Proportionate Review: Revised Process Pilot - Analysis Report

1. Background

The proportionate review of applications meeting the requirements of the "No Material Ethical Issues Toolkit" (NMEIT) was introduced in 2010. The purpose of the new initiative was to ensure that applicants could have a more rapid turnaround of their applications and that full REC meeting allowed members to concentrate their efforts on reviewing those studies which warranted review by a full committee.

Whilst PR has been successful in reducing time lines for ethical review for studies which are not deemed to have material ethical issues, there is suggestion that, on occasion, the overall standard of the service being delivered to the research community was not as efficient as it could be for these applications; this is possibly due to the pressure to not exceed the 14 day (calendar) timeline. An audit of invalidated applications was undertaken in 2015 which identified an invalidation rate of 23%, a large range of invalidation rates between RECs (0-70%), a range of reasons given for applications not being valid and differing practices regarding how to manage the validation process. Each application which is invalidated and resubmitted represents two (on some occasions three) bookings through CBS and two validation processes by REC staff, thus duplicating the workload for staff and causing additional work for the researcher. Additionally, feedback from REC Members has indicated that the pressure to review and respond in the short timeframe is sometimes unreasonable and difficult to fit in around their working and personal life.

The purpose of this project was to evaluate whether a Proportionate Review process which puts more focus on facilitating the REC application through the process by allowing increased time to work with applicants and ensure the information provided to the REC members is clear, accurate and complete.

1.1 Aims and objectives of the project

The aim of the project was to see whether the proposed revised process for Proportionate Review is more effective than the current process against set measurement criteria.

The objectives were:

1. To assess the impact of extending the length of review to 15 working days (21 calendar days).

2. To assess whether the revised process has an impact on the number of applications which are invalidated and therefore submitted as duplicate entries into the system.

3. To assess whether the revised process will impact on consistency in validation practices across RECs.

4. To assess whether the revised process will have an effect on the decisions issued as a first opinion.

5. To collect and assess the views of REC Members on the revised process

6. To collect and assess the views of REC Managers on the revised process.

7. To collect and assess the views of applicants and compare to feedback given about the current processes.

The project involved 15 RECs from across the UK and ran from March - August 2016.

1.2 Revised Process

➢ The application was booked to the PR REC via CBS as normal

➢ The application was to be accepted in HARP on the first working day

➤ The application was validated against the standard validation criteria as normal. The expectation was that this would take place on the first working day.

➤ If the application was invalid against the standard validation criteria, the REC Manager was expected to give consideration to whether the application could reasonably be made valid. For example, if the incorrect study category had been selected on the filter page and the required dataset had therefore not been submitted, it would unlikely this can be rectified.

➤ If the reason for the application being invalid was something that would be unlikely to be resolvable within the extended timelines, the application was invalidated and an invalidation letter sent.

➤ If the reason for the application being invalid was something that was likely to be resolvable within the extended timelines, for example a missing document, the following steps should have been followed:

   o The application was marked as validation under consideration on HARP

   o The applicant was contacted by telephone to inform them that the application was not valid and to ask whether the outstanding validation criteria could be provided by a given deadline* (*depending on when the request is made, the deadline could be up to a maximum of 5 working days from the application being submitted).

   o The telephone call should have been followed up with an e-mail confirming what had been agreed.

   o If reasonable efforts to contact the applicant by telephone had failed, an e-mail should have been sent but the REC Manager should have continued to make attempts to contact the applicant by telephone.

➤ If the outstanding validation criteria could not be met by the deadline* given, the application was invalidated and the invalidation letter issued.

➤ If the outstanding validation criteria were met by the deadline*, the following steps should have been followed:

   o The application marked as valid on HARP

o The application was made available to the Proportionate Review Sub Committee (PRSC) Members on HARP (and/or e-mailed depending on local arrangements). Meeting by correspondence, teleconference or face to face were all acceptable.

➢ PRSC Members should have been informed that they had up to 5 working days to complete the review and to issue an opinion.

➢ If a provisional opinion was issued, the review of the response should have been complete and the final opinion issued within 4 working days of the response being received.

➢ The full review and issuing the final opinion should take not have taken more than 15 working days (21 calendar days)

2. Analysis

2.1 To assess the impact of extending the length of review to 15 working days (21 calendar days).

2.2 To assess whether there is an impact on the number of applications which are invalidated and therefore lead to resubmission and duplication of entry into the system.

2.3 To assess whether the revised process will impact on consistency in validation practices across RECs.

The average rate of invalidation for non pilot RECs was 12% (which is significantly lower than when we did the audit last year when it was 23% so this would suggest that REC staff have amended practice after we raised this as an issue at the all staff day).

