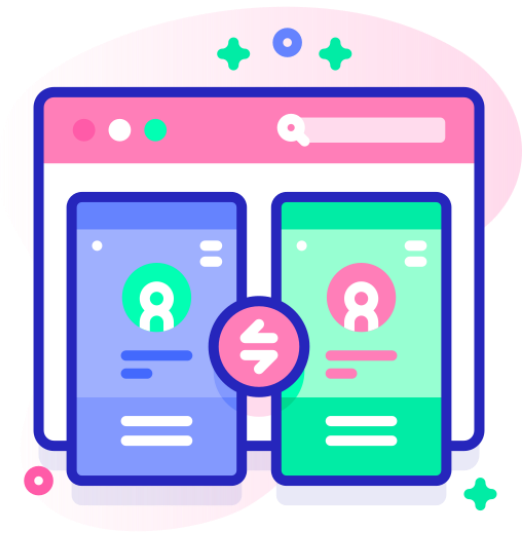
PILOT STUDIES WITHIN THE NHS.

A Quick Overview of Requirements for HealthTech Companies.

First of all, not all pilot studies are the same.

Broadly speaking, there are 3 categories:



User testing and feedback

Simulation studies

Clinical studies

The level of compliance you need to demonstrate is highly dependant on what type of study you are running.

If you are just **beta-testing** your product with a team of clinicians using no real patient data.

There is no other paperwork required.

Same goes with **simulation studies**.

However, if you are testing your product in a **clinical setting**, involving **real patients**,

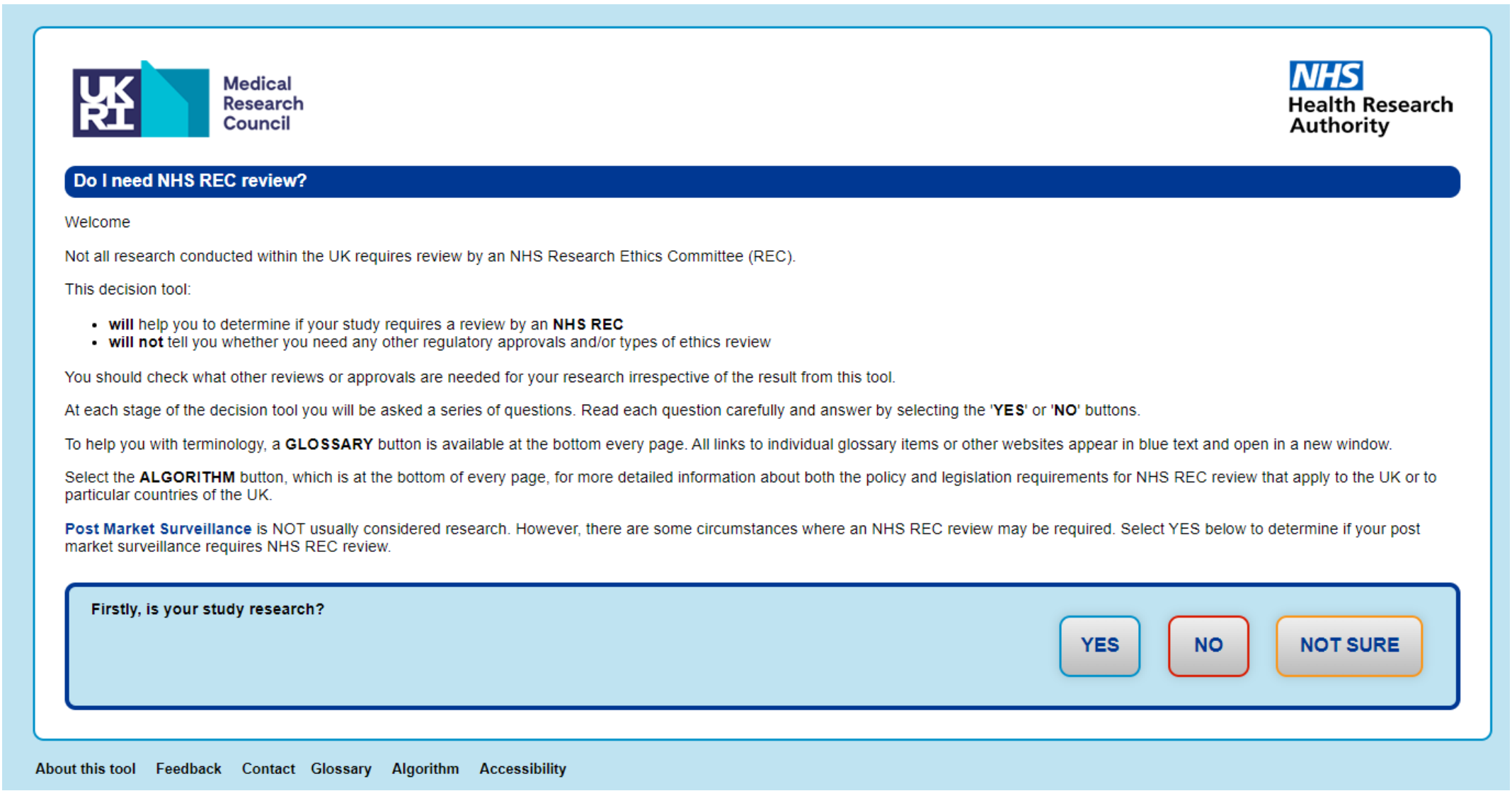
You will then have to consider the following **5 requirements**:

- **Ethics Approval**
- **MHRA Notification**
- **Information Governance**
- **Data security protection toolkit**
- **Data Protection Impact Assessment**

ETHICS APPROVAL

Ethical approval is required for **Clinical Trials** or studies involving the use of **Medical Devices**.

