Agenda item:	AOB
Attachment:	E

HRA Board
Cover Sheet

Date of Meeting:	20 October 2014

Title of Paper:	DH804 HRA Approval Programme Gateway 0 Report final issued with Senior Responsible Officer (SRO) Response
Purpose of Paper:	The report provides an independent evaluation of the HRA Approval Programme. It additionally provides a record of Janet Wisely's (SRO) response to the report as presented to the Programme Board.
Reason for Submission:	For information
Details:	See paper
Suitable for wider circulation?	Yes

Recommendation / Proposed Actions:	**To Approve**	
	To Note	
	For Discussion	**Y**
	Comments	

Name:	Janet Wisely
Job Title:	Chief Executive , Health Research Authority
Date:	24 October 2014

Senior Responsible Officer's Response to the Report

Janet Wisely's, (SRO) response to the report was presented to the HRA Approval Programme Board:

- she welcomed the input provided by the Gateway review,
- she thought that the amber rating felt right,
- she considered the Review Team had gained an impressive grasp of the issues and that the Chair was excellent,
- she suggests we accept suggestion to repeat a Gateway Review again in March/April and would be keen to have the same Chair and at least some continuity of panel members,
- **Recommendations 2,3,4,6** were not a surprise and they aligned with the priorities HRA had already identified,
- **Recommendation 5** was something that had already been considered, but now accepted that there was a need to formalise thinking in this area,
- **Recommendation 1**, upon reflection, highlighted that communications for HRA Approval was something that the HRA were not achieving/going to achieve with the current set up (even accepting the impact of delays in recruitment). As a consequence, she had asked Janet M to take forward proposals for additional resource to address this area and Ian Cook would review how that would sit with a broader review of HRA communications.
- She was provided with an opportunity to comment on the report and, as result, the Review Team agreed some changes to the text. They didn't change recommendations – and no request was made to change recommendations. However, they did extend the timing on final transition as the Review Team had not appreciated that the end of roll out milestone (current ambition December 2015) will not be the end of the programme as the final later phase would be the move from programme to operations. They also changed some of the text to address factual errors caused by misunderstandings of those interviewed. This was important because she did not want the communications challenge, which the Review Team themselves identified, increased by having misconceptions seemingly endorsed in the report.
- Whilst, the Review Team advised her that the report could be kept confidential. However, as a result of the review panel being able to accept the factual corrections made, she feels able to make the report public and it will be received by the Board on 29th October and will also be sent to the DH-NIHR-HRA interdependencies Board.
- The factual misunderstandings were reported to and noted by the Programme Board as areas to target further communications. The misunderstandings related to both HRA Approval and broader issues for the HRA.

Health Gateway Review 0: Strategic assessment
Programme Title: HRA Approvals Programme
Health Gateway ID: DH804

Department of Health

NHS

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Version 3.0 (Issued) July 2013

Health Gateway Review
Review 0: Strategic assessment

Version number: Final Issued

Date of issue to SRO: 25th September 2014

SRO: Dr Janet Wisely

Organisation: Health Research Authority

Health Gateway Review dates: 23/09/14 to 25/09/14

Health Gateway Review Team Leader:
Stephanie Finch

Health Gateway Review Team Members:
Janet Kells
Aileen Moss

Health Gateway Review 0: Strategic assessment
Programme Title: HRA Approvals Programme
Health Gateway ID: DH804

Background

The aims of the Programme:

The aim of the Health Research Authority (HRA) Approval Programme is to address the issues with current research approval processes, and the practical operation of these processes, that result in unnecessary duplication, inefficiency and complexity for researchers in both academia and industry.

The HRA was established with a remit to streamline the approvals process and establish proportionate standards for compliance and inspection. In response to this, a multi-disciplinary group reviewed current arrangements and stakeholder views, and set out proposals for a simplified system for approvals. A feasibility study, including small-scale piloting, was conducted by the HRA between January and June 2013. This study demonstrated that an HRA Approval based on one application and consisting of an integrated assessment addressing legal and management aspects of research applications, plus the Research Ethics Committee (REC) opinion, was feasible and would streamline and simplify processes, to achieve the Government's ambition of unifying the approvals system for health research.

