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.

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:
http://www.hra.nhs.uk/research-community/applying-for-approvals/hra-approval/

Need help?

Go to www.hra.nhs.uk for the latest guidance.

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Setting up your study

Formal site selection starts when you send the final protocol to the site, but you may engage with the site prior to that. When you and the site agree to do the study, you should send the following local package to the local research team, the R&D office and Local Clinical Research Network (where relevant) at the same time:

- Copy of completed IRAS form (combined REC and R&D form)
- Protocol and any amendments
- Participant information and consent documents
- Template Statement of Activity (non-commercial studies only)
- Relevant template contract/model agreement (if applicable)
- Costing template (commercially sponsored only) or Schedule of events (non-commercially sponsored only)
- Blank delegation log (commercial only)
- 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.

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).

NHS
Health Research Authority

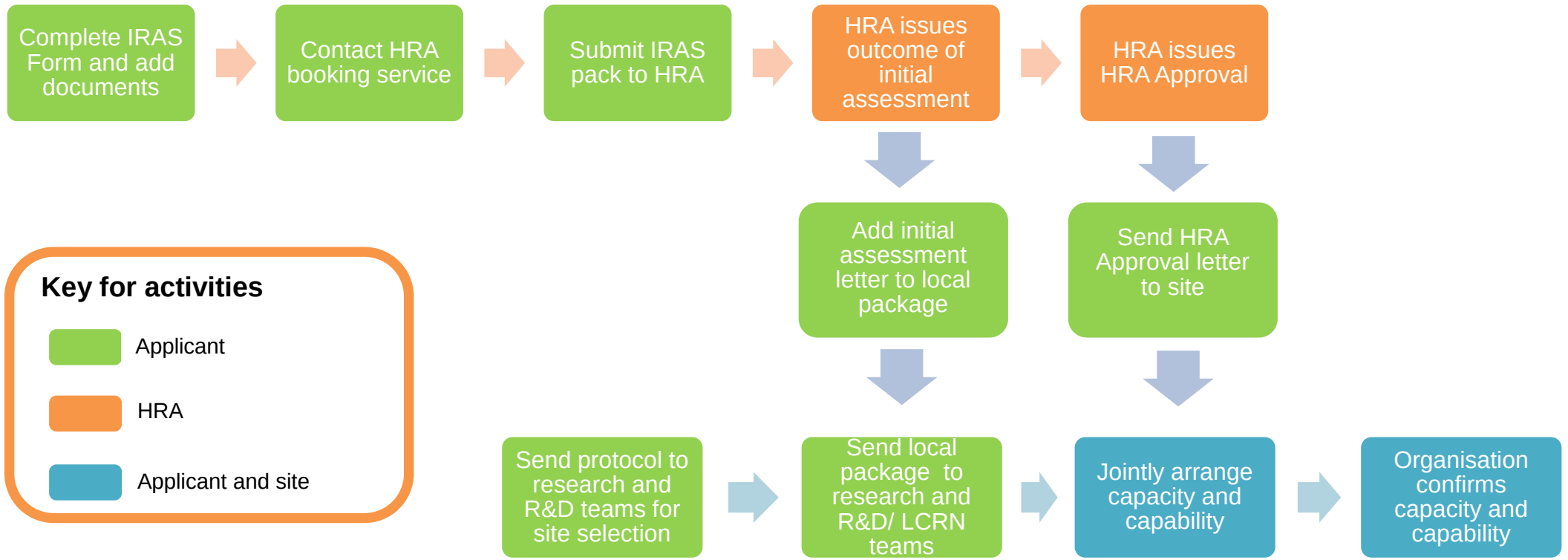
SETTING UP YOUR STUDY WITH

HRA Approval

Guidance for clinical trials and clinical investigations

This leaflet applies only to clinical trials of investigational medicinal products or interventions, and clinical investigations of devices.

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 NHS organisation can be accessed from www.hra.nhs.uk/hra-approval. Contact details are available at http://www.rdforum.nhs.uk/content/contact-details/.