HRA Approval
Benefit Realisation Plan

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This is the benefits realisation plan for the HRA Approval Programme.

Supporting each benefit identified will be a detailed data collection and analysis plan. These plans will be held on the HRA Shared Drive at G:\Shared Drive\HRA Approval Programme\Working - HRA internal\HRA Approval Programme documents\Benefits Realisation.

This folder is accessible to members of the HRA Approval Programme Team and members of the HRA Executive Management Team.
1. Executive Summary

The Benefit Realisation Plan provides details of how the benefits process will be applied to the programme. It describes the tasks, resources, time frame and approach to each step of the framework.

The intention of the HRA Approval programme is to achieve benefits for all parts of the health research environment:

For researchers – less time and effort setting up studies, with predictable and managed timelines
For participants – increased confidence in participation in research
For patients – more evidence from research to improve patient care
For public – more efficient use of tax payers’ money and research charity donations
For funders, including industry – more research funding spent on research rather than on paperwork and delays
For industry – delivery from investment in UK
For government – contribute to the UK economy by encouraging health research
For NHS – improve effectiveness and productivity of the NHS

As a continuing plan that will be reviewed and refined over time, the Benefit Realisation Plan aims to:

- Validate that the benefits described and their proposed measures are realistic and complete
- Manage the realisation and measurement of benefits
- Manage expectations of stakeholders
- Encourage ownership of benefit measurement by relevant stakeholders
- Ensure that realised benefits are described, communicated and adopted by stakeholders

The HRA has set an ambition to implement HRA Approval for all studies by the end of 2015. The HRA is refining the ambition into a detailed programme plan with phased roll out of HRA Approval during 2015. The expectation is that the longer term benefits of the programme will not be fully accrued until 2016. However, it will be important to achieve benefits for sub-sets of studies or from components of the process as early as possible and during the 2015 roll out phase.

Most of the elements of the plan have significant interdependencies on each other as well as on the NHS research landscape as a whole. The realisation of benefits from the programme relies on a combination of internal HRA activities, external activities and mutually dependent activities by partners. Although these dependencies add complexities to the measurement and monitoring of benefits, it is also anticipated that the overall benefits achieved by the combination will be greater than the sum of the parts.
It is also important to acknowledge that a range of other improvement activities by HRA and by others are anticipated to synergise with the HRA Approval programme. Some of these broader activities have been instigated in recognition of the inter-relationships between different parts of the regulatory system. The HRA’s broader Collaboration & Development programme includes related activities such as supporting non-commercial sponsors in creating and sharing good practice, and the development of protocol templates.

The implementation of HRA Approval will contribute to the creation of a more integrated regulatory system for health research. The assessment will include confirming to the applicant and to NHS sites that all relevant regulatory approvals are in place. This step has the potential to support further coordination and streamlining between regulators.

Although certain activities have measures within current processes, it must be recognised that the changes to the processes and systems envisaged by the programme will mean that many of these baseline measures cannot be extrapolated into the future: equivalent time points will not exist. For the purposes of ensuring fair comparison, some measures will be tracked through equivalent (or as near as possible) comparators. However, new measures will also be adopted, in recognition that one of the current identified issues is the absence of national measurement of parts of the existing system, leading to an incomplete picture.

Where data is currently not collected routinely, instead of creating a burden by purposive baseline data collection, a range of external parties have been identified that hold datasets for their internal purposes. These parties are being invited to prospectively collect similar datasets over the course of implementation of the programme to measure performance over time. These measures will have the benefit of using metrics for which data collection methods already exist, and also metrics that are meaningful to that party.
2. Definition

Benefits realisation is the process of identifying, planning, achieving and monitoring benefits. Responsibilities for carrying out these activities and the timelines will be described. Importantly, the process includes the arrangements for communicating the benefits to gain acceptance by the relevant stakeholders.

Some of the end benefits will be realised by a range of users – funders, industry, researchers, and NHS organisations – and therefore the HRA will be reliant on the contribution of these parties in order to track these benefits in an efficient way. The plan outlines the approach that will be taken to demonstrate these end user benefits through case studies.

3. Benefits Management Cycle

This cycle allows refinement of definitions and plans in response to information uncovered during implementation, more detailed analysis or external changes in the environment.

