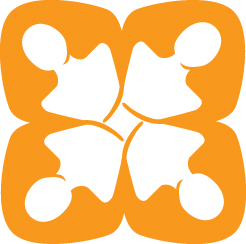
Consistency Improvement Plan

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| **Title:** | Consistency Improvement Plan |
| **Version Number:** | 1.3 |
| **Status:** | Draft |
| **Issue Date:** | 03/01/2017 |
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# Background

## Background

The HRA Business Plan 2016/17 included improving consistency as a key development and has been the subject of a paper produced by the National Research Ethics Advisors’ Panel (NREAP) in May 2014. This programme of work was undertaken to take forward the outstanding recommendations made by the NREAP (some recommendations already addressed) and also to take forward other areas of work which have been considered conducive to improving consistency within the REC service. These areas of work were identified via initiatives such as audit, feedback and business planning.

The programme included different areas of work which were at different stages of completion. The different areas of work fed into this Consistency Improvement Plan (CIP) which is the initial output from this programme of work and will be followed up by a period of implementation and a period of evaluation to measure whether the objectives of the programme have been met and therefore whether the programme has been successful. This Consistency Improvement Plan is intended to build on the existing infrastructure within the REC service with a view to improving consistency throughout the administrative and ethical review processes. When compiling the Consistency Improvement Plan, it was clear that the existing infrastructure already provided excellent mechanisms, such as comprehensive SOPs, training and communication methods and that staff and REC members provide a very good service. The aim of this programme is to build on this existing infrastructure to support staff and members of individual RECs to work to consistent standards across the service. It is also recognised that improving and maintaining consistency will be an ongoing task that will require engagement from REC members as well as RES staff at all levels. It is also anticipated that the work of the HRA Approval team may impact on this work. Additionally, it is also recognised that due to the nature of the work undertaken by the REC service, there is an inevitable degree of inconsistency as different committees have different backgrounds, experience and expertise and may therefore differ in perspective and opinion. This can be acceptable but it is important that the reasons for such decisions are well documented and defensible.

The areas of work included within the programme are as follows:

## Overview of individual projects

* **CP1 - User satisfaction feedback**

User satisfaction feedback is collected by the Quality Assurance team from service users and REC members. The feedback received between October 2015 and June 2016 was analysed to identify key issues which relate to service improvement and also inconsistency. The review was undertaken using Nvivo software to code the themes and identify key areas which relate to inconsistency. A report was produced which summarised the findings of this work and the key findings have been incorporated into this Consistency Improvement Plan.

* **CP2 - Shared Ethical Debate (ShED)**

ShED involves a set number of RECs reviewing a previously reviewed application so that a comparison can be undertaken. This involves a review of the ethical discussion by the REC Members and also the quality of the minutes produced by the REC Manager. The analysis which is undertaken to compare ethical reviews changed in August 2016 so that it can better identify variation; of individual RECs and also where there is a clear divide between opinions. The feedback which was received from the RECs on the new analysis format was reviewed as part of this project and indicated that RECs like to see where they are in comparison to other RECs. As part of this work, further consideration was given to how the outcome of the ShED could be taken forward to improve consistency.

* **CP3 - Audit of provisional opinions**

A review of provisional opinions issued between 1 October 2015 and 31 March 2016 was undertaken. The review included full REC and Proportionate Review Applications submitted to all UK RECs. The provisions listed in the provisional opinion letter were coded to identify commonality and the study type and sponsor type were also recorded to see if there were any trends. The audit highlighted opportunities to improve the consistency of REC practice, interpretation of the boundary between the provisional opinion and favourable opinion with additional conditions and the learning points to be made available to the wider research community.

* **CP4 - Proportionate Review (PR) Process Pilot**

A pilot ran from March - August 2016 to assess whether having a protected 5 working days for REC staff to validate and assess the suitability of PR applications and a protected 5 working days for REC members (total time increased to maximum of 15 working days - 21 calendar days) to review applications and contact applicants to get any clarifications required before issuing an opinion improved the quality and consistency of the review. The outcomes of the pilot were analysed and where appropriate, the key findings have been incorporated into this Consistency Improvement Plan. The full report can be found [here](http://www.hra.nhs.uk/documents/2016/11/pr-pilot-analysis.pdf).

