NHS
Health Research Authority

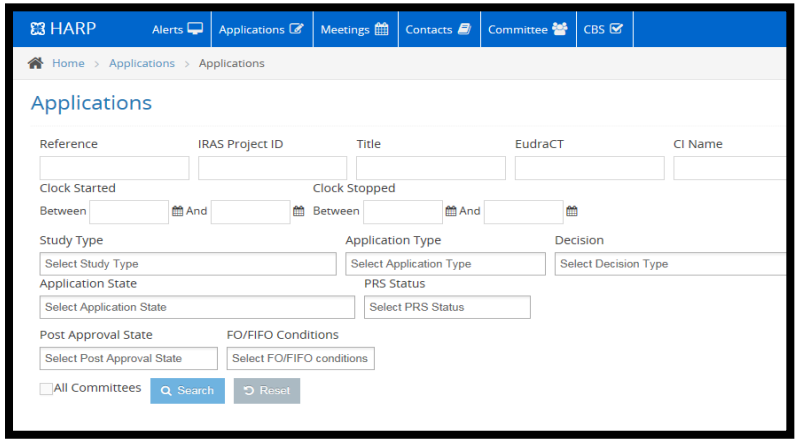
HRA Approval

Jen Harrison – HRA Approval Change Manager
19th September 2016

Health Research Authority

- Established 2011
- Protect and promote the interests of patients and the public in research
- Consensus and collaboration on standards rather than inspection

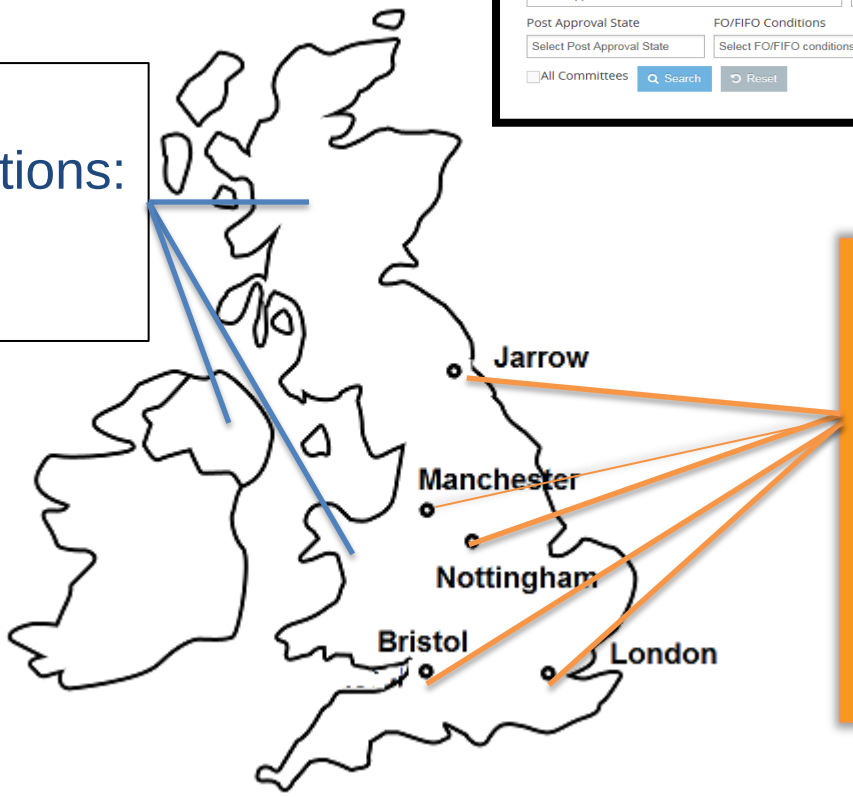
UK-wide arrangements



UK-wide IT system

Devolved administrations:

- RECs
- R&D



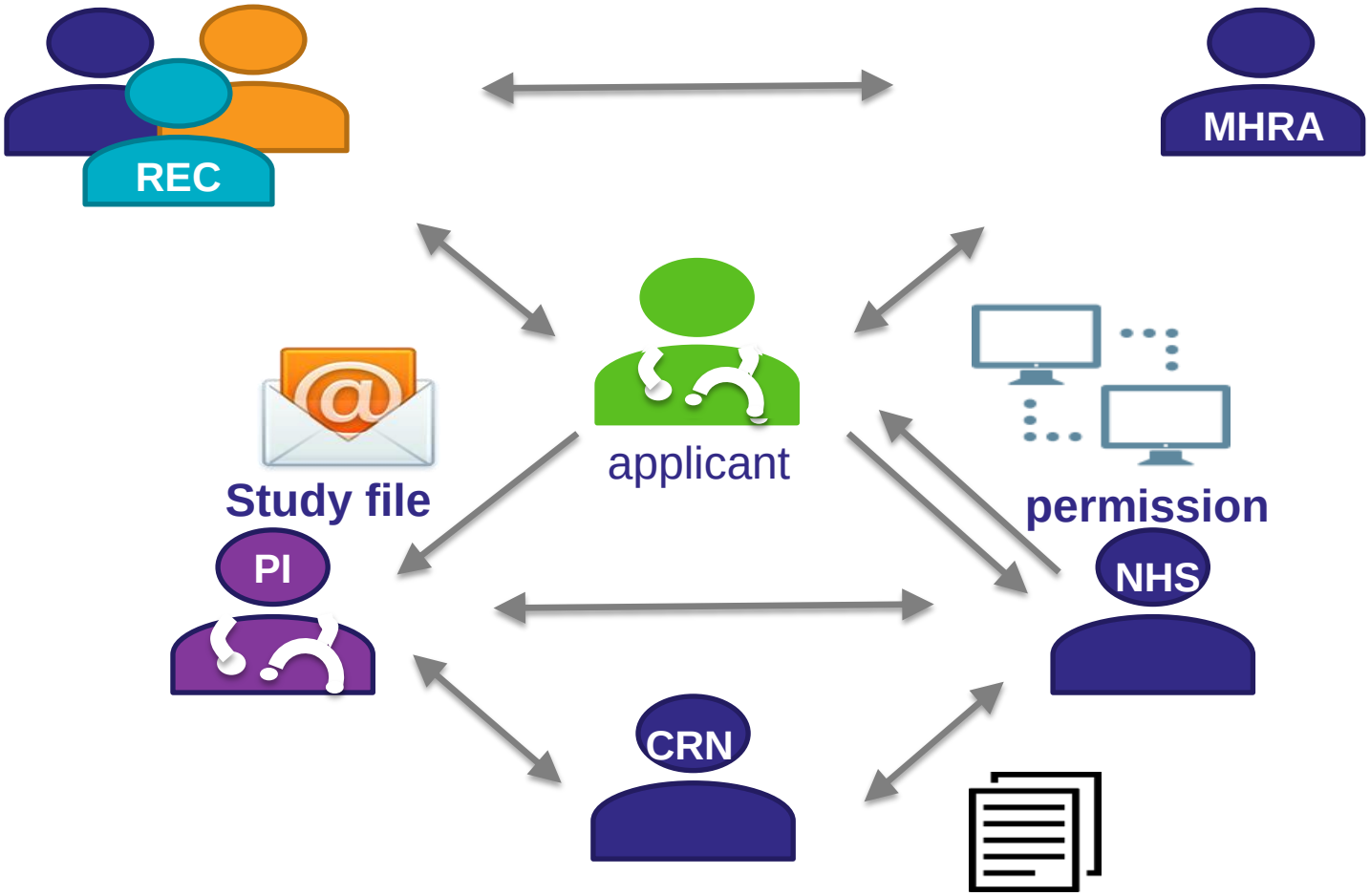
HRA - England

Research Ethics Service
Assessment team
Technical Assurance team
Confidentiality Advice Team

