HRA Approval:
operational overview for sponsors and host sites

Mark Terry, Clinical Research Consultant

The Experimental Cancer Medicine Centre Initiative is jointly funded by Cancer Research UK, the National Institute for Health Research in England and the Health Departments for Scotland, Wales and Northern Ireland.

How much do you already know?

What is the HRA?

Who forms the HRA?

Where is the HRA based?

What does the HRA want to do?

Why does the HRA want to this?

When does the HRA want to do this?

NHS
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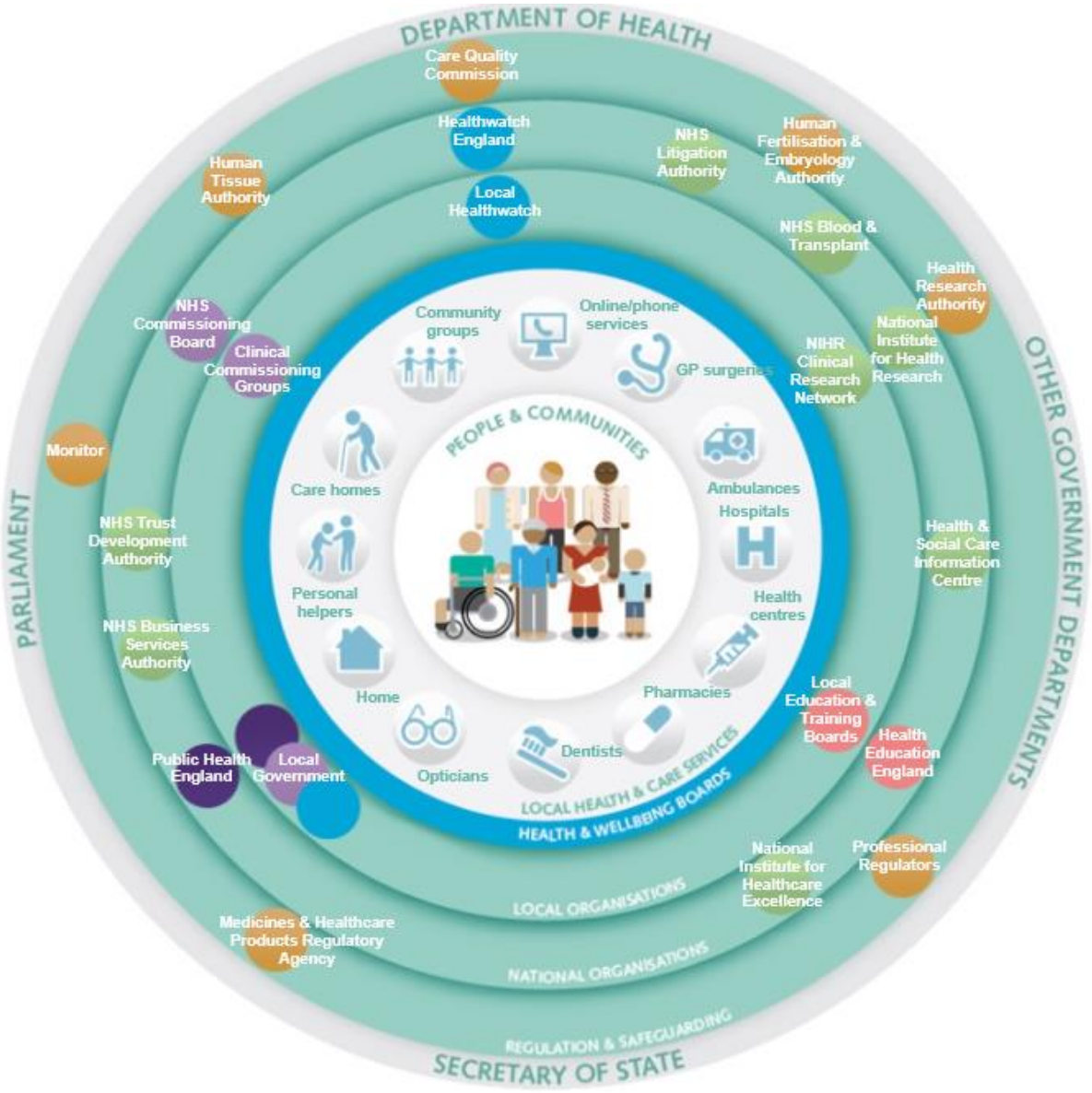
What is the HRA?



NDPB via Care Act 2014 funded by DoH

Works with partners eg. NIHR, MHRA

Quality, streamline, and consistency

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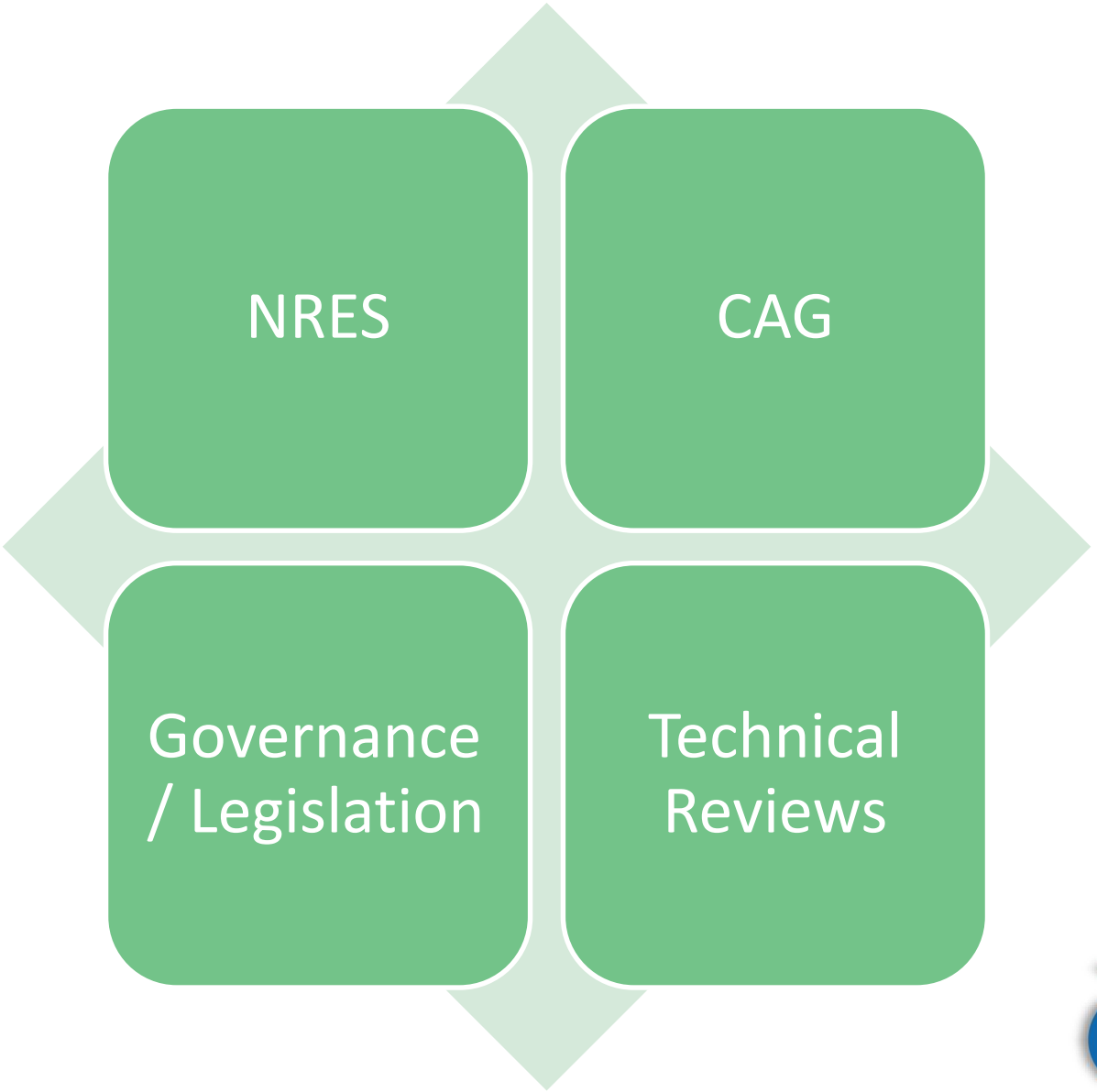
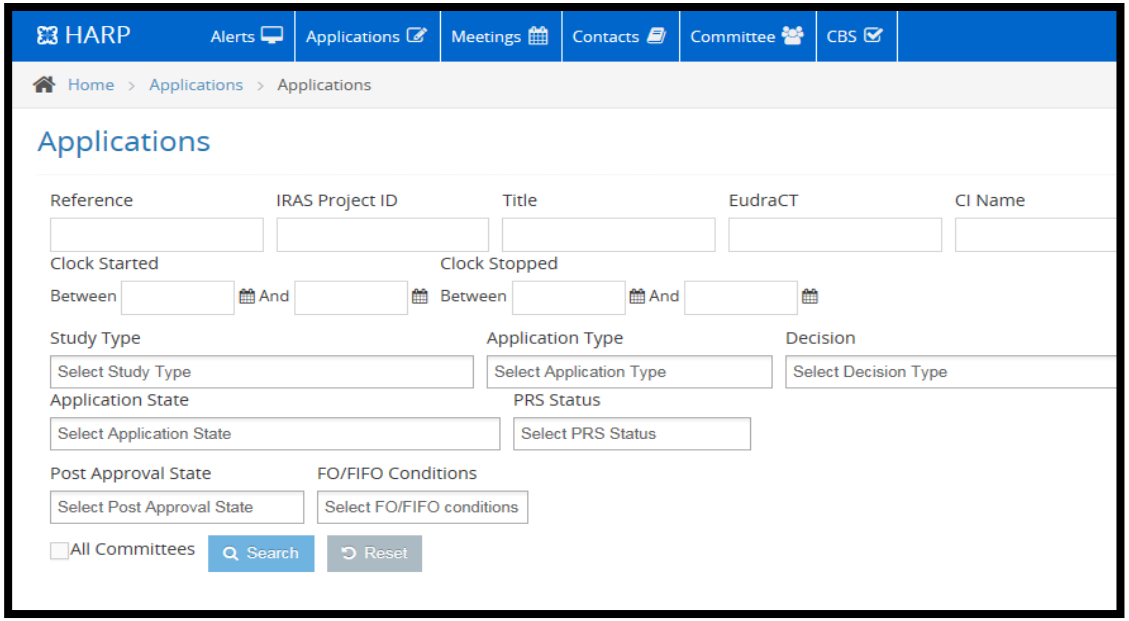
Who forms the HRA?