* **CP5 - Audit of Invalidations**

An audit of invalidations was undertaken to understand the common reasons for applications being invalid and whether validation under consideration (requesting the outstanding validation criteria rather than invalidating the application outright) was being used consistently across the service. This audit identified significant inconsistency and areas for improvement.

* **CP6 - REC Manager and REC Assistant training programmes**

Training programmes have been developed for new REC Managers and new REC Assistant to ensure that they receive structured training during the initial months of the role to develop the knowledge and skills required and therefore to improve consistency within these staff roles. The training programmes commenced in September 2016 and are open to newly appointed REC Managers and REC Assistants. The programmes will be evaluated on an ongoing basis to ensure they are effective in their aim and the key findings from this programme of work will be incorporated.

* **CP7 - Staff learning and development group and learning mapping**

A group was convened to direct the learning needs of REC staff and to advise and support learning implementation for RES staff. This group undertook a piece of work to map out how and where learning points can be fed back to ensure that the outputs from the consistency programme reach the relevant individuals and are effective at modifying knowledge, understanding and behaviour. This included communication routes as well as training. The staff learning and development group will also look to identify any gaps in current staff training programmes and areas where training may be improved, with the aim of improving staff knowledge and understanding and therefore consistency.

* **CP8 - Deputy Regional Manager (DRM) training programme**

The DRM role is crucial in ensuring that REC staff are following standard operating procedures and other guidance when undertaking their role. The DRM acts as a ‘technical expert’ to assist and advise staff on a day to day basis and also undertakes quality checks of the work undertaken by the REC staff.

A training programme is still to be developed for the DRMs to ensure that they have the knowledge and skills to undertake their role effectively and to ensure that they are able to support and assist the staff. The aim is that a structured programme will ensure a consistent approach across the 5 REC centres.

* **CP9 - Unfavourable opinion audit**

A review of unfavourable opinions issued between 1 April 2015 to 31 March 2016 was undertaken. The review was UK wide and included applications reviewed at full REC and Proportionate Review. The review involved the coding of the reasons for issuing an unfavourable opinion. It identified the reasons recorded for why the REC issued the unfavourable opinion and trends associated with particular IRAS and sponsor types in order to inform further development of guidance, the wording of the Standard Operating Procedures and the learning points to be made available to the wider research community.

* **CP10 - REC Flagging**

RECs are flagged to review certain study types. This is commonly based on experience and expertise of the Committee members. A piece of work was undertaken to define the requirements for flagging of certain types of research (e.g. research involving children and qualitative research) to ensure that all flagged RECs have the necessary experience and expertise for the flag which they have. A REC flagging policy was produced and it was agreed that the policy would be tested using RECs administered from the Manchester Centre to allow for changes to me made to the process before rolling out more widely.

* **CP11 - Precedent of approach across programmes of research**

Where a programme of research or a sponsor undertakes a number of different individual research projects which involve the same methodology, participant facing documentation or processes, there is a risk that an inconsistent approach may be taken by RECs. This piece of work will consider the feasibility of taking assurance from previous REC opinions when undertaking a review of a new application or a substantial amendment which involves an approach which is demonstrated to be the same (or at the very least sufficiently similar) to an approach which has received a favourable opinion previously. A report will be produced which will detail the findings of this work and set out options going forward. If this piece of work is able to demonstrate feasibility then future possibilities will be put to the HRA Policy Directorate with a view to inclusion in the 2017/18 business plan.

* **CP12 - Phase 1 extended review of applications as part of validation**

The process for a more in depth review of the application which is undertaken by the REC Manager at the validation phase has previously been developed but was not applied to all studies due to the overlap with the assessment element of the HRA Approval process. As phase 1 studies outside the NHS do not come under HRA Approval, this function will be rolled out to Phase 1 applications. The purpose of this function is to optimise the information available to the REC when undertaking the REC review to increase the chance of the study receiving a favourable opinion at first review. Further work will be undertaken which will specifically focus on Phase 1 clinical trial applications to ensure that this function is optimally effective for this type of research.

