

Changes to Staff Roles and the Approvals Process in the Health Research Authority

Charlotte Allen, Quality and Performance Manager



Overview

New staff roles and a new process to further integrate the ethical review and the assessment of the study against research governance standards was introduced on 1st April.

Changes were made for the following reasons:

- To provide an optimal service to researchers.
- To streamline processes and reduce duplication of effort.
- To respond to feedback received from applicants.

Creation of two new divisions within the Approvals Directorate:
Approvals Operations and Approvals Support

Changes to Roles

Approvals Operations Division

- Approvals Managers
- Approvals Specialists
- Approvals Officers
- Approvals Administrators



Approvals Support Division

- REC Member Recruitment
- Appointments of Members and REC Chairs
- REC Member Training
- Quality Assurance
- Performance Reporting



Key Process Changes

Status Updates

- User Feedback from applicants is that they want to know more clearly where their application is in the process.
- A status update is an email which will be used to communicate to the Applicant the stage at which their application is at.
- Status Update will be sent from the REC email address – and will provide an update on status for both the REC review and Assessment.
- Final REC decisions and the Approval will be still be attached to the status update as a letter.

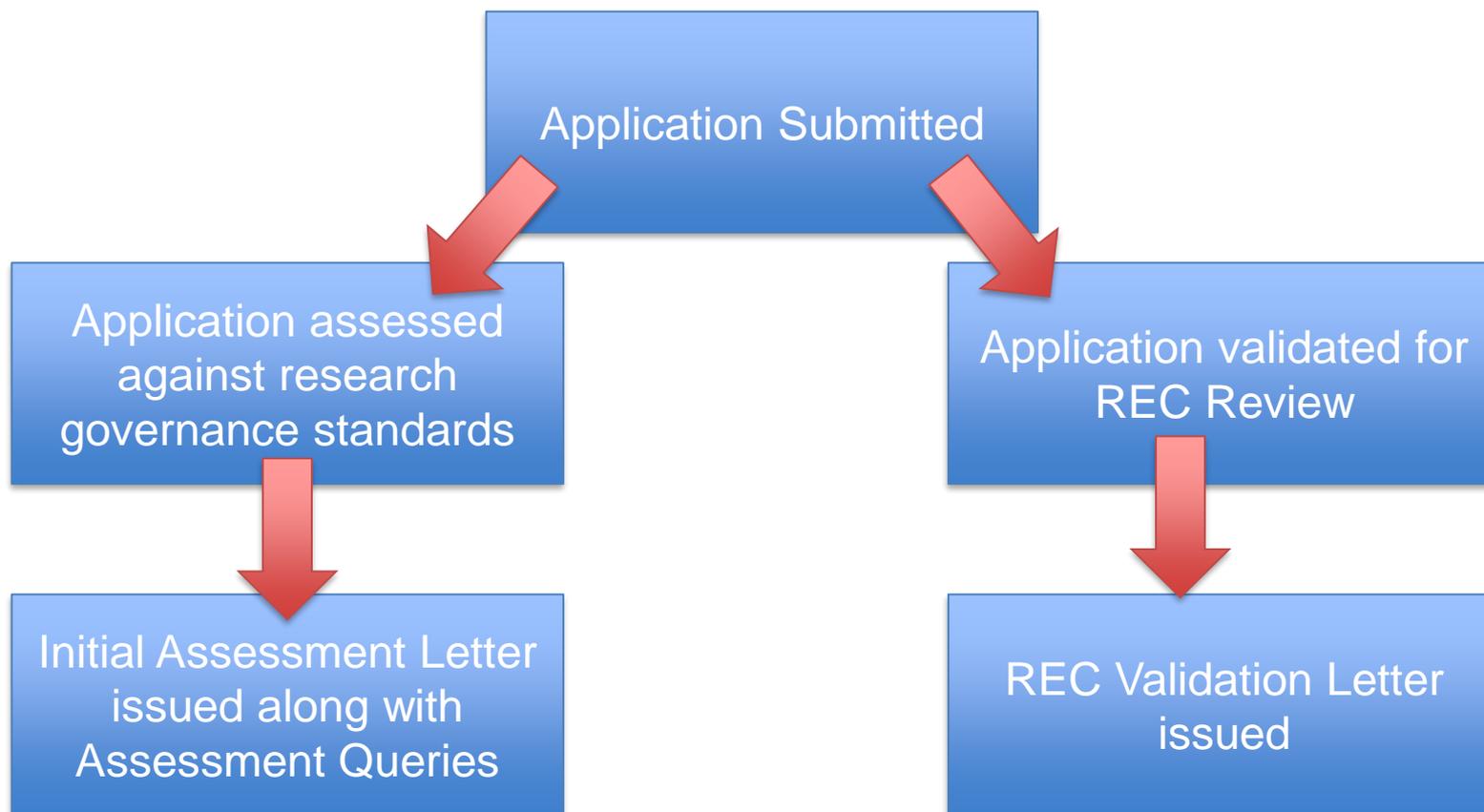
Pre REC Meeting

- Validation and Initial Assessment Letter issued together as a status update.

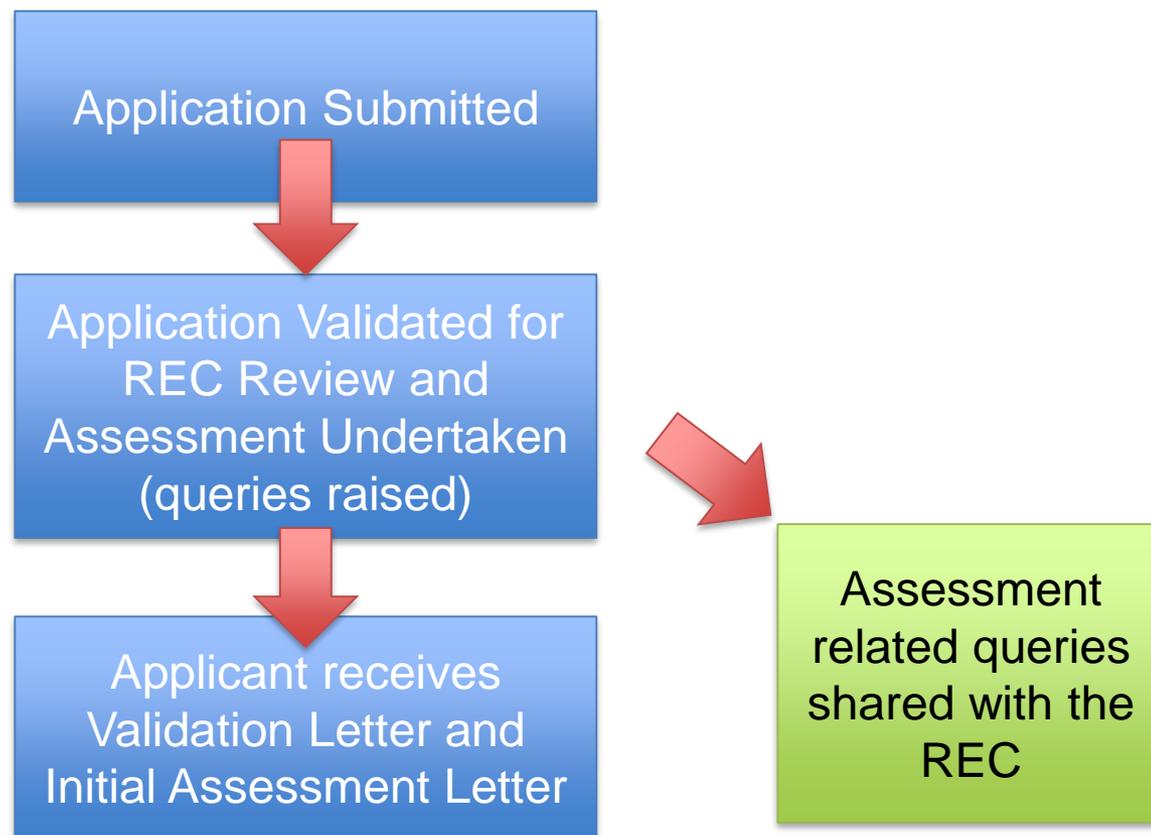


- Validation and Initial Assessment Queries raised together as a status update.

