

## **Board Report:**

# **Interim evaluation of the integrated process for HRA and HCRW Approval and its implementation**

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## 1. Executive Summary

HRA Approval was a driving factor in the establishment of the HRA: a single permission for research in the NHS in England. It was designed and implemented by the Chief Executive at the time, Janet Wisely, and Janet Messer. Following development and testing of component parts separately from the established Research Ethics Service (RES), HRA Approval was launched in 2016. The product of HRA Approval was a single permission on behalf of the NHS based on an assessment of matters relating to compliance, standards and governance by HRA staff. This process and the team undertaking it remained distinct from the Research Ethics Service during the earliest testing of the concept. Transformation Board then supported the full roll-out of the plan for an integrated Approvals Service which would be staffed to ensure frictionless travel of applications through the teams involved. Reconfiguration of the workforce commenced with the restructuring of Senior Leadership Team and the appointment in 2017 of Janet Messer, previously Director of Research Systems, Standards and HRA Approval as Director of the Approvals Service, and the retirement of the Director of Operations.

The aim of implementing the integrated process to deliver HRA Approval is to improve the applicant experience and the HRA's efficiency. As part of collaborative working with stakeholders and other regulators, and reflecting ongoing feedback from applicants, it was agreed that the two separate elements of assessment and REC review should be integrated to provide a more efficient service to the applicant and a more aligned approach between staff who previously worked in two separate teams. The integration of the separate REC and Assessment processes and teams was implemented from 1 April 2019 following an extensive workforce consultation with the affected staff and several pilots (undertaken as part of the Service Improvement Programme) to test new elements of an integrated process.

This report has been produced to review the programme and evaluate the impact of the first 5 months of implementing the integrated process in England and Wales. It describes some of the benefits that have been realised in the few short months since implementation as well as challenges perceived by staff. Data has been provided where applicable. However, it is important to note that it is still early to assess the full impact of the changes.

Although quality and the HRA's contribution to the delivery of high-quality research and improved patient and public outcomes are the drivers behind the integrated process, the HRA also operates within challenging financial boundaries. These have been brought about by the general context of public sector funding for health, and the requirement to deliver savings against the Grant in Aid funding. The key intended deliverables were therefore:

- Providing an integrated process for applicants with combined communication about REC and assessment elements of the application
- Simplifying navigation of the regulatory system and facilitating study set-up
- Achieving a reduction in pay costs

At five months after implementation of such a significant change to both roles and processes, outcomes and benefits are not yet fully realised. Although reductions in staff establishments were achieved without compulsory redundancy, the full anticipated savings have not been

reached due to the need to bring in additional temporary resources to manage workload. Feedback from RECs demonstrates early benefits from more senior staff input into the meeting, but this is not yet consistently in place. Inevitably a number of staff are still learning to work in new ways and with new processes, which is impacting on workload. Early analysis has also identified that several key assumptions around workload that informed the new structure were not, in fact, accurate as the changes have allowed us to have visibility of several tasks that were not being consistently undertaken by staff. This is creating an impact on workload for the operations team, while the member support team are having to undertake significant actions to address previously hidden problems.

Feedback from staff is being collected. Concerns appear to focus on workload, travel and cover arrangements. These are explored further below.

Importantly, as these plans for an integrated service were being developed, colleagues in Health and Care Research Wales (HCRW) agreed to implement a mirror service and structure. This report therefore refers to a single integrated process across England and Wales but references to staff relate only to HRA.

## 2. Background

The changes made as part of implementing the integrated process were designed to provide a more efficient service to the applicant and to remove duplication of effort between the separate Research Ethics Service and Assessment staff to facilitate further improvements for the research community.

The changes to the workforce structure resulted in the creation of two new divisions within the Directorate:

1. Approvals Operations – established to align operational and regulatory functions including the REC review and HRA assessment.
2. Approvals Support – established to provide a centralised range of support and assurance activity to facilitate the delivery of Approvals as well as the end-to-end volunteer member recruitment, support and management.

The anticipated high-level benefits of implementing the integrated process were as follows:

- **Integration** of functions and roles to deliver a single workflow for processing of applications and related functions.
- To enhance stakeholder perception by creating a more **positive user experience** overall.
- Reduction in the span of activities undertaken by individual roles so that staff could focus on developing **specific skills** regarding the regulatory aspects of managing research applications and to be able to offer **greater career progression**.
- **Reducing duplication** and the number of different contact points in the system for both applicants and staff.

### **3. Scope**

The focus of this report is to evaluate the implementation of the new processes to support the delivery of the integrated HRA and HCRW Approval programme. The suitability and attendant challenges of the staff structures to deliver this process are intrinsically bound to the processes and will be addressed throughout this report.

A closing report on the Workforce Consultation was made to HRA Board on 20 March 2019, reflecting on feedback and observation on the workforce consultation on the proposed changes.

A separate report was made to Board on 15 Jul 2019 specifically addressing areas of activity implemented since April 2019 which related to staff feedback on the integrated process. These activities commenced either in response to that feedback, or as part of planned developments, or based on early learning once the integrated process went live.

### **4. Preparation ahead of the integrated process**

Although significant process planning was undertaken as part of the Service Improvement Programme in parallel with the workforce consultation from April 2018, delivery of the integrated process for 1 April involved a significant amount of planning and preparation within a relatively short period of time. This included:

- Agreeing the 'process flow' for full and Proportionate Review applications.
- Early communication with the full teams to explain the need for the change and what the future process would look like, and then on-going communications via different methods (face to face; intranet; emails; sharing evaluations; workshops) to attempt to keep the team informed about what would be happening.
- In depth conversations in development meetings to debate and justify principles and concepts to be included in the new process and team structure.
- Planning training inputs based on successful methods used previously to inform the team of the new way of working.
- Planning and delivering input to new leadership team of Approval Managers to begin building that peer group and allow them time to create teams with some autonomy though within a consistent structure.
- Agreeing roles and responsibilities for each part of the process.
- Ensuring that there were UK wide working arrangements in place for studies led from Scotland and Northern Ireland, and arrangements for REC only and non-REC studies.
- Creation and publication of the work instructions.
- Allocation of staff to RECs and to micro teams.
- Maintaining business as usual during the transition.
- Identifying 'quick wins' and process changes to assist Approvals Officers and Approvals Administrators working with three RECs rather than two e.g. changes to the minute taking process in addition to the tasks removed from the previous REC Manager role.

- Planning system changes which needed to be in place before implementing the process e.g. changes to the minute taking guidance.
- The creation and renumbering of all the new email templates to move away from the previous process of issuing letters and to change to sending email status updates from HARP which is both quicker for staff and allows applicants to view a streamlined set of information 'at a glance' rather than needing to open a separate letter.

The Integrated Process Steering Group and Project Group, with representation from HCRW, oversaw and made these preparations. Approvals staff were involved in several workstreams in the HRA Approval service improvement programme, and other preparations for the implementation of the Integrated Process. Their insight was useful, and gratefully received.