* **CP13 - Proportionate Review (PR) suitability**

The PR suitability audit included a review of both REC staff transfers from PR escalated to Full REC review and transfers following a ‘No opinion’ by UK wide RECs between 01 April 2015 and 31 March 2016. The audit aimed to identify areas of inconsistency in the process and to identify any common themes or trends with regards to why the applications were transferred to full review. The audit highlighted some inconsistencies in the administration process and variation with the interpretation of the ‘No Material Ethical Issues Tool’. The NMEIT, supporting guidance, Central Booking Service question matrix and staff training were all reviewed and revised in light of the audit findings.

## Project Aim and Objectives

**Aim**

To identify areas of inconsistency within the RES service and produce a Consistency Improvement Plan (CIP). This CIP will detail areas where it was identified that consistency could be improved from each of the individual projects, improvement strategies and recommendations for implementation.

**Objectives**

• To reduce the percentage of provisional opinions and increase the percentage of favourable opinions with additional conditions by 5% over 12 months.

• To optimise consistency of REC decisions when issuing opinions (the same decision for roughly the same reasons[[1]](#footnote-1))

• To define the role of REC staff to support and assist the REC to adhere to the principles which would optimise consistency

• To establish the feasibility of giving consideration to previous decisions issued by RECs for comparable studies (particularly when from the same sponsor)

# Areas of Inconsistency Identified

## Review Process

### Validation

The validation audit (undertaken in 2015) identified a number of areas of inconsistency. Most notably, the audit identified that PR invalidation between RECs ranged from between 0% and 70% within the audit period. Such a significant difference is most likely due to different approaches being taken by different REC staff. When validation and invalidation processes were looked at in more detail, there were different processes being undertaken in terms of whether applications were invalidated on receipt if they did not meet the validation criteria, whether the applicant was given the opportunity to meet the validation when not met on initial submission, how the applicant was contacted to request further information, the time given to meet the criteria and how this process was recorded on HARP.

Actions already taken:

* At the RES all staff day in 2015 the findings of the invalidation audit were presented and staff were advised regarding the importance of working with applicants as much as possible to meet the validation criteria - the PR invalidation rate subsequently dropped from 23% to 12%.
* The submission process was followed to better understand why the validation criteria are not being met. It was quickly apparent that the validation criteria are not referenced anywhere in IRAS and the first the applicant will know the criteria is likely to be when they receive a letter (or other communication) saying the criteria have not been met. Information was developed in 2015 to include this information in IRAS but has not been added to IRAS to date.

The reasons for invalidation and further information requested also varied between different REC staff and in some cases there appeared to be a blurring of lines between what is required strictly to meet the validation criteria and what may be further information which would be beneficial to the REC as part of the REC review process.

Validation is something which is commonly undertaken by REC Managers who would then train their REC Assistant, who would sometimes then go on to become a REC Manager themselves. This means that misunderstanding and inconsistent practices may get passed on and become imbedded in the standard practice of individuals. This was considered to be a key factor in the degree of inconsistency which was noted between RECs.

The ideal situation is that applications are valid on submission which means that it is necessary to target advice and guidance to applicants before they submit. The most appropriate platform to communicate messages regarding the validation criteria is IRAS as all applicants will be using this system. The invalidation audit identified the most common reasons for applications not being valid on submission and these findings should be used to improve the information available to applicants. One of the main reasons for invalidation identified during the audit was documents not uploaded to the checklist. Additionally, the user satisfaction feedback included several comments about how user unfriendly the document upload functionality in IRAS is which can lead to issues with documents not being submitted with the IRAS form. Improving the functionality and/or guidance regarding uploading documents in particular would be a key improvement.

Where applications are submitted and the validation criteria are not met, a more consistent approach needs to be taken by REC staff. Additional guidance in the checklists on HARP would assist with ensuring the criteria are being applied consistently and a more defined process for requesting outstanding information would be beneficial; being mindful that in England this process will need to align with the HRA assessment process. The protected time for REC Managers to undertake validation should help to ensure that validation is undertaken thoroughly in accordance with the guidance and therefore consistently.

Recommendations:

1. Add the information to IRAS which would support applicants to meet the validation criteria on initial submission. Particular consideration should be given to document upload.
2. Update the validation checklist which is included in HARP to include additional guidance and instruction for staff. The validation criteria should be yes/no answers as much as possible to remove ambiguity and differing interpretations.
3. Provide a more defined process for requesting information or documents required to meet the validation criteria.
4. All REC staff to undergo refresher training on validation to ensure that they are all working to the same standard and applying the guidance in the same way.

