NHS Screening Programme Research Enquiries

NHS Screening Programme Impact Triage and Advice Scoping Tool

What this tool is for

This tool supports the identification and assessment of potential impacts of proposed research and related activity on NHS screening programmes.

- Identify potential risks, harms and operational impacts
- Support early triage and proportionate review
- Inform whether further advice or assessment is required

This tool is advisory and does not replace HRA, REC or other approvals.

Who completes which part

- The applicant completes Stage 1, Stage 2 and Stage 3

How it works

- Stage 1 — Factual questions about what your research does.
- Stage 2 and Stage 3 — Additional questions to support Stage 1.

Process map for using this form

This process map shows how applicants and NHS England use the triage and advice scoping tool from initial enquiry through to outcome recommendation.

Step	Applicant action	NHS England action	Output / decision
1	Confirm the research relates to an NHS population screening programme.	Advise whether the form is required if scope is unclear.	Proceed with the form, or confirm it is not required.
2	Complete applicant details and Stage 1 trigger questions.	Check completeness and identify which triggers have been flagged.	Initial trigger position recorded.
3	If no Stage 1 triggers apply, submit the form after Stage 1.	Review the Stage 1 responses and confirm whether further information is needed.	Outcome recommendation issued or clarification requested.

4	If any Stage 1 trigger applies, complete Stage 2 and the relevant Stage 3 sections using the trigger mapping table.	Check that the relevant Stage 3 sections have been completed and that the scale, risk and mitigation information is sufficient.	Complete information pack available for triage.
5	Provide any clarification, supporting documents or revised wording requested.	Assess questions, scale, pathway impact, data/IG issues, service impact, equity and safety monitoring.	Triage view formed.
6	Respond to further queries if escalation or expert advice is needed.	Escalate to appropriate programme, policy, data, clinical, QA or Expert Reference Group advice where required.	Advice route agreed.
7	Receive the outcome recommendation and address any actions or conditions before progressing the research.	Issue the outcome recommendation, including any conditions, caveats, further advice routes or reasons why progression is not supported.	Outcome recommendation recorded and communicated.
8	Keep NHS England informed if the proposal changes after advice is issued.	Review material changes and confirm whether further triage or advice is required.	Advice remains current, or revised advice is requested.

Key decision points

- If the research does not relate to an NHS population screening programme, the impact assessment is not required.
- If no Stage 1 trigger applies, NHS England can usually provide an outcome recommendation after Stage 1 review.
- If any Stage 1 trigger applies, Stage 2 and the relevant Stage 3 sections are required.
- Red lines, unresolved safety concerns, unclear accountability, significant pathway impact or national system implications may require escalation or expert advice.

Before you start — is this form for you?

Complete the impact assessment only if your research relates in some way to an NHS population screening programme: antenatal and newborn programmes (foetal anomaly, infectious diseases in pregnancy, newborn blood spot, newborn hearing, newborn and infant physical examination, and sickle cell and thalassaemia) or young person and adult programmes (abdominal aortic aneurysm, bowel, breast, cervical, and diabetic eye).

If your research is not related to one of these screening programmes, you do not need to complete this form.

Stage 2 — Scale and the risk of change

Scale and Risk

Most research touches the pathway in some way. Scope alone does not determine NHS England's interest; these questions assess the scale and risk of the change.

S1. Who is affected by or involved in this research?

When answering consider the points below (these are illustrations, not options):

NHS England is generally less concerned where…	NHS England is generally more concerned where…
• only people who consented to research are affected • participants can opt out and return to standard screening	• the live invited population is affected without opting into research • groups may be less able to question or opt out

S2. How many people are affected, and over what footprint?

When answering consider the points below (these are illustrations, not options):

NHS England is generally less concerned where…	NHS England is generally more concerned where…
• it is limited to a single site or a small defined cohort • it is a time-limited pilot	• it covers a whole region or national rollout • it is open-ended or scales rapidly

S3. What possible harms could be caused and how are they mitigated?

When answering consider the points below (these are illustrations, not options):

NHS England is generally less concerned where…	NHS England is generally more concerned where…
• there is clear mitigation of risk of harm built into the research	• there are unnecessary and avoidable harms created and no/limited mitigations in place

S4. How will the research be carried out?

When answering consider the points below (these are illustrations, not options):

NHS England is generally less concerned where…	NHS England is generally more concerned where…
• it uses retrospective data or a separate research pathway	• it runs inside the live screening service

• the live service is not altered	• real screening decisions depend on it while it runs

Stage 3 — Detailed follow-up

Which sections apply to you

If you flagged…	…complete section
T1, T2, T6, T13	3.1 — Change to the test, threshold, examiner, pathway step, national standard or QA requirement, including adding a new test, analyte, biomarker or condition
T3	3.2 — Change to information, offer or consent
T4	3.3 — Change to a significant personal or reproductive decision
T5	3.4 — Effects on relatives, partners or others not screened
T7, T14	3.5 — Change to who is invited, eligible, followed up or otherwise experiences the screening pathway differently, including equity impacts
T9	3.6 — Presentation as the national screening programme and clarity for participants, services and the public
T8	3.7 — Service delivery, frontline staff workload and operational capacity
T10, T11	3.8 — Data, information governance, live screening datasets and national IT system changes
T12	3.9 — Managing clinical, incidental or safeguarding findings about individuals
Any trigger	3.10 — Safety, monitoring and rollback

Worked examples (guidance for applicants)

These examples are for guidance only. They illustrate the difference between responses that clearly disclose contact with the screening pathway and responses that obscure it.

