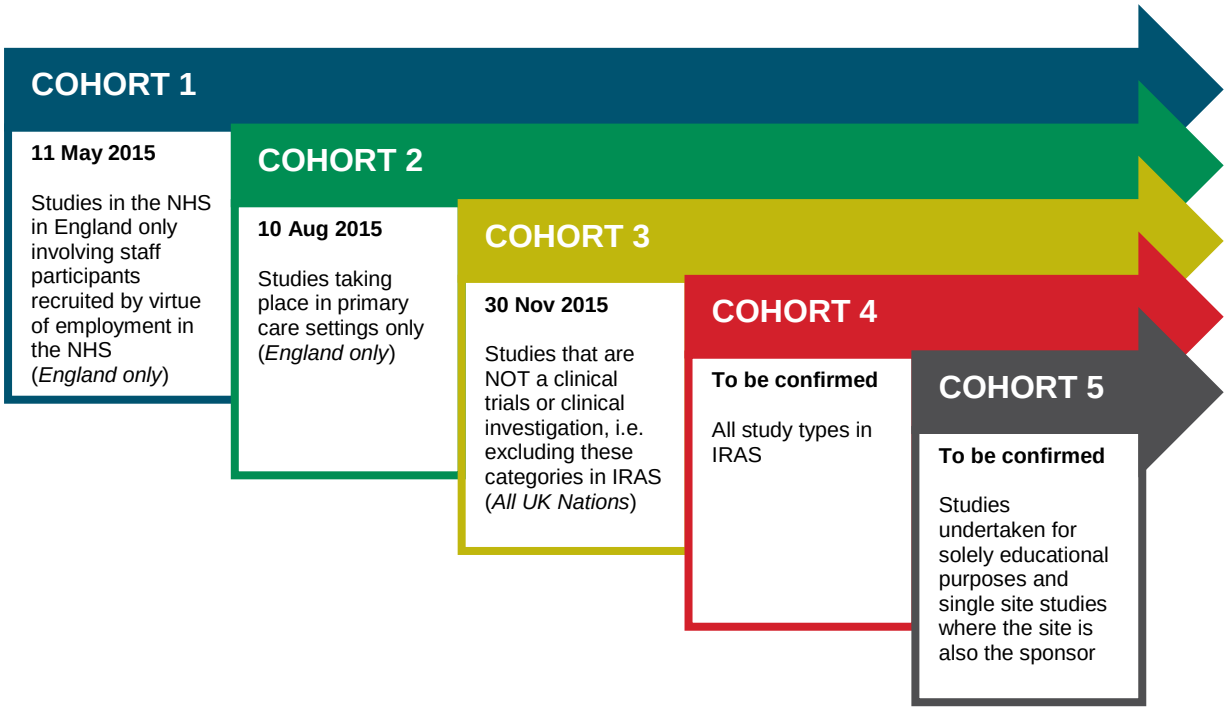
UK COMPATIBILITY
HEALTH RESEARCH AUTHORITY APPROVAL

WHAT IS HEALTH RESEARCH AUTHORITY APPROVAL?

Health Research Authority (HRA) Approval is a new process for the NHS in England that assesses a research study's regulatory and legal compliance, including NHS Research Ethics Committee (REC) review, where required.

HOW IS THE HRA IMPLEMENTING HRA APPROVAL?

The HRA is implementing HRA Approval in a phased and controlled way. Building on the implementation experience of each cohort, the HRA will refine processes and continuously improve the quality and efficiency of these developing processes.



COHORT 1 to 4 excludes:

- Studies solely for educational purposes
- Studies undertaken at a single site where the site is also the sponsor of the study

UK COMPATIBILITY AND HOW WILL IT CONTINUE?

UK compatibility continues to be a shared commitment between the Devolved Administrations and the HRA.

The existing UK compatible permissions systems will continue to 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.

A shared agreement between the Devolved Administrations and the HRA continues to ensure that the Devolved Administrations accept the centralised assurances from the HRA, and vice versa.

WHAT DOES UK COMPATIBILITY MEAN IN COHORT 3?

Studies with lead NHS R&D office outside England

For research studies eligible for HRA Approval, where the lead NHS R&D office is outside England, applicants should email the NHS/ HSC R&D Form and supporting application documents to the national NHS permissions coordinating functions according to the location of the lead NHS R&D office. Applicants should also submit REC applications separately using the REC Form.

The lead NHS permission coordinating function will then share the application and subsequent review with 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 by the lead national NHS permissions coordinating function (see Flow chart 1).

Studies with lead NHS R&D office in England

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 (see Flow chart 2).

What is the combined REC and NHS/HSC R&D Form?

The development of a combined REC and NHS/HSC R&D Form has reduced the duplication between the existing REC Form questions and the existing NHS/HSC R&D Form questions. Plans are underway to implement this across the UK nations.

Studies with lead NHS R&D office outside England

Where the lead NHS R&D office is outside England and until all UK nations implement the combined REC and NHS/HSC R&D Form, applicants will continue to apply for NHS Permissions using the NHS/HSC R&D Form. Applicants should also continue to apply for REC favourable opinion using a separate REC Form.