Programme objectives

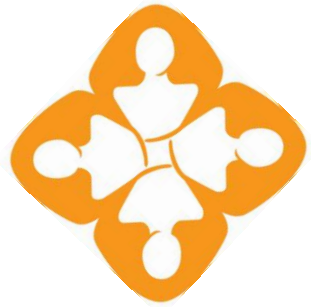
Previous system

Health Research Authority



CRN study support services

applicant

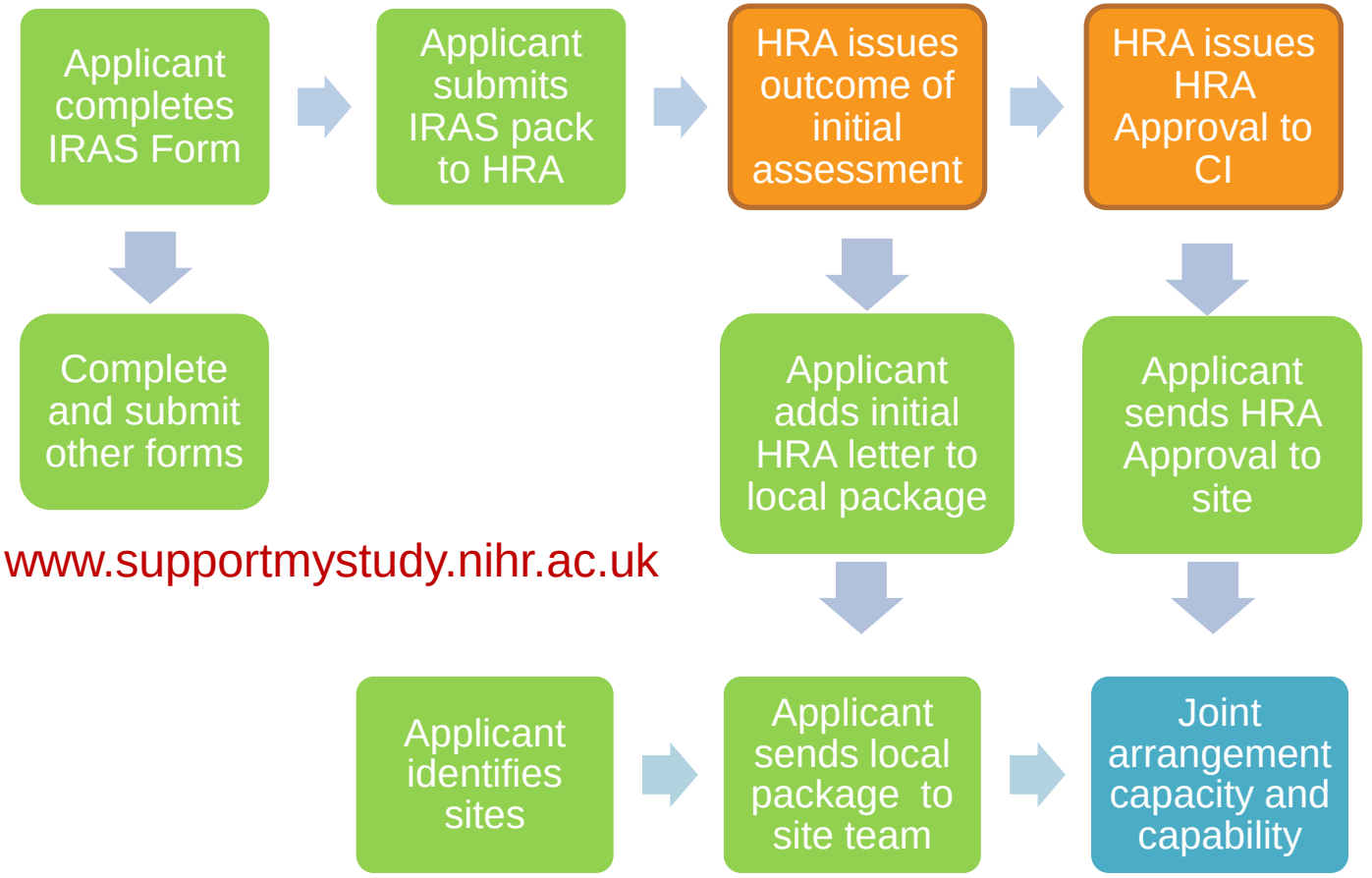


HRA Approval for the NHS

One document package
One joint decision about site

Site team supporting set up and delivery

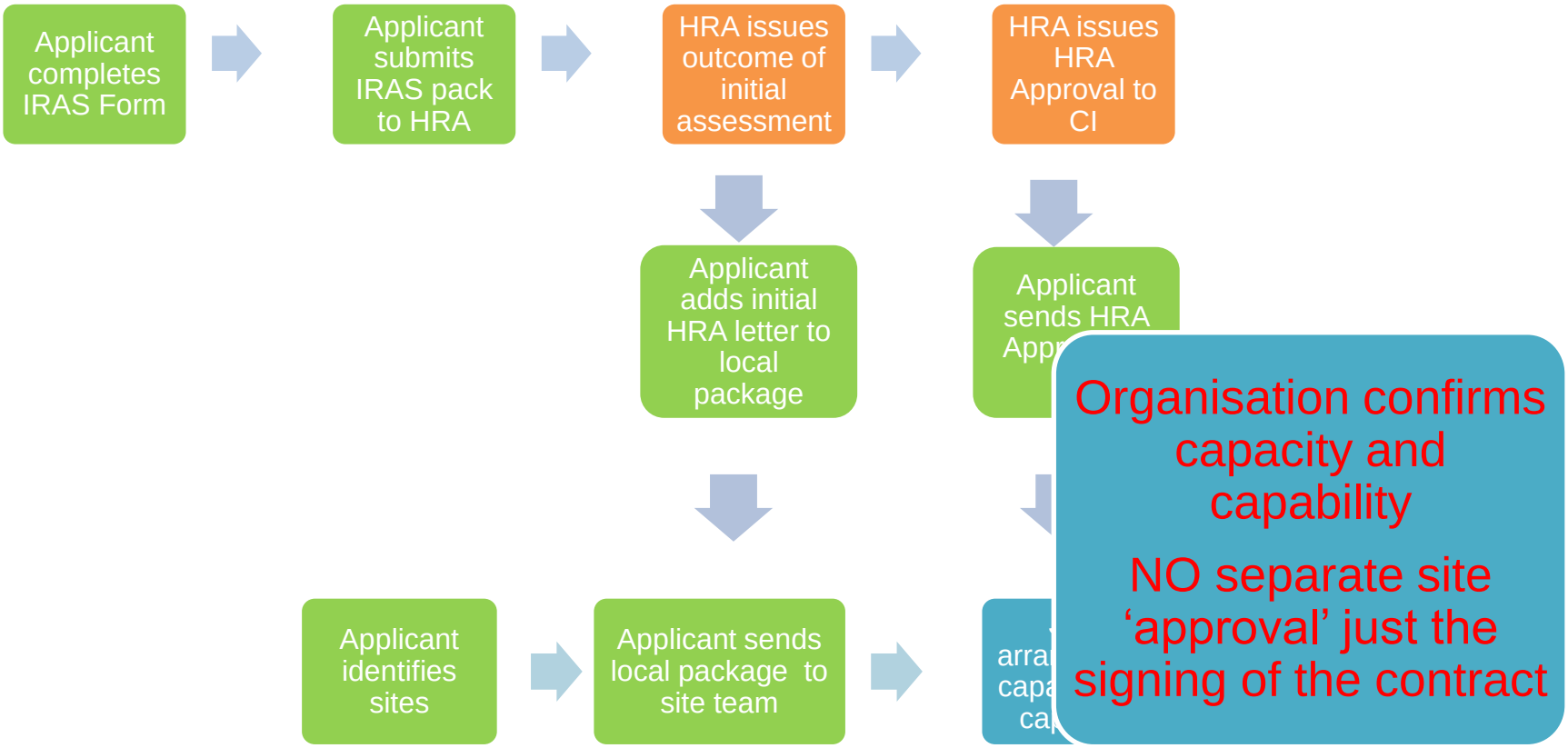
High level process with HRA Approval



www.supportmystudy.nihr.ac.uk

Site team = R&D team + research delivery team (PI, research nurses, etc) + LCRN team (for portfolio studies)
See www.rdforum.nhs.uk contacts