This cyclical process is consistent with the iterative approach to implementation in the programme plan, which allows for testing and refinement through controlled, phased roll out.
It will be important to review the overall programme plan and confirm decisions to proceed to next steps in the programme in the light of the information captured through benefits realisation. If anticipated benefits are not accrued, this may be because the business change has not been adequately implemented, or it may be because of unforeseen inhibitors.

4. Business Case Benefits Reconciliation

This section sets out the strategic vision for the programme and identifies the strategic objectives that the programme must deliver.

| The overall vision of the programme is to make it easier to undertake responsible health research in the NHS in England as part of a UK-wide system. |
| The overall aim is to simplify the process for approval of health research for researchers, thus reducing the time and cost of setting up studies. |

**Strategic objective: Simpler approvals process**

The business case noted that despite improvements over recent years, the reputation of UK health research is still hampered by overall complexity and variability of the approval process. Even where it works well, responsibilities are shared across too many organisations. The focus of implementation is, therefore, on achieving a simple framework for setting up research studies where funding for research can be focussed on delivery of research rather than navigating approvals processes. It is recognised that in addition to hard metrics, perceptions of researchers and the life sciences industry of the predictability and proportionality of the new system will be key.

**Strategic objective: Research waste reduced**

The aim is for a service where applicants submitting good quality, well prepared applications achieve approval to predictable and competitive timelines without the need for response to multiple or duplicate requests for clarification and amendment. This means that responsible research can be planned, delivered and completed efficiently, whilst poorly planned research and research that is not yet ready to be commenced is swiftly and efficiently sign-posted to the appropriate source(s) of advice and support, and therefore does not create blockages by diverting activity of the approvals system. Funding for research will go towards delivery of research rather than unnecessary bureaucracy, thus reducing waste.

**Strategic objective: More research activity in England**

Charity and government funders increasingly need to extract maximum value from the funding awarded to research, in return for charity donations and the use of tax payers’ money. Patients and the public expect their money to be used efficiently for the purpose of conducting research. The economy needs a vibrant life sciences industry, with investment in the UK, including the important R&D sector.
**Strategic objective:** More research activity delivered

Unanticipated time spent in gaining approvals, and resultant difficulties in completing studies, results in grant extensions with increasing costs to funders. If navigation of the approvals process takes less effort and time, and is more predictable, research funding is more likely to achieve more successfully completed research studies. For commercial research, delays in overall time to initiation of sites have an overall impact on recruitment of participants in the UK, with significant implications for budgets allocated from global companies to the UK.

**Strategic objective:** Research more patient-centred

An efficient and effective approvals system better protects research participants by ensuring clarity over the safeguards provided through approval. A complex and lengthy process risks researchers circumventing safeguards to avoid delays or because of confusion; a simple, clear process incentivises responsible behaviour. Public engagement by the HRA shows that efficient regulation with simple and transparent allocation of responsibility increases patient and public confidence in research. Charity-funded and publicly-funded research uses funding to deliver earlier access to improved care and treatments, as intended by donors and tax payers.

**Strategic objective:** Better evidence

Where studies fail to complete due to delays in set-up of sites, not only is the whole grant wasted but the potential results of the research are also wasted. Completed research that is published and disseminated in a timely way can deliver evidence to support an effective and innovative NHS.

**Strategic objective:** Compliance with EU regulations

A key purpose of the proposals is to ensure that the UK is well-placed to implement the requirements of the EU Clinical Trials Regulation, anticipated in 2017. A longer term objective is to achieve a future-proof system that can respond to future research challenges, whether resulting from legislative changes, technological changes or cultural changes.

5. **Development of Benefits Map**

The benefits map extrapolates the strategic objectives set out in the business case to programme objectives and benefits. The feasibility study, patient and public engagement and stakeholder engagement undertaken to support the business case defined the business changes required to achieve these benefits. The programme outputs to derive these changes were then determined and captured as programme workstreams.

A communication and engagement plan has been developed and will be reviewed on an ongoing basis alongside the benefits realisation plan, in order to achieve recognition and adoption of benefits by stakeholders.

