National Institute for Health Research

FASTER, EASIER CLINICAL RESEARCH

Introduction

The vision of the National Institute for Health Research (NIHR) is to improve the health and wealth of the nation through research. This document sets out how the NIHR works to influence the improving performance in the initiation and delivery of research in the NHS.

Context and approach

The NHS is a unique resource for health research in this country. Significant improvements have been made by funders and researchers in recent years in the time taken to get research in the NHS started and completed, There is still work to be done to make research faster and easier with a focus on outcomes so that research findings can benefit patients and the public more quickly and so that we can make this country a competitive location for life science industry research. In the context of the low risk involved in research, for some organisations this will involve a shift of focus from whether a researcher should be 'permitted' to carry out a study, to how the provider can deliver a study that is ethical, wherever it has the capability and capacity to do so.

The Department of Health (DH) and the NIHR want to influence the improving performance in the initiation and delivery of research in the NHS. The NIHR's approach is to**:**

a) make **NHS providers' performance in starting and delivering research transparent and accountable**, through changes to NIHR contracts, which includes a 70 day benchmark for initiation of research.
b) **provide support to help the NHS improve performance**, for example, through the NHIR Research Support Services framework.
c) **work with the HRA** to simplify approval processes for ethical research.

Taking these elements of the NIHR's approach in turn:

a) NHS providers' performance transparent with greater Trust accountability

The Government wishes to see a sustained improvement in the initiation and delivery of clinical trials to speed up benefits for patients and to develop the UK's competitive advantage including in the life sciences industry.

In support of this aim, NIHR contracts with providers of NHS services have for a number of years included requirements on the timeliness with which all clinical trials are undertaken by the contractor. Initial requirements are about reporting and publishing performance on the time it takes from receipt of a valid application for the trust to recruit the first patient to clinical trials; for commercial clinical trials the measure is on recruitment to time and target.

Providers who have been subject to the contract requirements for at least twelve months may find that their performance in recruiting the first patient to a trial can affect their funding. An element of research capability funding is being linked to performance in recruiting the first patient to a trial within 70 days of receipt of a valid research application.

Since April 2014, similar requirements have been included in contracts between DH and hosts of NIHR Local Clinical Research Networks (LCRNs), as well as in contracts or other forms of agreement between LCRN hosts and significantly research-active providers in their patch.

The NIHR's aim is to achieve a shared ambition of improving performance, not to catch organisations out, and we will be reasonable in any action. Even where organisations are not subject to the contract requirements, they should begin demonstrating their performance to research sponsors through monitoring and improvement. Further information is at www.nihr.ac.uk/policy-and-standards/Performance-in-initiating-and-delivering-research.htm and the platform for submission of performance data is at https://ccfctp.nihr.ac.uk/.

b) Provide support to help the NHS improve performance

Learning gathered from NHS organisations suggests that in order to make clinical research faster and easier in the NHS, it helps significantly if:

- The Board, researchers and managers work together in a partnership, developing and engaging others in a clear integrated approach to research.
- Organisations measure how long it takes to start studies and their progress with recruitment against target, and use this data to monitor performance, identify issues needing attention and plan and take action.
- Organisations develop a research management culture that understands and promotes the benefits of research to patients, is pragmatic and proportionate about risk (for example accepting credible assurances from others) and proactive in planning and managing studies throughout their life cycle, including recruitment.

Other learning shared with the NIHR by individual providers also found that performance in initiating and delivering research was improved by: refocusing R&D office staff from permission to delivery, monitoring performance, including board level KPIs, and taking action; marshalling public demand for opportunities to participate; pooling research nurses; developing lists of research-ready patients.

The NIHR's **Research Support Services (RSS) framework** (www.nihr.ac.uk/policy-and-standards/framework-for-research-support-services.htm) helps to facilitate a proactive approach to start-up of research, that enables providers and in particular their research managers to take a consistent, streamlined and risk-proportionate approach to considering their participation in research. This framework of tools includes:

- An Operational Capability Statement (OCS), to be tailored and agreed by each provider's Board or chief executive and showing the organisations strengths, interests and commitment to health research. The feedback received is that the process of developing the statements and getting Board agreement is helpful in clarifying an organisation's approach to research and its priorities, enabling staff to unite behind this more effectively. Organisations' OCSs can be added and viewed at www.nihr.ac.uk/policy-and-standards/rss-operational-capability-statement.htm.

- Planning tools that enable research managers, with the principal investigator, to identify and assess early and quickly any aspects of a study, which may cause delay so these can be proactively managed to inform the decision on whether and how the organisation will participate and avoid later problems.
- Guidelines for effective local standard operating procedures to help develop consistent, streamlined and risk-proportionate research management practice across the NHS in England.
- Competencies and induction information for Research and Development staff developed as an easy reference guide bringing together information from a range of sources. The two documents can be used alongside each other to help build knowledge, skills and support development.

c) Working with the Health Research Authority

The Health Research Authority (HRA) protects and promotes the interests of research participants and potential participants and the general public in health research and social care research. It does this by facilitating the conduct of research that is safe and ethical while enabling people to benefit from participating in research by simplifying the processes involved in approving ethical research. The Government established the HRA as a non-Departmental public body on 1 January 2015 through the Care Act 2014 to give it even greater independence and stability than it previously had as a special health authority.

The NIHR has worked closely with the HRA to support the creation of HRA Approval which was launched on 31 March 2016.

HRA Approval is now the unified approval process for research in the NHS in England. The new system simplifies the approvals process for research, making it easier for research studies to be set up and eliminating duplicate application routes. It brings together the assessment of governance and legal compliance and replaces the need for local checks of legal compliance and related matters by each participating organisation in England. This allows participating organisations to focus their resources on assessing, arranging and confirming their capacity and capability to deliver research studies. Patients will benefit from research into improved patient care and new treatments that is completed more quickly and research funding being dedicated to delivery of research rather than the navigation of complex approval systems.

More information can be found at: http://www.hra.nhs.uk/about-the-hra/our-plans-and-projects/assessment-approval/

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