Academic and Clinical Central Office for Research and Development

COMBINED REVIEW

Is This Relevant To Me?

If you are involved in the submission of Clinical Trials of Investigational Medicinal Products (CTIMPs) or Device-IMP combination projects to the MHRA and a Research Ethics Committee (REC), this document is relevant to you.

What is Combined Review?

- A single application route and MHRA-REC coordinated review, leading to a combined UK approval/opinion for CTIMPs.
- Part of a UK Government initiative to provide a more streamlined and efficient review service for research applicants.
- Applications are submitted via a reformed IRAS system.

How does Combined Review differ from the previous system?

- A single submission and coordinated review means that MHRA and REC requests for further information or changes are delivered as a single communication.
- You will be expected to provide a response within 14 days.
- MHRA approval and REC opinion will also be delivered via a single communication.
- Applicants must register for an account in a new part of IRAS for Combined Review.
- The HRA must be notified of a Combined Review submission via CWOW@hra.nhs.uk.
- The content of the IRAS form may not be the same as the forms you have previously used and you may not be offered your local REC when booking a meeting.
- You cannot generate a pdf of the IRAS form. Instead, reviews and revisions occur directly within the IRAS system, so you must ensure that relevant individuals have IRAS accounts with the correct functions and access rights.
- Communication from the MHRA and REC is delivered within the IRAS system.

Do I need to use Combined Review?

Submissions via Combined Review were mandatory from 1 January 2022.

Is submission of amendments different?

Only trials that have obtained initial approval/opinion via Combined Review will also submit amendments via Combined Review.

If you have any questions or want to seek advice before a Combined Review submission, please contact resgov@accord.scot.

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