The benefits map is shown at Appendix 1.
6. Baseline Measures

This is a new service replacing a fragmented current framework and as such, the metrics for the new process will not be directly comparable with the isolated metrics collected for the current process. For example, a key metric in the current system is from the date of valid submission of a Site-Specific information (SSI) application to the issuing of NHS permission. This measure forms part of the Clinical Research Network objectives and forms a stretch target for local networks. Similarly, the current NIHR benchmark for individual NHS organisations measures the time from the date of valid submission of an SSI application to the date the first participant is recruited at that site for clinical trials. Once HRA Approval is implemented, there will no longer be an SSI application to individual sites, and sites will not issue permission. Instead the local arrangements will be jointly confirmed between sponsor and site in an agreement. The activities taking place prior to submission of the SSI application and in the permission review process will change as a result of implementation of HRA Approval.

In addition, feedback to HRA shows that significant time is spent between the various measured elements. For example, there may be elapsed time between obtaining the REC favourable opinion and seeking NHS permission due to the complexity of navigating the processes in parallel. Sites are also often set up in staggered phases.

However, the process of review by a research ethics committee (REC) will remain as part of HRA Approval, albeit as one component of the wider HRA Approval. HRA currently collects timelines for the date of valid REC application to REC opinion, both with the time for any further clarification by the applicant included and excluded (ie with and without ‘clock stops’). Although HRA Approval is broader than the REC review process, it will be important to understand the difference in timelines between HRA Approval and REC review as it is likely that stakeholders may perceive the processes as equivalent. Equally, it will be important to track the impact of implementation of HRA Approval on the REC review process itself to ensure that there is no inadvertent impact on timelines.

Despite these changes to elements of the approval process as HRA Approval is implemented, the broader activity for researchers of getting a protocol and its associated documents approved, setting up study sites, and recruiting participants remain the same, so broad metrics covering larger parts of the process will remain relevant.

- Time from final protocol to first participant first visit
- Time from final protocol to first site initiation
- Time from final protocol to last site initiation
- Time from final protocol to final participant first visit

However, these data are currently not collected nationally and are only held by a limited number of individual sponsors. Before and after case studies through these individual sponsors will therefore have to be the main mechanism of tracking improvements in these timelines. Both qualitative and quantitative data will be needed to demonstrate improvements to the ability to plan and manage the entire process of site set-up and recruitment.

It would be possible to analyse baseline data for the combined current processes of REC review and NHS permission for NIHR portfolio studies, using the NIHR Open Data Platform.
and data from both HRA and the Clinical Research Network. However, it should be noted that this combined data will reflect the large variation in current activity, where some researchers apply for REC review and NHS permission in parallel, whereas others complete the process sequentially – in some cases with a considerable lag period between the two processes.

Analysis of a sub-set of studies in one region found that the median time from REC submission to completion of study-wide review was 146 days. This time encompassed a median time to final REC opinion of 65 days (with no clock stopping), and a median time to complete study-wide review of 86 days (including time waiting for the REC opinion). The data showed a median delay from REC submission to R&D submission of 46 days. Feedback from researchers indicates that applicants stagger the applications processes because of the complexity of navigating the separate processes at the same time.

Similarly researchers, particularly for non-commercial research, stagger the submissions for site permissions due to the time required to negotiate individually with each site. In an example provided to HRA, for 11 sites where permission had been obtained (further sites had not issued permission at the time the example was shared and were not included in the data), the elapsed time from the first submission to the last permission was 118 days, and the elapsed time from initial contact with the first site to the last permission was 155 days. In this example the median time from site submission to permission was 37.5 days, a little over the target time for CSP of 30 days, although some sites were still in process and would exceed target times. However, the median time from initial contact with the site to submission to the site was 57.5 days, with much of that time reported to be spent in liaison with local research teams and preparing local applications. Given that the initial contact with sites was not started in this study until eight months after REC approval, the total elapsed time from submission to REC, even before all sites were set up, was over eighteen months.

7. Benefits and Organisational Change

Implementation of HRA Approval requires significant organisational change for HRA: defining new standards, establishing new processes and SOPs, developing and releasing changes to information systems and deploying new operational resources.

However, key to the success of the implementation of HRA Approval is the implementation of change within NHS organisations, moving from the current system of review and permission, to a process of accepting HRA Approval and confirming the ability to deliver a study.

