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| --- | --- |
| **Agenda item:** | **12** |
| **Attachment:** | **G** |

**HRA BOARD COVER SHEET**

|  |  |
| --- | --- |
| **Date of Meeting:** | 18 November 2015 |

|  |  |
| --- | --- |
| **Title of Paper:** | Quality Assurance update to Board  |
| **Purpose of Paper:** | To advise the HRA Board on recent QA activity and progress towards external ISO9001 Certification and wider activity within the department, in line with previous updates. |
| **Reason for Submission:** | The business plan for 2015/’16, noted for QA to ‘Ensure all functions and services provided within and by the HRA are of a high quality, quality checked and continually improve in response to feedback’. This report provides an update upon developments and activity as we move towards the final quarter of the year and the fulfilment of the QA Business Plan activity. In addition this paper notes the first six months REC Accreditation Scheme reporting and User Satisfaction feedback for the same period. The Board, are asked to note and comment upon the work undertaken and endorse the continuing development through to ISO 9001 Certification external audit in Q4 this year, in line with our business plan and commitment within our Quality Policy. |
| **Details:** | Enclosed within. |
| **Time required for item:** | **30** |

|  |  |  |
| --- | --- | --- |
| **Recommendation / Proposed Actions:** | **To Approve** | **x** |
| **To Note** |  |
| **For Discussion** | **x** |
| **Comments** |  |

|  |  |
| --- | --- |
| **Name:** | Tom Smith |
| **Job Title:** | Director of Quality, Guidance and Learning |
| **Date:** | 09 November 2015 |

**Quality Assurance Department**

**Update - November 2015**

**Introduction**

In line with our Quality Policy, the HRA is committed to assuring the quality of our service through the establishment and maintenance of a Quality Management System aiming to be compliant with the requirements of ISO 9001:2008.

The Board will be familiar with the objectives for the Quality Assurance (QA) Department for the current year 2015/’16, which included the stated aims of widening the Internal Quality Audit function during 2015 to organisation wide and maintain the HRA ISO9001 Certification (June ’15 external ISO audit) for the Quality Assurance Department.

The Board will recall previous updates received in relation to the work against plan towards delivery of the business objectives.

**Activity update**

Building upon the update to the Board in July 2015, there has been very significant internal audit activity over the last c18 months, in undertaking audits and gap analysis work, working with colleagues across the Authority to ensure that functions embed Quality Management System (QMS) principles within their everyday work and in documented procedures, where applicable. This has been a significant undertaking, taking considerable time not only to audit, but also re-audit in the majority of areas and practically assist in terms of drafting documents. The benefits are however, not only that our documentation is more robust and better reflects the work undertaken but that our process as a single organisation, Authority-wide, have been strengthened to ensure that we continue to improve our services offered.

The benefits of embedding quality practices, are not only around reducing corporate risk as part of consideration of liabilities, but also importantly around delivering a high level service, continually improving and reducing duplication of working practice, saving time and resources and delivering upon our values statement.

Appreciating the significant amount of input and work development this has taken to date, particularly for the QA department staff team but also of the wider Authority this year, the improvements made are anticipated to bring significant benefits to the organisation moving forward. Noting also the considerable current project to fully implement a document management system (through HRA Hub) across the HRA, the review and development in future years of documentation will be less intensive, increasing robust and reduce corporate risk, increase confidence and ensuring that staff have access to current documents. Wider than documentation however, the investment made this year will bring benefits to the Authority moving forward through further embedding of QMS principles as a matter of norm, ensuring that services remain User focused (both for internally and externally received services) and we continue to improve services and our working practices, based upon accurate evidence, information and appropriate involvement from staff colleagues who deliver services.

The following (non-Operations) audits /gap analysis have been undertaken since April ’15;

In Q1 2015-’16 there were 16 areas with audit /gap analysis action plans due;

**Gap Analysis:**

Health & Safety – completed

Information Governance – completed

Equality & Diversity – completed

Communications – completed

Complaints – completed

Business Continuity – completed

Open Services – completed

Project Management Office – outstanding

Major Incident Planning – outstanding

CAG – outstanding

Guidance & Advice – outstanding

Public Involvement - completed

**Audits:**

Human Resources: Flexible working – completed

 Annual leave – completed

 Dress Code – completed

 Appeals - completed

In Q2 2015 –’16 there were 2 action plans due;

**Audit:**

Collaboration & Development – completed

**Gap analysis:**

Engagement & Policy - outstanding

In Q3 2015-’16 there were 17 areas with audit /gap analysis action plans due

**Audits:**

Operations - Recruitment of Members - completed

Queries Line - outstanding

Manchester REC Centre

Human Resources: Capability – completed

 Grievance and disputes – completed

 Probationary period -outstanding

 Lone worker -outstanding

 Whistle blowing -outstanding

 Organisational change-outstanding

 Retirement -outstanding

 Sickness absence -outstanding

 Bullying & harassment -outstanding

 Maternity, paternity & adoption -outstanding

 Recruitment of HRA staff -outstanding

Information Systems

Health & Safety – completed

Information Governance

In Q4 2015-’16 to date, there is one area with audit action plans which will be due, Communications.