High level process with HRA Approval

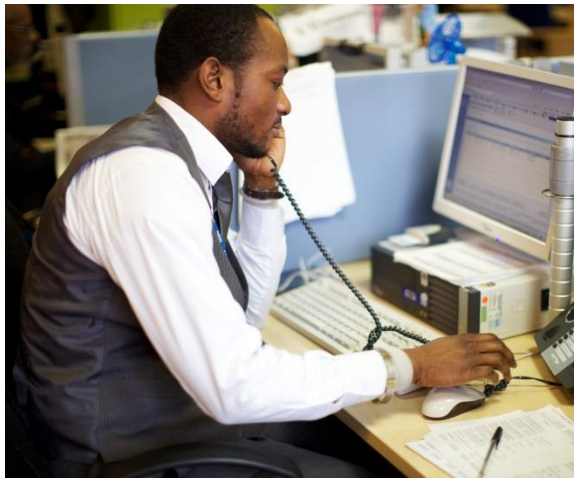


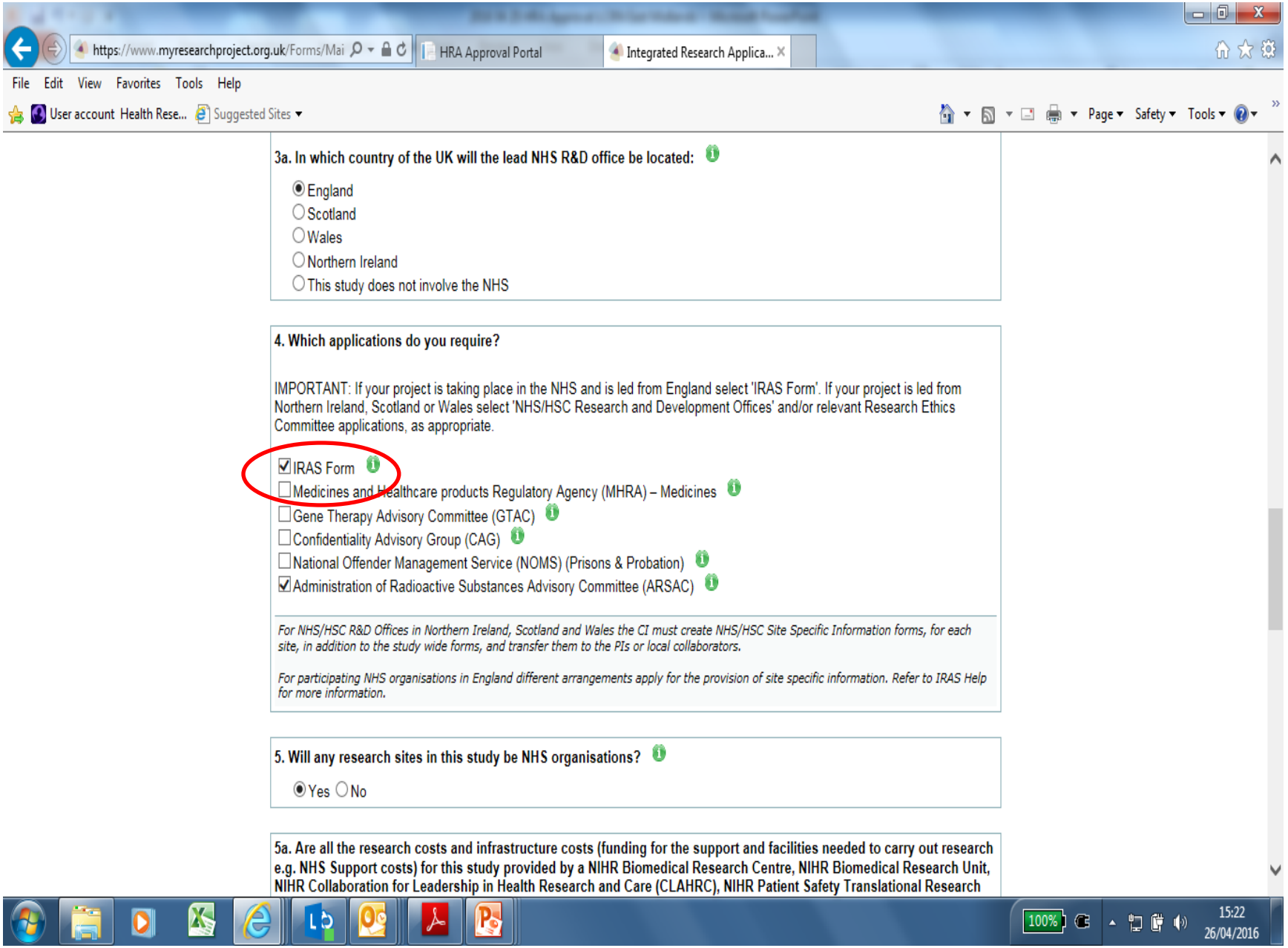
NHS
Health Research Authority

Application process

Applying to HRA

- One set of authorisations
- One set of documents to upload
- For all studies (including non-REC) contact the Central Booking Service




https://www.myresearchproject.org.uk/Forms/Mai
HRA Approval Portal
Integrated Research Applica...
File Edit View Favorites Tools Help
User account Health Rese...
Suggested Sites
Page
Safety
Tools
3a. In which country of the UK will the lead NHS R&D office be located:
England
Scotland
Wales
Northern Ireland
This study does not involve the NHS
4. Which applications do you require?
IMPORTANT: If your project is taking place in the NHS and is led from England select 'IRAS Form'. If your project is led from Northern Ireland, Scotland or Wales select 'NHS/HSC Research and Development Offices' and/or relevant Research Ethics Committee applications, as appropriate.
IRAS Form
Medicines and Healthcare products Regulatory Agency (MHRA) – Medicines
Gene Therapy Advisory Committee (GTAC)
Confidentiality Advisory Group (CAG)
National Offender Management Service (NOMS) (Prisons & Probation)
Administration of Radioactive Substances Advisory Committee (ARSAC)
For NHS/HSC R&D Offices in Northern Ireland, Scotland and Wales the CI must create NHS/HSC Site Specific Information forms, for each site, in addition to the study wide forms, and transfer them to the PIs or local collaborators.
For participating NHS organisations in England different arrangements apply for the provision of site specific information. Refer to IRAS Help for more information.
5. Will any research sites in this study be NHS organisations?
Yes
No
5a. Are all the research costs and infrastructure costs (funding for the support and facilities needed to carry out research e.g. NHS Support costs) for this study provided by a NIHR Biomedical Research Centre, NIHR Biomedical Research Unit, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC), NIHR Patient Safety Translational Research
100%
15:22
26/04/2016

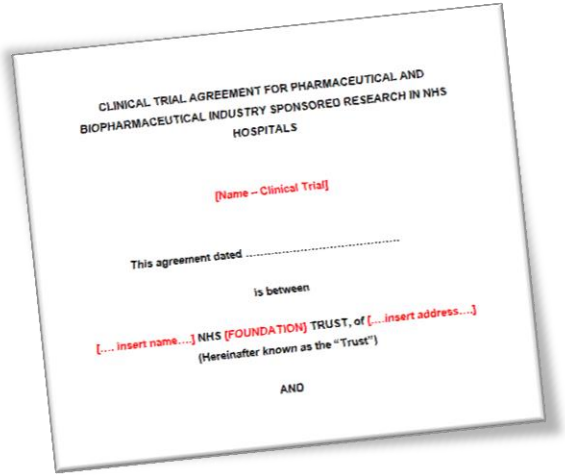
HRA Assessment Criteria and Standards

- What will be assessed and expected standard
- Single review of legality and compliance
- Supports study set-up

  http://www.hra.nhs.uk/hra-approval

Agreements – commercial/ non-commercial

- HRA will confirm whether a model agreement has been used
- Any variations will be highlighted to Trusts
- HRA may indicate acceptability of variations



CLINICAL TRIAL AGREEMENT FOR PHARMACEUTICAL AND BIOPHARMACEUTICAL INDUSTRY SPONSORED RESEARCH IN NHS HOSPITALS

[Name – Clinical Trial]

This agreement dated .....

is between

[.... insert name....] NHS [FOUNDATION] TRUST, of [.... insert address....]
(Hereinafter known as the "Trust")