The table below sets out the organisational changes, both within and outside HRA, to derive benefits, and describes the risks to these anticipated benefits of failure to deliver the changes.
<table>
<thead>
<tr>
<th>Component</th>
<th>Implementation requirements for HRA</th>
<th>Implementation requirements for other stakeholders</th>
<th>Impact of implementation</th>
<th>Risk if not implemented</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single validation</td>
<td>• Additional resource for delivery not required as equivalent process in current system</td>
<td>• Applicants submit complete applications</td>
<td>• Time saved for applicants</td>
<td>• Other components cannot be implemented without single validation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Funders cover costs of preparation upfront</td>
<td>• Predictable systems increase numbers of good quality application</td>
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<tr>
<td>Contract assurance</td>
<td>• Upfront costs to obtain agreement on standard templates and frameworks</td>
<td>• Sponsors use standard templates</td>
<td>• Reduction in duplication at sites with consequent cost savings</td>
<td>• Continued delays in contracting</td>
</tr>
<tr>
<td></td>
<td>• Review incorporated into HRA assessor roles</td>
<td>• Funders ensure NHS costs described and addressed</td>
<td>• Reduction in effort by applicants</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• NHS accepts standard templates</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>• NHS stops inappropriate negotiation of payments</td>
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<tr>
<td>Clinical Support Service (CSS)</td>
<td>• Upfront costs to establish system</td>
<td>• Review undertaken by existing staff, with variable charges being replaced by standard charge</td>
<td>• Reduction in duplication at sites</td>
<td>• Continued duplication and delays in site initiation</td>
</tr>
<tr>
<td>assurance</td>
<td>• Coordination in HRA assurance roles</td>
<td>• Funders ensure research costs of reviewers are covered</td>
<td>• Reduction in delays in site initiation</td>
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<tr>
<td></td>
<td></td>
<td>• NHS CSS stops duplication of review</td>
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<tr>
<td>Research Passports</td>
<td>• Upfront costs to review and improve guidance</td>
<td>• NHS HR stops applying local policies</td>
<td>• Reduction in duplication at sites</td>
<td>• Duplication by applicants with potential variation in requirements from organisations</td>
</tr>
<tr>
<td></td>
<td>• Review incorporated into HRA assessor roles</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Protecting Participants</td>
<td>• Upfront resources to engage with REC s</td>
<td>• NHS stops applying local policies</td>
<td>• Reduction in time to overall approval</td>
<td>• Issues with consistency of REC review not addressed</td>
</tr>
<tr>
<td></td>
<td>• Review incorporated into HRA assessor roles</td>
<td></td>
<td>• Reduction in effort for applicants negotiating different REC and R&amp;D requirements</td>
<td>• Duplication of review across separate systems continues</td>
</tr>
<tr>
<td>Compliance and Delivery</td>
<td>• Criteria agreed UK-wide</td>
<td>• NHS stops applying local policies and raising local queries</td>
<td>• Simpler for applicants to navigate the approvals system</td>
<td>• Staff continue to focus on inappropriate activities and are not able to focus on study delivery</td>
</tr>
<tr>
<td></td>
<td>• Review incorporated into HRA assessor roles</td>
<td></td>
<td>• Reduction in inappropriate ‘checks’</td>
<td>• Overall system remains complex</td>
</tr>
</tbody>
</table>
It is clear from the table that the impact of implementation is primarily in removal of unnecessary processes across local sites, resulting in a reduction in queries to researchers. The benefits of implementation of HRA Approval are therefore felt by researchers and sponsors in a simpler and easier process to achieve study set-up, and by the NHS in releasing of resources to support research more effectively.

8. **Implementation of HRA Approval**

HRA Approval consists of a number of components that have potential to deliver improvements when implemented as individual components, but are brought together in HRA Approval to achieve the overall vision of making it easier to undertake responsible health research.

The table above sets out the benefits expected from each component as part of HRA Approval. Early implementation of specific components will be tracked for initial impact, to provide an opportunity for adjustment prior to implementation as part of the full HRA Approval process, as well as achieving early benefits for stakeholders.

