

Research Ethics Committee (REC) Application Process Flowchart

version 6.0, 19 May 2014



Health Research Authority

Key:

- Process for obtaining ethical approval
- Site-specific assessment for non-NHS sites
- R&D Permission for NHS sites
- Proportionate Review

Electronically submit non-NHS SSI form to REC for review after REC form has been submitted and validated

If yes complete non-NHS SSI in [IRAS](#)

For non-NHS sites only: Does your study require site-specific assessment (SSA)?

- Requirements for site-specific assessment
- Guidance on SSA exemption

Develop your study idea

- [Is my project research?](#)

- [Requirements for Ethical Approval](#)

Ensure any external funding is agreed in principle before submitting REC & R&D applications

[What other approval\(s\) do I need as well or instead?](#)

All research involving [NHS research sites](#) requires [permission](#) for research for each site.

- Complete applications in [IRAS](#)

Complete REC form in [IRAS website](#) and develop supporting documentation

- [Participant Information Sheets and Consent Forms](#)
- [Other template documents](#)

- [Book in your REC Application](#) via [Central Booking Service \(CBS\)](#)
- Electronically submit your application and supporting documentation from [IRAS](#) to the REC

Applications deemed invalid must be modified and rebooked.

If your application is deemed not valid but outstanding information appears relatively straightforward, the REC Manager may contact you and request outstanding information before it can be validated.

The REC Manager [validates the application](#) within 5 working days of receipt.

- Validation will be confirmed by letter.

If your application is being considered at full committee you should [attend REC meeting](#)

Electronically submit requested outstanding information to REC

- [Application reviewed by REC](#)
- [Decision of the REC](#) is advised in writing.

Not requiring review by NHS REC

If you consider your study presents no material ethical issues, it may be eligible for [Proportionate Review Service](#)

If Proportionate Review decision is 'No Opinion'. Application referred to full committee

Provisional opinion pending consultation with specialist referee (*clock does not stop while awaiting advice; it only stops when advice considered and further information requested*)

Provisional Opinion - further information requested (*clock stops whilst awaiting response; you have two months to respond*)

Submit further information for review as requested (*clock restarts when further info received by REC*)

Unfavourable Opinion

Favourable Opinion with Conditions

If your response to REC is incomplete, you may be asked to supply a more detailed response but no new issues may be raised by the REC at this stage (*clock stops whilst REC awaits further information*)

Modify application and resubmit

- [Appeal](#)

Favourable Opinion

The REC is committed to returning an opinion within 60 days of receipt of a valid application or 14 calendar days of receipt of a valid application for studies accepted by Proportionate Review Service