The Department for Health (DH), on the basis of the business case submitted in October 2013, formally notified the HRA of approval and funding for the first year on 31 March 2014. A rapid planning and resourcing period of three months followed confirmation of funding, culminating in the production of a Programme Initiation Document (PID).

The new process will involve one application to HRA and an assessment conducted alongside the REC opinion to form an HRA Approval that will provide assurance to sponsors, researchers and NHS organisations hosting research that the necessary legal and ethical aspects of the study have been addressed. The implementation of the process will be supported by mechanisms to ensure that this approval is accepted by others (including clarifying that responsibility for audit and inspection findings relating to the approval rests with the HRA rather than local Trusts). This would eliminate duplication of assessment, requirements for extra documentation or further checking. It will provide a basis for unifying the approval system for health research with other regulators and review bodies.

The aim of HRA Approval is to simplify the approvals pathway for health research, in accordance with current HRA functions and the remit given to the HRA in the Care Act 2014. It will achieve this by:

- Managing variation of review
- Increasing reliability of review through centralisation, where appropriate, and quality assurance
- Improving flow of applications through the review process and reducing unnecessary waiting times
- Enabling local support and delivery

Health Gateway Review 0: Strategic assessment
Programme Title: HRA Approvals Programme
Health Gateway ID: DH804

The driving force for the Programme:

Currently, a typical clinical trial can involve thousands of patients from more than 20 NHS sites, to ensure enough people participate. The research team will need to get the study reviewed by a Research Ethics Committee and also seek permission from each NHS organisation before they can begin to recruit participants there. The remit for these changes is all research within the NHS and also includes small-scale student research and thus the range is extensive.

Researchers report that this process requires excessive effort and incurs unnecessary costs for all concerned, as well as causing delays to the overall research process and hampering the benefits of research for patients and the public. There is real concern in Government that this is deterring investment in research in this country.

The procurement/delivery status:

The Programme is not primarily about the delivery of Information Technology nor is it procurement driven.

The only procurement involved was to support necessary modifications to the existing systems IRAS and HARP in supporting HRA Approval. HARP is the new system replacing the research ethics management system, which was successfully launched on schedule in May 2014. IRAS and HARP have been linked so that applicants can now electronically submit applications direct to HRA. This new interface will support the single application for HRA Approval.

The HRA has completed the necessary procurement steps, selected the supplier, signed the necessary contracts and is currently scoping out the system requirements and the phasing of implementation with the selected supplier. If these cannot be completed within the required timescale, the Programme recognises that there may be a need to develop proposals to implement change using existing systems, at least in the short term.

Current position regarding Health Gateway Reviews:

This is the first Gateway Review.

<u>Purposes and conduct of the Health Gateway Review</u>

Purposes of the Health Gateway Review

The primary purposes of a Health Gateway Review 0: Strategic Assessment, are to review the outcomes and objectives for the Programme (and the way they fit together) and confirm that they make the necessary contribution to government, departmental, NHS or organisational overall strategy.

Health Gateway Review 0: Strategic assessment
Programme Title: HRA Approvals Programme
Health Gateway ID: DH804

Appendix A gives the full purposes statement for a Health Gateway Review 0.

Conduct of the Health Gateway Review

This Health Gateway Review was carried out from 23rd September 2014 to 25th September 2014 at Skipton House and Avonmouth House. The team members are listed on the front cover.

The people interviewed are listed in Appendix B.

The Review Team would like to thank the HRA Approvals Programme Team, and especially Aisha Ahmad, for their support and openness, which contributed to the Review Team's understanding of the Programme and the outcome of this Review.

Health Gateway Review 0: Strategic assessment
Programme Title: HRA Approvals Programme
Health Gateway ID: DH804

Delivery Confidence Assessment

AMBER

The HRA is a fairly new, small but significant organisation and one that has undergone a roughly 40% increase in budget, and is acquiring a 50% increase in staff and the assumption of significant new responsibilities for a streamlined HRA Approval. At the same time it will become a Non-Departmental Public Body (NDPB) under the Care Act 2014. This is the context within which the HRA Approvals Programme is operating. Recently the attention has been on restructuring the HRA and appointing new staff so the HRA can deliver HRA Approval.