Where is the HRA based?



UK-wide compatibility

England

- Health Research Authority via IRAS

Wales

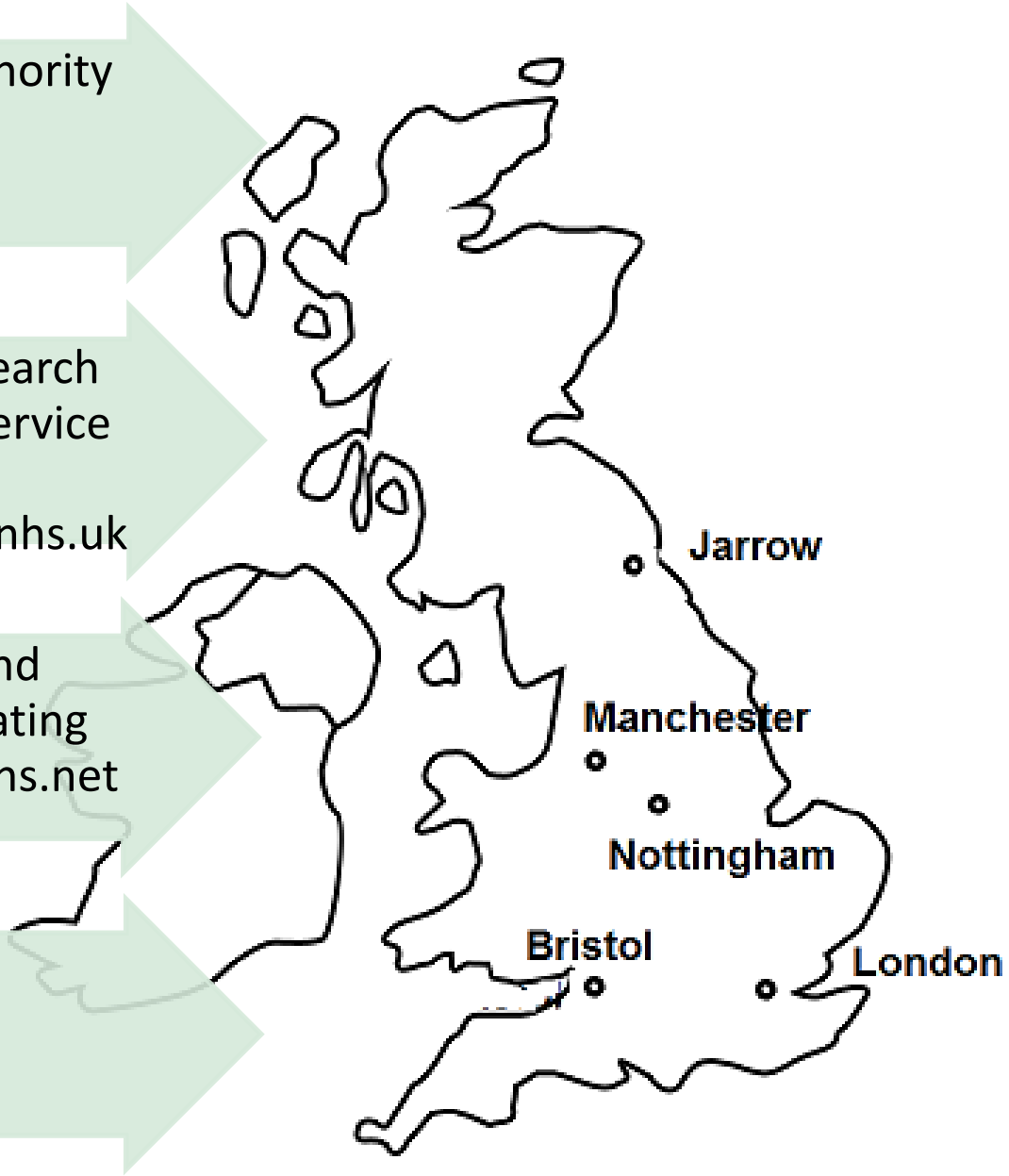
- Health and Care Research Wales Permissions Service via research-permissions@wales.nhs.uk

Scotland

- NHS Research Scotland Permissions Coordinating Centre via nrspcc@nhs.net

N. Ireland

- HSC R&D Application Gateway via gateway@hscni.net



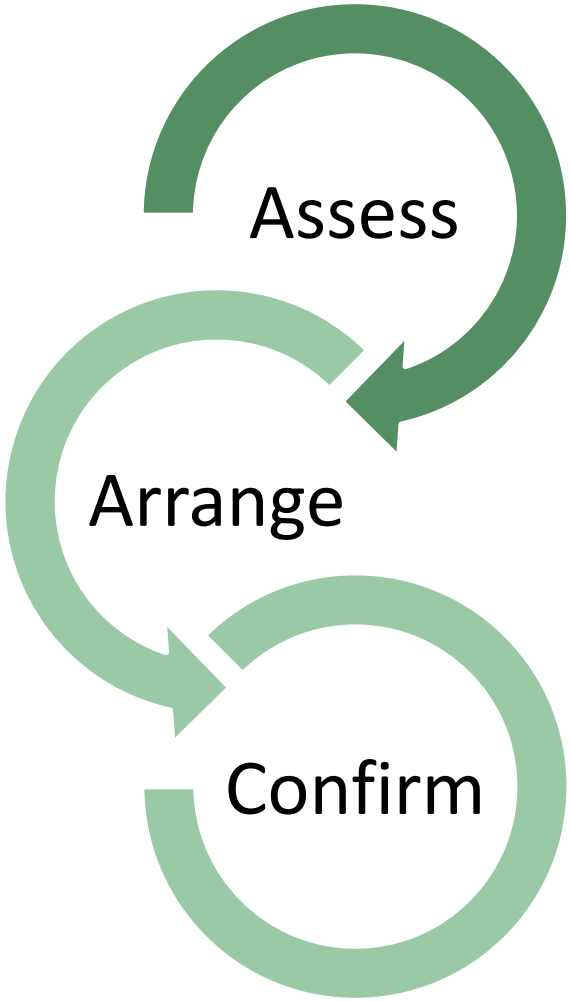
What does the HRA want to do?

Vision

- To make it easier to undertake responsible health research in the NHS in England as part of a UK-wide system

Aim

- To simplify the process for approval of health research for researchers, thus reducing the time and cost of setting up studies



Why does the HRA want to do this?

The Academy of Medical Sciences

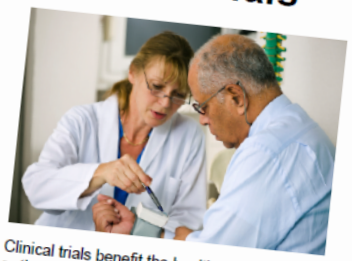
A new pathway for the regulation and governance of health research

Jan

HOUSES OF PARLIAMENT
PARLIAMENTARY OFFICE OF SCIENCE & TECHNOLOGY

POSTNOTE
Number 390 October 2011

Clinical Trials



Clinical trials benefit the health and safety of patients by making proven new treatments available more quickly. This industry is also very important for the UK economy. However, recent years have seen a drop in the number of trials held in the UK. This POSTnote summarises some of the most important reasons behind this decline, and the actions being taken to improve the situation. It also highlights areas identified by key industry partners as opportunities for growth.

Overview

- The UK is losing its global allocation of clinical trials, with negative effects for patients, the economy, and support for innovation in the NHS.
- To improve the situation, reforms of clinical trial regulation and governance are planned or already under way, at UK- and EU-level.
- A key aim is to make regulatory requirements proportionate to the risk posed by a trial, and to make the process of gaining trial approval faster to complete.
- A Health Research Authority (HRA) will be set up in 2011 to oversee all health research regulation in England.
- There will be an increasing need for changes in trial design and in the type of evidence required by regulators, to reflect both the changing nature of medicinal products, and the specific make-up of populations who use the medicines.

Clinical Trials

Purpose

Clinical trials are studies designed to test whether medical interventions are safe, effective, and work well in the intended patient population. In the EU, no new medicine can reach the market without being clinically tested and proven in humans. Globally, regulations vary for proving a treatment's medical safety and "efficacy" (capacity to produce the intended effect). Non EU producers must ensure that equivalent principles and standards have been met in their trials prior to being marketed in EU member states. With its academic and industrial science base, the National Health Service, and a high proportion of patients who are keen to participate, the UK has a strong basis for conducting high quality clinical research.

Design and Regulation

Different legislative instruments control how various medical treatments are regulated and tested in the EU. This POSTnote focuses on clinical trials of "Investigational Medicinal Products" (IMPs), which fall under the European Clinical Trials Directive 2001/20/EC (the CTD). These include traditional pharmaceutical medicines and also "biologics" (or "biopharmaceuticals"), derived from organisms or biotechnology processes. They include vaccines, monoclonal antibodies (immune system proteins), and recombinant proteins (artificially produced proteins such as human growth hormone). In some cases, stem-cell and gene therapies ("advanced therapies") are considered to be IMPs and therefore fall under the regulation of the CTD.

Clinical trials progress in phases, providing the results of each phase are favourable. First, "pre-clinical" studies are performed to test potential new treatments in animals, and sometimes also on cells in the laboratory. If those steps indicate that the treatment shows efficacy and no obvious medical safety issues, phases I-IV of clinical trials in humans follow (see Box 1).