### Written communication from RECs

The user satisfaction survey responses included a number of references to the written correspondence which was received after the REC review, with a similar number of positive and negative comments received. The written communication which goes out when issuing a REC opinion is very important as this is how the applicant will know what is required of them. Some of the feedback received indicated that letters did not always reflect the applicant’s recollection of the discussions at the meeting, it was not always clear what was required of the applicant, issues were raised in the letter which had not been mentioned at the meeting but could have been easily resolvable if they had, letters were poorly worded and one individual reported that they had received a favourable opinion letter which they queried as had not been expected this and were informed that this had been sent in error and should have been a provisional opinion letter.

Actions already taken:

The minute taking guidance has been revised and will be published in February 2017. This will be followed by staff training.

Written communication was also reviewed as part of the audit work looking at invalidation, provisional opinions and unfavourable opinions. Similar issues were noted in terms of clarity and quality.

The quality of REC minutes and letters is checked by the Regional Manager (may be delegated to the Deputy Regional Manager) as part of the QC process and also by the Quality Assurance team as part of the audit scheme.

It should also be noted that positive feedback was also received in regards to the letters. This included reference to letters being clear, easy to follow, comprehensive, thorough, straight forward, clearly articulated, succinct etc. This would therefore suggest that this is what applicants value and is what REC staff should be aiming to achieve when writing opinion letters.

Recommendations:

1. Where issues with the quality of letters (and minutes as quite often poor letters are due to poor minutes) are identified, an action plan should be completed by the Regional Manager to work with the member of staff to address the issue. The RES Manager should take responsibility for signing off the action plan when considered to be completed.
2. Should issues with the quality of letters continue to be identified for an individual after an action plan has been signed off, this should be escalated to the Head of the Research Ethics Service.
3. An additional sentence to be added to REC letters asking applicants to contact the REC manager if they do not feel the correspondence accurately reflects the issues discussed at the meeting.

## REC opinions

### Provisional Opinion

The audit of provisional opinions identified that there was inconsistency with how provisional opinions were applied. This was evident by the range of decision making in the 2015/16 annual reports between RECs of the percentage of provisional opinions issued. Within one REC Centre there was the following difference in decisions made:

REC 1

Provisional opinions 95%

Favourable with additional conditions 2%

REC 2

Provisional opinions 56%

Favourable with additional conditions 40%

Due to the significant difference between favourable and provisional rates between RECs, it is unlikely that this is due to the applications themselves and is more likely to be due to how the RECs are applying the criteria for provisional opinions and favourable opinions with additional conditions.

Actions already taken

* A workshop was held with REC Chairs at the annual training day to present the audit findings and to get feedback and the Chairs’ perspective on when and how a borderline provisional opinion could become a favourable opinion with additional conditions

The audit also identified some inconsistency in terms of how the criteria were applied. There was evidence of some RECs issuing provisional opinions for minor and clearly stated changes, which should have been a favourable with additional conditions, suggesting that there is some degree of misunderstanding of when a provisional opinion should be issued and when a favourable with additional conditions should be issued. Additionally, there was evidence of provisional opinions being issued for relatively simple changes but with only a vague direction of what was required to make the change. Due to the lack of clear instruction, a provisional opinion was issued so that the REC (or a representative thereof) would need to review the response submitted. In some scenarios however, it may have been possible to provide further clarity and direction which would have meant that a favourable with additional conditions could have been issued.

The REC Manager has a key role in supporting the REC when issuing an opinion. Whilst the final decision does remain the responsibility of the REC, the REC Manager should advise the Committee on the options available and support the Committee in wording requests in such a way that more favourable opinions with addition conditions can be issued. It is important that the REC Manager feels empowered to do this and that the Committee understand that this is part of the REC Manager responsibility.

For applications going through proportionate review, the revised PR process pilot indicated that there was a small increase in the likelihood that an application would receive a favourable opinion rather than a provisional opinion. This was considered to be due to more time being allocated for the review and to query any points of clarification with the applicant. Feedback from one REC Chair indicated that for that particular REC, contacting the applicant to discuss the application before issuing an opinion had been a significant improvement in terms of being able to issue a favourable opinion.