The HRA Approvals Programme has had DH approval and funding. It is now working to flesh out the detail of the desired systems and processes to a challenging timescale of applying them across all English health research by December 2015. It is acknowledged that all the detailed planning has not yet been worked through. The Programme Team are clear on the product and ambition of HRA Approval, but there are some important elements to agree in detail because of the key dependencies primarily on IS and staff recruitment) and also because some areas still need some detailed scoping.

The effect of that uncertainty is compounded by the fact that some elements have been progressed rapidly, because the HRA recognises the need for 'quick wins' and because some elements have been easier to describe and take forward, particularly where there was progress from other workstreams on which to build. Until all the detailed planning is completed, it is very difficult for the SRO and Board to be confident that the Programme has been effectively scoped and planned and that successful delivery is achievable to timescale and budget.

A key component of the work is the further development and replacement of the existing information systems in order to support the new process. It is unclear whether the work, which is currently being specified, can be specified, built, tested and launched in time to roll out the whole new approvals system by December 2015. Should this not be feasible, it is understood that the Programme Team will be developing alternative proposals to manage around the existing systems until the new IT development can be brought in. It is not yet clear whether this is a robust alternative. As a result, the Review Team cannot be confident that the changes can be delivered to the timescale of December 2015.

The Programme has a wide and complex range of stakeholders, many of whom we understand are very supportive of the proposals but who do not yet have a clear understanding of the detail of what is envisaged. There has been some good work done on communicating and engaging people but a more proactive approach is needed to segment the stakeholder group in order to reach less engaged stakeholders, such as clinical staff and managers in NHS Trusts, primary care and

social care. Work has started on developing a Benefits Realisation Plan and the metrics to measure them, which will be helpful in communicating benefits and progress towards delivering them. The importance of agreeing and establishing measureable outcomes will be key to delivery.

Finally, much of the success of this Programme will depend on staff and their contribution to the Programme. For example, working with Trusts and identifying if there are TUPE implications for staff in Trusts; how new staff will be appointed, inducted and managed; and how existing staff will be trained and how all new processes will be quality assured will be critical.

The delivery confidence assessment status should use the definitions below.

Colour	Criteria Description
G	Successful delivery of the project/programme appears highly likely and there are no major outstanding issues that at this stage appear to threaten delivery significantly
A	Successful delivery appears likely. However attention will be needed to ensure risks do not materialise into major issues threatening delivery
A	Successful delivery appears feasible but issues require management attention. The issues appear resolvable at this stage of the programme/project if addressed promptly.
A	Successful delivery of the project/programme is in doubt with major risks or issues apparent in a number of key areas. Urgent action is needed to ensure these are addressed.
R	Successful delivery of the project/programme appears to be unachievable. There are major issues on project/programme definition, schedule, budget, required quality or benefits delivery, which at this stage do not appear to be manageable or resolvable. The project/ programme may need re-baselining and/or overall viability re-assessed

A summary of recommendations can be found in Appendix C.

Findings and Recommendations

1: Policy and business context

Senior staff in the HRA have been committed to improving and streamlining the regulation of research prior to and since its establishment as a Special Health Authority in 2011. A range of nationally influential stakeholders expressed frustration that the current process is slow, unnecessarily bureaucratic, mired in duplication of processes and avoidable costs, that consequently may deter some global industries from conducting and investing in research in the UK .

In particular, the Academy of Medical Science, in its report "New Pathways for Governance and Research" in 2011 recommended the establishment of an Health Research Agency and the need for a centralised, consistent, single approval process. There is therefore considerable support and goodwill from the NHS, academic institutions, independent organisations and particularly pharmaceutical and bio-technical industries for the proposed changes.

Consequently there are high expectations of the HRA, in terms of successful delivery of this Programme and a clear recognition from DH and wider Government for the need to reform and improve research management, regulation and governance for the benefit of the wider UK knowledge-based economy.

Introduction of the single approvals process will also be needed to ensure compliance with EU Clinical Trials Regulations that are due to be introduced from 2016 / 2017.