Each EU state implements the CTD through its own national regulatory system. To carry out a clinical investigation in the UK, a strict pathway of regulatory and governance approvals must be followed (see Box 2). Steps along the

The Parliamentary Office of Science and Technology, 7 Millbank, London SW1P 3JA; Tel: 020 7219 2840; email: post@parliament.uk www.parliament.uk/post

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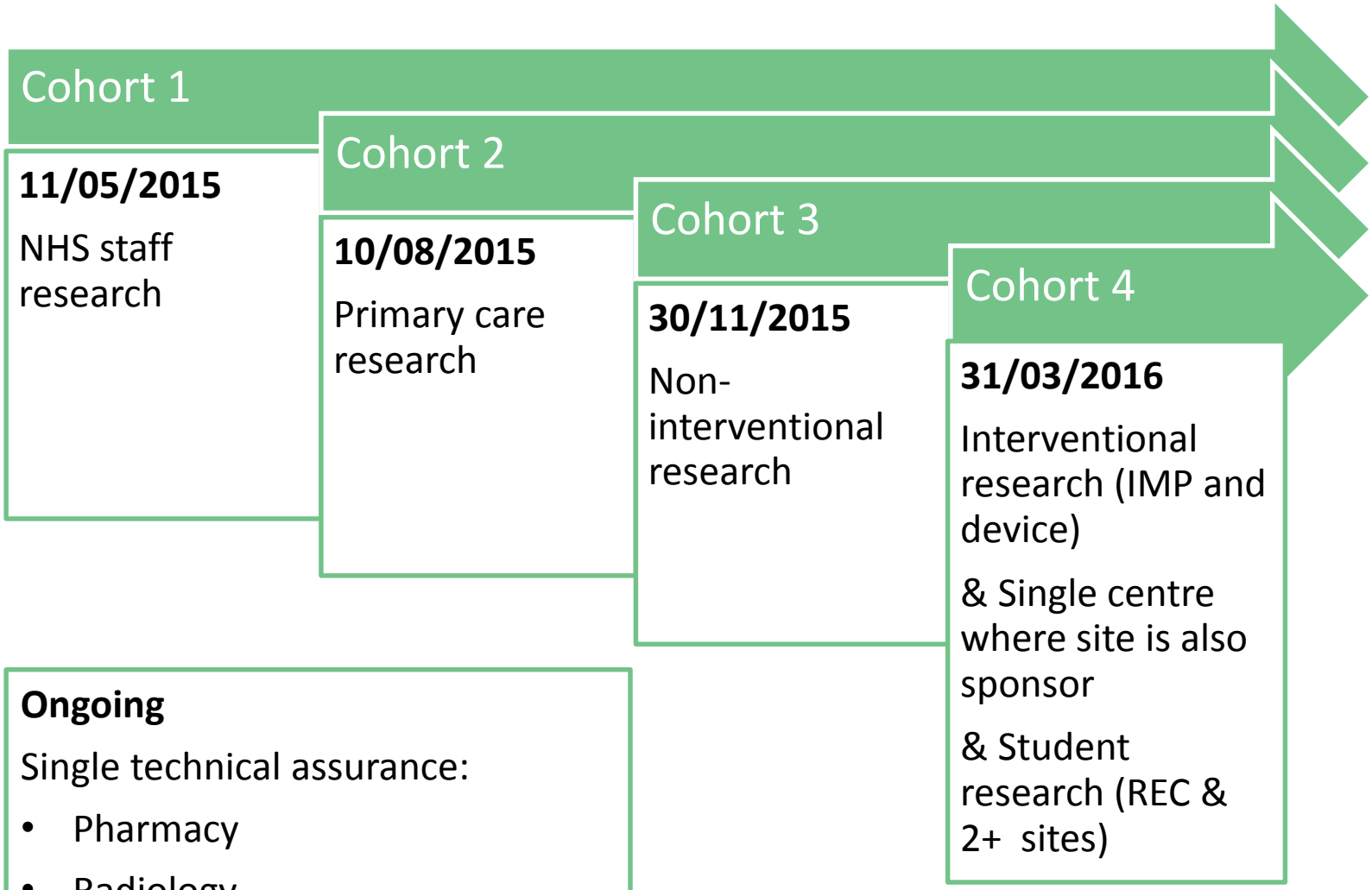
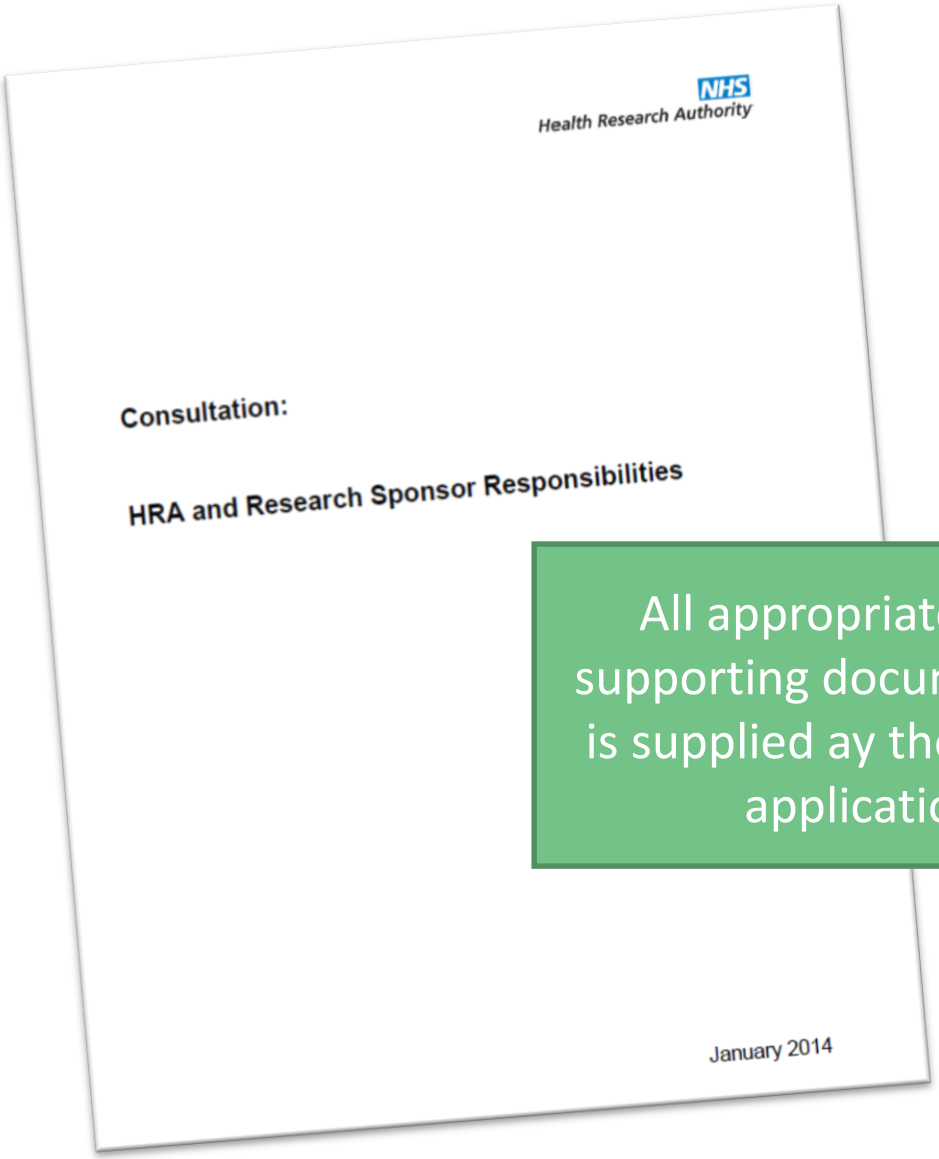
When does the HRA want to do?



HRA expectations



All appropriate, valid supporting documentation is supplied ay the point of application