<table>
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<tr>
<th>Early benefits tracking</th>
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<tbody>
<tr>
<td><strong>Contract assurance</strong></td>
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<tr>
<td>• Reduction in duplication at sites with consequent cost savings</td>
</tr>
<tr>
<td>• Reduction in effort by applicants</td>
</tr>
<tr>
<td><strong>Clinical Support Service (CSS) assurance</strong></td>
</tr>
<tr>
<td>• Reduction in duplication at sites</td>
</tr>
<tr>
<td>• Reduction in delays in site initiation</td>
</tr>
</tbody>
</table>

These benefits will be identified at site level, and therefore HRA will be dependent on individual sites and sponsors collecting data on impact. This data will therefore reflect the experience at particular individual sites and of individual sponsors and their specific studies. The information will therefore provide snapshots rather than a full picture.

9. **Post Go Live Benefits Tracking**

The benefits map sets out the programme objectives and the benefits that will be experienced by the research community. These benefits will be measured primarily in terms of timelines and financial savings, although perceptions reported by researchers and sponsors will be key to acceptance of the success of HRA Approval.

Given the wide range of bodies involved in the health research environment, and the anticipated broad spread of benefits from the HRA Approval Programme, it will not be possible for HRA to directly collect or assess the benefits accrued. As part of the stakeholder communication strategy, funders, industry, researchers, universities and NHS organisations will be invited to identify and describe the impact of implementation of HRA Approval. This definition and description will take a variety of forms, consistent with the performance indicators and success factors and publication routes that are relevant to each stakeholder. For example, although many charity and government research funders collect relatively limited information about timelines and progress of the approval process and subsequent delivery of studies, requests for grant extensions or additional funding resulting from delays...
in study set-up are critical factors and measurement by funders of any change in these measures over time would be particularly meaningful to funders.

Other organisations and representative bodies may also be in a position to survey their members of stakeholders to collect more qualitative data.

It is also worth noting that the activities of other organisations in response to, or in parallel to, the implementation of HRA Approval are likely to also contribute to the benefits described. It is unlikely to be possible to ascribe precisely the extent to which individual benefits relate to which individual organisation. Indeed any synergism between different activities makes attribution of the cause of success particularly difficult.

<table>
<thead>
<tr>
<th>Post Go Live benefits tracking</th>
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</thead>
</table>
| Less time and effort setting up studies | • Case studies from sponsors of site set-up, including time and costs  
• Qualitative survey of Chief Investigators |
| More research funding spent on research | • Funders’ reports of grant extensions  
• Savings to NHS from supporting permission re-directed to supporting study delivery |
| More global first participants | • Metrics for total approval timeline  
• Clinical Research Network and commercial sponsor reports of global first participants |
| Increased NHS staff productivity | • Case studies from NHS sites of releasing resources from reviewing to frontline clinical or research delivery |

The benefit profile template (see Appendix 2) will be used to manage the above measures. The sections below elaborate on the two key aspects of financial and timeline measurements which will be reported in the HRA’s public Key Performance Indicators.

**Financial benefits**

The table below sets out anticipated savings from implementation of HRA Approval. It should be noted that the principle purpose of the HRA Approval is not to achieve significant savings to the HRA, CRN or NHS budgets, but rather to deliver efficiencies for the wider research community at long term costs that are equivalent to, or lower than costs of existing approval and permission systems. The intention is therefore that the savings are achieved by re-directing the saved resources to support the conduct and delivery of responsible research, or, where appropriate, to front line care.

<table>
<thead>
<tr>
<th>Component</th>
<th>Anticipated direct efficiencies to CRN/ HRA/ NHS</th>
</tr>
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<tbody>
<tr>
<td>Single validation</td>
<td>• For non-portfolio studies validation at individual sites, based on an estimated three sites per study would not be required. Saving 1 hour per study.</td>
</tr>
<tr>
<td>Contracting</td>
<td>• Duplicate review at individual NHS sites removed, based on average up to five sites per study. Saving 10 hours for each hospital-based study.</td>
</tr>
<tr>
<td>Clinical Support Service review</td>
<td>• Duplicate review at individual NHS sites removed, based on an average up to five sites per study. Saving 8 hours for each hospital-based clinical trial.</td>
</tr>
</tbody>
</table>
**Component** | **Anticipated direct efficiencies to CRN/ HRA/ NHS**
--- | ---
**Research Passports** | • Duplicate review at individual NHS sites removed, based on estimate of three regions per study. Saving 1 hour for each primary care study with non-NHS staff.
**Protecting Participants** | • Reduction in provisional opinion rate. Saving 1 hour per study from reviewing revised documents.
**Compliance and Delivery** | • For non-portfolio studies the review at individual sites, based on an estimated three sites per study would not be required. This releases service staff currently involved in duplicate local checks, and allows R&D staff to be released to support delivery of research.
**NHS Decision to Deliver** | • For non-portfolio studies the review at individual sites, based on an estimated three sites per study would not be required. Saving 6 hours per study.

