UCL
GREAT ORMOND STREET INSTITUTE OF CHILD HEALTH

Great Ormond Street Hospital for Children NHS
NHS Foundation Trust

Division of Research and Innovation

HRA (*H*ealth *R*esearch *A*uthority) Approval. (non portfolio)

For all new research taking place in NHS England.

(Scotland, Wales and N. Ireland do not use this process)

THE HRA VISION/GOALS:

- Protecting Patient and Public Interests.
- Standardization and streamlining of Research.
- Simplify the Process and thereby make it easier to undertake research in the NHS in England.

Health Research Authority

- HRA approval is the new process for the NHS in England

- HRA approval has bought together the assessment of Governance and Legal Compliance. This replaces the need for local Governance review of legal compliance allowing participating sites to focus on assessing, arranging and confirming capacity.

Health Research Authority

- HRA approval will only be issued after other regulatory approvals (REC/MHRA) have issued their approval and any necessary conditions met.

- HRA approval will be requested wherever the study involves NHS organisations in England.

GOSH Clinical Research Adoptions Committee (CRAC)

CRAC is an internal review committee

- **Look at clinical[1] research projects** taking place within GOSH that are not externally funded (i.e. 'own-account projects'). The Committee conducts
  - Peer review – i.e. scientific quality
  - Use of resources
  - Looks for issues that can be predicted (if any)

- **CRAC reviews some student projects through an expedited process. Please ensure you highlight this in your application**

- For further information please contact CRAC.admin@gosh.nhs.uk

[1] It involves any GOSH resources, GOSH staff or GOSH patients (including patient samples or data)

The Chief Investigator (CI) must ensure that they:

- Plan ahead
- Cost the study appropriately- liaise with R&D
- Communicate efficiently with Host Sites
- Peer review process /Funding (CRAC)
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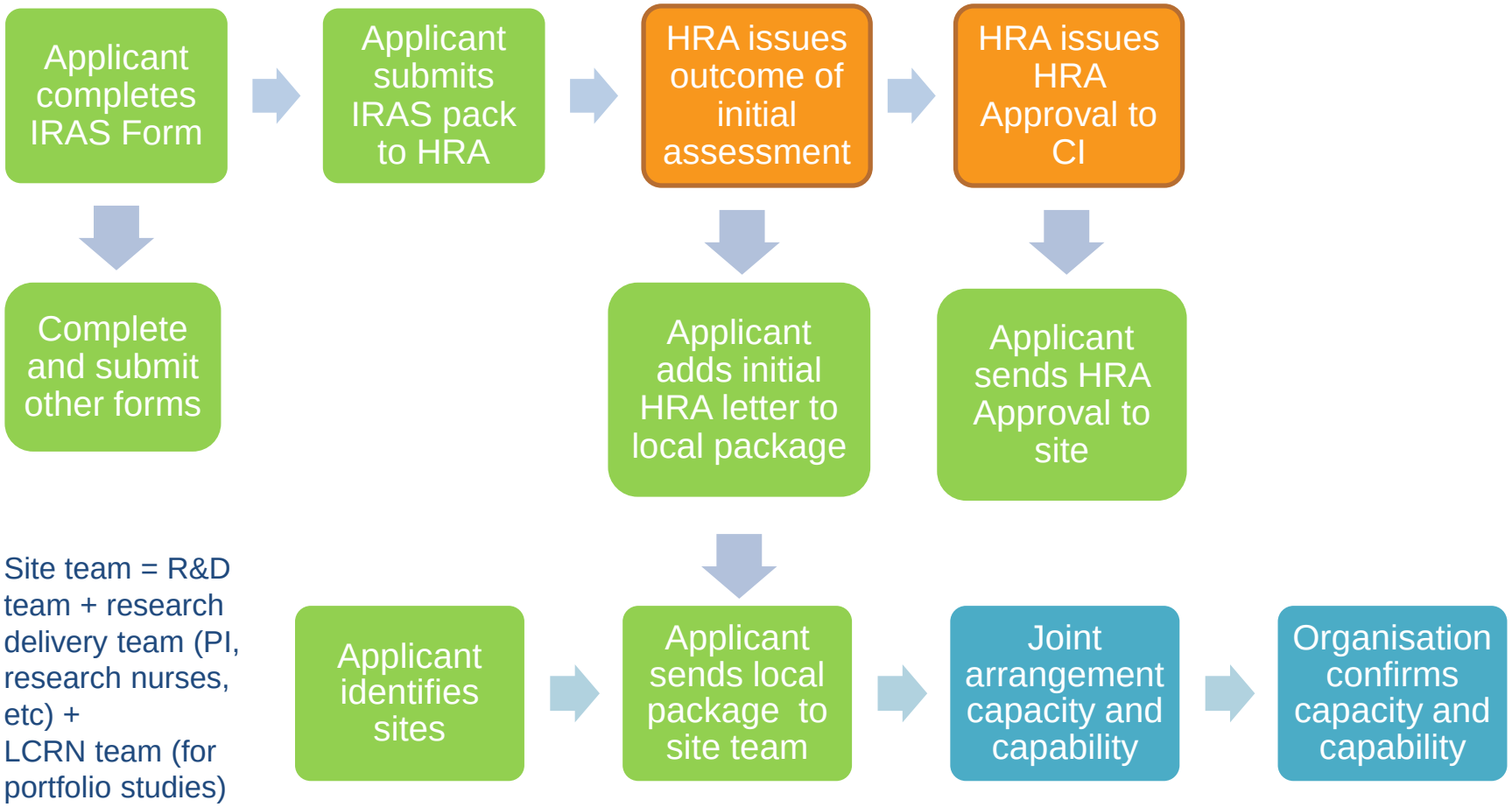
- Well written Protocols
- Transparency in study related documents (PIS/ICF)
- Patient and public involvement whilst designing the study