## **5. Guidance and Documentation**

Work Instructions for the integrated process were signed off ahead of the implementation date and the details of the process changes themselves were discussed at a Staff Training event. However, we hear and acknowledge the feedback from a number of staff that the Work Instructions are too complex, and not prescriptive enough in terms of who is responsible for each task. Understandably some staff are finding it is taking some time to get used to navigating between HRA/HCRW Work Instructions and the UK-wide REC Standard Operating Procedures. A useful workshop was held with a group of staff recently to discuss what improvements could be made to the work instructions. Some of the changes are straightforward and can be taken forward quickly (e.g. clarification of who is responsible for what and using a colour code for when different roles are referred to). Others are improvements to take into consideration as part of further planning. For example, the work instructions are naturally quite complex to cover the different nuances/scenarios between nations (which will hopefully improve itself as UK wide ways of working continue to develop). Longer term, a more intuitive case management system through the Research Systems programme should avoid some of these complexities.

## **6. Staff Training**

Two full days training were held for all staff in the Approvals Support and Approvals Operations divisions. Further face-to-face workshops were held in each HRA office and in Wales during March distinct from the routine office visits from the senior management in Approvals Operations and Support. Specific face-to-face training in terms of undertaking the HRA assessment of applications was delivered by an Approvals Operations Manager. A further training day was held on 1 May to pick up on further learning points and to respond to queries raised by staff during the first four weeks. Training plans and expectations for undertaking training were put in place for staff, and a series of lunch and learn sessions focussing on specific aspects of assessment were presented by the Approvals Managers.

A small number of new staff have been appointed since May from outside the existing team. These people have received on the job training, supervision from line managers, and oversight from Approvals Operations Managers to ensure they are suitably instructed and supported. Though new team members will always need a level of training and induction into the HRA it is welcome that energised, positive people are now in roles throughout the team to

add different perspectives and knowledge. The quality of training for these new members of the team is critical to ensure they take on the new way of doing things, and so who they are trained by and what they are trained on is a key aspect of the culture change within the team.

A key role in ensuring the effectiveness of the new Operations team structure, including training for new staff, is the Approvals Manager who leads each micro team. Although most already had had line management responsibilities, inevitably time for additional training and preparation of that group before the new structure took effect at the start of the financial year was limited as it was not possible to appoint managers in advance of other team members. Importantly, training in skills for line managers was commissioned and delivered to line managers within the Approvals Service. This, in conjunction with their own development and supervision with senior managers in Operations will enable them to support staff in general terms, as well as Approval-specific training.

We place great importance on the role of effective line management in supporting the wider staff group, though we recognise that with the scale of promotion we have been pleased to achieve, we need to support those newer managers. This includes process matters such as clarity on systems for requesting leave, or on the accrual of Time Off in Lieu or flexi time when travelling and working outside of office hours. We have also addressed more complex, sensitive issues such as supportive management of stress-related illness and return to work. Though the overall sickness picture is better in the team than the same period last year, the profile of stated absence reasons has changed.

As micro teams become ever more settled, and Approvals Managers and Approvals Specialists adopt the full gamut of line management responsibilities we will also support them in knowledge and skills around recruitment. This has been quite centrally managed by senior management since April. This is in part due to the complexity of the financial context and affordability, which needs accounting for in the Vacancy Control process, within a greatly reduced budget and a significant level of maternity leave due to the age and gender profile of the team, for which no additional resource has been available to recruit cover (budget arrangements for maternity cover are now being reviewed).

We note that recruitment due to staff leaving is no greater than previously the case, with the majority of the 14 leavers between April and August 2019 (after voluntary redundancies) being due to external promotion or career change (eg teacher, firefighter). However, the tiered structure has meant that in some cases, one individual leaving can create a wave of internal promotions and a junior external appointment, and this impact has been greater than in the previous structures. The same consequences apply to maternity leave cover arrangements, where fixed term opportunities for promotion arise. Internal recruitment for these series of promotions has been complex, and until now undertaken by senior managers to allow AMs to focus on staff support and delivery. This 'churn' contributes to a staff perception of frequent recruitment and therefore an inaccurate sense of the level of resignations. Inevitably the internal movement of staff for the best of reasons still poses operational challenges for continuity of service while roles are handed over. Working within the need for tight Vacancy Control, and an increased timeline for necessary financial review, we acknowledge that the Approval Managers need to work with the Workflow team to identify bottlenecks, and assist staff as necessary in the complex prioritisation of their work within the micro team and across REC teams.

The Approvals Service had also already commenced the development of a learning framework with the Head of Learning and Knowledge Management. We are pleased to have seen this brought into the Leadership Teams' organisational response to the HRA Staff survey, as reported to Board in July 2019.

## **7. Communications**

In terms of communicating the changes to the integrated process to the research community it was not necessary to publish any specific external messages as the changes were solely related to re-organising internal staff and processes.

REC Chairs were informed of internal changes to process via written communication, which was then shared with all members via the REC Member Information Exchange. Additionally, Chairs and other volunteers were aware of the rationale for these changes, and the proposed staffing structure, having been party to elements of the workforce consultation throughout 2018 that were appropriate to share with them.

Chairs Network Regional Meetings were held throughout April/May 2019 which gave time to discuss the integrated process with REC Chairs face-to-face to provide additional clarification and discussion.

Communications to staff were, as with the workforce consultation, made regularly by senior management of the teams. The Heads of Approvals Operations and Approvals Support are undertaking joint visits to regional offices, commenced during the workforce consultation. This gives staff the opportunity to discuss the process, how it is working, feedback from RECs and applicants, and how the integrated process affects them. This exchange of views and experience also helps management plan the service to reconcile some of the key challenges for staff, with a greatly reduced budget and the well-documented effects of organisational change in the workplace. It also gives staff an opportunity to discuss what elements of the new process and structure are working well. This is particularly important too, as whilst staff have fed back widely that they see the need to change, when there are challenges, it is important to give voice to the positive as well.

## **8. Line Management and Micro Teams**

A key benefit of the workforce restructure that resulted from the new integrated process was the opportunity to restructure the leadership model that had proved challenging in the past.