The average invalidation rate for the pilot RECs was 8%. Feedback from the REC staff involved in the pilot strongly indicated that the additional time did have a positive

> "I definitely think the extra time in the office has allowed a better dialogue with applicants to ensure applications can be made valid in time (and probably allows for a more thorough validation so that less mistakes are made in terms of judgment calls on suitability etc)."
>
> REC Manager

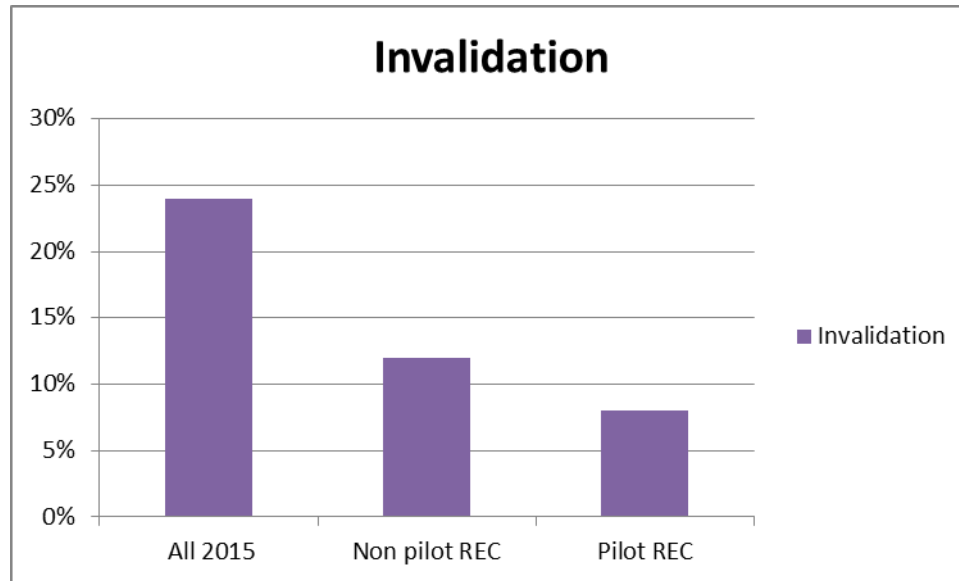impact in the ability to work with applicants to make the application valid before the REC review.

Table 1

2.4 To assess whether the revised process will have an effect on the decisions issued as a first opinion.

The percentage of favourable opinions issued at first review for the non pilot RECs was 44% and for the pilot RECs the percentage had improved to 50%.

The percentage of provisional opinions for the non pilot RECs was 47% and for the pilot RECs the percentage had dropped to 44%.

The higher percentage of favourable opinions and the lower percentage of provisional opinions for the pilot REC indicated that there was an improvement. Whilst this was not noted to be significant in itself, the principle of marginal gains would suggest that even small improvements are beneficial, especially when in the context of wider improvement programmes.

The percentage of unfavourable opinions stayed the same for both non pilot and pilot RECs and there was a 1% drop in the number of no opinions issued, from 6% - 5%. An unfavourable opinion on a PR study is given when an application is of a poor quality sufficient not to warrant a degree of reworking before it is suitable for further consideration.
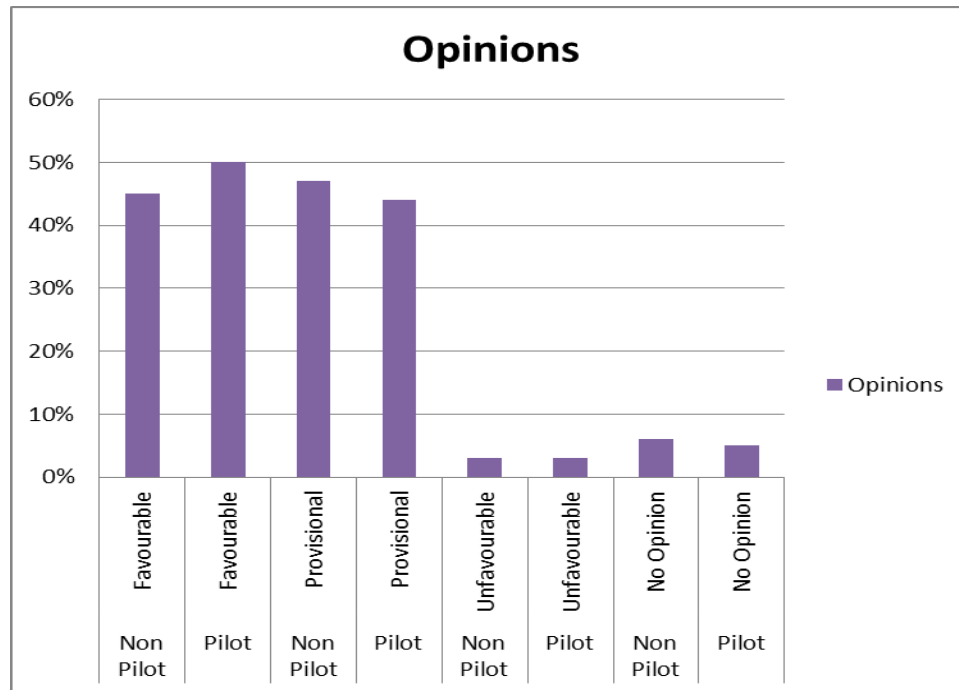

Table 2

In addition to the aims and objectives of the project, we also looked at applications which were deemed unsuitable for PR and transferred by either the REC Manager or the REC (as a no opinion) for review at a full REC meeting. It was noted that there was a significant difference in practice between RECs, by both staff and PRSCs, when determining suitability.