HRA Process


Applicant completes IRAS Form
Applicant submits IRAS pack to HRA
HRA issues outcome of initial assessment
HRA issues HRA Approval to CI
Complete and submit other forms
Applicant adds initial HRA letter to local package
Applicant sends HRA Approval to site
Site team = R&D team + research delivery team (PI, research nurses, etc) +
LCRN team (for portfolio studies)
Applicant identifies sites
Applicant sends local package to site team
Joint arrangement capacity and capability
Organisation confirms capacity and capability

HRA Process

- Studies that require HRA approval, will need to submit their application electronically via the Integrated Research Application System (IRAS).

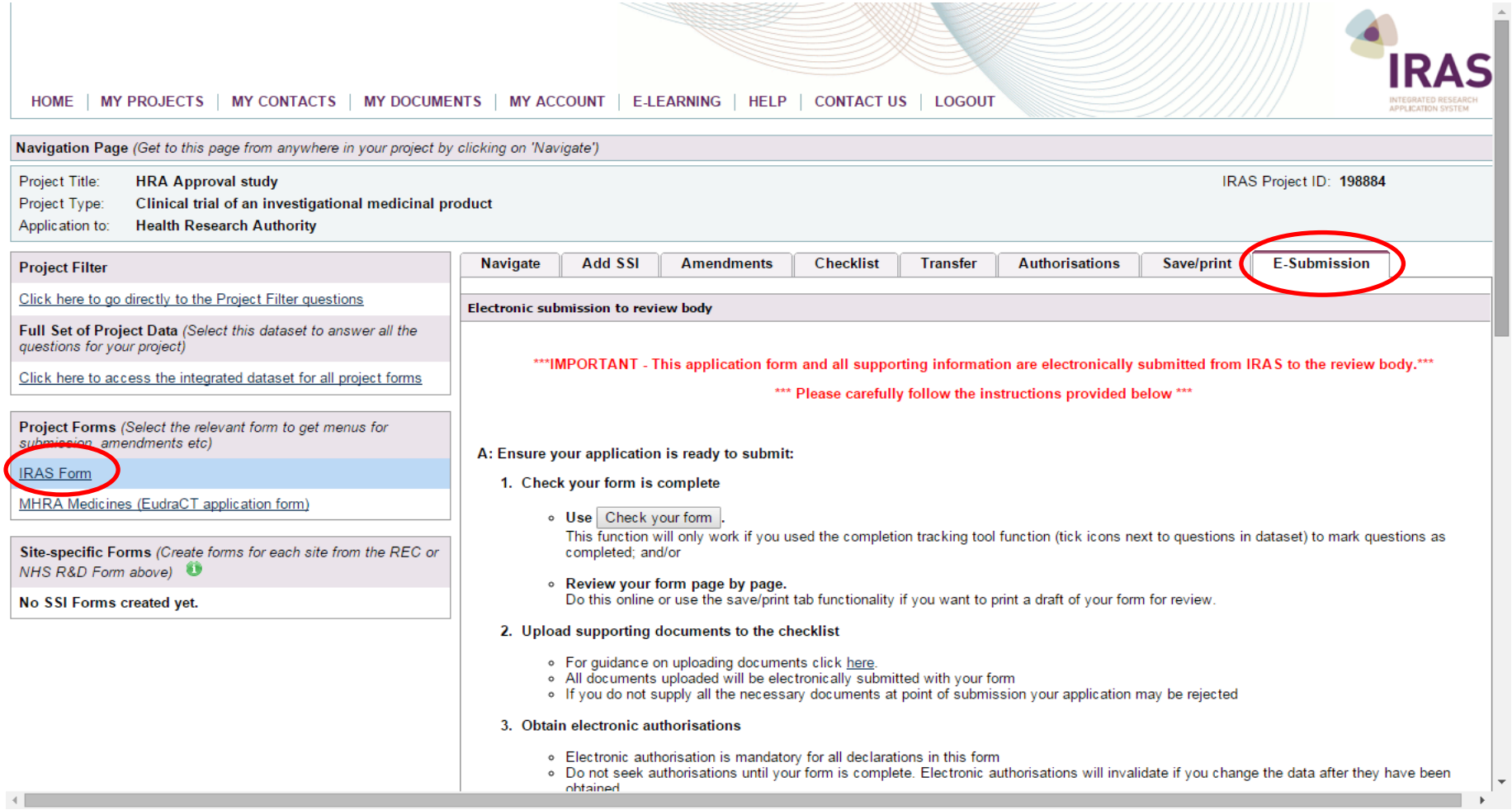
- IRAS is used for applying for permissions and approvals required for health and social care research in the UK (e.g. HRA, CAG, MHRA).