**Key Performance Indicator: Impact of implementation of HRA Approval on efficiency and cost of research process**

On average it is conservatively estimated that there would be a direct saving to HRA, NHS, or CRN of about 10 - 20 hours per study for hospital-based studies depending on the type of study, and about 10 hours per study for primary care studies. The proposed process has the potential to release clinical and non-clinical service staff who are involved to varying extents in duplicating review of studies, eg radiation, data protection, finance, and HR.

The savings in costs to sponsors will vary considerably depending on the staff currently allocated to obtaining approvals and permissions, but can be illustrated by a non-commercial case study supplied to the HRA in which 0.8WTE were required for a period of over six months to support the set up and initiation of a study with 23 sites, approximating to 20 hours per site. A CRO similarly reported allowing 20 hours per site to obtain permission, including contracting, for commercial studies. Taking into account the continuing need for sponsors to conduct feasibility, site assessment, site preparation and training and initiation, a conservative estimated saving of five hours per site for a study of five sites would save 25 hours.

Given that some elements of the interaction with both RECs and NHS R&D are undertaken by Chief Investigators and Principal Investigators who are often consultants, and other roles are undertaken by coordinators and research nurses, a conservative mid-salary of £40,000 is assumed. The saving of 25 hours per study for sponsors across 4000 studies involving the NHS would be in the region of £3,000,000 in a year.

These estimates will be reviewed and refined during testing and phased roll-out to ensure that maximum benefit is delivered.

**Timeline benefits**

It is important to distinguish between the metrics used to assess the success of implementation of HRA Approval and those used to monitor the ongoing performance of the operational service once delivered.

As noted above, due to the different activities and timepoints in the new process compared with current activity, the timeline comparison should be made across the research journey rather than at the detailed level of individual components as measured currently. Due to the
absence of national measures of these data, information will need to be obtained via sponsors and through case studies:

- Time from final protocol to first participant first visit
- Time from final protocol to first site initiation
- Time from final protocol to last site initiation
- Time from final protocol to final participant first visit

**Key Performance Indicator: Reduction in overall timeline for the research approval process compared with baseline**

It is proposed that there should be one primary metric to assess ongoing HRA performance:

- Time from HRA application to HRA Approval (encompassing both REC favourable opinion and assessment)

Within that metric, the performance of individual components of validation, assessment and REC review will be measured routinely.

**Key Performance Indicator: Percentage studies achieving target timelines for HRA Approval, including elements within Approval**

As noted elsewhere, an important measure of performance will also be the time to HRA Approval against the predicted time given at the start of the HRA approval process. This takes into account the importance of proportionality and predictability to support good planning, with well-managed studies being expected to proceed rapidly, whereas studies with complex requirements of novel considerations would be recognised as needing longer. Collection of data post Go Live will allow staff to develop the capability to make these predictions and in due course HRA will measure the accuracy of the predictions.

**NHS Performance metrics**

Although the HRA does not have direct control over or responsibility for the performance of individual NHS sites hosting research, HRA recognises the importance of site level metrics for study set-up in reflecting the effective use of research funding by NHS sites, and in capturing the experience of individual researchers within the NHS.

As noted above, it is important to recognise that site level metrics will not be directly comparable to existing measures for NHS permission.

