



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**

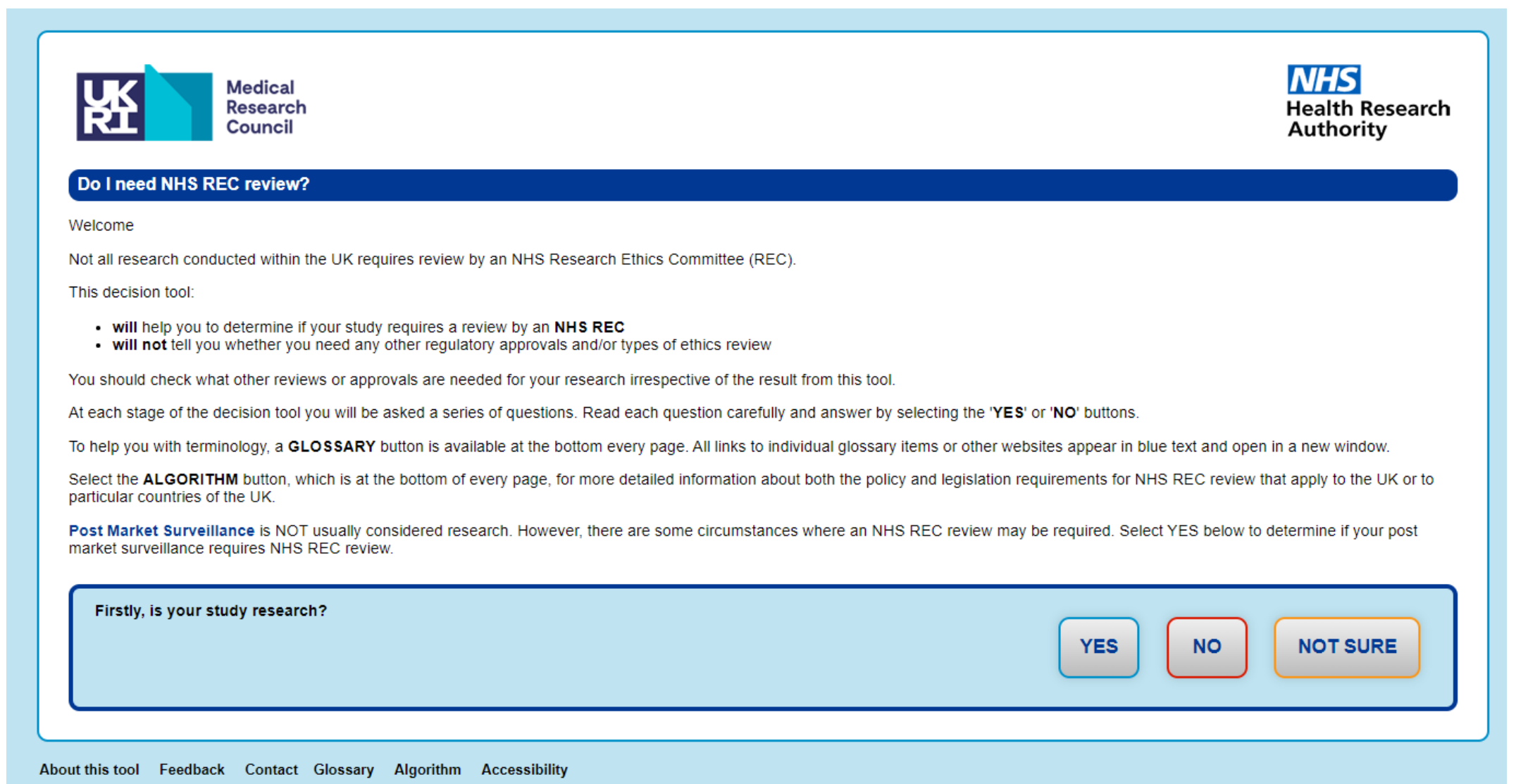
. **Data security protection toolkit**

. **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.



The screenshot shows the NHS REC decision tool interface. At the top left is the UKRI Medical Research Council logo, and at the top right is the NHS Health Research Authority logo. Below the logos is a blue header bar with the text "Do I need NHS REC review?". The main content area contains a welcome message, a brief introduction to the tool, and a list of bullet points: "will help you to determine if your study requires a review by an NHS REC" and "will not tell you whether you need any other regulatory approvals and/or types of ethics review". Below this is a question: "Firstly, is your study research?". At the bottom right of this question are three buttons: "YES", "NO", and "NOT SURE". At the very bottom of the page is a navigation bar with links: "About this tool", "Feedback", "Contact", "Glossary", "Algorithm", and "Accessibility".

<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.

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](#)

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.

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We are the national body for Caldicott Guardians in the UK

A Caldicott Guardian is a senior person responsible for protecting the confidentiality of people's health and care information and making sure it is used properly. We provide practical support, resources and networking opportunities for Caldicott Guardians and those fulfilling the Caldicott function within their organisations. We help people to uphold the eight [Caldicott Principles](#).



National Data Guardian guidance on Caldicott Guardians



Are you a new Caldicott Guardian looking for help?



National Data Guardian guidance on evaluating public benefit



NHS information governance portal

<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.



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.**

The screenshot shows the top of the Information Commissioner's Office (ICO) website. On the left is the 'ico.' logo with 'Information Commissioner's Office' underneath. To the right is the tagline 'The ICO exists to empower you through information.' and a search bar. Below this is a dark blue navigation bar with the following links: Home, For the public, For organisations (highlighted with a yellow underline), Make a complaint, Action we've taken, and About the ICO.

[For organisations](#) / [UK GDPR guidance and resources](#) / [Accountability and governance](#) / [Data Protection Impact Assessments \(DPIAs\)](#)

Data Protection Impact Assessments (DPIAs)

Share  Download options 

<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!