HRA Process

- You enter the information about your project once and the system will populate this information into all your application forms.

- IRAS uses filters to determine the type of study related questions you will need to answer.

- Accuracy in filling in filter questions is critical to generating the correct study related questions and identifying which bodies you need approval from.


HOME | MY PROJECTS | MY CONTACTS | MY DOCUMENTS | MY ACCOUNT | E-LEARNING | HELP | CONTACT US | LOGOUT
IRAS
INTEGRATED RESEARCH APPLICATION SYSTEM
Navigation Page (Get to this page from anywhere in your project by clicking on 'Navigate')
Project Title: HRA Approval study
Project Type: Clinical trial of an investigational medicinal product
Application to: Health Research Authority
IRAS Project ID: 198884
Project Filter
Click here to go directly to the Project Filter questions
Full Set of Project Data (Select this dataset to answer all the questions for your project)
Click here to access the integrated dataset for all project forms
Project Forms (Select the relevant form to get menus for submission, amendments etc)
IRAS Form
MHRA Medicines (EudraCT application form)
Site-specific Forms (Create forms for each site from the REC or NHS R&D Form above)
No SSI Forms created yet.
Navigate
Add SSI
Amendments
Checklist
Transfer
Authorisations
Save/print
E-Submission
Electronic submission to review body
IMPORTANT - This application form and all supporting information are electronically submitted from IRAS to the review body.
*** Please carefully follow the instructions provided below ***
A: Ensure your application is ready to submit:
1. Check your form is complete
Use Check your form .
This function will only work if you used the completion tracking tool function (tick icons next to questions in dataset) to mark questions as completed; and/or
Review your form page by page.
Do this online or use the save/print tab functionality if you want to print a draft of your form for review.
2. Upload supporting documents to the checklist
For guidance on uploading documents click here.
All documents uploaded will be electronically submitted with your form
If you do not supply all the necessary documents at point of submission your application may be rejected
3. Obtain electronic authorisations
Electronic authorisation is mandatory for all declarations in this form
Do not seek authorisations until your form is complete. Electronic authorisations will invalidate if you change the data after they have been obtained

Statement of Activities & Schedule of Events documents

- For Non-Commercial studies new additional documentation is now required.
- ***The HRA have introduced:***
- Statement of Activities
- Schedule of Events

Statement of Activities

- Replaced the SSI form.
- Statement of Activities should capture all study related information at a local level.
- If your study has more than one NHS research site & not all sites will be undertaking the same research activity then one statement of activity should be submitted to the HRA per site-type (not for each site) For example, 1 statement of activities should be submitted for 'Research'& one statement of activities should be submitted for 'PIC' sites.

Statement of Activities

- Word format

- Statement of Activities can be used as an agreement (NHS to NHS)

- Where the Statement of Activities will not be used as a site agreement, the appropriate agreement should be submitted to the HRA as part of the submission checklist from IRAS. If unsure about the agreement- contact the R&D for advice.

Schedule of Events

- Excel format.
- For all non-commercially sponsored studies.
- Aims to capture all information around study activities being undertaken at a local level.