Applications are not assessed against the wording used here. The purpose is to support accurate, transparent description of whether, and how, the research interacts with the screening pathway.

Example 1 — Does it touch the pathway?

Transparent disclosure

"The study is observational, but it uses the live call/recall dataset and, in phase 2, sends an additional reminder to non-responders, so some participants receive something different."

- States plainly which triggers apply
- Names the actual points of contact
- Lets us advise on exactly the right things

Example 2 — A threshold change

Transparent disclosure

"We propose lowering the diagnostic referral threshold from X to Y. This may raise early detection but also false positives and colonoscopy demand by an estimated 10–15%."

- Gives the actual change
- Quantifies the knock-on effect
- Surfaces the harm rather than burying it

Example 3 — Findings about individuals

Transparent disclosure

"The imaging sub-study may reveal incidental findings requiring clinical follow-up. A named consultant will review these within 48 hours and inform the participant's GP."

- Names the kind of finding
- Gives the route and the responsible role
- Shows the participant is not left in limbo

Describing the risk itself

The examples above focus on acknowledging that the research interacts with the screening pathway. The following examples address the more demanding task of describing risk in a way that enables appropriate review and action. Statements such as "minimal risk" or "could cause harm" are insufficient on their own. A useful risk description distinguishes likelihood from severity, explains the causal chain through which the change may lead to harm, and considers the downstream consequences beyond the initial effect.

Example 4 — Likelihood is not the same as severity

Distinguishes likelihood from severity

"A falsely reassuring result would be rare (estimated <1%), but for an affected pregnancy the consequence is severe and effectively irreversible — a missed condition that earlier detection would have changed. So this is a low-likelihood, high-severity risk, which is why we monitor it despite the low rate."

- States likelihood and severity as two separate things
- Names who carries the harm and how bad it is for them
- Explains why a rare risk still warrants attention

Example 5 — Show the chain of harm

Describes the mechanism step by step

"If sampling moves earlier, some babies will be tested before metabolite levels have risen to a detectable range; those cases would return a false negative; the condition would then be missed until the infant became symptomatic, by which point treatment is less effective. The harm is the delay, and it falls on the small number of affected infants sampled too early."

- Traces change → false negative → missed condition → delayed treatment
- Each step is checkable, so we can advise on where to break the chain
- Names the actual harm (delay) and who bears it

Example 6 — Follow the harm downstream

Considers the chain beyond the immediate effect

"Halving appointment volume eases capacity in year one. But over a two-year interval, a subset with fast-progressing retinopathy would now be detected later; some of those would progress to sight-threatening disease that annual screening would have caught; and the resulting referrals would arrive at treatment services in a delayed, possibly clustered way. The capacity gained upstream partly reappears downstream as more urgent, later-stage treatment."

- Carries the analysis past the immediate benefit
- Names the subgroup who lose out and the harm they face
- Shows the downstream and cumulative effect, not just the first-order one

Example 7 — Describe what happens when it partly works

Describes failure and partial implementation scenarios

"If the tool works as intended, workload falls. But if it is adopted in only some units, women in different areas get effectively different reading standards; and during transition, running human-only and AI-assisted reading in parallel is the riskiest state, because responsibility for a missed cancer becomes unclear. We treat the transition period, not the end state, as the main risk."

- Names what the half-implemented version does to real people
- Identifies the transition as the danger point
- Gives us the actual thing to advise on, not the success story

Example 8 — Say who the change does not reach

Identifies those not reached by the change

"Self-sampling should raise uptake among under-screened groups. But it relies on postal address accuracy and literacy in the invitation language; people with no fixed address, or for whom the materials are not accessible, may be further disadvantaged as the mainstream route receives less attention. We will monitor uptake by these subgroups, not just the overall rate."

- Distinguishes who benefits from who is missed
- Names the specific groups at risk of being left behind
- Commits to watching the denominator, not just the headline number

Example 9 — Be honest about what cannot be undone

Acknowledges irreversibility transparently

"We can stop issuing the revised invitation at any point, but men who were not invited, or invited late, during the pilot cannot have that window returned — for a fast-expanding aneurysm a missed scan is not recoverable. So "stopping" limits future exposure but does not undo harm already done; our monitoring therefore has to be near-real-time, not retrospective."

- Separates stopping the change from undoing its effects
- Names the harm that is already irreversible at the point of stopping
- Explains why that forces faster monitoring