Revised PR process pilot_Analysis_V1.4_24.11.16

Name of REC	No. REC Manager transfers	No. No opinions By PRSC
Brighton and Sussex	2	2
Cambridge East	4	0
Cornwall and Plymouth	0	3
Edgbaston	6	0
East of Scotland 2	0	0
Exeter	0	2
GM East	6	2
Haydock	1	0
Newcastle and North Tyneside 1	1	1
Newcastle and North Tyneside 2	0	2
North of Scotland 1	1	0
Oxford C	0	0
Wales REC 7	0	0
West of Scotland 3	1	0
York	1	0

When reviewing the reasons for applications not being suitable for PR, the issues identified included;

1. No opinions which were more appropriate for an unfavourable opinion as due to the quality of the application.
2. Applications which did appear to be suitable for PR being transferred by the REC Manager and No Opinions being issued for applications which did appear suitable.

Table 3

NHS
Health Research Authority

Due to the variation of practice between RECs, which is a separate issue, it was decided that the above figures should not be considered directly relevant to this pilot (included for information only). A piece of work will however be undertaken into PR suitability separately.

2.5 To collect and assess the views of REC Members on the revised process

The feedback from (or on behalf of) REC members was fairly low but similar themes came through across the board. The general opinion on the extended time period was positive, although some members reported that they didn't notice much difference and some members suggested that 5 working days was still not long enough. However, the feedback on whether there was improvement to the quality of applications, whether the REC was more inclined to contact the CI and whether the REC was more likely to issue a favourable rather than a provisional was fairly neutral. The approach taken by individual RECs in this regard appears to have varied between RECs and in most cases, the REC members were of the opinion that their approach had been the same and had not changed to take account of the additional time allowed.

"As a member of the PRSC I would say that ensuring that PR members have a minimum of 5 working days to consider applications is very positive both for the reviewing members and also for the thoroughness of the process.

The former system was likely to cause time problems or pressure for reviewing members which had a potential to result in less thorough consideration."

2.6 To collect and assess the views of REC Managers on the revised process.

The feedback from the REC staff was notably positive with only one REC Manager giving a comment which was considered neutral and one comment which was considered negative (same REC Manager) but all other comments were positive. The neutral comment was that the 5 working days sometimes wasn't required and that usually one or two members will reply and the third will follow on shortly after. The negative comment was that if the full 21 days was used, t the REC would be starting to receive applications for the next PRSC, which had been an issue.

The positive comments received related to the additional time relieving pressure, manage workloads, allowing the REC staff time to work with the applicant to get the application valid rather than just invalidating, having more time to improve the quality of the application and more time to check PR suitability.

> "For me it has eased some of the stress and pressure associated with PR.
>
> Simply being able to give people a little longer to sort their applications out has meant that I haven't had to invalidate as many applications, which has meant I haven't had to read as many new ones."
>
> REC Manager

2.7 To collect and assess the views of applicants and compare to feedback given about the current processes.

We have not yet had the time to contact applicants for specific views. However, during the pilot, before an application was booked to a pilot REC, the applicant was informed about the pilot and asked whether they were willing for the application to go to that REC. There were no applicants who requested to not go to a pilot REC and on one occasion, an applicant booked a second application and specifically asked whether they could go to a pilot REC. It is not expected that applicant feedback would add much value to the analysis as it is not likely to be possible to compare the original process with the revised process and the difference from an external perspective is likely to have been negligible.

3. Timelines

During the pilot period, the mean number of days to issue a final opinion was 13 - during the same period, the average number of days for non pilot RECs to issue a final decision was 11. In 63% of cases for the pilot RECs, the final opinion was still issued in 14 days or less.

The rate of overruns (>21days) for pilot RECs was 4% (two RECs had one overrun each due to an application being booked too far in advance and REC Manager annual leave but one REC had five overruns, all of which were due to the Chair or other PRSC members not responding in time). The rate of overruns (>14day) for non pilot RECs during the period was 10%. The high rate of overruns may be, at least partly, due to the high volume of applications received in April and the number of bank holidays over Easter which fell within the pilot period.

4. General observations

- There was considerable variation between REC staff in terms of practice and adherence to SOPs and guidance, particularly in relation to PR suitability and validation. It was noted that for some RECs, it is the role of the REC Assistant rather than the REC Manager to manage PR applications and this may be an issue, particularly for new REC Assistants where there is no checking being undertaken by the REC Manager.
- Different RECs appear to apply PR suitability differently which may be due to the view of the REC members rather than the REC staff in terms of what would be considered suitable for PR.