SCOTLAND & HEALTH RESEARCH AUTHORITY APPROVAL

HEADLINES

- No impact on approved studies or studies already submitted for approval
- No change to the process or requirement for ethics review, or the UK applicability of the Research Ethics Committee (REC) favourable opinion
- No change to the submission process for NHS permission in Scotland

WHO ARE THE HEALTH RESEARCH AUTHORITY (HRA)?

The Health Research Authority (HRA) is an English non-departmental government body. They are responsible for protecting and promoting the interests of patients and public in health research. They are also responsible for streamlining the regulation of research.

They host the UK Research Ethics Committee (REC) service. The UK REC service reviews and ethically approves health research making sure people receive the information they need to decide if they want to take part in research.

WHAT IS HRA APPROVAL?

HRA Approval is a new process for the NHS in England that assesses a research study's regulatory and legal compliance, including NHS REC review, where required. For those research studies eligible for HRA Approval, where the lead NHS R&D office is in England, the HRA will be responsible for carrying out the lead regulatory and legal compliance review, sometimes called the study wide review.

A shared agreement between the Devolved Administrations and the HRA continues to ensure that existing UK compatible permissions systems support cross border research studies. The lead nation provides assurances about the governance assessment and legal compliance of a research study.

Each participating nation accepts these assurances, as far as they apply, removing unnecessary duplication. HRA Approval rollout in England brings together the assessment of governance and legal compliance, with the independent REC opinion.

WHAT MAKES UP THE HRA APPROVAL?

Three elements make up the HRA Approval:

i. **HRA assessment** – the HRA conducts the assessment of a study's regulatory and legal compliance for NHS England where the lead NHS R&D office is located in England. Under the UK compatibility arrangements, the participating nations will accept the review carried out by the HRA.

ii. **NHS REC review** – the ethical review of a research study, although part of the HRA Approval, provides an independent opinion, where applicable. There are no changes to the arrangements for ethical review, with the review carried out by independent committees. The REC favourable opinion will be applicable UK wide. No separate REC application will be required in Scotland for studies that use HRA Approval unless, as per current guidance, an opinion is required from Scotland A REC.

iii. **Technical Assurance** – HRA Approval will include technical assurances for pharmacy and radiation once fully rolled out. These are a review of pharmacy and radiological aspects of the research study to ensure the safety of the proposed protocol procedures. The HRA coordinates the technical assurances carried out by NHS staff, on behalf of the NHS in England. For studies that use the HRA Approval process, the technical assurances will be available to participating nations.

HOW DO I SET UP MY STUDY IN SCOTLAND?

Single centre studies conducted entirely in Scotland

Applicants should email the NHS / HSC R&D Form and supporting application documents to the R&D office of the participating site.

Multi-centre studies conducted entirely in Scotland

Applicants should email the NHS / HSC R&D Form and supporting application documents to the NRS Permissions Coordinating Centre. The NRS Permissions Coordinating Centre will share the application and subsequent study wide review with the participating NHS R&D Offices in Scotland.

Studies with the lead NHS R&D office in Scotland, including sites in other UK nations

For research studies eligible for HRA Approval, where the lead NHS R&D office is in Scotland, applicants should email the NHS / HSC R&D Form and supporting application documents to the NRS Permissions Coordinating Centre. The NRS Permissions Coordinating Centre will share the application and subsequent study wide review with the participating NHS R&D Offices in Scotland, the other participating national NHS permissions coordinating functions and the HRA. Under the UK compatibility arrangements, the participating nations and HRA will accept the review carried out within Scotland.

Studies with the lead NHS R&D office in England, including sites in Scotland

1. Studies eligible for HRA Approval, including sites in Scotland

For research studies eligible for HRA Approval, where the lead NHS R&D office is in England, applicants should electronically submit through IRAS the combined REC and NHS / HSC R&D Form and supporting application documents. Applicants can choose a REC in any UK nation when booking their application for review.

The HRA will then share the application and subsequent review with the other participating national NHS permissions coordinating functions in the Devolved Administrations. Under UK compatibility arrangements, the Devolved Administrations will accept the review undertaken by the HRA.

2. Studies not yet eligible for HRA Approval, including sites in Scotland

HRA Approval is being rolled out during 2015/16. For research studies not yet eligible for HRA Approval, where the lead NHS R&D office is in England, applicants should electronically submit the NHS / HSC R&D Form and supporting application documents through IRAS.

For studies currently still processed through the NIHR Coordinated System for gaining NHS Permission (CSP), it will then share the application and subsequent review with the other participating national NHS permissions coordinating functions in the Devolved Administrations.

For other studies not yet eligible for HRA Approval or eligible for processing through CSP, applicants should email their NHS / HSC R&D Form and supporting application documents to the national NHS permissions coordinating function of each participating nation or for England submit to each participating site R&D Office.

WHAT ABOUT SITE SPECIFIC INFORMATION (SSI) FORMS?

Applicants will need to create NHS Site Specific Information (SSI) Forms for each participating NHS organisation (the lead nation will let you know if any exceptions apply to this).

The Chief Investigator should transfer NHS SSI Forms to the Principal Investigators at the research sites listed in the Part C of IRAS. The Principal Investigator or local research team should complete, authorise and submit the NHS SSI Form and supporting documents according to the relevant national processes. The Principal Investigator or local research team are responsible for contacting the local NHS R&D office about the study.

Site Specific Information (SSI) forms, along with supporting application documents, will be required for each participating NHS organisation in Scotland. For NHS organisations in Scotland, applicants should email NHS SSI Forms and supporting application documents to the R&D Office of the participating sites.

For other UK nations, applicants should follow the appropriate national processes.

The following web page describes other UK national processes. http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/

WHERE CAN I GET MORE INFORMATION?

You can contact your local NHS R&D Office or, for multi-centre studies, contact the NRS Permissions Coordinating Centre

http://www.nhsresearchscotland.org.uk/services/permissions-co-ordinating-centre/permissions

You can find out more information about carrying out research in Scotland at

http://www.nhsresearchscotland.org.uk/

You can find detailed information about applying for HRA Approval at

http://www.hra.nhs.uk/resources/hra-approval-applicant-guidance/