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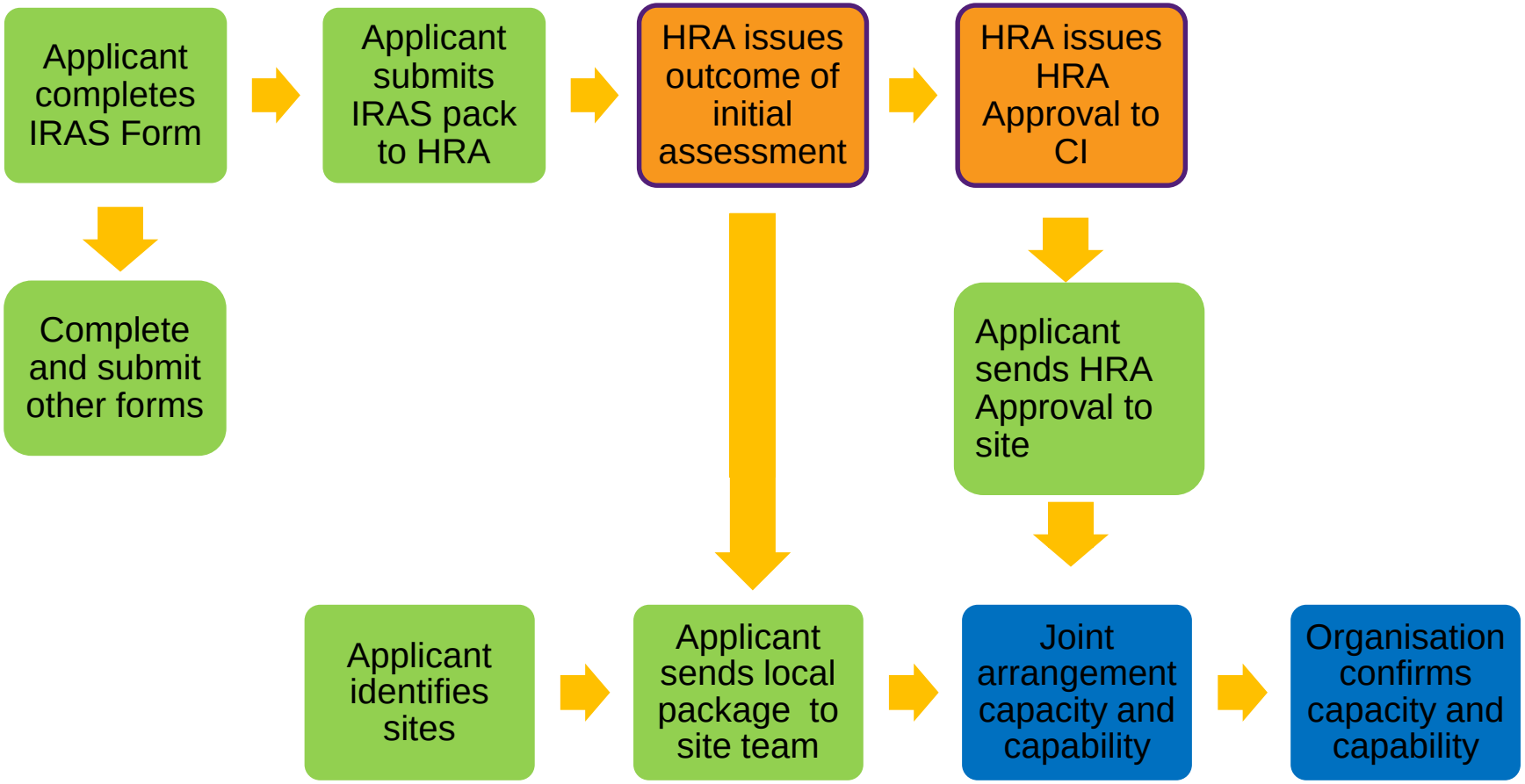
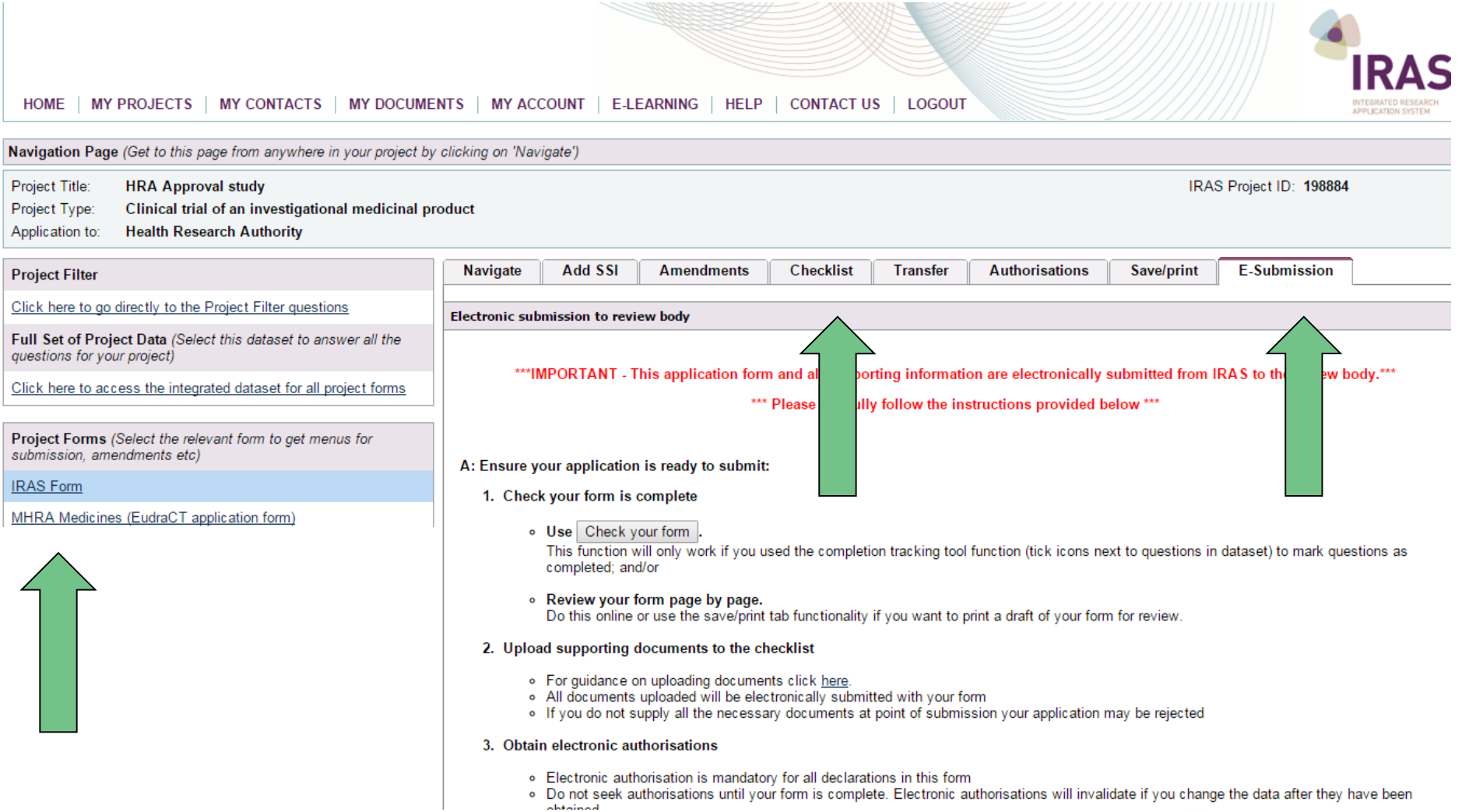
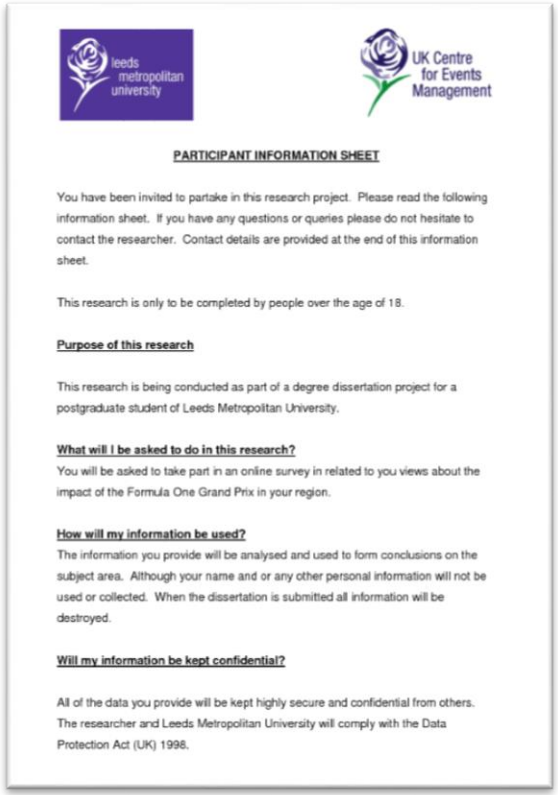
Submission: high level process map



Complete IRAS Form



Complete other forms



leeds metropolitan university

UK Centre for Events Management

PARTICIPANT INFORMATION SHEET

You have been invited to partake in this research project. Please read the following information sheet. If you have any questions or queries please do not hesitate to contact the researcher. Contact details are provided at the end of this information sheet.

This research is only to be completed by people over the age of 18.

Purpose of this research

This research is being conducted as part of a degree dissertation project for a postgraduate student of Leeds Metropolitan University.

What will I be asked to do in this research?

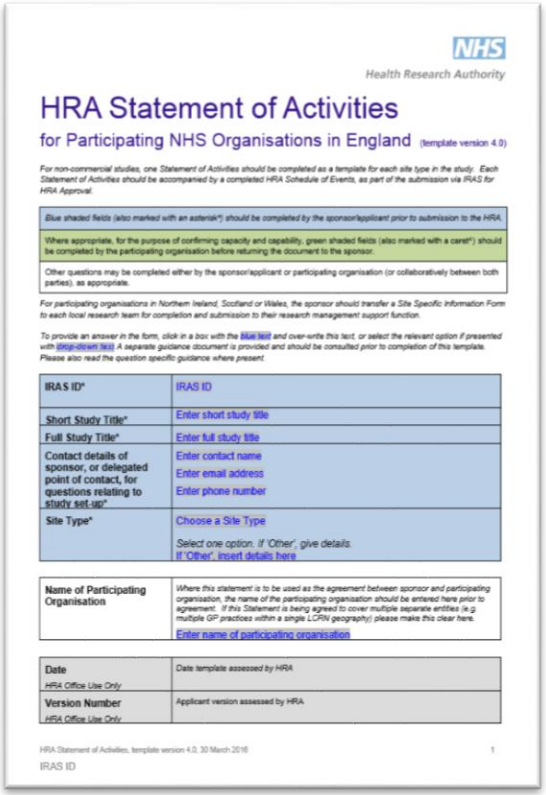
You will be asked to take part in an online survey in related to you views about the impact of the Formula One Grand Prix in your region.

How will my information be used?

The information you provide will be analysed and used to form conclusions on the subject area. Although your name and or any other personal information will not be used or collected. When the dissertation is submitted all information will be destroyed.

Will my information be kept confidential?

All of the data you provide will be kept highly secure and confidential from others. The researcher and Leeds Metropolitan University will comply with the Data Protection Act (UK) 1998.



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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.