The HRA submitted a cogent Business Case, based on the principle of establishing a single submission and approval process that had been feasibility tested and piloted, to DH in October 2013.

From January 2015, the HRA will be established under the Care Act 2014 as an NDPB, with statutory responsibilities for functions it already holds for regulating research approval, including appointing authority of NHS Research Ethics Committees and additional responsibilities for research policy. This status also brings with it a requirement for NHS organisations and other bodies to collaborate and comply with HRA requirements and processes. The necessary Establishment Orders, regulatory framework and Memoranda of Understandings are still to be finalised and could affect timescales. The commitment is to complete the process in this Parliament.

This change of status clearly presents opportunities and risks that are recognised by the current HRA Board and staff. These include the facility to exercise greater control to ensure high standards of research governance and management. However, with the likelihood of new Non- Executive Directors being appointed (with the exception of

the Chair) and the influx of significant numbers of new staff for HRA Approval, new governance requirements etc, there are challenges to address regarding risks to continuity, stability and organisational development and management. These programmes of change are being operationally managed on a separate basis but have clear inter-linkages and interdependencies and undoubtedly create significant pressures at Executive Team level.

In addition, while this Programme concentrates on research in England, the HRA has a remit to ensure consistency and compatibility with systems in the devolved administrations in the rest of the UK.

2: Business case and stakeholders

The Business Case was based on an additional investment of approx £12.4 m revenue over 3 years, exclusive of information systems (IS) requirements, that would result in the HRA staffing establishment growing by approx 80 posts. (i.e the organisation in terms of budget and staffing, to deliver new functions, would grow by approximately 50%). Formal approval of the first year funding was given at the end of March 2014 as part of the annual budget settlement.

There is confidence, internally, that the required level of funding will be made available over the next two years. Delays in appointing staff has meant that funds in 2014/5 may be underspent, which could have implications for funding in future years. In addition, the HRA will be required to continue to make savings from its budgets, and this Programme is also expected to make savings within the overall system of c£3m. These latter efficiency savings will need to be demonstrated as part of the outcome measures of success.

A final PID was agreed in July 2014. The Business Case and PID set out what the Programme is intended to achieve and a high level statement about processes, governance, deliverables and benefits. These have provided a good platform for the organisation to share what is proposed with its stakeholders and what it has to put in place for programme management.

We recognise that the organisation is small and the additional 80 staff will be key to effective development and delivery of the Approvals Programme. We found that there was a potential for a misunderstanding amongst stakeholders that work was or had been progressing within HRA whereas the reality has been that the organisation has needed the approval of additional funding to begin to recruit staff to enable development and implementation work to proceed. This may not be completed for some months. Inevitably, this will have an impact on achieving the stated deadline of December 2015.

Commitment and support by all stakeholders was evident to us. We heard that in general engagement has been good including the approach to patient and public engagement.

The Programme is at a critical stage of needing to give health service-based stakeholders particularly, more substance about what is planned to be delivered, by when, to maintain ongoing support and organisational credibility. We recognise the factors that have influenced the current phase of planning and shape of communication but we were made aware that there is now a need to be more definitive and realistic about scope and delivery plans. Transparency, even in the face of uncertainty, will help staff to be informed and exercise organisational commitment.

Stakeholders continue to be very committed to the Programme but it is important to manage expectations and to identify progress on the basis of a realistic, detailed assessment of what can be delivered by when. This will also enable stakeholders to influence and lobby positively on behalf of the HRA.

Some concern was expressed that engagement with the NHS had been predominantly with those staff directly involved in research and that more would be needed in relation to very senior staff including Chief Executives of Trusts to secure successful implementation.

A draft HRA Approvals Strategic Communications Plan has been developed and resources put into additional communications staff who are not yet all in post. Whilst not solely focused on information dissemination it appears to be reactive rather than proactive. We found that there was a focus on communicating information rather than on stakeholder management. A stakeholder mapping exercise, with an analysis of stakeholders, that considers who needs to know what and by when, at the different phases of the Programme, would help to manage successful implementation. In particular, the work needs to reflect the fact that some stakeholders will be more engaged at different time in the different work streams. The time frames for delivery are constrained and there is awareness of the impact of the 2015 election.