By way of an illustration of the benefits secured from internal audit ahead of ISO9001 Certification across the wider Authority, arising from one audit within one department function there were four action plans raised; assisting to ensure that current practice was more closely aligned with policy and the process being undertaken by staff, strengthening the data collection and data retention principles, leading to the direct undertaking of quality checks to assure the service and highlighted a service provision where a procedure required to be documented. Through such audits there is visible movement in improving our service offered, not least to the benefit of staff colleagues.

All of the above noted activity is in addition to the well-established REC Accreditation Scheme, the report of which for April –Sep ’15, for the HRA and Devolved Administrations is included at Appendix 1 and User Satisfaction, with the April – Sep ’15 report included at Appendix 2.

Noting in particular those areas where non-conformities have been raised and actioned, visibly demonstrates the reduction in our potential liabilities and risks. The direct benefits that arise from the investment that has been made during this year, will ensure that we benefit in future through continually reviewed services that build and improve on feedback and learning lessons; bring benefits to the Authority and the research community.

**Recommendation**

The Board are therefore asked to;

* Note the REC Accreditation Scheme, report for April –Sep ’15,
* Note the User Satisfaction report for April – Sep ’15,
* Note and comment upon the audit and gap analysis work undertaken since April ’15, as part of our continual improvement to improve our services,
* Approve the continuing direction as per the HRA Business Plan in respect to the HRA extension of current ISO9001 Certification, by way of external audit in Q4 by an ISO9001 Certification body.

**Tom Smith**

**09 November 2015**

**Appendix 1** REC Accreditation Scheme, report for April –Sep ’15

**HRA AND DEVOLVED ADMINISTRATIONS**

**ACCREDITATION SCHEME REPORT**

**FOR PERIOD APRIL 2015 TO SEPTEMBER 2015**

**Introduction**

This report includes data relating to REC audits conducted and action plans completed between April 2015 to September 2015.

1. **REC audits and accreditation status awarded**

|  |  |  |
| --- | --- | --- |
| **Name of REC** | **Audit period**  | **Accreditation status awarded**  |
| London – Queen Square | Jan 2014 – Dec 2014 | Accreditation with conditions |
| North West – GM East  | Feb 2014 – Jan 2015 | Accreditation with conditions |
| HSC A | 17 Feb 2014 – 16 Jan 2015 | Full accreditation |
| South West – Cornwall & Plymouth | Feb 2014 – Jan 2015 | Accreditation with conditions |
| London – Camden & Kings Cross | Feb 2014 – Jan 2015 | Full accreditation |
| South West – Central Bristol  | Mar 2014 – Feb 2015 | Full accreditation |
| South East Coast – Brighton & Sussex | Mar 2014 – Feb 2015 | Accreditation with conditions |
| HSC B | Mar 2014 – Feb 2015 | Full accreditation |
| London – City Road & Hampstead | Mar 2014 – Feb 2015 | Full accreditation |
| West of Scotland 1 | Apr 2014 – Mar 2015 | Full accreditation |
| Wales REC 4 | Jan 2014 - Dec 2014 | Provisional accreditation |
| West Midlands – Edgbaston | May 2014 – Apr 2015 | Full accreditation |
| North West – GM South  | Jun 2014 – May 2015 | Provisional accreditation |
| Yorkshire & The Humber - South Yorkshire | Jun 2014 – May 2015 | Full accreditation |