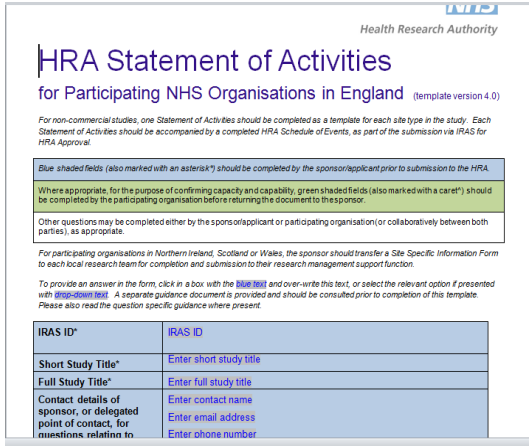
AND

Costing – commercial studies

- Seek early validation of costing template by CRN via lead R&D office (portfolio studies)
- If not validated, HRA will validate (but this will delay if portfolio)
- Initial Assessment letter from HRA will document outcome for sponsor and Trusts

Statement of Activities – non-commercial

- Submit one template per 'site type' to HRA
- Add known local information before sending one to each site as part of local information package
- Complete the template during site set-up
- Can act in place of any other form of site agreement/contract).



Health Research Authority

HRA Statement of Activities

for Participating NHS Organisations in England (template version 4.0)

For non-commercial studies, one Statement of Activities should be completed as a template for each site type in the study. Each Statement of Activities should be accompanied by a completed HRA Schedule of Events, as part of the submission via IRAS for HRA Approval.

Blue shaded fields (also marked with an asterisk) should be completed by the sponsor/applicant prior to submission to the HRA.*

Where appropriate, for the purpose of confirming capacity and capability, green shaded fields (also marked with a caret^) should be completed by the participating organisation before returning the document to the sponsor.

Other questions may be completed either by the sponsor/applicant or participating organisation (or collaboratively between both parties), as appropriate.

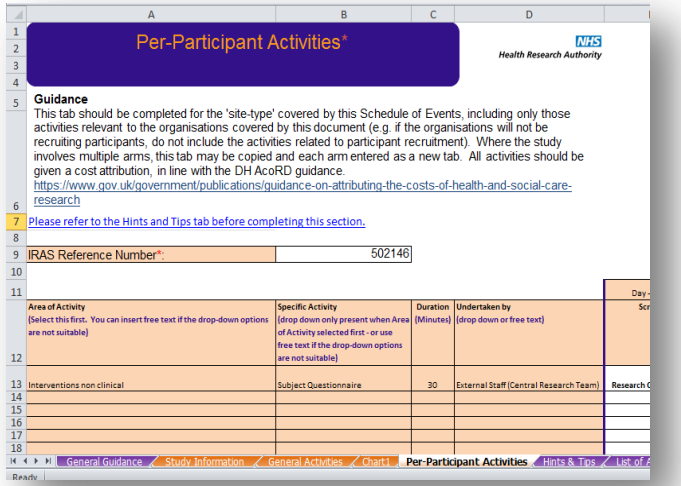
For participating organisations in Northern Ireland, Scotland or Wales, the sponsor should transfer a Site Specific Information Form to each local research team for completion and submission to their research management support function.

To provide an answer in the form, click in a box with the blue text and over-write this text, or select the relevant option if presented with drop-down text. A separate guidance document is provided and should be consulted prior to completion of this template. Please also read the question specific guidance where present.

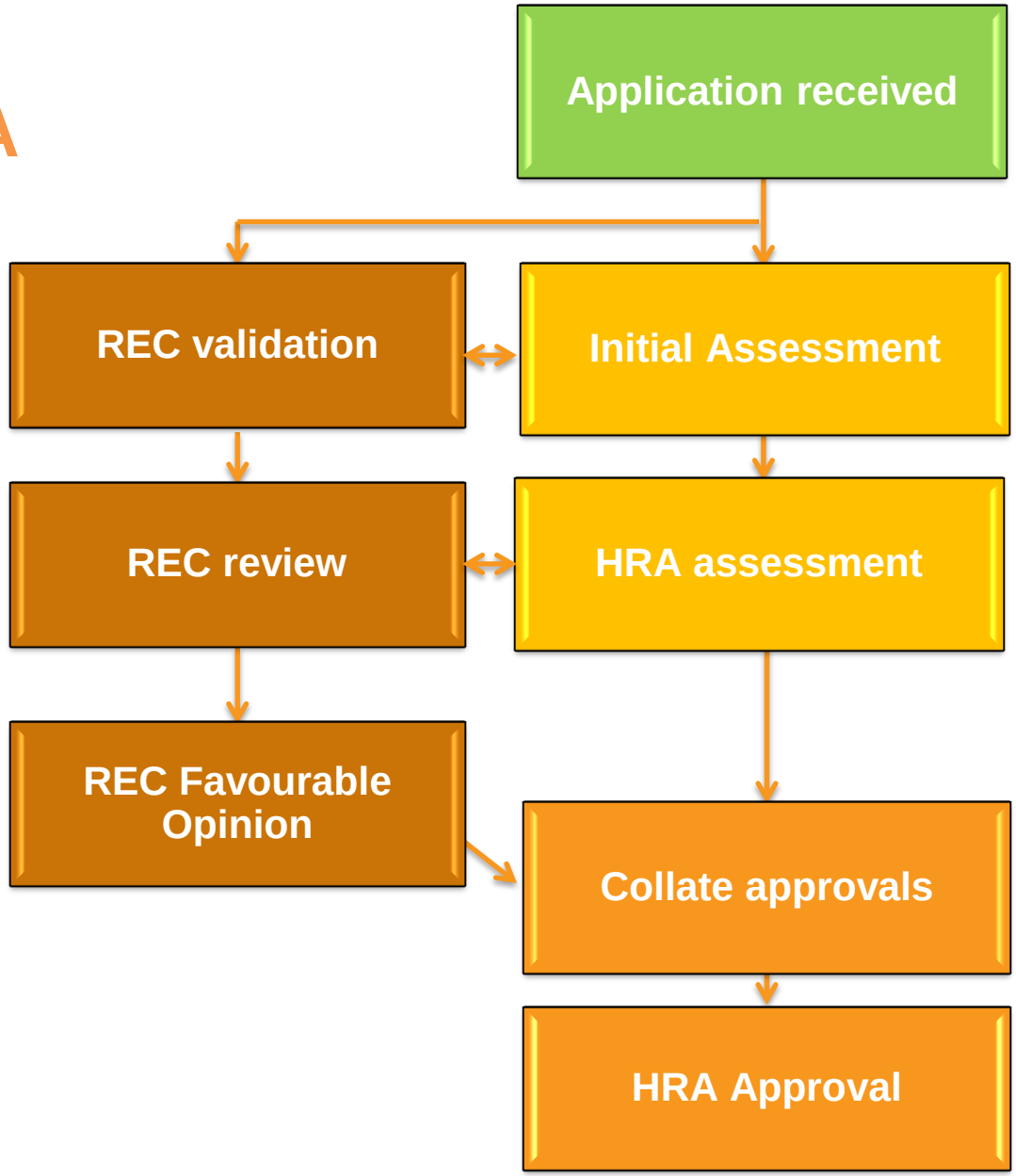
IRAS ID*	IRAS ID
Short Study Title*	Enter short study title
Full Study Title*	Enter full study title
Contact details of sponsor, or delegated point of contact, for questions relating to	Enter contact name Enter email address Enter phone number

