

Single form replaces separate ethics and R&D application forms on a UK-wide basis – Information for UK wide Research Ethics Service

As indicated in OMEA 81 issued on 5 June 2017, from the evening of 28 June 2017 a combined IRAS form that merges the REC and R&D forms will be used across the UK. Already in place for projects where the lead NHS R&D office is based in England, the single IRAS form should be used for projects where the lead NHS/HSC R&D office is based in Northern Ireland, Scotland or Wales.

The streamlined single system is a result of the work of the Four Nations NHS/HSC Compatibility Programme and contributes to making it easier for applicants to undertake research in the NHS/HSC. Adoption of the single IRAS form UK-wide will save time and effort for applicants and sponsors and help build UK-wide consistency.

The IRAS form is very similar to the REC Form but there are additional data items and additional documents on the checklist that only apply to the study wide review against NHS/HSC standards (study wide review) and do not impact ethical review. The checklists have been updated and are attached so that you can see the differences (note the text in the checklist has been updated to help applicants attach the correct documents to their application for review against NHS/HSC standards).

From the evening of 28 June 2017, projects newly created in IRAS with NHS/HSC sites will have an IRAS form created in IRAS Filter Question 4 in place of separate REC and R&D forms. Researchers with projects that have already been created in IRAS are advised to continue to use the existing forms; REC and R&D form applications will continue to be accepted by RECs and national coordinating functions for approximately 6 months. Where a REC or R&D form has already been submitted, changing forms is not recommended as the applicant will lose their submission history and be unable to create substantial amendments.

For projects led from Northern Ireland, Scotland, or Wales, although a single form will replace the separate REC and R&D forms, this single IRAS form will continue to be separately submitted for ethical review (where applicable) and review against NHS/HSC standards as per current processes.

Clear instructions on how the application is booked to a Research Ethics Committee (where applicable) and then immediately emailed for review against NHS/HSC standards by the lead nation will be provided in the IRAS form submission tab and within IRAS Help. The instructions include where to email applications and what to do about single site studies in Scotland and Northern Ireland.

The single electronic submission of the IRAS form and accompanying documents for both ethical review and review against NHS/HSC standards will remain in place for projects led from England.

When advising applicants, please ensure they are aware that before submitting the IRAS form for REC review (where applicable) they need also to be ready to submit all documents needed for review against NHS/HSC standards (i.e. study wide review), including template agreements and

any applicable costing template. Applicants are to be encouraged to read the advice and guidance within IRAS and to seek support from their lead NHS/HSC R&D office.

There is no change to SSI Form functionality for NHS/HSC sites in Northern Ireland, Scotland or Wales at this time.

Over the coming year more work will be carried out to further streamline the application process so that the current submission functionality for projects led from England, is extended to projects led from Northern Ireland, Scotland and Wales.

Applications for Research Tissue Banks, Research Databases, and for research projects not taking place in the NHS/HSC will continue to use the REC Form. Applications for studies where the lead NHS R&D office is based in England are not affected by this change.

A set of questions and answers will be available from 28 June to assist understanding of the change. Research Ethics Service staff are encouraged on or after 29 June to create a test project in IRAS so that they understand the changes to the project filter, submission tab and checklists and can therefore better advise applicants. Additional support is available from the Research Ethics Service leads and Operational Leads in each nation.