1. **RECs Achieving Full Accreditation after completion of an action plan**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name of REC** | **Latest date which action plan should be completed (including extensions)** | **Date completed action plan received from REC** | **Date full accreditation received** |
| London – Surrey Borders | 07-Apr-15 | 07-Apr-15 | 09-Apr-15 |
| London – Chelsea | 16-Apr-15 | 16-Apr-15 | 22-Apr-15 |
| West Midlands - Coventry and Warwickshire | 22-Apr-15 | 21-Apr-15 | 05-May-15 |
| London - Westminster | 05-May-15 | 05-May-15 | 07-May-15 |
| Wales REC 2 (previously South East Wales B) | 17-Mar-15 | 19-Mar-15 | 02-Apr-15 |
| Wales REC 3 (previously REC for Wales) | 20-Feb-15 | 20-Feb-15 | 24-Feb-15 |
| Wales REC 1 (previously South East Wales D) | 15-Jun-15 | 27-May-15 | 08-Jun-15 |
| West Midlands - South Birmingham | 15-Jun-15 | 11-Jun-15 | 15-Jun-15 |
| London – Stanmore | 22-Jun-15 | 15-Jun-15 | 13-Jul-15 |
| Wales REC 5 (previously North West Wales) | 20-Apr-15 | 07-Apr-15 | 13-Apr-15 |

1. **Numbers of issues in relation to number of RECs audited identifed through the reporting period**
2. **Standards not met**

The trends in standards unmet are listed below. Graphs 8a and 8b show the trends of standards for RECs reviewed and are illustrated using 2 key areas; membership and administration.

**Trends in the issues identified through the 2013 audit scheme**

**Graph 8a**

NB: the blue line for “compliane with SOPs/Processes” follows the same trend as the red line for “HARP” and therefore it is not visible as it is underneath the red line.

**Graph 8b**

1. **Report Turnaround Times**

All the HRA QA procedure timelines were met during the reporting period.

1. **Analysis of recommendations detailed in audit reports**

Recommendations are issues which are deemed to be low enough risk not to warrant an action plan requiring review and sign off by the HRA QA department. Compliance against recommendations raised is checked through 6 monthly Quality Control (QC) checks.

The recommendations made in relation to the 14 audits, conducted during the reporting period, have been collated and analysed to provide broad trends on the two key areas – membership and administration of RECs.

**Membership**

3 issues were raised in relation to appointment and terms and conditions; issues ranged from issues missing in the appointment letter to adjustment of term to cover gap between officer appointment and member appointment.

8 separate recommendations were detailed in the audit reports relating to recording and uploading of documents to members HARP membership files; representing over a 50% decrease since the last reporting period.

The capacities of 9 members were questioned with a request to seek advice from the HRA Board Secretary and Chief Executive Business Manager to confirm membership capacities. Recommendations were made in relation to staggering appointments to ensure that not all expertise is lost at one once, to obtain professional registration numbers to enable a cross reference to the appropriate register (relevant when a number of people are listed with the same name) and to obtain a CV/application form to confirm capacity of member.

There were 9 separate recommendations relating to the completion of the training requirement by members; issues included non-completion of self-directed learning logs (SDL), induction and chairing skills training required, and requests to continue to monitor and manage members training.

A recommendation to continue to monitor and manage members’ attendance to ensure compliance with Terms and Conditions (T&Cs) was detailed in 5 audit reports.

 **Administration**

309 separate issues were raised in relation to non-compliance with administration; SOPs, timelines, minutes/letters, HARP and management of the HARP clock.

102 issues related to non-compliance with the HARP Dataset. The majority of issues, again, related to the non-uploading of documents. Other issues raised included the marking of lead reviewers, clear audit trails relating to the review of applications and amendments, the need to enter reasons for applications being marked “validation under consideration” and the non-clearance of publication alerts.

19 recommendations were raised in relation to non-compliance with SOPs; 4 of which related to the use of favourable with conditions and 4 were in relation to timely reminder letters for progress reports not being sent out.

76 separate recommendations related to minutes (main, sub and PR) and letters. The majority of the issues related to the minute taking and letter writing guidance.

1. **Feedback from REC Managers of audited RECs**

Feedback is sought from REC Managers of RECs undergoing audit seeking their views on the accreditation procedure. REC Managers are sent a copy of the feedback form along with their final decision letter. 4 RECs have provided feedback from the fourteen RECs audited. A report detailing feedback can be found in Appendix 1.

1. **Conclusion**

Of the fourteen RECs audited during the reporting period, eight were awarded full accreditation, four were awarded accreditation with conditions and two provisional accreditation with action plans. There is a welcomed increase in the number of full accreditations being awarded (100% increase from the last reporting period – October 2014 to March 2015) and a marked decrease in provisional opinions.

There were no issues raised in action plans in relation to constitution and quoracy, training, attendance and recruitment. Issues relating to indemnity has increased slightly; these related to the issuing of reappointment letters and terms and conditions for members and appointment letters for officers of the REC.

Issues relating to non-compliance with minutes and letters has decreased, being raised in two out of the 6 action plans issued.