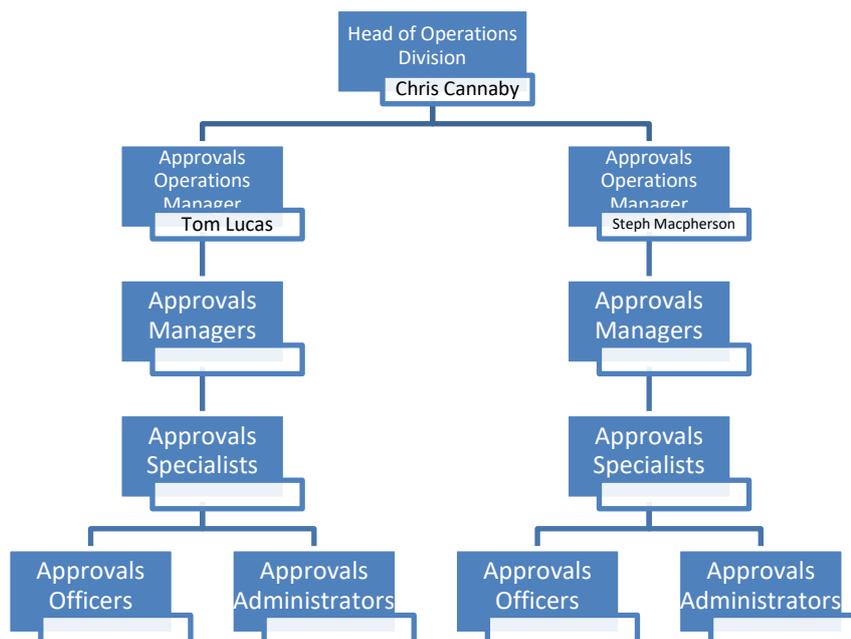
Before the integration of the teams there were two distinct leadership structures within the REC and Assessment teams.

The REC structure consisted of one Regional Manager based in an office who was responsible for leading and managing a team of between 15 and 30 people (depending on the size of the office) at band 5 and 4 level. The Regional Manager had overall management responsibility though some of the role was delegated to Deputy Regional Managers, with the

nature of what was delegated differing from office to office. Leading a team of this size was a challenge in terms of understanding the individual needs of the team.

The newer Assessment team structure comprised several band 7 Senior Assessors (who reported to an Assessment Manager) and who each had responsibility for 2 or 3 Assessors. This smaller team structure allowed individual understanding of the staff reporting to them and ensured we could offer personalised approaches to developing individuals as they required. Team members’ development was regularly discussed, and oversight of how each individual was performing and developing in the role was maintained. The small team structure ensured that there was no opportunity for people to be missed or left behind and the Assessment leadership team could be assured that the processes were followed in the correct ways and the service to the applicant was of a high standard.

The opportunity was taken in designing the leadership structure to deliver the benefits of the assessment model in the wider integrated team. Twelve micro teams were created, each led by an Approvals Manager who has their own proportionate allocation of applications and RECs in addition to leadership and line management responsibilities. The concept behind the micro teams was to create a small enough team to offer each individual personalised leadership experience from the Approvals Manager so that we can develop each team member based on their needs, to be able to function well and feel supported.



Other intended benefits of the structure are:

- Creating more leaders within the team to move toward a ‘leaderful organisation’ and so delegate out ownership of team leading from one or two ‘heroic’ leaders to several engaged and empowered team leaders – starting with the Approvals Managers and then moving to the AS level, to give many people the drive to provide leadership functions within the team rather than a few
- The allocation of team members to micro teams was purposely done to mix geographies to move away from silo offices which created their own identity, ways of working, service

to applicants and type of pastoral support to team members. Mixing the geography enables conversations between offices, sharing ideas and experiences, and so support the endeavour to provide a consistent service provision and individual support regardless of location.

- Supporting staff to work without co-location of team-members was also important to make the allocation of staff to RECs work.

Operations staff have understandably questioned why micro teams cannot align with the REC allocations. This would have merit, particularly in relation to covering the REC-facing work across a team with increased sense of shared ownership, and with the same team leader. Management spent considerable time examining whether this was achievable, but logistically it is simply not possible. However, there are also benefits in the resulting model:

- Working with colleagues across offices and outside of the micro team promotes cross working and sharing of good practice and experiences, whilst reducing the possibility of siloed working and a single REC team 'branching off' without challenge
- Encouraging conversations between HRA team members outside of the micro team (or old team structure) fosters a collegiate environment
- The mobility of the Operations team is greater than the previous RES team – and so changes to REC allocation that need to be made for operational and cover purposes, can be achieved without needing to change line management routes or team presence.
- Not all the work coming to the individual team members is based on REC allocation, this is just one part of the workload provision. And though supporting the RECs is a vital part of all of our roles, there will be more and more work that is not based on REC allocation e.g. PR studies

The team's experience of this model has been mixed, with some clear positives being reported, and some misgivings as to how the system will work. A key role in ensuring the micro team structure is effective will be the Approvals Manager who leads the team. Unfortunately, it was not possible to train and prepare the Approvals Manager team leaders before the teams were created, as the consultation process included the Approvals Manager allocation with the rest of the team to give the opportunity for all to express interest in the role, whilst also being considered for alternatives. Leadership training is being offered now as part of a HRA-wide approach to staff development. Resources available to provide bespoke upskilling to this line of team leaders, or any other in the HRA is limited, and so much of the development for these roles is in peer support, day to day experiences and conversations with their line managers – the Approvals Operations Managers. However, this is consistent with the 70:20:10 approach to learning and development we adopt in the HRA. It also allows heads of function to be central in using their experience, expertise and leadership aplomb directly with their management team, developing their own senior leaders.

Integrating two distinct models of leadership is a cultural change for all in the team and so will take time to embed and demonstrate the benefits – though we have seen already clear benefits of this new model:

- Quickly understanding where additional training is needed for team members
- Time and focus for conversations to support team members effectively

- Clear communication from Operations leadership team to the micro teams allowing messages to be individually tailored

There are perceptions from staff that there is an increase in the need to cover for sickness, leave and for vacancies. Cover arrangements are particularly important for those staff attending REC meetings. In fact, sickness absence is less than last year. As noted above, staff turnover is also not significantly different from the previous year. The concerns about arranging cover are therefore primarily a result of the change in team structure, and the greater impact of waves of internal moves as described above. Whereas previously cover was usually arranged by a single regional manager from within the staff in an office, the new structure does not allow for one person to re-direct the tasks of a large number of individuals in the same way. As staff become more familiar with arranging cover, this should feel less like reactive fire-fighting, but we recognise it is currently causing concern for both those arranging cover, and those providing cover.

## **9. REC Meeting Minutes**

It was agreed from the outset within the Approvals Service, and specifically within the Integrated Process Project Group, that the format of REC meeting minutes needed to change significantly to reduce the time spent writing minutes, and to focus on informing applicants of the outcome of the REC review as soon as possible after the meeting. A new template and guidance for writing REC meeting minutes has been produced and training was delivered in each of the offices. The initial feedback on the new format of the minutes was that staff were finding it difficult to summarise the discussion to speed up the time it took to publish them. However, a round of refresher minute taking training was held throughout July and staff were very positive about the new approach. Anecdotal feedback was that minutes were being completed within three working days of the meeting date as opposed to the suggested two however, this was due to staff having to prioritise other tasks rather than due to the length of time to write the minutes specifically. A small number of REC Chairs provided feedback to say that they would have liked to have been consulted on the changes to the minutes in advance however, due to the number of changes needing to be implemented in a short period of time it was not possible to do so.