The fast-moving nature of the Programme means that messages will change over time. It will be important that clear and consistent messages are communicated and tailored to respective audiences.

Recommendation 1

To ensure a Stakeholder Analysis is carried out to strengthen stakeholder management and the Communications Strategy.

3: Management of intended outcomes

The Review Team understand that the ambition is to have all applications for all research studies in England using the new approvals process by December 2015. While a number of stakeholders are aware that the Programme is working to a target of Dec 2015, not everyone could explain what would be in place by then and what needs to be delivered in what sequence. Many were concerned about how realistic a full roll-out by then is, given the delay in getting approval from DH, which left the

deadline unchanged. Thus an already challenging deadline, which runs across the General Election, now provides even less time to deliver.

We heard that the delay in approving the Programme, coupled with extensive recruitment to new posts, has meant that the Programme planning has not yet been fully scoped. Some decisions have been taken about achieving some quick wins, such as with pharmacy reviews, and how the phased roll-out across study types will be ordered, but the Programme Team has not yet described the detail of the components of the process, how it will work and the dependencies. Thus, there is still much work to be done to articulate the new approvals process and implementation of it.

We find that, whilst individuals have a sense of the products that will emerge, we did not see a comprehensive written description of these elements. The process needs to be fully articulated in terms of the various stages of assessment and approval, specific expectations, for instance, in terms of standards, protocols, documentation and the system for accrediting assessors. These will vary according to study type and should address the Programme aims of:-

- Managing variation of review
- Increasing reliability of review through centralisation, where appropriate, and quality assurance
- Improving flow of applications through the review process and reducing unnecessary waiting times
- Enabling local support and delivery

Without the detail outlined above, it is difficult to develop a realistic timetable. The Review Team heard that the intention has been to develop the details of the system and the proposals for its development with the IS supplier and then to develop a more detailed plan.

Although the Programme Plan is being drafted, it does not yet include all workstreams and does not yet set out the dependencies, milestones and critical path. A programme planner is being recruited to complete this work. There is recognition that stakeholders do not have sight of individual milestones leading up to the target and deadlines for implementation.

We found that stakeholders did not always understand the concept of dependencies, often directing us to the Inter-dependencies Board which manages the dependencies between the HRA, DH and NIHR specifically for HRA Approval. Our interest was in identifying the dependencies between the different components of work in the Programme and how people could understand how problems with the delivery of one component might impact on other components or on overall delivery. Without this understanding, the critical path for delivery remains unclear.

In the absence of this level of planning detail, it is hard for the Review Team and the SRO and the Board to evaluate the realism of the plans and the likelihood of successful delivery to timescales, nor whether the Programme is on track. The Review Team therefore cannot be confident that the plans are achievable.

It is recommended that a more detailed Programme Plan is developed that includes a good articulation of the connections between streams of work and of the critical path for deadlines. Clarification of deadlines is also needed. This will improve the management understanding of risks including slippage in timeframes for delivery. It would also allow HRA to manage risks to its reputation if key deadlines slip.

Recommendation 2

To ensure that a detailed Programme Plan is developed as soon as possible, with dependencies, milestones and critical path in order to demonstrate that delivery to the timescale required is achievable.

4: Risk management

The Programme has a Risk Register which is reported on through the HRA corporate risk management structure. We understand that there is no Issues Log yet although there are plans to develop one, which we would support.

Now that the Programme Office has been established, the Risk Register might benefit from a review to assure the Board that it is as comprehensive as possible. It will be helpful to identify a Programme Risk Manager, for example, and to ensure that all risks, including the HR risks are covered and actively managed, acknowledging that some high risks to the Programme lie outside the direct control of the HRA. The Programme would benefit from reviewing how these might be mitigated. In addition almost all Risks are owned by the Programme Director. Having a range of other owners, chosen by their ability to best manage each risk, would encourage ownership within the HRA.

5: Review of current outcomes

It is clear that the time gap between submission of the Business Case and its approval has had a significant impact on what could effectively be achieved in taking the Programme forward.