There has been an increase in issues being raised in relation to non-compliance with SOPs and HARP dataset featuring in two action plans and also an increase in timeline non-compliance which was raised in three action plans.

The limited feedback from REC Managers on the accreditation process has been positive.

 **HRA QA Department**

 **19th October 2015**

Appendix 1

**Feedback received from audits completed between April 2015 and September 2015**

**Views of REC Managers on the audit procedure**

|  |  |
| --- | --- |
| **Activity**  | **Percentage per score****Rating guideline 1=poor, 5=excellent**  |
| **1** | **2** | **3** | **4** | **5** |
| The checklist made clear the standards to be met in the audit.  |  |  |  | 25 | 75 |
| Completing the checklist helped to prepare for the audit |  |  |  |  | 100 |
| The interpretation of standards during the audit was a fair reflection of GAfREC, SOPs and other NRES guidance. |  |  |  |  | 100 |
| The audit was fair and reasonable with the opportunity to discuss and clarify issues during the process  |  |  |  |  | 100 |
| HRA QA staff were approachable, fair and methodical |  |  |  |  | 100 |
| The issues raised in the audit report and action plan were a fair reflection of the situation. |  |  |  |  | 100 |

**Comments received from REC Managers through the feedback form**

**REC 1**

*Jane Martin made us feel at ease while conducting the interview and carefully explained the process.*

*I thought the order of some of the questions in the checklist could be re-ordered. Also the formatting of the text where the answers are put was all different so text appeared in different colours, fonts and size. This may seem minor but would reduce the time taken to complete the checklist.*

**REC 2**

*Thank you very much for the support and feedback.*

**REC 3**

*The audit telephone interview was far less harrowing than I thought it might be. This was probably due to the Regional Manager making the Auditor aware of some background details and the Auditor taking these on board to avoid going over these at the interview.*

*Please convey my thanks and kind regards to Jane Martin who conducted the audit interview, and explained what would be covered.*

*It was very encouraging to receive acknowledgement of work undertaken and praise where it is due, and comments have also been forwarded to the Committee.*

*Perhaps the feedback area could be modified so that the user can indicate the score. I have used highlighting.*

**REC 4**

*Thank you Jane & Nicki for all the work you have done especially allowing an opportunity to clarify some of the issues post audit. Has helped greatly towards achieving full accreditation.*

*Just a comment. Would it be possible to consider Sub Committee work as part fulfilment of a members expected attendance at meetings in the year? Just like PR?*

Appendix 2

**Chart detailing data collected relating to accreditation trends**

|  |  |  |  |
| --- | --- | --- | --- |
| **Category**  | **Apr 2014 – Sep 2014 (31 issues / 11 RECs)****%** | **Oct 2014 – Mar 2015 (19 issues / 14 RECs)****%** | **Apr 2015 – Sep 2015 (11 issues / 14 RECs)****%** |
| **Membership****Indemnity**  | 6 | 0 | 18 |
| **Membership****Training** | 6 | 24 | 0 |
| **Membership****attendance** | 4 | 9 | 0 |
| **Membership****Constitution** | 10 | 14 | 0 |
| **Membership****Recruitment** | 6 | 0 | 0 |
|  | **32** | **47** | **18** |
| **Administration****SOPs/processes** | 26 | 5 | 18 |
| **Administration HARP** | 16 | 5 | 18 |
| **Administration Minutes/letters** | 10 | 24 | 18 |
| **Administration Timelines**  | 6 | 19 | 28 |
| **Other** | 10 | 0 | 0 |
|  | **68** | **53** | **82** |

**Appendix 2** - User Feedback, April – Sep ’15 report

**USER SATISFACTION REPORT**

**HEALTH RESEARCH AUTHORITY** **(including those using the REC service in the Devolved Administrations)**

**FOR THE PERIOD**

**01 April 2015 to 30 September 2015**



1. Introduction

This bi-annual User Satisfaction report presents data collected during the six month period (April 2015 to September 2015) from UK wide users of the HRA and those using the REC service in the devolved administrations.

The Health Research Authority (HRA) routinely seeks feedback from its users to continually monitor and assess its performance. This helps to identify our strengths but also highlights areas for improvement, given the resources available. The HRA Quality Assurance Department has responsibility for the User Satisfaction function.

Data presented in this report has been collected using the following methods.

