**HRA Approval** is coming….

The process for obtaining NHS Permission is changing. This new process will start on the 11th May 2015 with a controlled roll out by study type and will be called HRA (Health Research Authority) Approval.

What is **HRA Approval**?

HRA Approval will provide a single approval for research in the NHS that will comprise of a review by a Research Ethics Committee (where applicable) as well as an assessment of regulatory compliance and related matters by dedicated HRA staff. HRA Approval will be used for all studies in England, that is, NIHR portfolio studies and non-portfolio studies

HRA Approval will provide authoritative assurance to NHS organisations about the suitability, compliance and quality of research proposals. HRA Approval will meet the Government commitments in the Plan for Growth, and address the concerns raised by the Academy of Medical Sciences on Clinical Trials.

The key change for applicants will be to submit a complete application package to the HRA which is ready to proceed through the whole approvals process (currently there is little difference between the R&D and REC forms on IRAS and many applicants apply to REC well before they are ready to set up sites resulting in protocol amendments). HRA Approval will be based on acomplete application package validated once by the HRA, which will be made available to local staff (R&D departments and research staff) to support consideration of local capacity and capability. It will be the sponsor’s responsibility to provide appropriate documentation to participating sites to allow them to consider local capacity and capability.

HRA Approval will be implemented in a controlled roll out by study type and will start on the 11th May with:

**Cohort 1:** Types of health services research in the NHS in England that only involve participants who are NHS employees.

This will then be followed by the following cohorts:

**Cohort 2:** Studies taking place in primary care settings only i.e. all study types (including CTIMPs) that take place only in primary care settings and no protocol driven activities take place in secondary or tertiary care settings.

**Cohort 3:** Studies types which exclude the first four categories of IRAS. i.e. not clinical trials and clinical investigations.

**Cohort 4:** All study types in IRAS.

* Excluding studies solely for educational purposes
* Excluding studies undertaken at a single site where that site is also the sponsor of the study. Where applicable REC review would still be required and if additional sites were added HRA Approval would need to be sought.

**Cohort 5:** Studies undertaken solely for educational purposes and single site studies where that site is also the sponsor.

Following each roll out, the HRA will further develop processes as part of learning from and building on experience. Each roll out will build on the previous one. There will be changes to IRAS to accommodate future roll outs.

**The key changes will be:**

* Site-specific information (SSI) forms will no longer be required for studies.
* Studies supported by the NIHR Clinical Research Network **will not use** [**NIHR CSP**](http://www.crn.nihr.ac.uk/can-help/funders-academics/gaining-nhs-permissions/) as **NHS Permission will no longer be required**.
* NHS organisations will need to confirm readiness to start delivering a study either by signing an agreement with the sponsor or by using the new ‘Statement of Activities’ (to be released shortly) and agreeing by email.

**Amendments**

It is the intention that:

* Amendments for studies that have been given HRA Approval will be processed by the HRA. A submission process will be put in place.
* Amendments for studies that were granted NHS permission and/or obtained a favourable opinion from a NHS REC before HRA Approval was put in place will be processed by HRA from a date yet to be decided. From an applicant and NHS perspective this should be from the implementation of Cohort 4 but will require further work to ensure the HRA are ready to take on this increased workload.
* The addition of sites to studies that were granted NHS permission and/or obtained a favourable opinion from a NHS REC before HRA Approval was put in place will also have to be implemented concurrently with Cohort 4 to avoid confusion for both sites and investigators.

For further information please refer to northyorksresearch@york.nhs.uk or [www.hra.nhs.uk](http://www.hra.nhs.uk) or contact the R&D department.