## **10. Quality Assurance and Governance**

The remit of the new Approvals Support Division is not only to centralise support to REC members, creating efficiencies in areas such as travel and expenses. Amongst other things, it also provides the Appointing Authority function for RECs in England and oversees the quality assurance framework for maintaining REC recognition and authorisation. This centralisation was established to address the absence of continual monitoring of REC membership, constitution, and succession planning in the existing research ethics service, as this was all devolved down to individual staff, and only reviewed at three-yearly accreditation. The audit and accreditation scheme for RECs uses a UK-wide set of standards and there are instances where the changes made for the integrated process in England and Wales have progressed from the detail (but not the principles) of the standards (for example, issuing a provisional opinion status update instead of a provisional opinion letter). The intention is to update the

standards in advance of changes, where possible, although the time needed for consultation across the UK will sometimes mean that steps are taken ahead of updating the standards.

Audit findings are identified as either REC Membership issues (to be followed up by the Support team) or to Operational processes (to be followed up by the Approvals Operations team). Experienced Approvals Managers also undertake quality control checks of assessments undertaken by newly appointed Approvals Specialists and Approvals Managers.

Since implementing the new structure, some operational staff formerly employed as REC Managers have not perceived a relinquishing in activities to the Support Division and therefore only register an increase in one area of their work, ie attending up to three RECs instead of the two previously allocated. Now that central oversight is established, we have been able to identify that the membership-related tasks had not been completed consistently before April. Some REC Managers had de-prioritised membership tasks to focus on meeting timeline targets that were historically very closely tracked. This compromised the membership of RECs making it more difficult for individual meetings to be quorate. In the past, addressing membership matters appears to have often been reactive rather than proactive. In a context where clinical staff are increasingly not being released for REC membership, this has compounded problems. A corresponding increase in co-option of members between committees has been noted over the last year. We are grateful to members who have at short notice joined other committee meetings to ensure each meeting is quorate.

The Support Division has been auditing membership, including assurances around standards for 'flagged' RECs. 'Flagged' RECs are those that have been identified and trained to review specific research types eg research involving adults lacking capacity. The team has been able to develop a standard approach to following up membership issues identified from REC audits, and this has allowed the Division to plan recruitment carefully and expeditiously as a centralised activity which confers benefit in assuring the constitution of all HRA RECs. It also ensures operational staff can focus on direct support in meetings and to applicants.

Interview panel dates for new members have been set for 2019 and are advertised on the website making the process more streamlined for potential new members, and 2020 date are being finalised. People applying to become a REC member are now interviewed more quickly than previously. A centralised team dedicated to member recruitment and appointment allows a more focussed and consistent approach with more succession planning, though it may take some time to achieve the benefits fully whilst we address current shortfalls in REC constitutions.

The new Support Division has also produced a webinar for new members complementing the induction training already offered. Rather than ad hoc, committee-based training sessions, five regional training days for members have been set up for 2019/20 covering several topics in a more consistent way. We have worked with the Royal Colleges to establish the process for clinicians to seek CPD points for their REC work, noting this in recruitment material in the hope of attracting more applications from clinicians, the numbers of which currently pose some level of risk.

Appendix 2 sets out a more detailed review of progress against anticipated benefits in relation to the Support division.

## 11. Key Interim Indicators

### 11.1. Timelines

HRA and HCRW Approval provides a single approval for research in the NHS in England and Wales, to a high review quality within agreed timeframes. The integrated process seeks to make it easier to conduct those high-quality reviews in a more streamlined way, reducing duplication whilst maintaining the reliability of timelines for Approval. Predictability of review timelines is especially important for commercial studies – more so, than speed as an isolated factor. This aligns with the philosophy of HRA Approval that we should not focus on reducing timelines for our section of the research journey, where this may have negative effects at another stage. Nationally, the overall time for study set-up and recruitment are of paramount importance, though most of this metric is of course outside the remit of the HRA and HCRW alone.

The caseload of open applications has been increasing since February 2019, with a higher number of applications received per month than those approved or closed per month. This means that the open caseload has increased. However, the data below shows that overall performance for full REC applications has not been significantly affected, whereas proportionate review applications with a much tighter turnaround time have been impacted by the changes, and reflect where staff are feeling workload pressures.

#### 11.1.1. Median time from REC final Opinion to HRA Approval being issued

*Figure 1- median number of calendar days from the date of the final REC opinion to the date of HRA Approval being issued*

	Apr-19	May-19	Jun-19	Jul-19
<b>Commercial (Full &amp; PR)</b>	7	4	0	2.5
<b>Non-Commercial (Full &amp; PR)</b>	1	0	1	2

Comparison data for 2018:

	Apr-18	May-18	Jun-18	Jul-18
<b>Commercial (Full &amp; PR)</b>	4	2	2	7.5
<b>Non-Commercial (Full &amp; PR)</b>	0	0	0	1

This is a key deliverable for the integrated process. The spread of the data shows that in the majority of cases, applicants are receiving the HRA Approval outcome on the same date as the final REC opinion which means that the applicant receives this as a single communication.

#### 11.1.2. Median time from submission to valid application

The aim is for the application to be valid within 5 calendar days however, where applications are booked in well in advance of the meeting date, it is helpful to provide the applicant with more time to respond to validation queries in order to prevent applicants from needing to

rebook to a different REC. This is reflected in the figures for full applications as these applications are often booked in far ahead of the meeting date for example, if an applicant chooses to book to a specific REC.

Figure 2 - median number of calendar days from submission to the date on which the application was valid for REC review

	Apr-19	May-19	Jun-19	Jul-19
<b>Full - Commercial</b>	13	14	13	13
<b>Full - Non-Commercial</b>	16	14	14	19
<b>PR – Commercial</b>	3	1	2	5
<b>PR – Non-Commercial</b>	3	6	2	3

Comparison data for 2018:

	Apr-18	May-18	Jun-18	Jul-18
<b>Full - Commercial</b>	10	11.5	11	23.5
<b>Full - Non-Commercial</b>	11	12	13	22
<b>PR – Commercial</b>	2	0*	3	4
<b>PR – Non-Commercial</b>	3	5	5	4

\*Median is zero as 9 out of the 15 applications were valid on the day of receipt. The average number of days from submission to validation for PR commercial studies is 5 calendar days in May.

### 11.1.3. Median time from submission to validation outcome

Figure 3 - median number of calendar days from submission to the date on which the applicant was notified whether their application was valid on receipt or whether any further information was required in order for the application to be valid

	Apr-19	May-19	Jun-19	Jul-19
<b>Full - Commercial</b>	9	9	9	7
<b>Full - Non-Commercial</b>	11	9	8	9
<b>PR – Commercial</b>	2	1	1	4.5
<b>PR – Non-Commercial</b>	1	4	1	2

Comparison data for 2018:

	Apr-18	May-18	Jun-18	Jul-18
<b>Full - Commercial</b>	6	4	5	6
<b>Full - Non-Commercial</b>	4	4	4	6
<b>PR – Commercial</b>	1	0*	0**	1
<b>PR – Non-Commercial</b>	1	2	2	1

\*Median is zero as 9 out of the 15 applications were validated on the day of receipt. The average number of days from submission to validation for PR commercial studies is 2 calendar days in May.