* Online feedback survey via SurveyMonkey. Information is routinely received via the HRA website from those who choose to complete an online survey and from chief investigators, students and sponsor representatives who have been targeted to provide feedback because they made an application to a specific Research Ethics Committee (REC) or the Confidentiality Advisory Group (CAG) during a selected month. Applicants and sponsors submitting applications to approximately 16 REC / CAG meetings are contacted every month to request feedback on the service they received.
* REC / CAG Chairs and Members online feedback form. Information is gathered from Chairs and Members wishing to put forward their views, concerns and ideas.
* HRA staff suggestions / ideas feedback pilot scheme.
1. The management and use of feedback in the HRA

The HRA takes the views of users of our service seriously and ensures these are reviewed at a senior level and used to consider improvements to our service. The HRA Executive Management Team (EMT) and the United Kingdom Research Ethics Development Group (UKREDG). The role of the EMT is to take an overview of the trends in feedback and consider if there are any overarching system considerations that need to be addressed. The role of the UKREDG is to consider the operational issues in feedback to monitor and assess performance over time as well as considering the comments made by respondents. Managers from the appropriate HRA Directorates and Devolved Administrations are asked to consider and feedback on issues raised in the previous User Satisfaction reporting period to ensure that issues are being addressed and lessons learnt.

1. Findings from the online user satisfaction survey

This section of the report presents findings from the survey (a total of seventeen open and closed questions). For the six month reporting period 208 respondents completed the online feedback survey; very comparable to the previous reporting period (October 2014 to March 2015) where 210 respondents completed the survey. .

Feedback is reported on services provided directly by the HRA and functions that are provided by the HRA through HRA Operations. Respondents are given the opportunity to receive feedback on their responses, from a senior member of management. Senior Management may follow up respondents comments with the REC / CAG involved (not disclosing details of the respondents without their consent).

For open ended questions respondents’ comments are categorised as either positive, negative or neutral; where a response to a questions covers more than one category these have been subdivided allow for more accurate categorisation.

**Figure 1. Responders to the survey were asked to specify their role**

**Figure 2. Responders were asked whether or not their application was reviewed through the PR Service\* or Precedent Set Review**

*\*The Proportionate Review Service (PRS) provides for expedited, proportionate review of research studies which raise no material ethical issues. Under the PRS, new applications are reviewed by a sub-committee rather than at a full meeting of a REC, with the aim of notifying the final decision to the applicant within 14 calendar days of receipt of a valid application*

**Figure 3. Breakdown of responses by HRA REC Centre, Confidentiality Advisory Group (CAG) & Devolved Administrations**

Responses from the Devolved Administrations accounted for a quarter of responses compared to one fifth of total responses for the last reporting period. The proportion of responses from the HRA REC Centres in England remains constant with the previous reporting period.

**HRA Services**

**Figure 4. Respondents were asked to rate their experience of a different aspects of HRA services**

* 98% of respondents rated REC/CAT staff either excellent or good.
* 93% of respondents scored the service provided by the HRA queries line either excellent or good.
* 90% of those responding to how they found the HRA website rated it excellent or good.
* All HRA Services rated as either excellent or good by 80% of respondents.

**Trends in User Satisfaction**

Below are graphs showing trends in responses to users experiences of different aspects of HRA services, over the last 18 months. The IRAS specific questions have changed over the reporting periods; therefore trends are not presented here.

**Key to graphs**



**Figure 5. HRA Decision Tools**

84% of respondents rated HRA Decision Tools as either excellent or good, compared to 92%

(Oct 14 – Mar 15) and 89% (Apr – Sep 14).

**Figure 6. Online Guidance**

82% of respondents agreed that the Online Guidance were either excellent or good, compared to 90% (Oct 14 – Mar 15) and 85% (Apr – Sep 14).

**Key to graphs**



**Figure 8. HRA Website**

* 90% of those responding to how they found the HRA website rated it excellent or good, this being the same score as the previous reporting period, and a 5% improvement on Apr – Sep 14.
*

**Figure 9. HRA Queries Line**

93% of respondents scored the service provided by the HRA queries line either excellent or good, compared to 94% in the previous two reporting periods.

**Figure 10. REC / CAT Staff**

98% of respondents rated REC/CAT staff either excellent or good, compared to 94% in the previous two reporting periods.

**IRAS Feedback**

Respondents were asked to note any comments in connection to their experience of using IRAS.