You can refer to this very helpful tool by the **UKRI** to determine whether your research project require NHS Ethics approval.



https://www.hra-decisiontools.org.uk/ethics/

MHRA NOTIFICATION

You may need to carry out a **clinical investigation** as part of the process to obtain a **UKCA / CE / CE UKNI** marking for your **medical device**.

You must inform the MHRA if you are planning to do this **at least 60 days** before starting your investigation.

GOV.UK Menu

Home > Health and social care > Medicines, medical devices > Clinical trials and investigations

Guidance

Notify the MHRA about a clinical investigation for a medical device

How to notify the MHRA of your intention to carry out a clinical investigation for medical devices.

From: Medicines and Healthcare products Regulatory Agency

Published 18 December 2014

Last updated 21 September 2023 — See all updates

https://www.gov.uk/guidance/notify-mhra-about-a-clinical-investigation-for-a-medical-device

INFORMATION GOVERNANCE

The Caldicott process ensure health and care information is used ethically, legally and appropriately.

Many health authorities will require **a Caldicott form** to be completed prior to the commencement of any research project involving patient information.

https://www.ukcgc.uk/

DATA SECURITY PROTECTION TOOLKIT

The DSPT is an online self-assessment tool that allows organisations to measure their performance against the National Data Guardian's 10 data security standards.

All organisations that have access to NHS patient data and systems **must** use this toolkit to provide assurance that they are practising good data security and that personal information is handled correctly.

NHS England

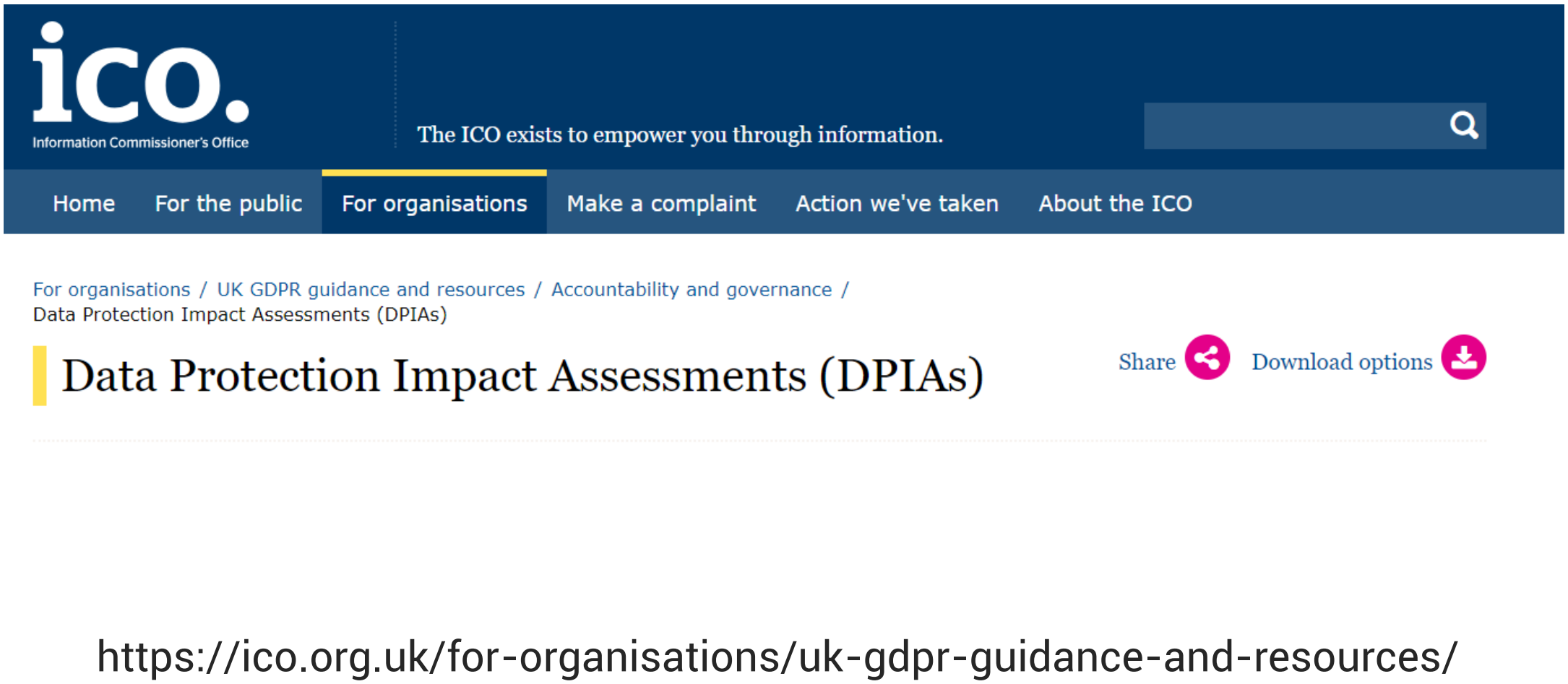
Data Security and Protection Toolkit

https://www.dsptoolkit.nhs.uk/

DATA PROTECTION IMPACT ASSESSMENT

Under the UK GDPR, you are **legally BINDED** to produce a DPIA if the data processing activities are 'likely to result in high risk'.

Healthcare data processing falls under the higher risk category and **therefore this is mandatory**.



https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/

Hope you found this helpful!

This is a series we are making to help HealthTech Innovators access better resources.

Just our small way of helping!