Although HRA will not have primary responsibility for collecting or reporting this performance data, HRA proposes that there might be three site level metrics, whose value differs in different situations:

1. Time from HRA Approval to site ready to recruit (this metric is not relevant to sites invited after HRA Approval as there will be a lag after Approval)
2. Time from formal confirmation from sponsor to site (issuing of unexecuted contract) to site ready to recruit
3. Time from sponsor invitation to site to participate (usually by provision of protocol) to site ready to recruit (this metric is not relevant to studies where an invitation to specific sites is not relevant)

Site metric 2, ie time from formal confirmation from sponsor to site ready to recruit is therefore the key metric relevant to all study types. The other metrics remain of relevance to monitor impact on key related activities at site level which could be inadvertently affected by a focus on a single site metric.

For all three metrics the time from the site being ready to recruit to recruitment of the first participant (or first data collection for research not involving recruitment) will provide additional performance data.

Experience of current performance measures suggests that it will be vital to accurately define the activities within each of the above measures and the start and end points for each, in order to provide valid comparisons between sites.

The diagram below illustrates the site activities and the proposed site level metrics that may be of interest in assessing performance of individual NHS sites:
10. **Summary**

**Strategic objectives:**

- Simpler approvals process
- Research waste reduced
- More research activity in England
- More research activity delivered
- Research more patient-centred
- Better evidence
- Compliance with EU regulations

**Programme objectives and measures:**

The following measures will be tracked during the course of implementation and post Go Live to assess the success of the overall programme:

1. Less time and effort setting up studies
   - Case studies from sponsors of site set-up, including time and costs
   - Qualitative survey of Chief Investigators
2. More research funding spent on research
   - Funders’ reports of grant extensions
   - Savings to NHS from supporting permission re-directed to supporting study delivery
3. More global first participants
   - Metrics for total approval timeline
   - Clinical Research Network and commercial sponsor reports of global first participants
4. Increased NHS staff productivity
   - Case studies from NHS sites of releasing resources from reviewing to frontline clinical or research delivery

**Key Performance Indicators:**

The following key performance indicators will form part of the HRA’s organisational dashboard to monitor operational delivery and to report to the public and to government:

- Impact of implementation of HRA Approval on efficiency and cost of research process
- Reduction in overall timeline for the research approval process compared with baseline
- Percentage studies achieving target timelines for HRA Approval, including elements within Approval
### Benefit Profiles

<table>
<thead>
<tr>
<th>Benefit title</th>
<th>Unique Number: A1</th>
<th>Benefit Owner:</th>
</tr>
</thead>
</table>

#### Benefit Overview:

#### Current business problems:

#### Solution:

<table>
<thead>
<tr>
<th>Enabling functionality</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Change required Business, Technology, Organisation, People and Process (BTOPP)</td>
<td></td>
</tr>
<tr>
<td>Processes to stop</td>
<td></td>
</tr>
<tr>
<td>Business case variation</td>
<td></td>
</tr>
<tr>
<td>How will this be measured, source of information and frequency</td>
<td></td>
</tr>
<tr>
<td>Baseline measurement and date</td>
<td></td>
</tr>
<tr>
<td>Target performance and realisation dates</td>
<td></td>
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<tr>
<td>Risk potential to this benefit</td>
<td></td>
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<tr>
<td>Risk mitigation</td>
<td></td>
</tr>
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<td>Status update and date</td>
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</table>
### Origin and Responsibility

<table>
<thead>
<tr>
<th>Author</th>
<th>Programme Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Janet Messer</td>
<td>HRA Approval programme</td>
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### Change History

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<tr>
<td>0.1-0.5</td>
<td>Draft</td>
<td>12/01/2015</td>
<td>Initial Drafts</td>
</tr>
<tr>
<td>0.6</td>
<td>Draft</td>
<td>25/01/2015</td>
<td>Revisions following Programme Board, primarily to sections 1 and 9</td>
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<tr>
<td>1.0</td>
<td>Final</td>
<td>01/03/15</td>
<td>Approved by Programme Board</td>
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### Distribution List

<table>
<thead>
<tr>
<th>Name</th>
<th>Role</th>
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<td>Programme Board</td>
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### Document Sign-Off

<table>
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<tr>
<th>Date</th>
<th>Name</th>
<th>Role</th>
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<tbody>
<tr>
<td>16/2/15</td>
<td>Janet Wisely</td>
<td>Senior Responsible Owner</td>
<td>1.0</td>
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