What is HRA Approval?

HRA Approval comprises an assessment of study compliance with applicable regulations and standards. For studies that require review by an NHS research ethics committee (REC), it also includes the separate but coordinated REC review.

Studies that are undertaken solely for educational purposes or are taking place only at the NHS sponsor's site are currently excluded from HRA Approval.

Clinical Research Network support

If your study is eligible for the NIHR portfolio, please liaise with your Local Clinical Research Network, who will support the delivery of your study.

For further details go to:
www.supportmystudy.nihr.ac.uk.

Working with your sites

The HRA will provide you with the outcome of the HRA's assessment. You should provide this information to your sites.

It is critical that you involve both the research management function (e.g. R&D office and local clinical research network staff) supporting each organisation and the local research team (where there is one) in setting up your study.

Working with Devolved Administrations

For details, go to:
www.hra.nhs.uk/resources/hra-approval-applicant-guidance/

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Setting up your study

You should send the following local package to both the local research team and R&D/LCRN support team at the same time, unless advised otherwise by the HRA:

- Copy of completed IRAS form (combined REC and R&D form)
- Protocol and any amendments
- Participant information and consent documents
- Statement of Activity
- Relevant template contract/model agreement (if applicable)
- Schedule of events
- Any other study 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 and (when issued) HRA Approval letter and final document versions

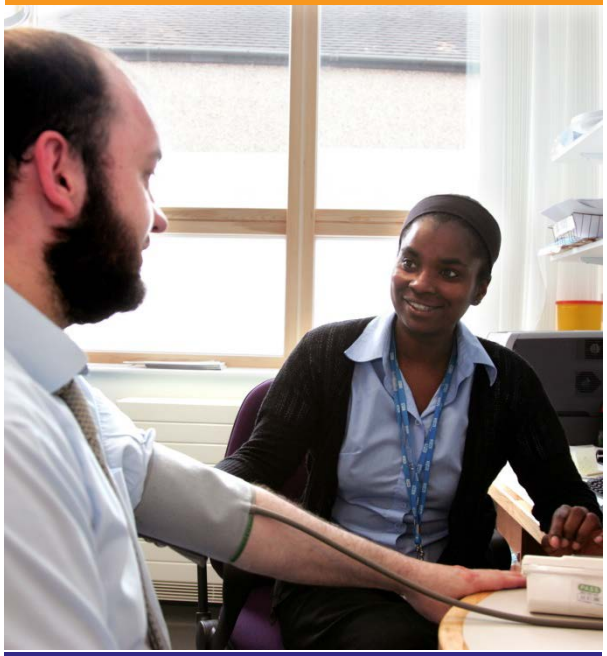
If any of the local research team are not employed by the site they should liaise directly with the R&D office to make the necessary HR arrangements.

For more information go to:
www.hra.nhs.uk/hra-approval

NHS
Health Research Authority

SETTING UP YOUR STUDY WITH

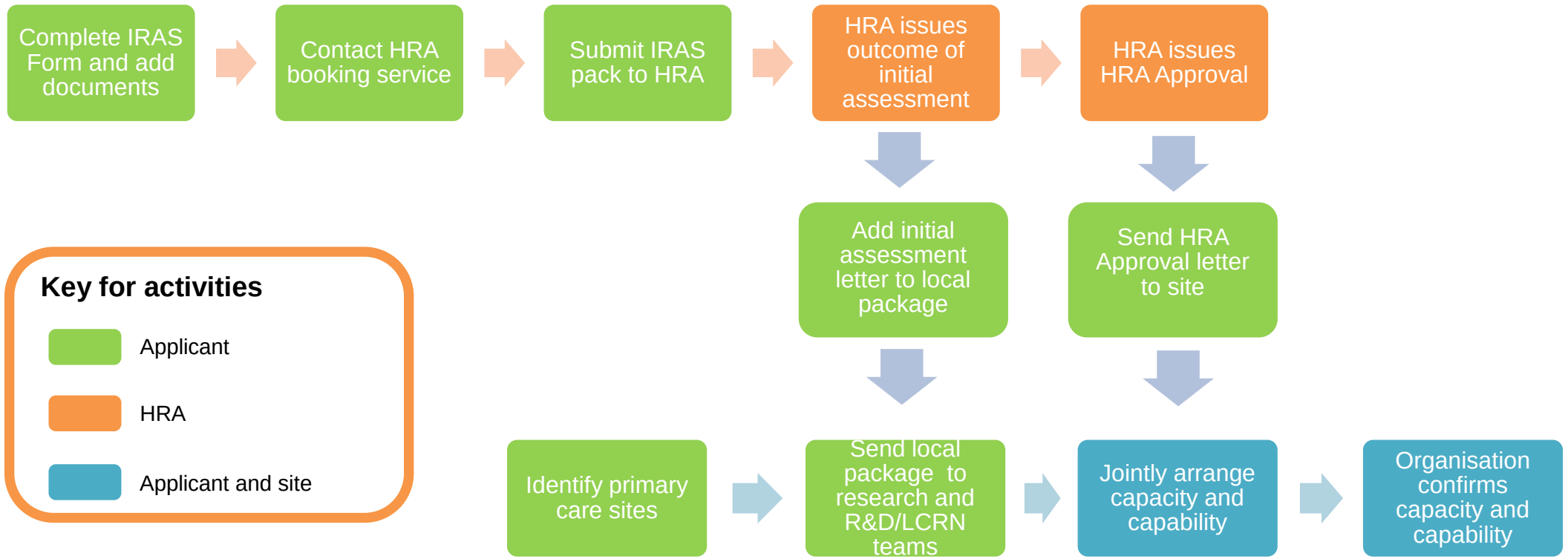
HRA Approval



Guidance for primary care research studies

This leaflet applies to non-commercial studies taking place in primary care settings in England only.

Setting up your study with HRA and your NHS sites in England



Working with your sites

HRA Approval provides a proportionate system. HRA will advise you in the initial assessment outcome how you should set up your sites. The site means the local research team supported by the R&D team and, where applicable, the Local Clinical Research Network. Further information about working with the research management function for each GP practice can be accessed from www.hra.nhs.uk/hra-approval. Contact details are available at http://www.rdforum.nhs.uk/content/contact-details/.