Recommendations:

1. Develop guidance which more clearly defines when an opinion should be a provisional opinion and when it could be a favourable opinion with additional conditions. This guidance will also detail how RECs and REC staff may be able to provide the direction required for a favourable with additional conditions when issuing the opinion letter.
2. The guidance should set out the responsibility of the REC Manager in regards to working with the Committee to provide suitable wording which would mean that a favourable opinion with conditions could be issued.
3. REC staff should discuss with the PRSC members to establish a process for contacting the applicant to obtain further information or to address point of clarification. This may be the lead reviewer/Chair who contacts the applicant directly or may be via the REC staff. A culture of contacting the applicant should be encouraged as much as possible where further information or clarification would be beneficial.

### Unfavourable Opinions

The most notable finding from the unfavourable opinion audit was in relation to the sponsor type. The audit identified that the sponsor types which receive an unfavourable opinion most commonly are academic (45%) and NHS organisations (31%). The main issues which were identified as being reasons for unfavourable opinions were in relation to the science and design of the study, safety and risks and burdens.

Recommendations:

1. Further consider ways to ensure that science and study design have been suitably reviewed and the outcome communicated to the REC. This might include a function within the organisation which reviews the application and makes an assessment on whether further information is required in advance of the review. This may be a member of the Committee or staff.
2. Work should be undertaken with the Collaboration and Development team to see how the findings of the audit could be linked up with ongoing or planned work with academic and NHS sponsors.

### No opinion & Unfavourable Opinion - Proportionate Review

The audit of applications which were booked to PR and subsequently transferred, either by the REC Manager as unsuitable or as a no opinion by the REC, identified a number of areas of inconsistency. It was however also noted that most of the issues identified were from applications which were earlier on in the audit period and lessened towards the end of the audit period. This may be due to the actions already taken. There was some confusion noted about when to issue an unfavourable opinion and when to issue a no opinion. There were unfavourable opinions issued for the study involving material ethical issues and applications given a no opinion and transferred to full committee due to the poor quality. When no opinions were issued, the letter didn’t always make it clear why this was the case.

The audit also identified that applications were often given a no opinion where there were a number of issues which the PR sub committee (PRSC) thought would be better addressed at a full committee with discussion with the applicant, rather than there being a particular ethical issue. For these applications in particular, it was often not explained in the letter to the applicant why the application was considered to have material ethical issues. Additionally, the letter often included the outcome of the PRSC review which stated what further information and changes would be required. This was particularly confusing when the application was transferred to another REC for the full review.

Where applications were transferred to a full REC meeting due to having material ethical issues, the most common ethical issues identified were vulnerability of the participant group, the potential for distress, potential for incidental findings and the PRSC being unable to determine from the application how invasive the procedures were. Other ethical issues also identified were in relation to data security and management of tissue samples; which may be addressed should the assessment element of HRA Approval be provided to the REC to give assurance on these areas.

Actions already taken:

1. PR suitability guidance produced to support staff and members.
2. PR suitability training delivered for all staff

The review of the transferred applications also noted that sometimes, the full study title included key words which indicated that the study may involve sensitive areas or vulnerable groups but the applications still reached the PRSC. These areas included sexual abuse, sexual health, premature birth etc. Consideration will also need to be given to the context and how well any ethical issues have been addressed in the application.

Recommendations:

1. Include in the PR suitability guidance that when the PRSC REC is of the opinion that the application would be better reviewed by a full Committee due to the complexity of the application or the lack of clarity, rather than definable ethical issues, then this would be acceptable. Any issues which have been identified by the PRSC should be detailed in a letter to the second REC (if different to the PRSC REC) but should not be sent to the applicant to prevent confusion.
2. Review the No Material Ethical Issues Tool (NMEIT) to ensure the areas which were commonly identified as being reasons for transfer are reflected in the tool.
3. Revise the PR suitability guidance to reflect the revision of the NMEIT and to further elaborate on areas identified by the audit as requiring clarification.
4. Revise the Central Booking Service (CBS) question matrix to reflect the revision of the NMEIT.
5. Review the role of CBS in checking PR suitability, such as asking for the full study title and/or a brief summary of what the study will involve when an application shows as being suitable for PR. This will be more of an option when the staffing of CBS changes to REC Assistants on a rotational basis as they will be more experienced in determining PR suitability.
6. Revise the PR training module and deliver to all REC staff.