Schedule of Events

- If your study has more than one NHS research site & not all sites will be undertaking the same research activity then one schedule of event document should be submitted to the HRA per site-type (not for each site) For example, 1 schedule of event document should be submitted for 'Research'& one schedule of event document should be submitted for 'PIC' sites.

- The HRA Schedule of Events guidance document available on the HRA website.

Application Pack for HRA Approval

- IRAS form (combined REC & R&D form)
- Protocol
- Schedule of Events (excel format)
- Statement of Activities (word format)
- Patient Facing Documents (PIS, ICF, etc.)
- Evidence of Funding
- Evidence of insurance/indemnity
- Any other documents relevant to study

Guidance for having your research approved

Project Registration
Research.Registration@gosh.nhs.uk

Clinical Research Adoptions Committee (CRAC) approval if project involves GOSH patients, tissue or data (unfunded studies)

- NHS REC approval if NHS patients, tissue or data involved
- HRA approval
- UCL REC approval for healthy volunteers

R&D Governance review

Any other issues or approvals (Divisional Director approval, Finance approval, agreement.)

R&D approval or confirmation of participation (for HRA approval studies)

Local Process at GOSH- Access, Arrange & Confirm (AAC)

GOSH identified as site. Email received inviting us to take part in study

Assess, Arrange & Confirm performed by Governance Team for non-Portfolio studies or CRN NT for Portfolio.

Notice of No Objection issued for GOSH site.

Research Team can begin their study.

Notification that GOSH is a Host Site-Access, Arrange & Confirm (AAC)

- Sponsors/CIs contact prospective sites before the HRA Approval process begins. This will informally enable organisations to assess their capacity and capability to participate in the study.

- Sponsor/Chief Investigator invites sites to take part in a study. A formal invitation should be made after a final protocol is ready for regulatory applications. This will be in the form of an email to the Governance Inbox.

- As soon as an applicant to the HRA has received their 'HRA Initial Assessment Letter' (*or HRA Approval Letter if no assessment letter received*) they can then begin organising local arrangements for study delivery at the host sites (though this doesn't mean they can't discuss a study with sites prior to this).

Notification that GOSH is a Host Site- Access, Arrange & Confirm (AAC) continued…

In order to facilitate study set-up, each Host Site should be sent the local information pack. The Sponsor or Chief Investigator is responsible for providing:

- Copy of the HRA Assessment Letter *(or HRA Approval letter if assessment letter not received)*.
- Any other regulatory approval (REC,CAG,MHRA)
- Study documents (Information/Consent sheets etc.).
- Copy of IRAS form submitted to the HRA.
- Protocol & any amendments to the study.
- Template contract/model agreement and a costing template (if required).
- Statement of Activities & Schedule of Events.
- Any other documents the Sponsor wishes to provide

Access, Arrange & Confirm (AAC)

- Once GOSH has been selected as a site, a local review will take place to assess GOSH's suitability to be a research site for the study. This is done through a process called 'Assess, Arrange & Confirm'

- Local sites (or in the case of portfolio studies the North Thames CRN) will perform the following AAC checks to ensure local suitability of the site.

Access, Arrange & Confirm (AAC)

- ✓ **Assess:** Assessing whether or not the NHS organisation has the capacity and capability to participate in the study. (NB this stage will not be required, or will be minimal, for some types of studies where it is automatically expected that the NHS organisation will participate, eg. emergency public health research)

- ✓ **Arrange:** Putting any practical arrangements in place to provide the capacity and capability to deliver the study.

- ✓ **Confirm:** Confirming that the NHS organisation has the capacity and capability in place to deliver the study. This confirmation is given through the mutual confirmation of the contents of the statement of activities for non-commercial studies or sign-off on an agreement.

Access, Arrange & Confirm (AAC) continued….

- Honorary Contracts and/or Letter of Access are to be discussed and prepared at this stage.

A **Statement of Activities** (SoA) and a **Schedule of Events** (SoE) is completed.

Sponsor/CI provide one SoE and SoA for each site. May differ between site types. Non-Commercial Sponsors may propose to HRA that the SoA is used with Host Sites as a form of site agreement. SoA &SoE should provide clarity on what funding the Sponsor will be providing to cover Research Costs.

For GOSH Sponsored studies, we will still have to perform the above tasks for the GOSH site

Confirmation of Capacity and Capability

- Once all the local arrangements at GOSH are in place, the R&D office can confirm Capacity and Capability.
- Confirmation of Capacity and Capability confirms that we are satisfied with the local arrangements and feasibility has been completed. This enables the research team to begin their study.