Studies with lead NHS R&D office in England

Where the lead NHS R&D office is in England, applicants will apply for HRA approval using the combined REC and NHS/HSC R&D Form.

The combined form replaces the NHS Research Ethics Committee (REC) Form and NHS Research & Development (R&D) Form for applications for HRA approval.

NIHR Clinical Research Network (CRN) Portfolio

Studies with lead NHS R&D office outside England

If you would like to apply to the NIHR Clinical Research Network (CRN) Portfolio for support for the English research sites, please inform the national NHS permissions coordinating function. The national NHS permissions coordinating function will then pass on the information when they share the application with the HRA. The HRA will then in turn pass the information on the CRN.

Studies with lead NHS R&D office in England

If you are applying to the NIHR CRN Portfolio, you will need to submit a Portfolio Application Form (PAF) for the study before submitting the HRA Approval application.

You will need to create and submit the PAF in IRAS. The HRA will share relevant application information with the CRN so that they can make a decision on NIHR CRN Portfolio eligibility.

WHAT ABOUT SITE SPECIFIC INFORMATION (SSI) FORMS?

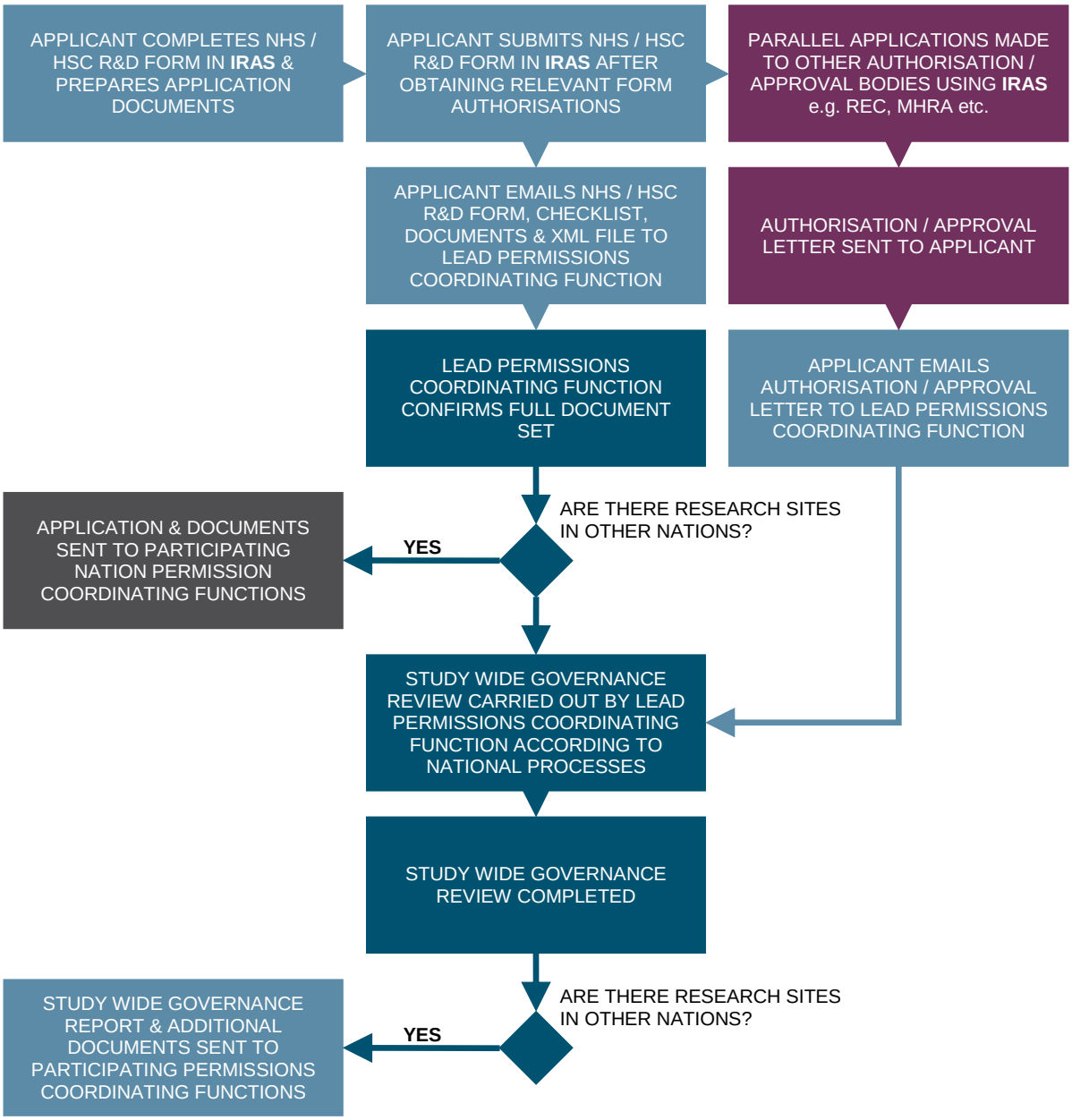
You will need to create NHS Site Specific Information (SSI) Forms for each participating NHS organisation.

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.

You can find further details about the national processes from the following:

http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/

Flow chart 1 – Studies with lead NHS R&D office outside England



Flow chart 2 – Studies with lead NHS R&D office in England