## User satisfaction

### Value and helpfulness

The evaluation of the user satisfaction survey feedback indicated very strongly that ‘helpfulness’ was valued highly by applicants accessing the REC service. This was due to the high number of positive comments which stated that the REC, the process and/or the REC staff had ‘helped’ the applicant in some way. This was the largest individual comment type which would suggest that helpfulness is something that service users attribute high value to.

Types of helpfulness referenced

* Assisting with the application submission process
* Prepare for the meeting, including meeting the validation criteria
* The REC/REC review helping to improve the quality of the research and/or information sheets
* Supporting applicants to meet the provisions required to obtain a favourable opinion

The user satisfaction survey also included limited feedback which referred to experience of unhelpfulness from both staff and RECs. This would therefore suggest that there is a degree of inconsistency in approach in this area. Due to the high volume of positive comments which were received and the apparent value which applicants placed on helpfulness, consideration should be given to how helpfulness could be more embedded in the service being provided.

Recommendations:

1. REC staff and members should be made aware of the positive feedback which has been received and the value which applicants place on the helpfulness to highlight how much this part of the service is appreciated. Whilst individual positive feedback is passed on to RECs and staff, general feedback regarding what applicants value should be shared more generally.
2. Consideration should be given to having more formal help functions. For example, early checking of applications, supporting documentation review and feedback, meeting preparation discussions etc. Such additional support would not only add value to the applicant’s experience but may also increase the quality of the applications being reviewed by the REC and therefore the likelihood of a favourable opinion on initial review.

# Consistency Improvement Methods

The programme aimed to identify areas of inconsistency within the REC service and to suggest ways to improve consistency. To be able to implement the recommendations made, it is important that the learning and information sharing infrastructure is effective, for both REC members and staff. Therefore, as part of the overall programme of work, consideration was also given to how learning can be optimised by improving the infrastructure of information sharing and the learning culture which means that information is heard, understood and actioned. This work was undertook via the RES staff learning and development group and involved a learning mapping session to better understand the barriers to effective learning. The key areas which the group identified were;

* It is important to repeat key messages and to deliver the information in both oral and written formats.
* It is important to confirm understanding and not just communicate information and assume understanding.
* It is important to explain *why* something is happening or required rather than just saying *what* is happening or required.
* It is important to promote a positive culture where individuals feel valued.

## Training

### Staff

The majority of the REC work is defined in the RES Standard Operating Procedures (SOPs) and this document therefore has a crucial function. Training modules for the SOPs have existed for a number of years with an expectation that training modules are delivered approximately monthly. Feedback from staff indicated that this was not happening due to issues with the accuracy of the modules and availability of time. The SOP modules have been updated by the Deputy Regional Manager Group to ensure accuracy and a new schedule for delivery has been agreed. Some modules have been combined to create 10 modules with an expectation that all 10 modules are delivered each calendar year in each REC Centre.

Recommendations:

1. Compliance with the SOP module delivery schedule is the responsibility of the Regional Manager and should be monitored annually by the RES Manager responsible for the Centre. Where non compliance is identified, action should be taken to ensure the modules are delivered.

### Members

It will be necessary to ensure that the findings from the projects within this programme are incorporated into established and future training modules. The Operations team and the Learning team have worked together and will continue to liaise to ensure that key findings are reflected.

Recommendations:

1. Map out the member learning routes to identify which established training sessions should be revised to incorporate key findings.

The Shared Ethical Debate exercise is a useful tool to assess consistency/inconsistency between RECs, identify any training or guidance needs and to feedback to individual RECs. As part of the ShED analysis work, consideration was given to how the outcomes of each exercise could be utilised to improve consistency and how the findings more generally could feed into member training and guidance. The ShED analysis reports will identify outlying RECs which will need to be managed on an individual basis with targeted training and support and will also highlight general ethical issues which require wider consideration, such as at member training days.

Key areas to incorporate in member training:

* Opinions - Provisional or favourable, no opinion
* Proportionate review - contacting applicants for points of clarification
* Supporting applicants through the process

Recommendations:

1. Each ShED analysis report should highlight any ethical issues which were considered to be divisive and would warrant wider discussion, guidance and/or training.
2. Where individual RECs are considered to be a significant outlier, consideration should be given to local training needs.
3. A lessons learned from each ShED would be shared following analysis of the ShED looking at both ethical and “non-ethical” issues drawing attention to current existing guidance.