Confirmation of Capacity and Capability

What needs to be in place before confirmation of Capacity and Capability can be issued?

- ✓ Complete document set for the study (protocol, IRAS form, study documents etc.).
- ✓ Statement of Activities for GOSH site needs to be completed and finalised with the study Sponsor.
- ✓ If required, a contract needs to be in place. For commercial studies, we need to have a corresponding costing template.
- ✓ Divisional Director Authorisation.
- ✓ Pharmacy/Radiology approvals (*if required*).
- ✓ HRA Approval Letter plus any regulatory approvals from the REC or MHRA.

Amendments

- From 1st April 2016, amendments for all English- led studies taking place in the NHS will be categorised by the HRA.

- Amendments will no longer be submitted to NIHR CSP.

Amendments

- Upon submission of an amendment to the REC/HRA, the HRA will categorise the amendment (Category A, B or C) and notify the Sponsor/CI within 5 days.

- The Categorisation process informs participating NHS sites if the amendment will need to be reviewed prior to implementation. This is in addition to the Sponsor confirming if the amendment is substantial or non-substantial.

Categorisation of Amendments

- **Category A-** Amendment made to a study where ALL participating NHS sites are expected to consider.

- **Category B-** Amendment made to a study that impacts/affects specific NHS sites. Only these sites would need to review the amendment prior to implementation.

- **Category C-** Amendment made to a study where NHS sites are NOT expected to consider the amendment or issue continued permission.

Processing Substantial Amendments

- Upon submission of the amendment to REC, the HRA will be notified of the amendment by REC via an internal process. While REC reviews the amendment, the HRA will categorise the amendment (within 5 days) and send the categorisation email to the Sponsor/CI.

The Sponsor/CI can share the categorisation email along with any associated documentation to participating sites. Sites may begin to review the amendment however; the amendment should only be implemented once the HRA have shared the final outcome of their assessment. Governance Team have 35 days to review the amendment and make arrangements for implementation.

Processing 'Non-Substantial' or 'Minor Amendments'

- There's no requirement for the researcher to notify the main REC of Non-Substantial or Minor amendments. There are no legal requirements to obtain an ethical opinion prior to implementation.

- Good research practice is to submit documents together with a brief cover letter of modifications to the REC for information only purposes. REC will acknowledge these documents as confirmation of their status. This is not required prior to implementation.

- Although there is no requirement to notify REC of any non- substantial or amendments, from 1st April 2016, any non-substantial amendment or any amendments that do not require REC review should be submitted to the HRA via email (hra.amendments@nhs.net) for approval using the non-substantial amendment form.

- Upon receipt of a Non-Substantial or minor amendment the Governance Officer will ensure there is clear communication surrounding the amendment and its classification from the Sponsor, Ethics Committee and the HRA.

Once HRA acknowledge/approve the non-substantial amendment, as no formal NRES acknowledgment is required prior to implementation, the governance officer, once satisfied with the review and within the 35 day implementation deadline, will send an email to the PI, copying in the Sponsor contact, confirming acknowledgement of the amendment.

Outline of the Amendment Process

Sponsor/study team submit complete amendment application in R&D Office

R&D Office is notified of the amendment

The PI is responsible for reviewing, agreeing to and localising the appropriate amendment documentation before implementing at the site

The R&D Office then has 35 days to raise any objections or notify the study team/sponsor of no objection to the amendment being implemented at the site

If a finance, contract or governance issue is raised as a result of the amendment, the R&D office will liaise with the supporting departments and inform the investigator/study team and sponsor.

If no issues or objections are identified, the R&D Office will issue an email to study team and sponsor (if study not GOSH/ICH sponsored) confirming that the amendment can be implemented at GOSH. (Provided that all applicable regulatory approvals are in place.)

Contact us: GOSH/ICH Joint Research and Development Office (R&D)

Research Management & Governance Team

- Dr Thomas Lewis – 020 7905 2249
- Manju Agarwal – 020 7905 2845
- Anika Kadchha- 020 7905 2846

Email: Research.Governance@gosh.nhs.uk

Website:

http://www.gosh.nhs.uk/research-and-innovation/researchers/rd-office/research-governance/

Useful Links:

- https://www.crn.nihr.ac.uk/can-help/funders-academics/ - This website has various services to help research applicants deliver their research. The research delivery pathway shows how the Clinical Research Network (CRN) can help all the way from developing your idea to study closure.

- http://www.nihr.ac.uk/funding/pgfar-patient-and-public-involvement.htm

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

- *Source: http://www.hra.nhs.uk/resources/hra-approval-nhs-organisation-guidance/#NHS*