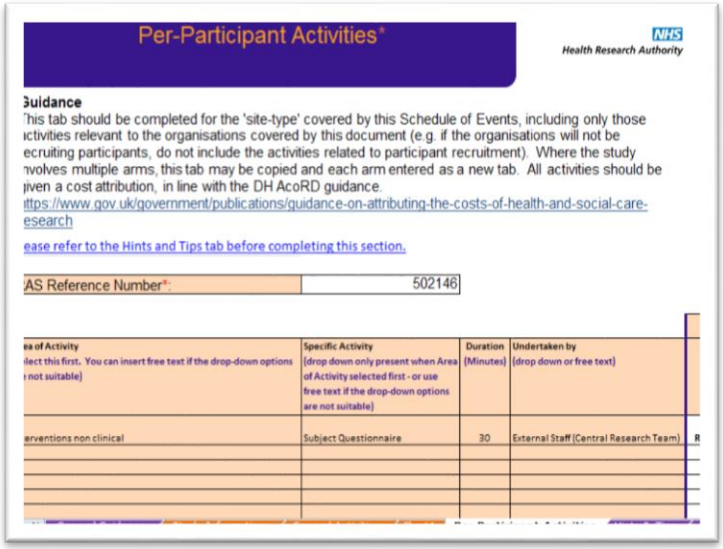
For participating organisations in Northern Ireland, Scotland or Wales, the sponsor should transfer a Site Specific Information Form to each local research team for completion and submission to their research management support function.

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 study set-up*	Enter contact name Enter email address Enter phone number
Site Type*	Choose a Site Type *Select one option. If 'Other', give details.* If 'Other', insert details here

Name of Participating Organisation	*Where this statement is to be used as the agreement between sponsor and participating organisation, the name of the participating organisation should be entered here prior to agreement. If this Statement is being agreed to cover multiple separate entities (e.g. multiple GP practices within a single LCRN geography) please make this clear here.* Enter name of participating organisation

Date *HRA Office Use Only*	Date template assessed by HRA
Version Number *HRA Office Use Only*	Applicant version assessed by HRA



Per-Participant Activities*

NHS
Health Research Authority

Guidance

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https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research

Please refer to the Hints and Tips tab before completing this section.

IRAS Reference Number*:	502146

ea of Activity lect this first. You can insert free text if the drop-down options not suitable)	Specific Activity (drop down only present when Area of Activity selected first - or use free text if the drop-down options are not suitable)	Duration (Minutes)	Undertaken by (drop down or free text)	
erventions non clinical	Subject Questionnaire	30	External Staff (Central Research Team)	R

ECMC

Statement of activities

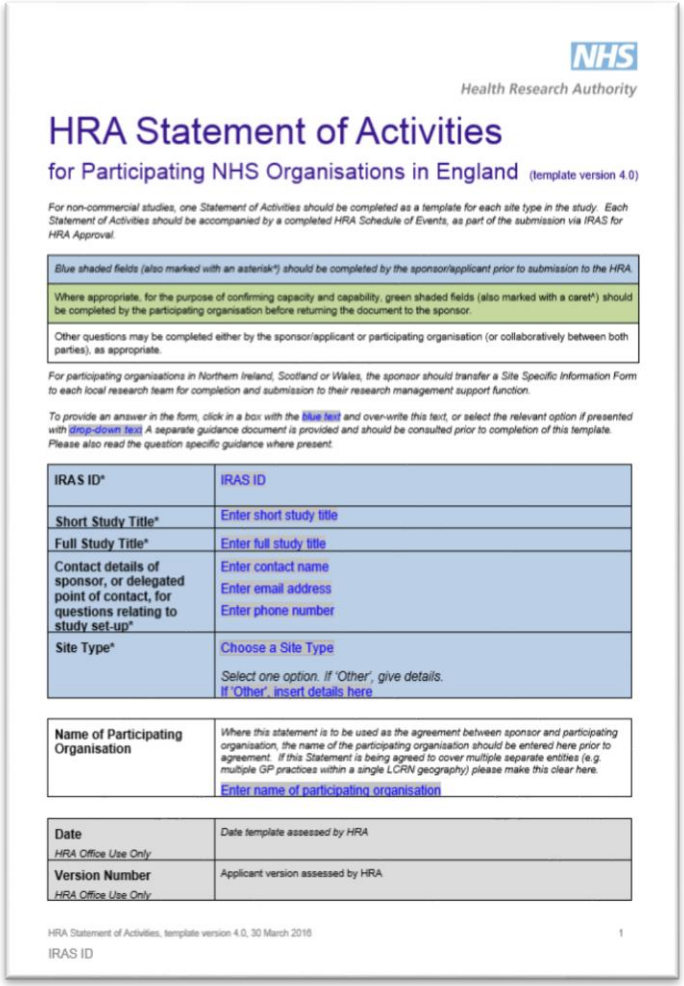
One template per site type – tailor to site type

Completed by non-commercial sponsor

Emailed to site – add known local information

Can act in place of any other form of site agreement/contract

HRA review template – not localised document



NHS
Health Research Authority

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Date *HRA Office Use Only*	*Date template assessed by HRA*
Version Number *HRA Office Use Only*	Applicant version assessed by HRA

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Statement of activities

NHS
Health Research Authority

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Short Study Title*	Enter short study title
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Date *HRA Office Use Only*	*Date template assessed by HRA*
Version Number *HRA Office Use Only*	Applicant version assessed by HRA

1. Does the sponsor intend that this document forms the agreement between itself and the participating organisation/s in England?*

For non-commercial studies other than clinical trials and clinical investigations, the HRA encourages use of the Statement of Activities as the only form of agreement between sponsor and an English participating organisation, in place of bespoke agreements created by sponsors. For research in primary care settings, the Statement may be used for a geographical area, e.g. at the LCRN level, although agreement should be between the sponsor and independent legal entity (e.g. GP Practice). For clinical trials and clinical investigations the HRA expects that sponsors will use the relevant model agreement, where one exists.

Select 'yes' or 'no'

2. Date this Statement of Activities confirmed by participating organisation, if applicable.^

Enter date confirmed

3. Confirmation on behalf of participating organisation provided by (insert name and job title), if applicable.^

Enter name and job title

It is not intended that this confirmation requires wet-ink signatures, or a passing of hard copies between the sponsor and participating organisation. Instead, sponsors are expected to accept confirmation by email from an individual empowered by the participating organisation to agree to the commencement of research (including any budgetary responsibility, where the study involves the transfer of funds).

4. If this Statement is not intended to form the agreement with the participating organisation/s in England, will the sponsor be using an unmodified model non-commercial agreement?*

Select 'yes' or 'no'

5. If no, please provide details of the modifications made to the model agreement and the reasons for them. If the sponsor intends to use an agreement not based on the model agreement, please provide detailed justification for this (templates of all 'site agreements' to be used, including for sites in the devolved administrations (where applicable) should be provided as part of the submission for HRA Approval).*

Provide details of modification made to model agreement and the reasons for them

6. Predicted Participant Recruitment, if applicable.

This is recruitment or identification at participating organisation, not overall for the study. Please clarify if this refers to participants, samples or data. Please clearly state if this is per month, per year, overall etc. Leave blank if not applicable to this site type.

Enter predicted participant recruitment or identification (or state if not applicable)

7. Proposed start date of research/participant identification activity at participating organisation.

Where it might otherwise be open to interpretation, please specify whether this date refers to the commencement of screening, the recruitment of the first participant, etc.

Enter proposed start date (DD/MMM/YY) of research/participant identification activity

Specify the activity to which this date refers

Statement of activities

8. Predicted end date of research/participant identification activity at participating organisation.

Where it might otherwise be open to interpretation, please specify whether this date refers to the recruitment of the final participant, the final visit of the final participant, database lock, etc.

Enter the proposed end date (DD/MMM/YY) of research/participant identification activity

Specify the activity to which this date refers

9. Person responsible for research activities at site.*

Select person responsible

The HRA expects Principal investigators to be in place at participating organisations where locally employed staff take responsibility for research procedures. Where this is not the case, the HRA expects Local Collaborators to be in place where central study staff will be present at site to undertake research procedures (the role of the Local Collaborator is to support practical arrangements for the presence of research staff under Letters of Access or Honorary Research Contracts). Where existing data is being provided for research purposes without additional research procedures and without the presence of central research team members at site, the HRA does not expect that a Principal Investigator or Local Collaborator is appointed and you should select Chief Investigator.

10. Are you requesting support to identify a Principal Investigator or Local Collaborator?*

Please indicate whether support from the host organisation is being requested to identify a Principal Investigator/Local Collaborator and provide further information on expectations below. Where a Principal Investigator or Local Collaborator has already been identified, their details appear on Part C of the IRAS Form.

Select 'yes' or 'no'

11. Further Information (where applicable).*

Please provide further information on sponsor expectations for a Principal Investigator/Local Collaborator, to help participating organisations identify an appropriate individual if required (e.g. Profession, specialty, seniority etc.)

Provide information on the support required

12. The following capabilities and capacity are needed locally in order to deliver the study, e.g. specific equipment, patient/participant groups, service support nursing time, excess treatment costs, etc.*

Any funding or support from the sponsor/funder to the participating organisation is set out in the Finance Schedule.

Provide information on sponsor's expectations for local capacity and capability

13. Projected NHS Treatment Cost savings at this site type, if applicable.*

Although many studies incur Excess Treatment Costs (see AcoRD for information on cost attribution) many studies also give rise to treatment cost savings during the study (e.g. a two armed study comparing standard care to a less intensive, and less expensive, alternative treatment). Please describe below any projected treatment cost savings, so your participating organisations may include this information when considering the overall treatment costs/cost savings of their portfolio of research. Any funding or support from the sponsor/funder to the participating organisation is set out in the Finance Schedule. Excess Treatment Costs will be indicated above (question 12) and in the HRA Schedule of Events.

Provide information on projected treatment cost savings (or leave blank if not applicable)

14. The following training for local staff will be provided by the sponsor. Where only specific team members (e.g. the Principal Investigator) will receive this training, this is described below.*

Enter details of training to be provided by the sponsor

15. In addition to the above training, to be provided by the sponsor, the sponsor also expects that the following local research team members will undertake the following training.*

It would not be usual for the sponsor to expect study specific training additional to that which it will provide, this section does however allow sponsors to state that they will accept, for example, NIHR CRN training in Good Clinical Practice where the study is a Clinical Trial of an Investigational Medicinal Product etc.

