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

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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 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

Application Submitted

Application assessed against research governance standards

Initial Assessment Letter issued along with Assessment Queries

Application validated for REC Review

REC Validation Letter issued

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Pre REC Meeting – New Process

Application Submitted

Application Validated for REC Review and Assessment Undertaken (queries raised)

Applicant receives Validation Letter and Initial Assessment Letter

Assessment related queries shared with the REC
During the REC Meeting

- 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

Applicant attends -> REC meeting

Provide support to REC members in meeting
   Approval Specialist

REC minutes taken and decisions recorded
   Approval Officer

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Post REC Meeting: Approvals Finalisation

- 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).
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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.
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?