Schedule of Events – non-commercial

- Submit one template per ‘site type’ to HRA
- Details activities and their cost attribution
- HRA Approval will not be conditional on correct attribution or full research costs but information will be passed to sites.



HRA



HRA Initial Assessment Letter

- Clarifies if any site types do not need to confirm capacity and capability (eg some PICs)
- Flags issues to be resolved so sites don't duplicate
- Applicant provides to sites as part of local document package

NHS
Health Research Authority

Dr Arthur Smith
Red Health Hospital NHS Trust
Red Health Road
London
L1 4TT

Email: hra.approval@nhs.net

6 February 2016

Dear Dr Smith

Initial Assessment Letter

Study title:	**DUMMY STUDY: To determine whether Drug A is more effective than Drug B in Chronic Heart Failure.**
IRAS project ID:	**502136**
EudraCT number:	**1111-100000-22**
Protocol number:	**XX1234**
REC reference:	**16/HRA/9999**
Sponsor:	**Red Heath Hospital NHS Trust**

Thank you for your application for HRA Approval. HRA Approval comprises an assessment of study compliance with applicable regulations and standards and a separate but coordinated review by an independent Research Ethics Committee (REC), where applicable. You will have already received notification that your application is valid for REC and proceeding to a REC meeting.

I, (Ms Ann Assessor – hra.approval@nhs.net) have been assigned to this application and have undertaken my initial assessment, the findings of which are detailed in Appendix B. **You and the sponsor should now work with participating organisations to finalise local arrangements in preparation for HRA Approval, on this basis.**

I will continue to work with you to resolve any outstanding questions whilst local arrangements are finalised prior to HRA Approval. I may need to contact you by phone or email if any clarifications are required.

Following the review of your application by the HRA assessment team and REC (where applicable) you may be asked to make changes to the documents submitted in your application. If you envisage that changes might be required prior to the outcome of the review, I would ask that you contact me for advice.

Scope

HRA Approval provides an approval for research involving NHS patients or staff in England. Organisations listed in your application are not obliged to undertake this study; arrangements for organisations to confirm their capacity and capability to undertake the study, where formal confirmation is required, are detailed in *Appendix B (Participating NHS Organisations, Capacity and Capability* and *Agreement* sections).

Page 1 of 9

HRA Approval Letter

No provisional or conditional. If approved:

- Lists documents approved – including any revised documents
- Reports outcome of assessment – including resolution of issues

Health Research Authority

Dr Arthur Smith
Red Heath Hospital NHS Trust
Red Heath Road
London
L1 4TT

Email: hra.approval@nhs.net

17 March 2016

Dear Dr Smith,

Letter of HRA Approval

Study title:	DUMMY STUDY: To determine whether Drug A is more effective than Drug B in Chronic Heart Failure.
IRAS project ID:	502136
EudraCT number:	1111-100000-22
Protocol number:	XX1234
REC reference:	16/HRA/9999
Date of REC favourable opinion with conditions	21 February 2016
Sponsor:	Red Heath Hospital NHS Trust

I am pleased to confirm that the above study has been given HRA Approval, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Scope

HRA Approval provides an approval for research involving NHS patients or staff in England. Organisations listed in your application are not obliged to undertake this study; arrangements for organisations to confirm their capacity and capability to undertake the study, where formal confirmation is required, are detailed in *Appendix B Summary of HRA assessment (Participating NHS Organisations, Capacity and Capability and Agreement* sections).

If your study involves participating organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice
http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

Participating NHS Organisations in England

The HRA has determined that participating NHS organisations in England that are **Participant Identification Centres** or **organisations collecting blood samples only** do not need to formally confirm their capacity and capability to host this research, because a formal agreement with the sponsor is not required for these types of activities. It is expected that these organisations will become