Since approval, focus has been given to strategic communication with stakeholders, particularly responding to external players; establishing some “early wins” in application management (e.g. pharmacy and radiation single technical reviews roll-out through interim policies and good practice); recruitment of new staff on a phased basis and addressing IS requirements to support the new processes and systems.

Full Programme staffing has yet to be recruited or in place. Key roles, associated with operational assessment and approval processes, are not yet filled which places

pressures on delivery and associated organisational development such as induction, training and cultural integration in the short-term. Also the process for transition and migrating functions and staff into mainstream HRA business, as opposed to a system change programme, needs to be practically addressed.

Clarity needs to be established about exactly which staff are "at risk" from the proposed organisational changes and the potential scope/timescale for addressing TUPE implications. We were made aware that whilst staff across organisations i.e. NIHR, NHS Trusts' R&D functions and the HRA itself, are supportive of proposed changes, inevitably there is some general anxiety about what are the implications for individual members of staff. Slippage in starting the Programme means real concerns on the ground about the achievability of the 2015 delivery date.

There is a real risk to the whole research system, given shortage of key skills and capabilities, that change if not well-managed, could result in unintended consequences and destabilisation for a range of organisations. There is an acknowledgement that there is a substantial and significant range of human resources issues many of which sit outside the HRA that are key to the successful delivery of the Programme that need to be fully identified and appropriate management action identified and incorporated into the critical path and inter-dependency planning. This has not yet been fully articulated. An HR Plan needs to be developed to cover all these inter-dependencies, proposals, any required TUPE issues and training and induction. This will have to be done collaboratively with the current employing organisations.

Recommendation 3
To develop a comprehensive HR Plan.

There are similar issues in relation to IS systems to support the new processes. The HRA intends to further develop existing HRA provided IS systems and establish a different process than is currently in place. Anxiety was expressed to us by a number of interviewees about the timescales, given experience of the difficulties of establishing some of the existing systems.

Concerns were expressed regarding data migration; the costs of the current infrastructure/platform; incomplete specifications and other issues. We also heard anxiety from stakeholders about, for example, whether the key time metrics could be delivered without a new IS system and the potential for reputational damage if there are problems.

At present, we are not clear what the timescale is for completing the work to specify developments to the IS systems nor how robust the alternative of workarounds on existing systems for a period is, if timescales slip. This needs to be fully defined and risk mitigation clarified. The successful delivery of IS is key to the success of the Programme and needs to be incorporated into the critical path.

Recommendation 4

To review the proposed approach on developing the IS proposals, their impact on the critical path and the robustness of the potential for alternative solutions in order to provide assurance that the proposals will meet requirements.

6: Readiness for the next phase: Delivery of outcomes

The current draft Programme Plan is not complete and high level so it was difficult to pin point what is perceived to be the next phase. To do the detailed development work and have a good level of appropriate stakeholder involvement, the HRA has identified specific early areas to prioritise and roll out, such as the Pharmacy and Radiation reviews and required further IT development. Those involved in the Programme have a good understanding of this and a focus on early wins is important, but it is less obvious to those not so deeply involved whether the Programme is making progress. There is confidence that the HRA can be trusted to deliver but there is a sense of a tipping point as time goes on with no detail other than the ambition that everything will be delivered by December 2015.

HRA is reorganising itself to be able to deliver HRA Approval which is their main driver and in doing so has captured what is necessary to meet its new requirements as a NDPB Its budget has doubled in size with HRA Approval. The Approvals Programme will at some point move from being a change programme into the mainstream business of the organisation. If the plan is for the programme deliverables to be in place by December 2015, planning for that final transition to the business as usual departments of the HRA during the following year needs to begin.

Recommendation 5

To develop a Transition Plan to take the Programme into mainstream business as usual for the HRA.

Longer term the Programme will be accountable for demonstrating that the benefits have been delivered. The Benefits Realisation Plan is in draft form and further work is being done. A key issue will be to clarify what can be delivered by the end of 2015 and how the other benefits will roll out over time. We understand that the metrics being considered need to be appropriate and that there are different views for example on the 70 day metric. There should be work done with sponsors and key stakeholders to develop the short and longer term metrics for measuring benefit realisation.