Enter details of sponsor's additional training expectations

Schedule of events

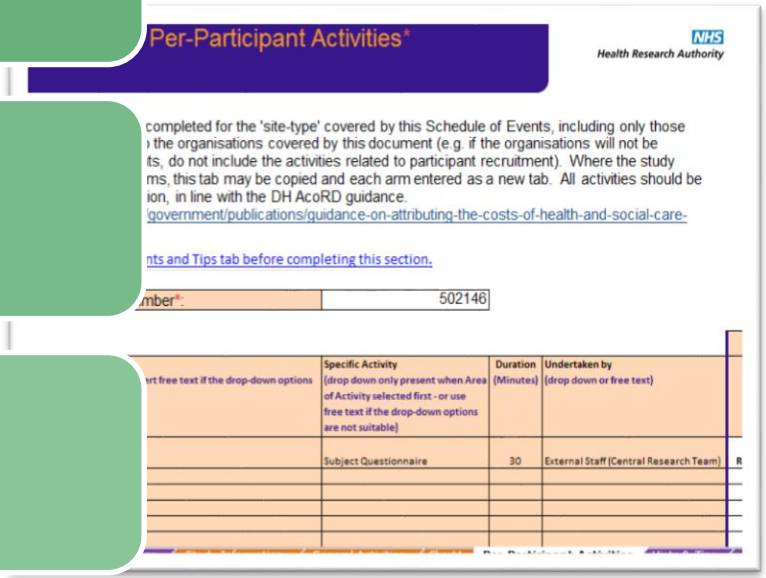
One template per site type – tailor to site type

Completed by non-commercial sponsor (*or NIHR CRN)

Emailed to site

Details activities and cost attribution

HRA review template – approval not conditional upon correct attribution


Per-Participant Activities*

NHS Health Research Authority

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government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-

nts and Tips tab before completing this section.

mber*: 502146

rt free text if the drop-down options	Specific Activity (drop down only present when Area of Activity selected first - or use free text if the drop-down options are not suitable)	Duration (Minutes)	Undertaken by (drop down or free text)
	Subject Questionnaire	30	External Staff (Central Research Team)

Schedule of events

General Activities

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Health Research Authority

Guidance
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https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research

Please refer to the Hints and Tips tab before completing this section.

IRAS Reference Number: 0

Area of Activity (Select this first. You can insert free text if the drop-down options are not suitable)	Specific Activity (drop down only present when Area of Activity selected first - or use free text if the drop-down options are not suitable)	Duration (Minutes)	Undertaken by (drop down or free text)	Day -x to -y	Day 0	Day x
				Screen	Base	Visit 1

General Guidance | Study Information | General Activities | Per-Participant Activities | Hints & Tips | List of Activities | User Feedback | Sheet1

Schedule of events

Per-Participant Activities

NHS
Health Research Authority

Guidance

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IRAS Reference Number:	0
Number of Participants	

Area of Activity (Select this first. You can insert free text if the drop-down options are not suitable)	Specific Activity (drop down only present when Area of Activity selected first - or use free text if the drop-down options are not suitable)	Duration (Minutes)	Undertaken by (drop down or free text)	Day -x to -y	Day 0	Day x
				Screen	Base	Visit 1

General Guidance | Study Information | General Activities | Per-Participant Activities | Hints & Tips | List of Activities | User Feedback | Sheet1

Industry costing template

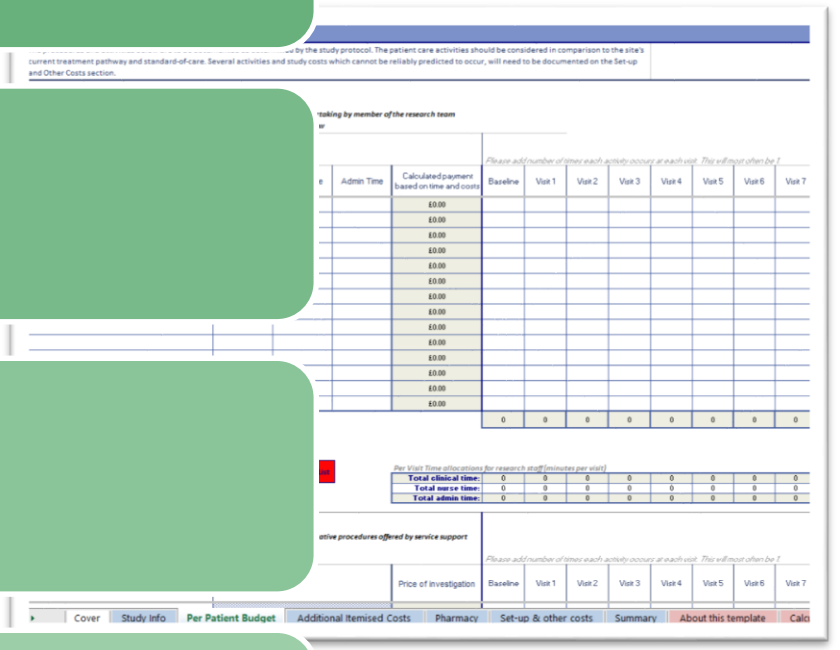
One template per study

Completed by commercial sponsor

Emailed to site

Details activities and cost – tool for local negotiation

Seek early validation by CRN via email to Lead R&D office (Portfolio) – if not validated, HRA will validate



Initial assessment letter

- Emailed from HRA to CI/sponsor
- Sponsor emails to sites as part of local document package
- Indicates start of HRA Approval review
- 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

NHS
Health Research Authority

Dr Arthur Smith
Red Heath Hospital NHS Trust
Red Heath 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).

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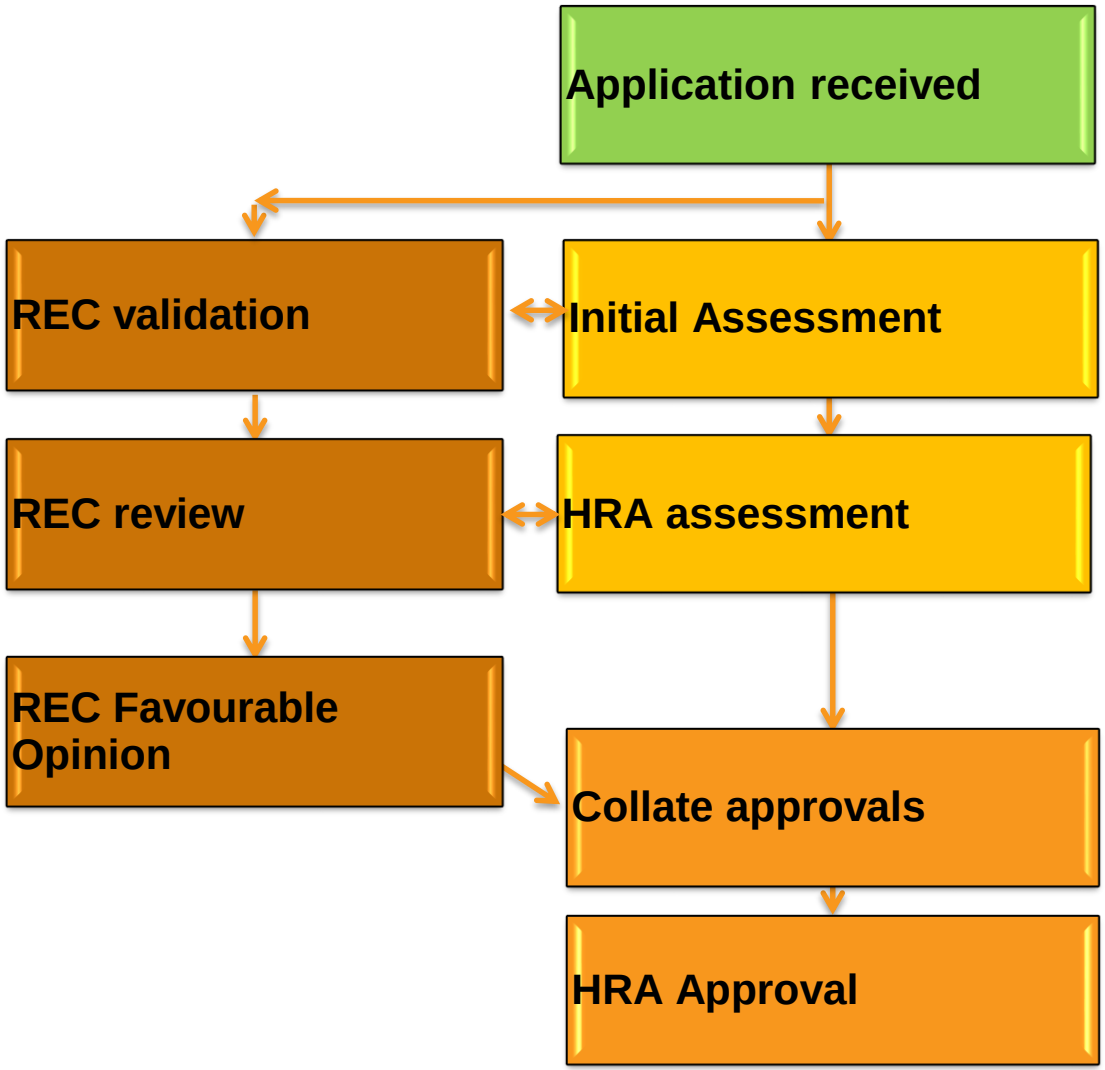
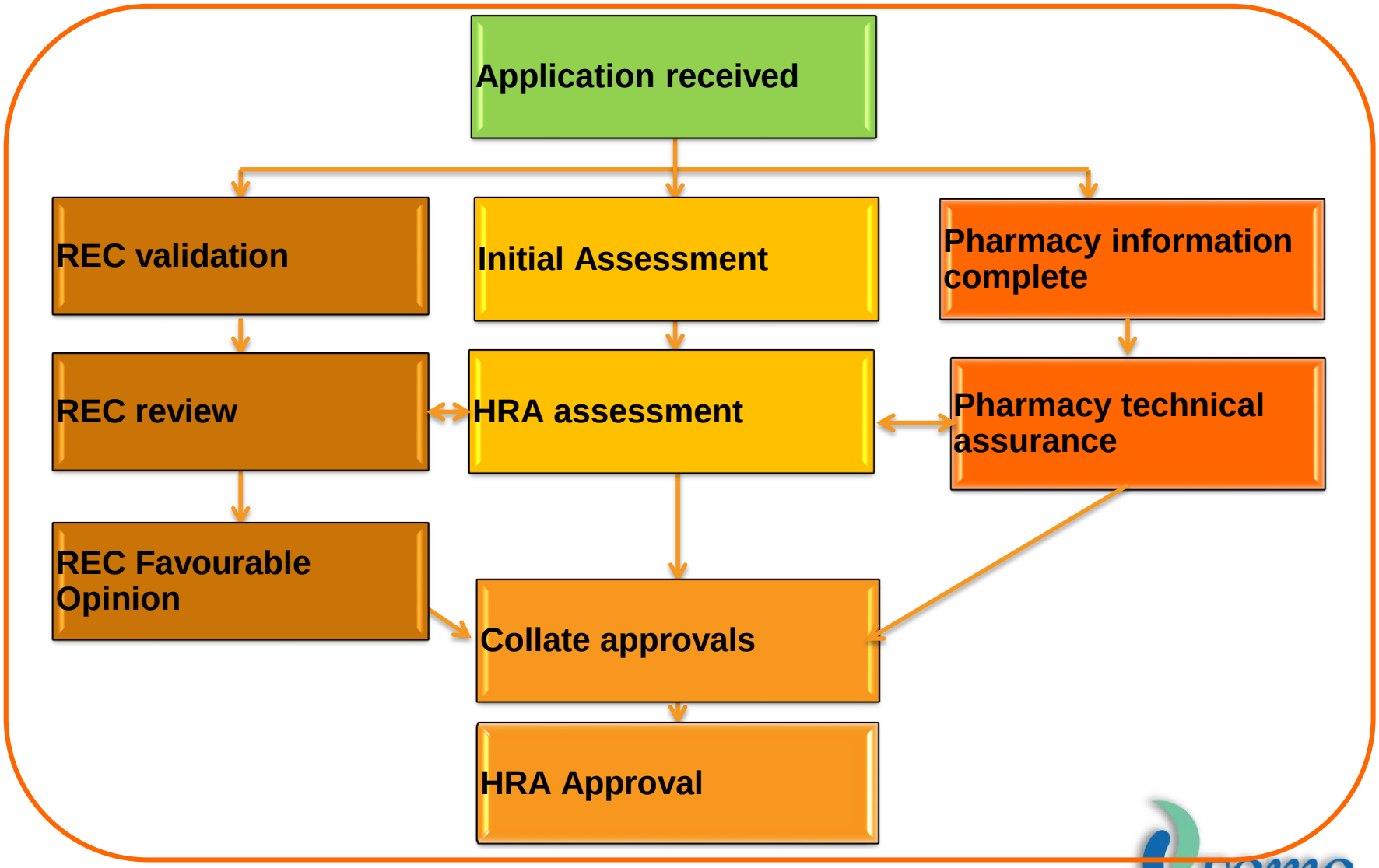
ECMC