\*\*Median is zero as 6 out of the 8 applications were validated on the day of receipt. The average number of days from submission to validation for PR commercial studies is 2 calendar days in June.

Priority has been given to validation of Proportionate Review Applications and Substantial amendments. In turn this influences the output time for validation letters for full applications, which are often booked in very far in advance of the REC meeting date.

#### 11.1.4. Median time from submission to REC meeting date

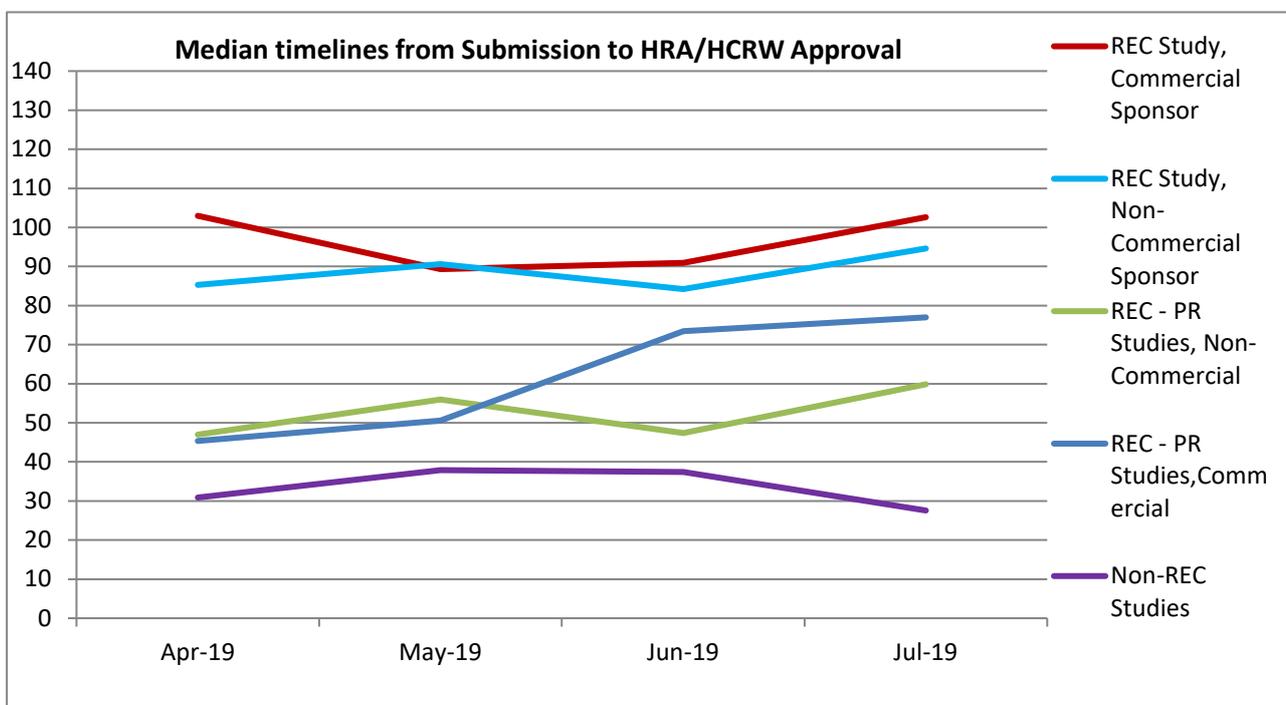
Figure 4 – median number of calendar days from submission to meeting date based on month of meeting

	Apr-19	May-19	Jun-19	Jul-19
<b>Full - Commercial</b>	28.5	28.5	28.5	29
<b>Full - Non-Commercial</b>	31	29	29	33
<b>PR – Commercial</b>	15.5	17	18	21.5
<b>PR – Non-Commercial</b>	16	21	20	22

These data show that applications to full REC meetings are normally booked well in advance, as applicants choose a date and meeting to suit their requirements and plans. For proportionate review applications, applicants are simply booked to the next available meeting. The longer submission time in July reflects a reduction in available slots in the summer period.

#### 11.1.5. Median time from submission to HRA/HCRW Approval.

Figure 5 - median number of calendar days from the date of submission to the date of HRA Approval being issued



This data includes the time for applicants responding to a provisional opinion from the REC. Approval from other regulatory bodies (e.g. MHRA, ARSAC) may also need to be received

prior to HRA Approval being issued. Although the open caseload has increased, the median timelines for overall approval timelines remain within previous ranges.

### 11.1.6. Compliance with REC targets

*Figure 6 - Full reviews completed within 60 day target (number and percentage)*

These figures measure REC activity only and exclude the time for the applicant to respond to any queries.

FULL REC REVIEWS	Apr-19	May-19	Jun-19	Jul-19
Median time to complete full review	34.5	35.0	38.0	36.0
% full reviews complete in 60 days	94.8%	89.4%	88.3%	89.5%
total studies completed	230	263	265	287
total completed in 60 days	218	235	234	257

Although the percentage of studies meeting the target has decreased, the median time has not increased significantly.

*Figure 7 – PR applications complete within 21 days (number and percentage)*

PR REC REVIEWS	Mar-19	Apr-19	May-19	Jun-19	Jul-19
Median time to complete full review	19.0	20.0	20.5	21.0	24.0
% full reviews complete in 21 days	74.3%	66.7%	56.3%	52.1%	38.9%
total studies completed	140	90	112	96	126
total completed in 21 days	104	60	63	50	49

Proportionate review applications have been affected by workload pressures. The median time for REC processes has increased and the percentage meeting the target has decreased significantly. This is consistent with the data in figure 5 which shows the overall HRA/HCRW Approval have also increased.

### 11.2. Impact on REC meetings

One of the key changes that the new integrated system includes is the attendance at REC meetings of either the Approvals Specialist or Approvals Manager. These roles are more senior than the previous REC Manager role, and the intention is that these more senior and experienced staff are able to play a role in increasing the consistency of the REC review process. Though this aspect of the role has not yet shown its full value, we are beginning to see positive examples of how the Approvals Specialist and Manager are supporting the committee and influencing the development of consistent approaches in the RECs.