Page 1 of 10

EXAMPLE

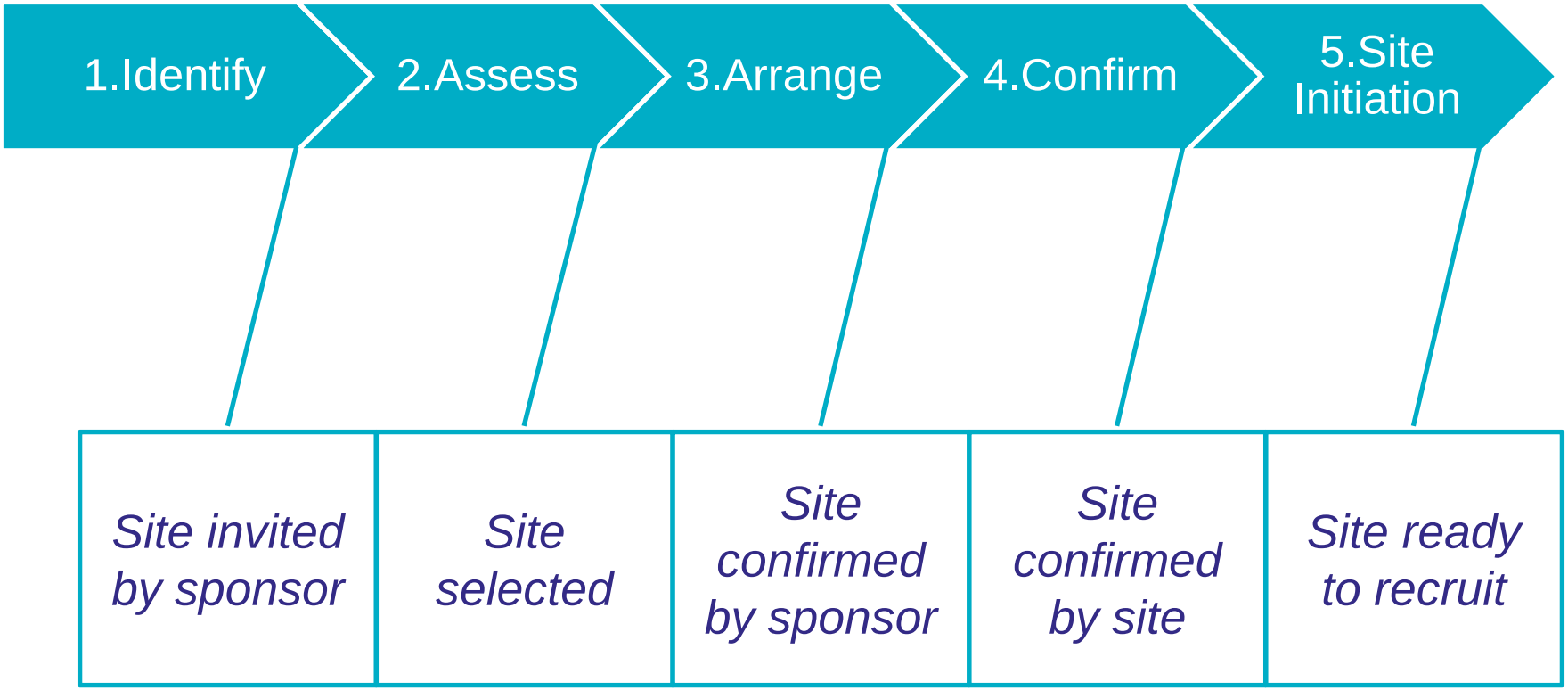
Cross-border studies

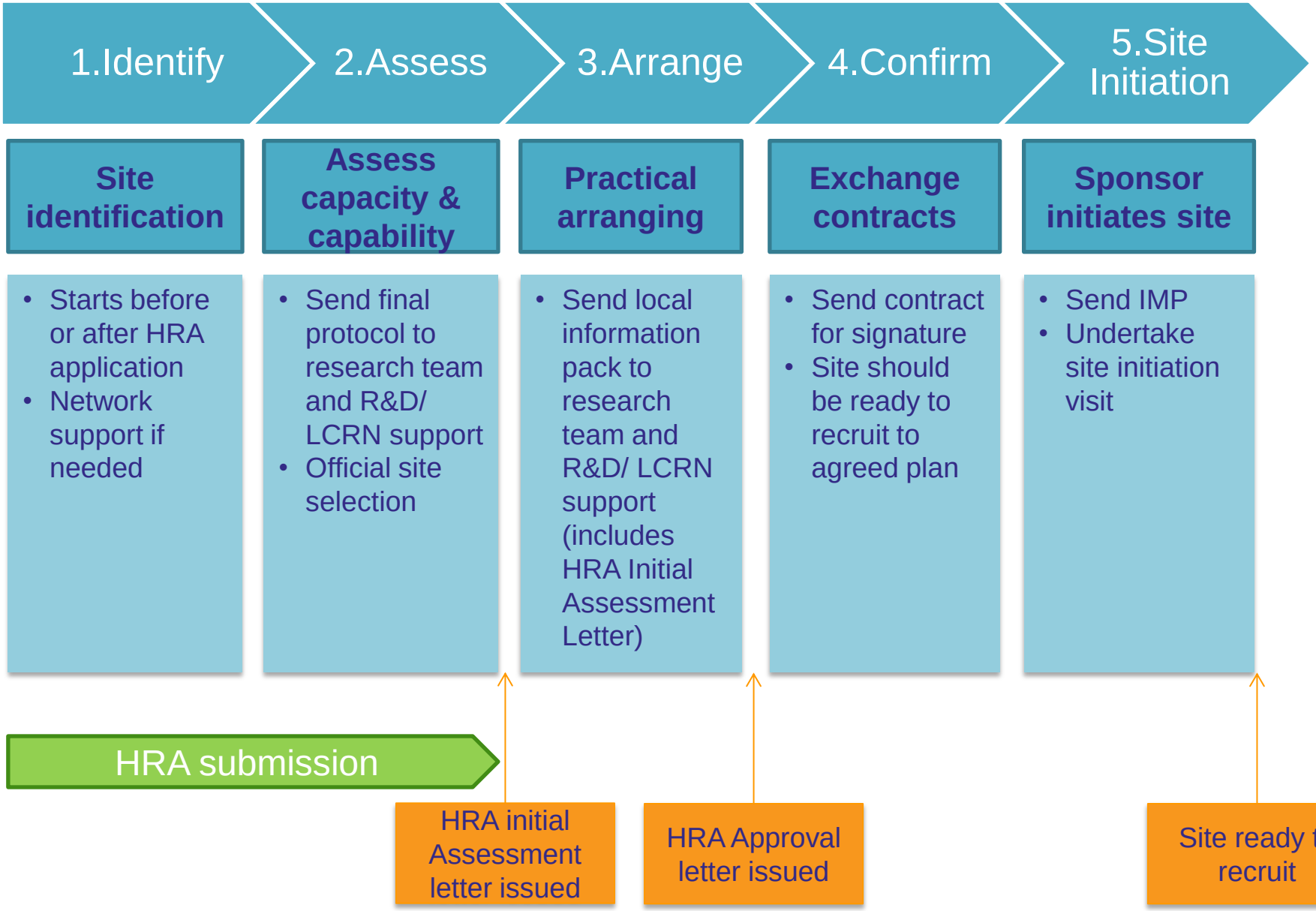
- Based on existing UK compatibility
- If Lead R&D office in England – HRA Approval
- If Lead R&D office elsewhere – study-wide review
- Outcome shared UK-wide and country-specific aspects added
- Site set-up according to country process
- REC may be anywhere in UK