Recommendation 6

To develop and agree a Benefits Realisation Plan with appropriate metrics by which to evaluate success.

The next Health Gateway Review is expected in March 2015, when the HRA will have become an NDPB and be implementing plans to develop and roll out the new approvals system.

APPENDIX A

Purposes of Health Gateway Project Review 0: Strategic assessment

- Review the outcomes and objectives for the programme (and the way they fit together) and confirm that they make the necessary contribution to the overall strategy of the organisation and its senior management.
- Ensure that the programme is supported by key stakeholders.
- Confirm that the programme's potential to succeed has been considered in the wider context of the organisation's delivery plans and change programmes, and any interdependencies with other programmes or projects in the organisation's portfolio and, where relevant, those of other organisations.
- Review the arrangements for leading, managing and monitoring the programme as a whole and the links to individual parts of it (e.g. to any existing projects in the programme's portfolio).
- Review the arrangements for identifying and managing the main programme risks (and the individual project risks), including external risks such as changing business priorities.
- Check that provision for financial and other resources has been made for the programme (initially identified at programme initiation and committed later) and that plans for the work to be done through to the next stage are realistic, properly resourced with sufficient people of appropriate experience, and authorised.
- After the initial review, check progress against plans and the expected achievement of outcomes.
- Check that there is engagement with the market as appropriate on the feasibility of achieving the required outcome.
- Where relevant, check that the programme takes account of joining up with other programmes, internal and external.

Health Gateway Review 0: Strategic assessment
Programme Title: HRA Approvals Programme
Health Gateway ID: DH804

APPENDIX B

Interviewees

Name	Role
Janet Wisely	Chief Executive and SRO - HRA
Janet Messer	Programme Director - HRA
Mary Cubitt	Programme Manager - HRA
Ian Cook	Director of Corporate Services - HRA
Philip Millne	Chief Information Officer - NIHR Clinical Research Network
Simon Denegri	NIHR National Director for Public Participation and Engagement in Research
Debbie Corrigan	Director of Finance - HRA
Simone Bayes	Deputy Director - Head of Research Standards & Support and Programme Sponsor
Shaun Griffin	Director Comunications, Engagement and Partnerships
Kate Greenwood	Research Manager - Portsmouth Hospitals NHS
Alison Jeynes-Ellis	Non Executive Director - HRA
Nick Wong	Project Lead, ECMC Network - Cancer Research UK
Anne Tunley	NRES Manager (North) - HRA
Naho Yamazaki	Head of Policy - Academy of Medical Science
Clare Morgan	Research Delivery Director - NIHR
Steph Garfield Birkbeck	Assistant Director, NETSCC – Health Services & Delivery Research (HS&DR) Programme - NIHR
Marc Taylor	Critical Friend - Member of Confidentiality Advisory Group
Helen Quinn	Chief Operating Officer - NIHR CRN : South West Peninsula

APPENDIX C

Summary of recommendations

The suggested timing for implementation of recommendations is as follows:-

Do Now – To increase the likelihood of a successful outcome it is of the greatest importance that the programme/project should take action immediately.

Do By – To increase the likelihood of a successful outcome the programme/project should take action by the date defined.

Ref. No.	Recommendation	Timing
1.	**To ensure a Stakeholder Analysis is carried out to strengthen stakeholder management and the Communications Strategy.**	**Do by Nov Programme Board**
2.	**To ensure that a detailed Programme Plan is developed as soon as possible, with dependencies, milestones and critical path in order to demonstrate that delivery to the timescale required is achievable.**	**Do now**
3.	**To develop a comprehensive HR Plan.**	**Do now**
4.	**To review the proposed approach on developing the IS proposals, their impact on the critical path and the robustness of the potential for alternative solutions in order to provide assurance that the proposals will meet requirements.**	**Do now**
5.	**To develop a Transition Plan to take the Programme into mainstream business as usual for the HRA.**	**Do by June 2015**
6.	**To develop and agree a Benefits Realisation Plan with appropriate metrics by which to evaluate success.**	**Do by January 2015**