### 3.1.3 External

A number of issues which were considered within this programme are influenced by factors which are external to the REC service, such as the quality of the application on submission or the actions of the applicant or sponsor. It will therefore be necessary to also consider what external training, guidance and support, prior to submission of the application, may help to improve the consistency of the review process once submitted to the REC. The key areas for external training and support identified as part of this programme were:

Submitting an application which meets the validation criteria.

Ensuring appropriate scientific review has been undertaken and that this is clearly detailed in the IRAS form, with a copy of the review submitted where possible.

Ensuring that participant information sheets are in accordance with the guidance, are written in lay language and adequately describe the study.

Recommendations:

1. Review all researcher and sponsor training programmes to see where learning points could be incorporated.
2. Work with the collaboration and development team to see how these learning points could link up with other ongoing or planned pieces of work.

## Guidance

### Staff

The guidance which is issued to staff was reviewed as part of the learning mapping project. Guidance is issued as a formal guidance document but may also be issued as an individual piece of information or via an Operational Management E-mail Alert (OMEA). It was recognised that this method was sometimes problematic as after the initial e-mail was issued, it relied on recalling that some information was issued and going back through the previous OMEAs to find the relevant part. Additionally, information in the OMEAs remains in the archived version regardless of whether it has been superseded by further information. This meant that there was a risk of referring back to out of date information.

The learning and development group agreed that a better way to archive the information which is communicated via OMEAs should be identified so that it is easily searchable and it is clear which information is current and out of date or superseded information can be archived. A test database has been set up using the HRA hub to see if this format might be a preferable way to save the information within OMEAs.

It is expected that OMEAs are included on the agenda for Centre network meetings and should be a standing agenda item. As part of the learning mapping group, it was agree that it would be important to not only communicate the information within the OMEA but to encourage discussion and confirm understanding. This should be at the meeting at which the OMEA was presented and also when going through the minutes at the subsequent meeting to further confirm understanding.

Recommendations;

1. Transfer previous OMEA information into the OMEA database on the HRA hub and then use this format to save OMEA information going forward. This will need to be kept under regular review to ensure that the information is up to date.
2. OMEAs to be discussed at REC Centre network meetings and for understanding to be confirmed when reviewing the minutes at the subsequent meeting. This should be checked at the 6 month review meetings in each centre.

### Members

Currently members receive information via the member information exchange and where this information references a guidance document, this is usually provided as a web-link. The guidance documents are usually on the HRA website but can be difficult to locate when not using a direct web-link. REC members are encouraged to use the member portal to access meeting documents and as such this seems to be a logical place to save the information exchanges and also details of the relevant guidance available and the link to access the guidance.

Recommendations:

1. Create an area in the member portal to save information exchanges and link to relevant guidance.

# Communication Management Strategy

Existing communication routes will be utilised.

Internal

* HRA News
* Operational Management E-mail Alerts (OMEA)
* Committee Information Exchange
* Management meetings

External

* HRA latest
* Stakeholder meetings

# Summary of recommendations

Validation

1. Add the information to IRAS which would support applicants to meet the validation criteria on initial submission. Particular consideration should be given to document upload.
2. Update the validation checklist which is included in HARP to include additional guidance and instruction for staff. The validation criteria should be yes/no answers as much as possible to remove ambiguity and differing interpretations.
3. Provide a more defined process for requesting information or documents required to meet the validation criteria.
4. All REC staff to undergo refresher training on validation to ensure that they are all working to the same standard and applying the guidance in the same way.

Written communication

1. Where issues with the quality of letters (and minutes as quite often poor letters are due to poor minutes) are identified, an action plan should be completed by the Regional Manager to work with the member of staff to address the issue. The RES Manager should take responsibility for signing off the action plan when considered to be completed.
2. Should issues with the quality of letters continue to be identified for an individual after an action plan has been signed off, this should be escalated to the Head of the Research Ethics Service.
3. An additional sentence to be added to REC letters asking applicants to contact the REC manager if they do not feel the correspondence accurately reflects the issues discussed at the meeting.