Pre REC Meeting – Old Process



Pre REC Meeting – New Process



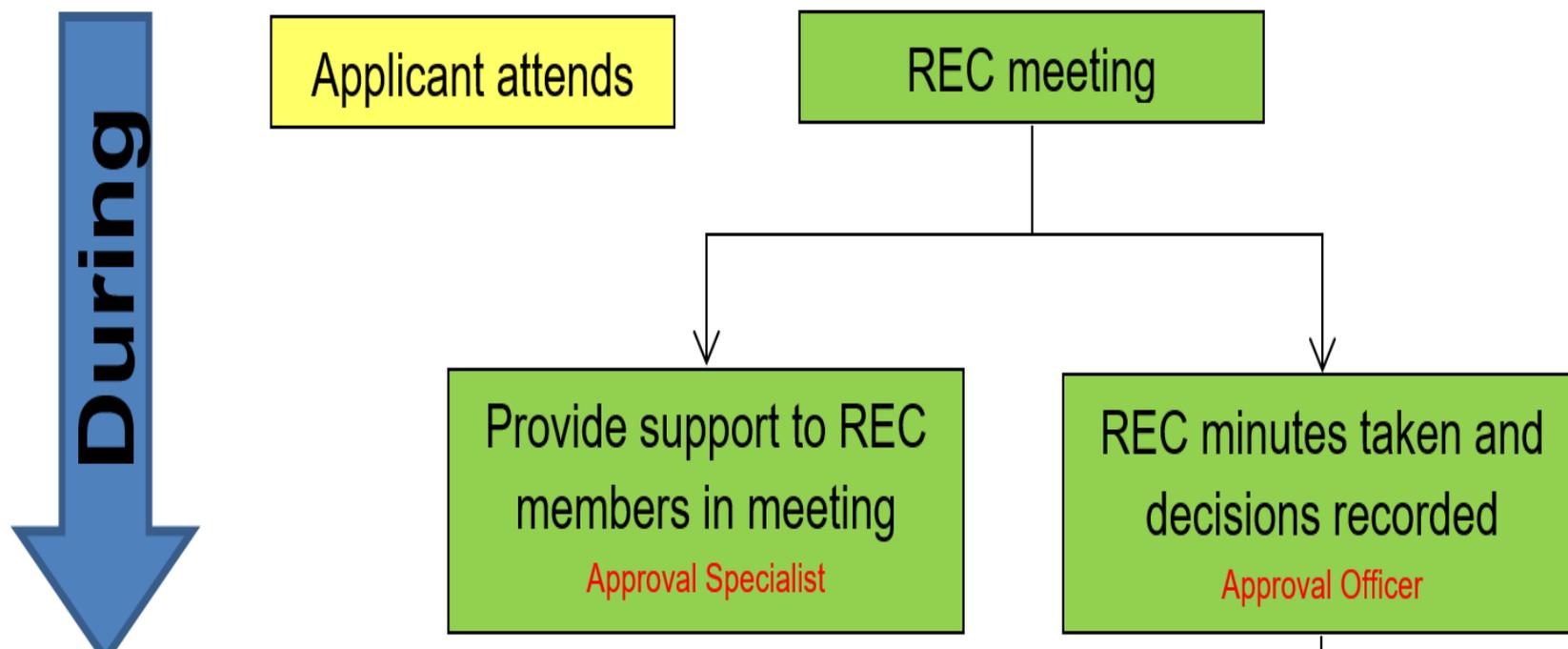
During the REC Meeting



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- The Approvals Specialist attends the meeting to provide support and guidance to the REC and to ensure that all questions are raised with the applicant.
- The Approvals Officer also attends the meeting to take the meeting minutes.
- Questions which have been identified as part of the assessment may be raised with the applicant.
- Where an application is being submitted through the CWoW pilot, the Approvals Specialist will facilitate the review at the meeting.