The principle behind the Approvals Specialist or Approvals Manager attending the meeting is to build on the potential identified in the actions of some of the most experienced and effective REC Managers previously. The functions for the Approvals Specialist or Approvals Manager in the REC meeting are:

- Supporting the committee to reach an appropriate decision based on thorough knowledge of the appropriate guidance and legislation to ensure compliance
- Demonstrating a joined-up approach to study review by including assessment queries in the conversation with the applicant
- Acting as an advocate alongside the applicant to support their REC experience
- Taking on delegated responsibility from the Chair to address appropriate responses that would not need to go back to the committee
- Working in conjunction with the Chair to support and deliver a professional, consistent and positive meeting environment and experience for the applicant
- Advising the committee on REC SOPs where necessary
- Review REC minutes to ensure compliance with both assessment standards and the ethical review

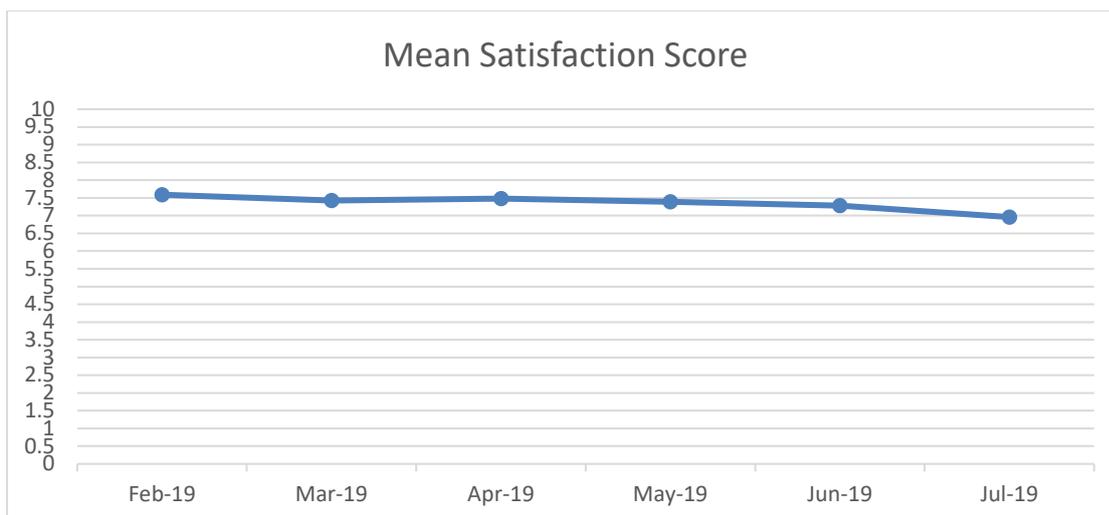
Staff were requested to contact the chair and begin building rapport before the meeting, and then gradually introduce the various inputs they will have. There has been range of experiences reported regarding the positive nature of the Approvals Specialist or Approvals Manager's attendance at the REC. Where there is a Chair who is conscious of the proposed benefit and is welcoming to new support coming into 'their' REC there has been value demonstrated. Conversely in other cases, staff are not yet confident in bringing up these roles within the meeting, or the Chair is still adapting to the new type of support. In such cases the team are attempting a slower burn interaction with the committee and adding demonstrable value where possible.

This is a new concept to some of the team, even those who have a REC background, and there is still misunderstanding of the role in terms of what they need to provide to the committee. Training on this matter has been delivered, support from senior management in Operations further to the training is ongoing, and a further day focussed on how to provide this service to the committee is planned for October so that we can work with the Approvals Specialists and Approvals Managers to ensure a consistent level of service is provided.

The increase in staff travel due to distinct roles working with the REC, and some staff attending three RECs per month where they might have attended two previously in RES, or none if from the Assessment team, understandably adds to the sense of pressure some staff experience. However, feedback from former RES staff has consistently identified how important the rapport between staff and REC members is. To that end, we think it is vital that in the first instance staff attend the meeting to garner the trust and support of members in the new support available to REC and applicant. We will look to rationalise attendance, supporting the REC and proceedings remotely where this is viable, and when the new process has bedded in, and its full benefits are more widely recognised.

### **11.3. Qualitative Feedback from User Satisfaction Reports**

User satisfaction data is routinely collected from applicants on a monthly basis. The data show a slight downward trend since April 2019. The free text information provided by some of the respondents.



#### Positive Feedback:

- Having a single point of contact was good.
- Positive comments relating to the helpfulness of staff
- Clear and useful communications
- Helpful to receive the REC queries at the same time as the assessment queries
- A more streamlined process now REC and assessment work in parallel

#### Areas to Address:

- Problems in contacting staff
- RECs not contacting applicants by telephone when unable to attend in person
- Delays in re-enabling e-submission (need this to be automated)
- Delay in being notified of the outcome following the REC meeting
- Delays waiting for amendments to be approved

This feedback confirms that the new process is achieving the benefits intended for applicants. However, the workload impacts have affected overall service delivery for some applicants and this has driven the slight decrease in overall satisfaction.

Work is underway to address areas for improvement as detailed in Appendix 2. However, it should be noted that many of the medium- and long-term actions are reliant on developments to our Research Systems led by the Transformation and Corporate Services directorate. A number of long-term improvements will be predicated on the technology available in meeting venues, though this needs to be balanced with the cost of suitable meeting locations. Telephony and broadband connection at REC meetings are an area being reviewed by the Finance, Procurement and Estates directorate with input from the Head of Member Support. Other actions are dependent on achieving agreement from Scotland and Northern Ireland to a UK-wide change, or agreement to differences between England/ Wales and the other nations.

As of this month, additional short-term resource has been identified to process outstanding amendments, which will also allow substantive staff to focus on business as usual and ongoing adaptation to new roles and ways of working. This area has been selected, as a pilot is underway to remove this aspect of amendment processing from staff roles. The additional resource allows the value to workload reduction to be delivered in advance of the full implementation of the pilot.

## 12. Financial evaluation and considerations

The aim of the workforce changes was primarily to create an integrated team to deliver an integrated process, with reduction of duplication and a focus on having the right skills and knowledge at the right point in the process.

A proposal for optimised Operations and Support Divisions was discussed at Workforce Board in February 2018. This proposal was not agreed on the grounds of affordability. A significantly reduced proposal with lower headcount than the original proposal, and with a reduction in existing Approvals Service staff numbers, was subsequently presented. This was agreed and consequently, the implemented structure has had to ensure effective delivery of the core functions of HRA Approval and dedicated support to Research Ethics Committee (REC) membership whilst realising around 80% of the financial savings target for the directorate of £300,000 for the year 2019-2020. This was in line with the overall savings expected of HRA across all Directorates by the Department of Health & Social Care.

	17/18		18/19		19/20			17/18 to 18/19 budget change	18/19 to 19/20 budget change
	Budget	Actual	Budget	Actual	Annual Budget	YTD Budget	YTD Actual		
Pay - excluding Staff Vacancy Factor	4877k	4741k	5164k	4942k	4836k	1605k	-	288k	-328k
Pay budget including SVF	4739k		4971k		4642k	1540k	1532k		
Travel	275k	301k	270k	281k	327k	109k	102k	-5k	57k
Postage, printing, stationery etc.	307k	285k	234k	226k	239k	81k	72k	-73k	5k
Overall saving								209k	-266k

Savings in staff costs have been realised in line with the revised proposals put to Workforce Board. It is worth noting that the pay budget in 18/19 was increased due to significant uplifts through Agenda for Change. The reduced funding for the delivery of HRA Approval has put pressure on delivery at a time when staff are also affected by the pressures typically seen in organisational change.