Provisional opinions

1. Develop guidance which more clearly defines when an opinion should be a provisional opinion and when it could be a favourable opinion with additional conditions. This guidance will also detail how RECs and REC staff may be able to provide the direction required for a favourable with additional conditions when issuing the opinion letter.
2. The guidance should set out the responsibility of the REC Manager in regards to working with the Committee to provide suitable wording which would mean that a favourable opinion with conditions could be issued.
3. REC staff should discuss with the PRSC members to establish a process for contacting the applicant to obtain further information or to address point of clarification. This may be the lead reviewer/Chair who contacts the applicant directly or may be via the REC staff. A culture of contacting the applicant should be encouraged as much as possible where further information or clarification would be beneficial.

Unfavourable opinions

1. Further consider ways to ensure that science and study design have been suitably reviewed and the outcome communicated to the REC. This might include a function within the organisation which reviews the application and makes an assessment on whether further information is required in advance of the review. This may be a member of the Committee or staff.
2. Work should be undertaken with the Collaboration and Development team to see how the findings of the audit could be linked up with ongoing or planned work with academic and NHS sponsors.

No opinion and unfavourable opinions for PR

1. Include in the PR suitability guidance that when the PRSC REC is of the opinion that the application would be better reviewed by a full Committee due to the complexity of the application or the lack of clarity, rather than definable ethical issues, then this would be acceptable. Any issues which have been identified by the PRSC should be detailed in a letter to the second REC (if different to the PRSC REC) but should not be sent to the applicant to prevent confusion.
2. Review the No Material Ethical Issues Tool (NMEIT) to ensure the areas which were commonly identified as being reasons for transfer are reflected in the tool.
3. Revise the PR suitability guidance to reflect the revision of the NMEIT and to further elaborate on areas identified by the audit as requiring clarification.
4. Revise the Central Booking Service (CBS) question matrix to reflect the revision of the NMEIT.
5. Review the role of CBS in checking PR suitability, such as asking for the full study title and/or a brief summary of what the study will involve when an application shows as being suitable for PR. This will be more of an option when the staffing of CBS changes to REC Assistants on a rotational basis as they will be more experienced in determining PR suitability.
6. Revise the PR training module and deliver to all REC staff.

Value and helpfulness

1. REC staff and members should be made aware of the positive feedback which has been received and the value which applicants place on the helpfulness to highlight how much this part of the service is appreciated. Whilst individual positive feedback is passed on to RECs and staff, general feedback regarding what applicants value should be shared more generally.
2. Consideration should be given to having more formal help functions. For example, early checking of applications, supporting documentation review and feedback, meeting preparation discussions etc. Such additional support would not only add value to the applicant’s experience but may also increase the quality of the applications being reviewed by the REC and therefore the likelihood of a favourable opinion on initial review.

Staff training

1. Compliance with the SOP module delivery schedule is the responsibility of the Regional Manager and should be monitored annually by the RES Manager responsible for the Centre. Where non compliance is identified, action should be taken to ensure the modules are delivered.

Member training

1. Map out the member learning routes to identify which established training sessions should be revised to incorporate key findings.

External training

1. Review all researcher and sponsor training programmes to see where learning points could be incorporated.
2. Work with the collaboration and development team to see how these learning points could link up with other ongoing or planned pieces of work.

Staff guidance

1. Transfer previous OMEA information into the OMEA database on the HRA hub and then use this format to save OMEA information going forward. This will need to be kept under regular review to ensure that the information is up to date.
2. OMEAs to be discussed at REC Centre network meetings and for understanding to be confirmed when reviewing the minutes at the subsequent meeting. This should be checked at the 6 month review meetings in each centre.

Member guidance

1. Create an area in the member portal to save information exchanges and link to relevant guidance.

# Document Control

## Change History

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| --- | --- | --- | --- |
| **Version** | **Status** | **Date** | **Changes** |
| V1.0 | Draft | 03.01.2017 |  |
| **V1.1** | **Draft** | **09.01.2017** | **Director of Operations –minor drafting changes and issues for discussion** |
| **V1.2** | **Draft** | **01.02.2017** | **Reviewed at Operational Management Group** |

## Publication

### Publication

Publication (once document approved): Externally via HRA Website

1. Consistency in REC Review - Published by the NREAP [↑](#footnote-ref-1)