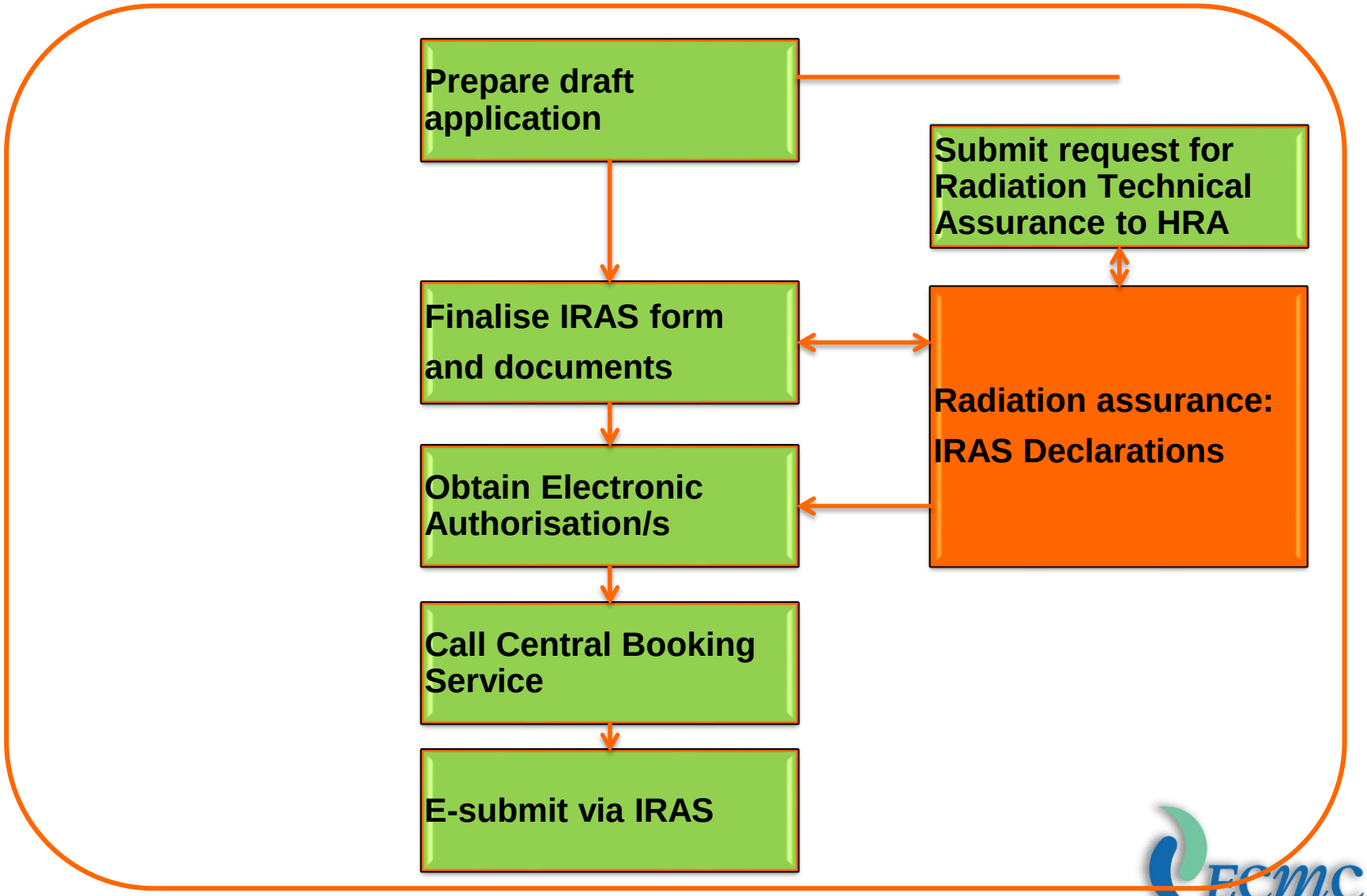
Inside the HRA



Pharmacy technical review



Radiology technical review



HRA Approval letter

- No provisional or conditional
- Lists documents approved – including revised documents
- Reports outcome of assessment – including resolution of issues
- Sites not listed in original application need to be added via amendment
- Emailed to CI/sponsor

NHS
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-hso-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

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SAMPLE

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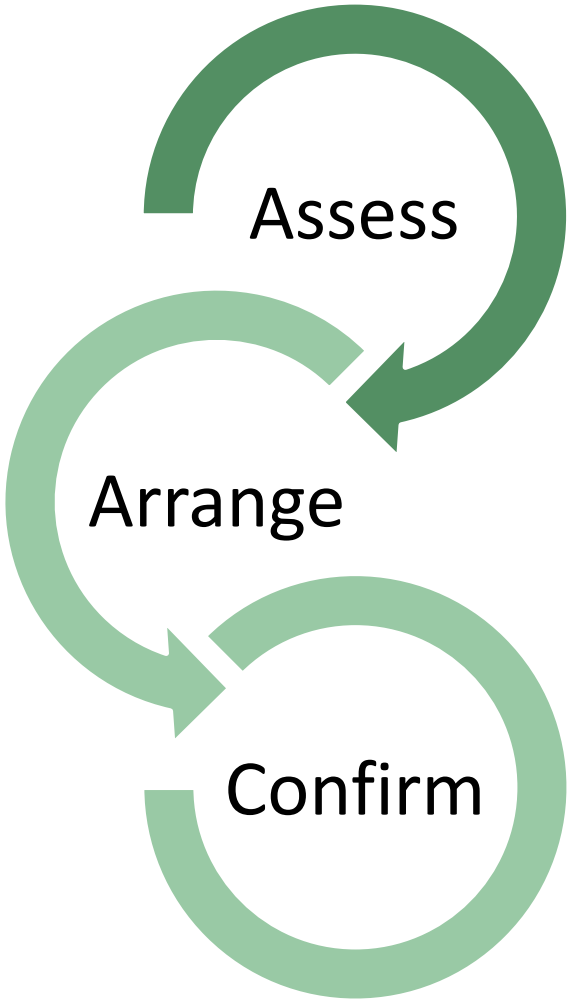
Local information pack

- IRAS Form
- Protocol and amendments
- PICF (without logos)
- Relevant (model) agreement – as required
- Statement of Activity and Schedule of Events – non commercial only
- NIHR industry costing template (validated) – commercial only
- Any other documents sponsor wishes to provide to site to support set up and delivery

Arrangement of capacity and capability



NHS
National Institute for Health Research

Clinical Research Network

CRN Principles for assessing, arranging and confirming local capacity and capability

DRAFT FOR COMMENT v.17SEP2015

A- Introduction

Purpose

This Guidance Document outlines the CRN principles for activities relating to assessing, arranging and confirming local capacity and capability by organisations in receipt of CRN funding.