111 comments were received in total (25 positive, 51 negative and 36 neutral). *Comments are copied directly from the online survey.*

Many of the positive comments received related to the ease of use of IRAS acknowledging the helpfulness of the supporting guidance and additional functions to facilitate the application process. One applicant noted ‘the information buttons are helpful land by reading then thoroughly it is apparent what is being asked.’ A few comments highlighted the usefulness of the supporting online IRAS training facility, with one respondent noting, “The learning exercise guided me well and helped me to navigate smoothly*”*

Negative comments received relating to IRAS described the system as ‘clucky’, ‘non-user friendly’ ‘unclear’, ‘frustrating’ ‘repetitive’ and ‘out-dated’. Some respondents noted their experience of ‘glitches with the system and there were multiple references to the time taken to complete the form. One respondent stated “*It is hard to navigate and figure out what you have to add/fill in when you never used it before; it also takes a lot of time to figure out what you really need. The system should be more user friendly for people who don't do this all the time and are mostly doing benchwork instead of paperwork.”*

Many of the neutral comments received indicate that the system is satisfactory to users with one respondent noting, “*I think it takes a bit of getting used to. All the information is there, but there are no easy short-cuts. Not everyone has the confidence to phone someone up to ask. I know people new to research find it very challenging indeed*”. A number of respondents made suggestions for further improvements, such as “*Providing word documents as template forms with embedded guidance would make creating an application a lot easier*” and “*While it is great to have a system that integrates multiple applications and we love the idea in principle, the ongoing need for signatures across multiple applications and from multiple people is cumbersome. It would have been helpful to have a "validation" review of the entire application where problems were ironed out prior to actual submissions.*”

**Attendance at the REC/CAG meeting**

**Figure 11. Respondents were asked whether they attended the REC/CAG meeting, and if so were they treated fairly and with respect by the Committee**

The proportionate of respondents who answered ‘no’ to this question has reduced from 4% to 1% when compared to the previous reporting period (Oct 14 – Mar 15);

Respondents were asked whether or not they wished to comment in connection with their attendance at the REC/CAG meeting.

75 comments were received (55 positive, 08 negative and 12 neutral). *Comments are copied directly from the online survey.*

As with the previous reporting period comments a significantly high proportionate of the received from respondents attending the REC /CAG meeting were classed as positive (73% for the reporting period compared to 68% in the last reporting period) A number of the respondents described their experience as ‘excellent’ with many acknowledging the friendliness, supportiveness and helpfulness of the Committee. *One respondent noted “I felt very welcomed by the committee and I appreciated the positive comments they made about my application, especially as it was much first one, it was very encouraging. I also found the questions they asked and recommendations helpful.* Another respondent commented*, “We were made to feel extremely welcome at the REC meeting, and all of the committee members were polite in their questioning. Questions asked were appropriate for the nature of the study, and the comments made at the REC meeting were valid.”*

Of the 75 comments received eight of these categorised as negative. Respondents who wished to comment in connection with their attendance at the meeting highlighted areas of concern pertaining to lack of specialist knowledge on the committee, inadequate pre-meeting preparation, with one respondent noting their dissatisfaction in the incongruity of the meeting minutes.

A range of neutral comments were noted; of the 12 comments received one respondent noted that more time with the committee to discuss detail would have been helpful, another highlighted poor telephone connection which impacted on hearing all members, and a couple of respondents suggested that the committee members with the relevant expertise attend the meeting

**Post-meeting information**

**Figure 12. Respondents were asked whether or not they felt the information they received post meeting was clear, useful and assisted them in advancing their research?**

This chart provides a comparison to findings from the previous two reporting period.

Respondents were asked whether they had comments to make on the outcome (from review) information they had received.

59 comments were received (37 positive, 11 negative and 11 neutral).*Comments are copied directly from the online survey.*

Several respondents made specific reference to the clarity, helpfulness and promptness of the information received post meeting. Some respondents expressed their appreciation for the committees suggestions; “*The conditions to be met for a favourable opinion were superb. They highly improved the patient information sheet and participant consent form to give few examples.*” And “*I had a small number of changes to make to the initial application before clearance was provided. These made sense and were useful to the project”.*

Ten negative comments were received covering issue around delays in information being received post meeting and ambiguity and errors in the information provided. .

Eleven neutral comments were noted around the outcome of information received following review. One respondent noted, “*It would have been useful to have the opportunity to correspond directly with the chair of the REC regarding outstanding issues rather than always through other REC staff, to reduce delays”.*

**Review process and added value**

**Figure 13. Respondents were asked whether or not they believed that the REC/CAG review process had added value to their application.**

This chart provides a comparison to findings from the previous two reporting period.

Respondents were asked to make comments on the review process.