Through the activities in the integrated process and the Support Division, we have also seen financial savings in areas of printing and postage. Work planned to commence in Autumn to accelerate the uptake of HARP Member Portal will further increase this saving. Other financial

benefits are realised by the establishment of the Approvals Support Division. There is now a dedicated centralised team for travel bookings for staff and members travelling to REC meetings, which make the process simpler and more consistent and importantly allows for increased booking of cheaper advance fares. Travel budgets were increased in anticipation of more staff travelling to REC meetings, but good management has kept costs in check despite ticket price rises. The support team is also responsible for booking meeting venues (previously devolved out to each regional office), which has made invoice payment, budget monitoring and financial forecasting easier and uses less staff time.

### **13. Further changes post implementation**

As communicated to all staff at the outset, it has been essential to review how processes are working and to implement changes quickly when necessary to continue delivering the service. For example, it was identified early on that Approvals Officers were finding it hard to complete the REC validation within the required timeframe alongside covering three meetings a month which meant that responsibility for undertaking validation was transferred to the Approvals Specialists from May.

The Approvals Operations Managers and Head of Approvals Operations have also subsequently produced and prioritised a list of future changes to explore where further improvements can be made (Appendix 2). Whilst the benefit of many of the proposals to HRA/HCRW is clear, there are limiting factors of the resource to develop and test further process improvements. Additionally, for reasons of interoperability and provision of a UK-wide service, changes need discussion and negotiation with policy and management groups of the Four Nations, as well as the UK Research Ethics Development Group. As such, staff and researchers may feel that the rate of improvement, whilst visible, is at times slow.

### **14. Conclusions and Next Steps**

The Integrated Process itself is working as envisaged. However, as we would expect of a significant, transformative change to process, and the working arrangements for more than 100 people within a reduced budget, this has presented significant challenge for staff. Approvals Management espouses a team approach where staff can discuss issues and worries with their line managers and senior management, all of whom have significant experience of working within the REC and/ or R&D system. Concerns have also been raised through the Staff Forum, although this meets just once a month and cannot provide either immediate or tailored responses, and it does not allow management to hold a complete picture of the challenges that staff are experiencing. We therefore encourage staff to raise individual concerns directly with managers, escalating directly with senior managers where they feel the need to do so. We are aware that sometimes staff can feel that they have not been heard, when in fact the change that they are seeking has been considered but not accepted. The management team tries to provide explanations for decisions to the team to counter this, which Staff Partnership Forum cannot. If these discussions are collated in real time by the Approvals Managers and the Approvals Operations Managers, we can make sure that the most effective feedback, particularly around difficult decisions on understandable suggestions, is given to staff in their own staff meetings, and summarised monthly in the Directorate Videoconference.

A significant range of activities are in hand to achieve quick wins and longer term aims to continue to improve processes, reduce workload and burden for staff, and streamline the process for applicants. Most of these activities could not be implemented until the new integrated structure and process were in place. The pace of implementing these changes has to take account of the burden on staff of learning and implementing new procedures, even where those changes make things simpler or easier.

Other features of the Integrated Process and Service Improvement/Transformation projects will realise further benefit. Senior Management in Approvals recognise that while these will ultimately support staff and improve outputs, it needs balancing with the Directorate staff's capacity and appetite for change. There are further process refinements, such as Information Systems improvements like e-booking of applications and electronic submission of amendments to reduce staff administrative overheads. These are dependent on the large-scale programme of work in Research Systems. Other refinements include 'Ready for Review' to improve the quality of applications received, and the speed and consistency with which they will therefore be reviewed. Some improvements, eg to Proportionate Review bookings need discussion on a Four Nation basis to get UK wide consistency.

Work on refinements, for example, moving to single validation and removal of validation letters has already begun to ease the challenges faced by the team since the transition. Work is ongoing to maximise the benefit of micro teams, and we acknowledge, as do staff, that any significant change will always provide both challenges and wins.

## Appendix 1

### Anticipated benefits of the Support Division and progress

The following list details the anticipated benefits of the Approvals Support division having been established, and provides an update on benefits achieved so far:

- **Member Recruitment**

The establishment of the Support Division means that the recruitment of new REC members can be managed centrally. There are a number of opportunities that can be realised from this such as improved succession planning to identify vacancies, a consistent interview and appointment process, taking forward improvements to the recruitment process identified from the SIP volunteer recruitment project, and improving our documentation used throughout the recruitment process. Benefits achieved so far include the development of a slide about joining a REC to be added to presentations delivered by the HRA and by REC Chairs, the introduction of an electronic review of an application form during member interviews, and updated versions of the member starter and leaver checklists.

- **Member Management**

The recording and following up of member attendance, training and checking that RECs are correctly constituted is the responsibility of the Support Division. Benefits achieved so far include:

- i. A Systems change so that a central report of REC membership can be produced from HARP.
- ii. Training delivered to the Member Support Administrators so that information relating to REC members is recorded in HARP consistently with clear naming conventions for documents.
- iii. A standard approach to following up membership issues identified from REC audits.

- **Member Learning**

The following benefits have been achieved so far since April 2019:

- i. Sign off of the Research Tissue Bank e-learning module
- ii. New content for the REC member induction to be tested from September 2019 to respond to member feedback and to make the session more interactive.
- iii. Programme and dates for the Regional Member Training days have been finalised and published.
- iv. A webinar to assist new members with reviewing their first set of meeting papers is being developed.
- v. Discussions have been held with the HRA Learning Team regarding suggested improvements to the Learning Management System to meet the needs of REC members.
- vi. Establishment of a working group (UK wide) to take forward a new learning objectives based approach to Member Learning as opposed to an arbitrary expectation that members complete a minimum of 5 hours training per year.

- **Quality Assurance**

The following benefits have been achieved so far since April 2019:

- i. A process for following up actions identified from audits has been developed by the Support division to agree an approach for how both operational findings and membership findings will be managed between the two teams.
- ii. Operational updates produced for staff now include a 'Quality Assurance' section as standard to feed back on key findings.
- iii. There were a number of gaps identified and errors in terms of RECs not being correctly constituted and members missing key appointment documentation prior to the restructure. The Support team are starting to be able to prepare more proactively for upcoming audits.