These principles are intended to be supportive but not prescriptive. They provide the mechanism through which a consistent approach to assessment, arrangement and confirmation of local capacity and capability at individual participating organisations can be achieved across the NHS to improve the researcher and life-science company experience. This guidance builds upon the work on consistency introduced through the Coordinated System for NHS Permission local review process and reflects the main purpose of HRA Approval: to make it easier for researchers to undertake good quality research.

The organisations in receipt of CRN funding are expected to work with their Local CRN to establish a consistent approach across their local region for assessing, arranging and confirming local capacity and capability in line with national principles. This should include scenarios where Local CRNs provide resource for activities on behalf of organisations e.g. for General Practices.

CRN funding for activities related to establishing and delivering the principles in this document to ensure consistency for researchers will be determined as part of the annual review of the LCRN funding allocation model.

Suitable studies

The principles are applicable to all CRN Portfolio studies submitted for HRA Approval.

At the discretion of and supported by the organisation involved, the principles of this guidance could also be applied to:

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Amendment process

- Applies to all historic studies led from England, or with NHS sites in England
- Set up prior to CSP
- Set up through CSP
- Non-Portfolio studies
- HRA Approval studies
- CSP decommissioned 31/03/2016
- All amendments or new sites via HRA processes

UK-wide compatibility

England

- Health Research Authority via hra.amendments@nhs.net

Wales

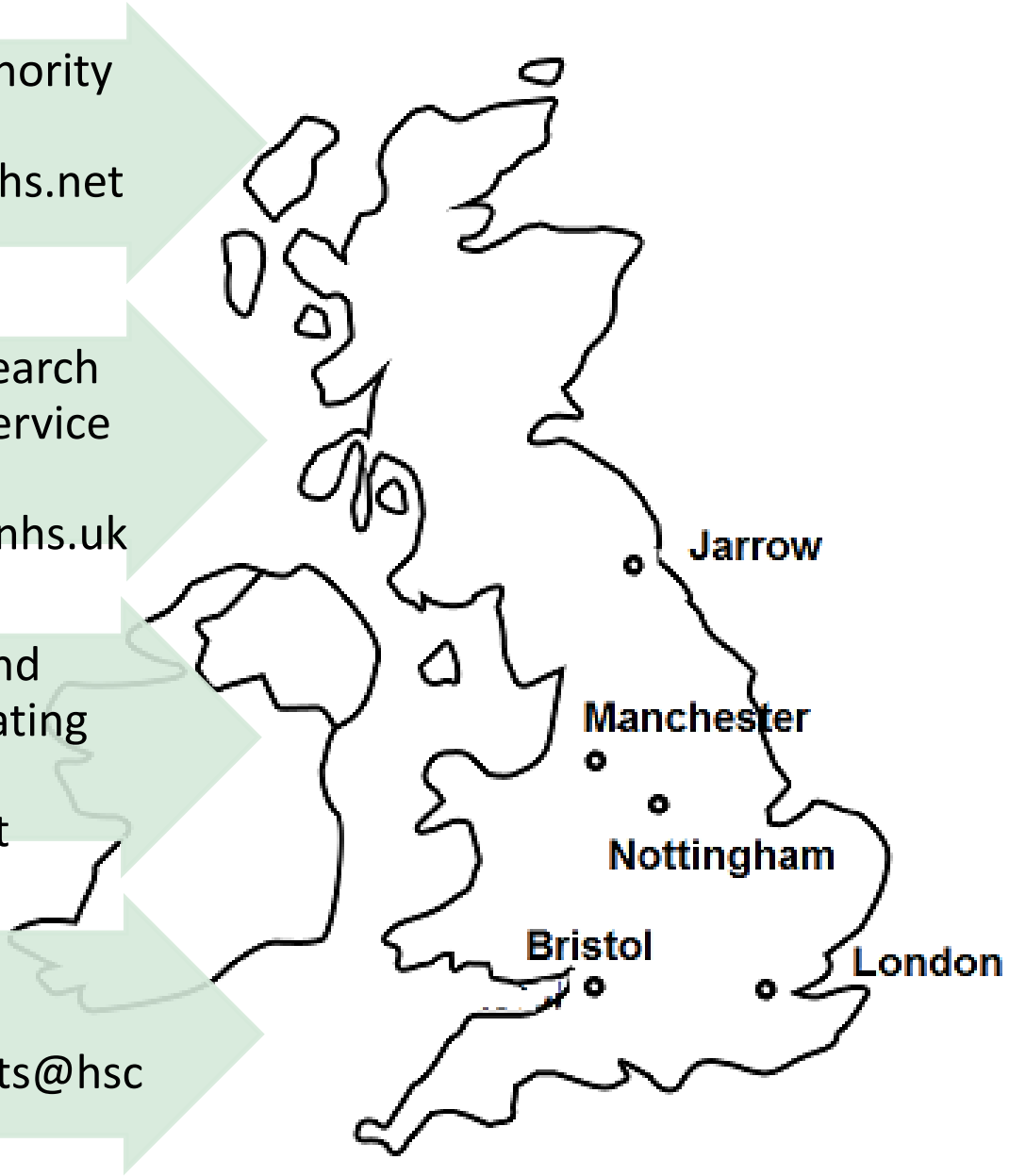
- Health and Care Research Wales Permissions Service via research-permissions@wales.nhs.uk

Scotland

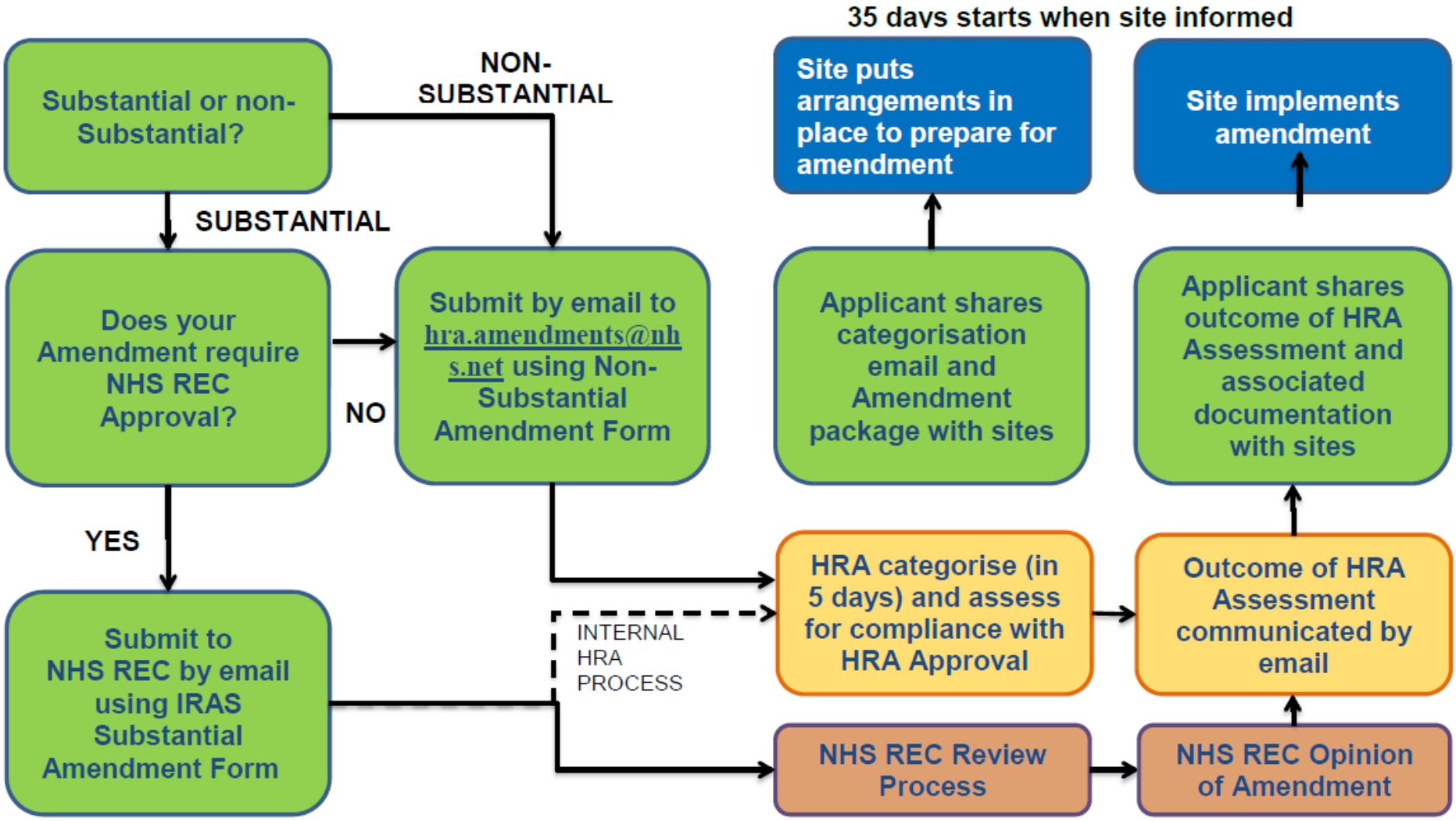
- NHS Research Scotland Permissions Coordinating Centre via nhsg.nrspcc@nhs.net

N. Ireland

- HSC R&D Application Gateway via research.amendments@hsc ni.net



Process map


35 days starts when site informed
Substantial or non-Substantial?
NON-SUBSTANTIAL
SUBSTANTIAL
Does your Amendment require NHS REC Approval?
NO
YES
Submit by email to hra.amendments@nhs.net using Non-Substantial Amendment Form
Submit to NHS REC by email using IRAS Substantial Amendment Form
INTERNAL HRA PROCESS
HRA categorise (in 5 days) and assess for compliance with HRA Approval
NHS REC Review Process
Applicant shares categorisation email and Amendment package with sites
Site puts arrangements in place to prepare for amendment
Site implements amendment
Applicant shares outcome of HRA Assessment and associated documentation with sites
Outcome of HRA Assessment communicated by email
NHS REC Opinion of Amendment

Session conclusion