58 comments were received (48 positive 05 negative and 05 neutral). *Comments are copied directly from the online survey.*

Nearly 83% of the comments received on the review process were categorised as positive, compared to just above 60% during the last reporting period. Respondents described the process as ‘fair’, ‘efficient’ ‘robust’, ‘professional’ and ‘an excellent learning opportunity’. Comments included, “*The review process forces you to consider your protocol carefully particularly the impact it may have on research participants. It results in better research* and *the process highlighted some issues we had not considered or given sufficient thought”.* One respondent noted that the process had “*added an extra layer of reflection and review. It also acknowledges that research governance to protect patients has been adhered to*”.

A small number of negative comments were noted, and therefore it is different to identify any themes. Of the comments received one related to ‘impractical’ suggestions made by the committee and their lack of appreciation and recognition of the rights of the research sample population. One respondent noted that the quick turn round time were ‘*challenging’* and described how communication issues had impacted the process of re-submitting papers.

Five neutral comments were received. One respondent noted that, “*The REC required a number of actions in their provisional opinion, some of which have benefitted the study. Others, particularly certain details that had to be added to the PIS's and the protocol seemed unnecessary and therefore cannot be said to have added value.”* Another applicant noted*, “The comments were not unhelpful but I don't think they made a difference to the value of the research*.”

**Service received**

Respondents were asked whether they wished to make any comments on any aspect of the service they received and make any suggestion as to possible improvement.

68 comments were received (38 positive 07 negative and 23 neutral). *Comments are copied directly from the online survey.*

Committee staff received a number of positive comments regarding their professional manner and helpfulness. One respondent commented, *The REC staff were very helpful. They were knowledgeable, quick to respond, clear and accommodating. The REC review experience from beginning to end was very professional and instructive*. Another applicant noted, ‘*When the forms were all in place however I found the whole process to be very efficient and timely. Everyone I dealt with in the process was extremely helpful and genuinely seemed to be trying to make things progress rapidly’*. It is very encourage to note that a number of respondents described the service they received as either ‘very efficient’ ‘excellent’, ‘timely’, ‘helpful’ and ‘supportive’.

Seven comments out of the 68 received were categorised as negative (compared to 20 out of 61 in the previous reporting period). A couple of respondents portrayed their experience of booking in their application for review as ‘rushed’. Another respond anted noted, “*We did not always find the people who answered the IRAS helpline necessarily knowledgeable about the multiple applications that were included in the IRAS form and we could have used slightly more expertise from those people*.”

Of the 23 neutral comments received a number of constructive suggestions were made, essentially around the need to reduce the number of forms and improve timelines for obtaining approval. There were other suggestions around the need for training sessions on IRAS as well as adding more variation between the REC meeting dates across the year.

1. Review and action taken in respect of the issues raised in the User Satisfaction Feedback Report for the period Oct - March 2015

This section outlines the review and action taken by the appropriate HRA Directorates and and the Research Ethics Committees for the Devolved Administrations in respect of the issues raised in the User Satisfaction Feedback Report for the period October 2014 to March 2015 (See [Annex 2](#Annex2) for detailed report).

**4.1 Research Ethics Service (England)**

The Report was reviewed by the HRA Director of Operations and Approval, the Head of Research Ethics Service (England), the Research Ethics Service Managers (England) and the Regional Managers; thirty six RECs received positive comments from one or more responders; letters were sent to the REC Managers and Chairs of those committees. Fourteen negative comments/concerns were identified which were related to individual RECs for further investigation and review so that action could be taken where appropriate and also to determine whether there was any link to complaints.

A change to the wording of the survey had increased the number of responders asking to be contacted following the completion of the survey and individual feedback on investigation and actions taken was provided to fifteen responders as requested.

**4.2 Devolved Administrations**

**Wales**

The Report was reviewed by the NISCHR Research Ethics Service (RES) Operational Manager; six RECs received positive feedback from respondents which was fed back to the appropriate individuals. One issue was raised by an applicant to a Welsh REC regarding the Central Booking System, which was followed up appropriately with the RES Management (England).

**Scotland**

The Report was reviewed by the Scientific Officers. Three negative comments/concerns were identified which were related to individual RECs for follow up and review so that action could be taken where appropriate. At the time of reporting one respondent is awaiting a follow up response. Six RECs received positive feedback.

**Northern Ireland**

The Report was reviewed by the Head of the Office for Research Ethics Committees Northern Ireland (ORECNI). One REC received positive comments feedback and this was shared with the REC Manager and committee concerned.