- **Electronic Review of REC Meeting Documents**

The Electronic Review of REC Meeting Documents is a key project for the Support Division for the next year. The following progress has been made so far:

- i. Prepared a proposal to seek feedback from REC Members and Staff for how the distribution of REC meeting documents will be standardised. Following a review of the feedback, this approach will be introduced from 2<sup>nd</sup> September which will be beneficial to staff in terms of consistency when covering other RECs as well as increased use of the Member Portal (meaning time savings and cost savings).
- ii. A new post in the Support division is currently being advertised for a Member Portal Development and Support Officer meaning that each REC will benefit from a visit and face-to-face demonstration of how application documents can be viewed electronically.
- iii. The new format for Member Induction will include an activity involving members reviewing an application electronically.
- iv. Responsibility for the set up and distribution of the new netbooks.
- v. New fields in HARP so that we can report on the uptake of electronic review much more easily and accurately.

- **Update of UK wide RES SOPs and maintaining links with Research Ethics Service Colleagues in Scotland and Northern Ireland**

- i. Version 7.3 of SOPs have been published to reflect the new UK wide process for the ethical review of participating non-NHS sites.
- ii. The Support team will be delivering minute taking training to colleagues in Scotland and Northern Ireland to ensure a consistent approach UK wide.

## Appendix 2

### Proposals for improvements to operational processes

The following are proposed improvements that are being analysed. Many need discussions with other parties, particularly devolved administrations.

Proposal	timing	Staff benefit
Voice mail recordings to advise Applicants that CBS should only be utilised for new application bookings. Queries relating to applications already booked in should be directed towards the relevant REC / member of staff.	Quick win	Queries routed to the most appropriate person
Data capture at CBS booking stage in terms of full REC meeting utilisation and RECs which are less used.	Quick win	Better and more consistent slot utilisation and even distribution of workload
Training for CBS bookers on suitability for PR.	Quick win	Less transfers of applications, huge staff time saving
Reducing PR meeting slots to 3 applications (currently 4 applications).	Quick win	Better slot utilisation and more even distribution of workload
SCR to create an automatic email to the REC inbox to state that the application has been submitted.	Quick win	Assist the Approvals Specialist and Approvals Officer knowing that an application has been submitted
Reduce the number of checks at validation.	Quick win	Time saving, reduce non value adding checks, align with CWOW
Supporting Approvals Specialists to be more pragmatic in reviewing document version numbers and dates for non-commercial by doing a sense check.	Quick win	Time saving, reduce non value adding checks, align with CWOW
status update to remove validation letter	Quick win	Reduction in the number of outputs produced, streamlined communication
status update to remove acknowledgment letter	Quick win	Reduction in the number of outputs produced, streamlined communication
Look at how the data produced on REC statistics is utilised.	Quick win	More effective data
Template email requesting advice to go into HARP	Quick win	Easier to contact experts
Standardise the allocation of lead and second reviewer.	Quick win	Easier to provide cover across RECs
Streamline the REC agenda.	Quick win	Reduce time deleting sections not used
Utilisation of a Member attendance sheet to assist with quoracy.	Quick win	Assist with quoracy, know in advance the need to co-opt

Revise minute signing - minutes to be ratified within the meeting but electronically signed.	Quick win	Reduced audit findings, easier for staff to upload
More automated SC minutes	Quick win	Staff Benefit, reduced audit findings
Only make the REC report available on the portal.	Quick win	Better use of staff time, financial saving
Explore the removal of confirmation of favourable opinion with conditions letter.	Quick win	Reduced output, more streamlined approach
Automated re-submission enabled when a provisional opinion or favourable opinion with conditions is issued.	Quick win	Reduction in emails / phone calls from Applicants, less steps for staff
Make the standard conditions available on the website. Removing the need to attach the standard conditions to the outcome.	Quick win	Removing the need to attach the standard conditions to the outcome.
Remove the need to upload letters in word and pdf format.	Quick win	Reduced steps
Reduce the need to send amendments to Scotland and Northern Ireland.	Quick win	No need to send documents to Scotland and NI
Revisit the need for post approval activity, progress reports, safety reports etc.	Quick win	Remove the need for the applicant to submit and staff to process
Revisit the need to list REC committee members in the Provisional Opinion letter following feedback from Sponsors. It is not clear in GCP or anywhere else that its warranted.	Quick win	Remove queries being raised by sites
Explore adding a line to favourable opinion letter to state that the committee was correctly constituted in line with GCP .	Quick win	Remove queries being raised by sites
SCR to remove the need to check contact on HARP when importing a study submission. The SCR should consider if this change needs to apply to all REC's or could be England and Wales specific.	Short term	Reduced steps on HARP, time saving
Revisit the functionality of the verification tool to enhance the checks undertaken by the tool.	Short term	Reduction in the number of checks done by staff, better submissions
Revisit the functionality of the verification tool to enhance the checks undertaken by the tool.	Short term	Reduction in the number of checks done by staff, better submissions
Refine the definition of a REC condition. Minor things, for example, typographical errors, version number to not be included.	Short term	Streamline and reduce the number of responses staff need to see and applicants need to change
Streamline the process for publishing the summary of opinion.	Short term	Reduced steps

Explore adding an automated alert for where an unfavourable opinion is sent to inform the devolved nations	Short term	Reduction in email traffic
designating some RECs as PR only. They would still be constituted as full RECs and have enough people at the meeting to be able to review something there and then if it was deemed not to be PR, but they could aim to get through 5-6 PRs in one meeting. ie one REC could cover 2 RECs worth of PR,	Short term	Better slot utilisation
Refresh of guidance for appeals process.	Short term	Streamline
Electronic review of REC meeting papers.	Short term	Better use of staff time, financial saving
Guidance improvements to support applicants on how to book applications.	Medium term	Better applications means reduced time for validation and queries
Revisit SIP proportionality to look at booking PR applications to a holding pen and then allocating once valid.	Medium term	Better slot utilisation and reduced time wasted in re-allocating PR applications
Algorithm discussed as part of SIP to be created thereby reducing the number of non-valid applications.	Medium term	Reduction in the number of checks done by staff, better submissions
Broaden the pool of existing experts Update database	Medium term	Easier to identify experts
All document changes to be listed on the lead and second review sheet in advance of the meeting and if agreed at the meeting copied and pasted direct into the minutes.	Medium term	Reduced time minuting and reduced changes needed by applicant
Automated clock management on HARP.	Long term	More accurate data, less steps for Staff
Development of HARP and IRAS for more automation of clocks	Long term	More accurate data, less steps for Staff
E-booking and e-submission in IRAS to HARP.	Long term	Removal of CBS telephone calls
Guidance improvements for applicants on suitability of PR	Long term	Better applications means reduced time for validation, queries and better slot utilisation
Screening tool for PR built into IRAS.	Long term	Reduction in incorrect PR submissions and wasted staff time
Dashboard on IRAS as a communication tool.	Long term	Better communication to applicants, reduced email traffic
Ready for review.	Long term	Reduced duplication of review and questions
Role specific (as opposed to REC specific) HARP dashboard.	Long term	Enable staff to manage own workload