During the REC meeting



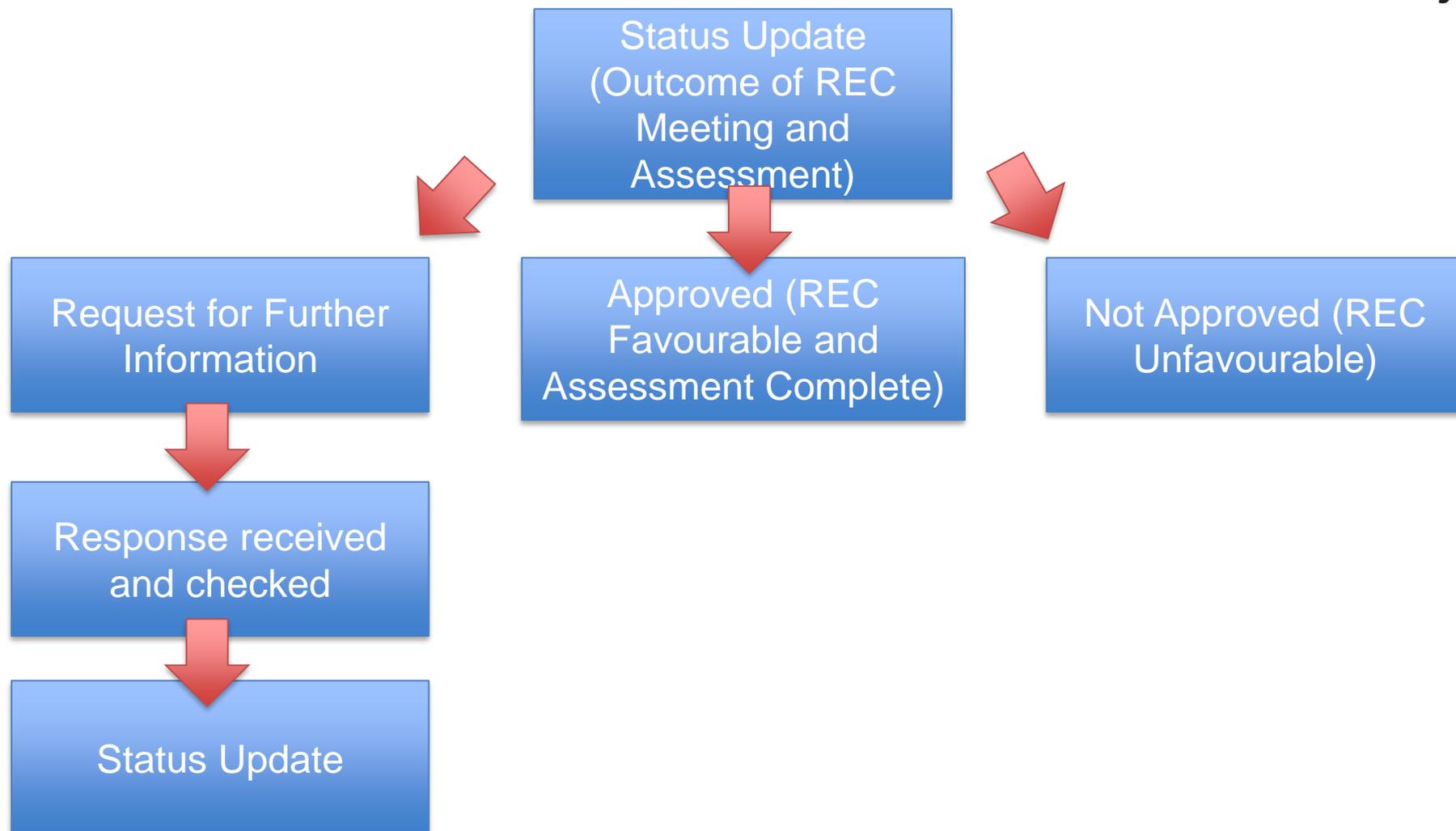
Post REC Meeting: Approvals Finalisation



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- Approvals Finalisation Status Update issued which lists both REC and Assessment queries as a **single communication**.
- Focus is on issuing the status update **as soon as possible** after the meeting.
- Provisional Status Update email replaces Provisional Opinion Letter
- The applicants response to a request for further information may be reviewed by a member of staff as opposed to the REC Chair (resulting in a quicker review time).

Approvals Finalisation



Summary of Benefits

- **Integrated** ethical review and Assessment (and for CWoW studies the MHRA review is also integrated).
- Senior member of staff attending the REC meeting.
- Emphasis on informing the applicant of the decision as soon as possible.
- Joint Communications and requests for information.





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Upcoming Developments

Upcoming Developments



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- UK Local Information Pack
- New process for assessing the suitability of non-NHS sites
- Developments to IRAS platform

The HRA is also continuing to work alongside the MHRA and Devolved Administrations in the Combined Ways of Working pilot.



Further Information

- Please sign up to our HRA Latest Newsletter to keep you up-to-date with developments in the HRA: <https://www.hra.nhs.uk/about-us/hra-latest/>
- Questions?