**4.3 Systems and Development Directorate**

The User Satisfaction Report was reviewed by the Director of Systems and Development and members of the team. Many of the issues raised in relation to IRAS, and the associated guidance, were very similar and we continue to work with the IRAS partners to agree the priorities for developments to IRAS. Feedback from users is particularly valuable in this respect. We had previously received particular feedback on the authorisations process. This information has allowed us to identify the complex technical issues causing some of these problems and we are pleased that the level of feedback in this area has substantially decreased. The nature of Information Systems development is such that it is not possible to achieve major developments quickly. However, we endeavour to fix faults quickly in response to issues raised through the IRAS Helpdesk.

We continue to refine and improve our guidance, and encourage applicants to consult the guidance on our website and on IRAS. We are working on options to better align the guidance on the HRA website and IRAS to make it easier for applicants to prepare and submit their applications for review by the HRA.

We are in the middle of an extensive programme implementing a new HRA Approval for health research in the NHS, which will combine an assessment by staff alongside the REC opinion. This will address a number of the concerns raised in feedback about identifying problems with applications early and address duplication in review across the NHS. For example we are testing the use of a combined form for REC and R&D, instead of separate applications. This will also simplify the application process and the linked guidance and instructions for applicants.

1. REC and CAG Chairs and Members’ feedback

REC / CAG Chairs and Members are contacted once a year inviting them to give feedback, via an online form, on issues affecting them as part of their REC / CAG role and any improvements they can suggest to the system The Chairs/Members feedback is forwarded onto the appropriate member of HRA staff to consider and respond to, copying in the QA Department to the response for recording within one month of receipt.

For this reporting period the decision was taken to suspend targeted feedback for REC and CA Chairs/Members due to the additional work pressures on senior management generated through the roll out of HRA Approval. Consequently, there is no REC / CAG Chairs and Members to note for this reporting period. Targeted feedback is due to recommence in October 2015.

For the October 2014 to March 2015 reporting period one member’s feedback comment was carried over from the previous reporting period ([See Annex 3](#Annex3)) The respondent did receive a response, however the target time of within one month of the Chairs/members providing feedback was not achieved.

1. HRA Staff Feedback

HRA Staff are given the opportunity to forward their ideas, suggestions and other forms of feedback to via an email system managed by Quality Assurance Department. The scheme was piloted from September 2014 for one year, with a midway review to seek feedback and suggestions on how the scheme could be improved. The pilot phase was completed in September 2015; the Quality Assurance team will undertake a review of the scheme and make recommendations to HRA management groups.

For this reporting period six ideas were submitted by members of HRA Staff (compared to eight in the previous reporting period). The feedback / ideas submitted were predominately from staff in the HRA Operations and Approval Directorate and covered areas such as; providing a Word version of the checklist for new REC members (instead of just a PDF), offering a ball pen as a token of thanks to members at the end of their service (instead of a paperweight), making it a requirement that substantial amendments contain a short, lay summary of the amendment to be added to HARP, the opinion letter and the minutes in order to assist with review and identification of the amendment; improving the layout / format of standard letters used in HARP.

All staff members received a standard acknowledgment email within the target time of three days from the QA Business Support Manager, specifying which senior manager the idea had been shared with. Senior managers are requested to reply directly to the member of staff who put forward their idea, copying in the Quality Assurance Department to the response, which are then subsequently recorded. All staff members have received a response from a senior manager(s) with details of if and how their idea can be progressed (See [Annex 4](#Annex4) for detailed report).

1. **Conclusion**

Feedback received from users of HRA services throughout this reporting period has been generally very positive. The service received by REC / CAG staff continues to score exceptionally high (98% of respondents scoring this as either excellent or good). This is supported by a number of positive comments collected via the online feedback form.

Other services that respondents were asked to rate including the HRA decision tools, website, queries line, online guidance and IRAS continue to be rated as either excellent or good by at least 80% of respondents. Feedback on user’s experience of IRAS received the greatest number of negative comments; however the report provided by the Systems and Development Director demonstrates that work is underway which should address a number of issues raised.

It is encouraging to note that the number of attendees at the REC /CAG meeting who reported that they were not treated fairly and with respect by the committee has dropped in comparison to the previous reporting person. A number of committees received very positive comments and were thanked for their support and suggestions to improve the applicants research project. Very few negative comments were noted in relation to the respondent’s attendance at the committee meeting.

Over 80% of respondents agreed that REC/CAG review had added value to their application; this was reinforced with nearly 50 positive comments from respondents about the review process.

The number of staff using the staff feedback / ideas scheme remains constant with the previous reporting period. The pilot phase has been completed and the next steps will involve the QA Department undertake a review of the scheme to inform recommendations to

HRA management groups.