NHS
Health Research Authority

HRA Approval: site level processes

Site set-up stages





Local Information Pack

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
Statement of Activity and Schedule of Event templates – non-commercial only
NIHR Costing template (validated) and delegation log– commercial only
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

Cross-border studies

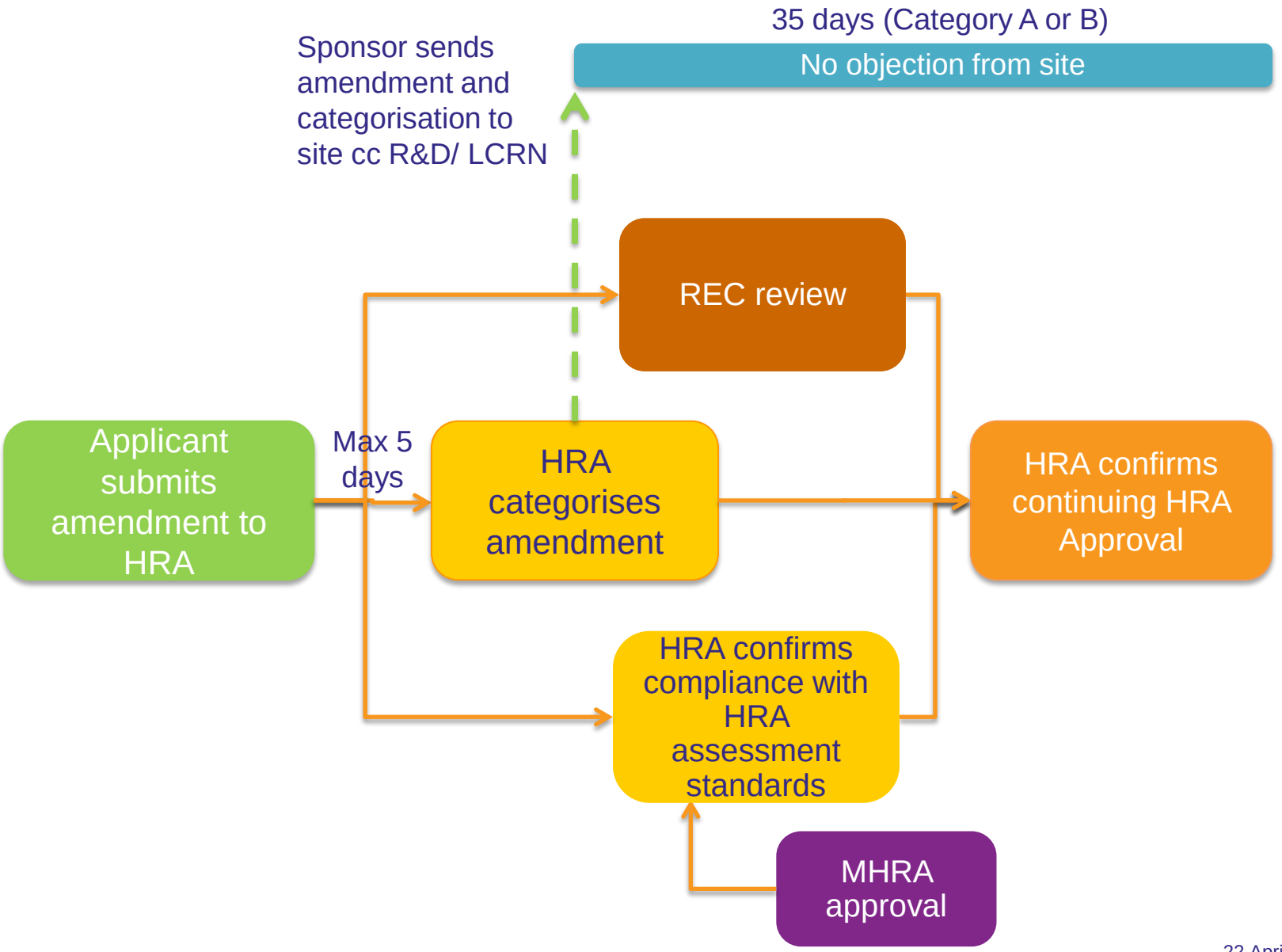
- HRA shares outcome of HRA Approval with devolved nations' coordinating functions which conduct additional nation-specific checks
- Site level process for devolved nation sites according to each country's instructions
- Each R&D office for a devolved nation site will issue a permission letter as well as signing the contract

NHS
Health Research Authority

Amendments

Amendments For studies led in England

- Submit substantial amendments to the relevant NHS REC (where REC review is required for the study type). They will also be accessed by the HRA Assessment Team.
- Other amendments which do not need to be submitted to an NHS REC should be sent to hra.amendments@nhs.net.


35 days (Category A or B)
No objection from site
Sponsor sends amendment and categorisation to site cc R&D/ LCRN
REC review
Applicant submits amendment to HRA
Max 5 days
HRA categorises amendment
HRA confirms continuing HRA Approval
HRA confirms compliance with HRA assessment standards
MHRA approval

HRA Approval will continue to develop further

- Technical assurance roll-out
- Revisions to remaining model agreements
- Revisions to Research Passport guidance
- Develop REC – HRA assessment interaction
- Develop IRAS further
- Prepare for EU Clinical Trials Regulations

http://www.hra.nhs.uk/about-the-hra/our-plans-and-projects/assessment-approval/

Useful links

Please always refer to website for up to date information:

- Questions and answers
- Statement of activities
- Schedule of events
- Assessment – standards and criteria

- Feedback: hra.approvalprogramme@nhs.net

Thank you

hra.approvalprogramme@nhs.net
www.hra.nhs.uk