Local Information Pack

HRA Approval is testing the use of a new local information pack for NHS participating organisations in England. The sponsor does not need to obtain detailed information from the local research team before sending the pack below by email to the local research team, the R&D office and Local Clinical Research Network (where relevant). The details are then completed jointly between all relevant parties and then confirmed in writing.

- Copy of IRAS application form (combined REC and R&D form) as submitted for HRA Approval
- Protocol and amendments
- Participant information and consent documents (without local logos/ headers)
- Relevant model agreement
- Commercial studies only - NIHR Costing template (validated) and delegation log (including known research team names but not signatures)
- Non-commercial studies only - Statement of Activity and Schedule of Event templates (including known information)
- Any other documents that the sponsor wishes to provide to the site to support the set up and delivery of the study
- Copy of HRA Initial Assessment letter

When HRA Approval has been issued, the sponsor should send the Approval letter and any revised documents to the local research team, the R&D office and Local Clinical Research Network (where relevant).

Note: The arrangements for sites in Scotland, Wales or Northern Ireland are provided at http://www.hra.nhs.uk/research-community/applying-for-approvals/nhs-management-permission/

Latest guidance at www.hra.nhs.uk. .

NHS
Health Research Authority

SETTING UP YOUR STUDY WITH

HRA Approval

Guidance for local research teams

This leaflet applies to local research teams delivering HRA Approval studies

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Study set-up steps for local research teams

This diagram shows the process for setting up NHS participating organisations in England. For more information go to: www.hra.nhs.uk/hra-approval