

UK Local Information Pack webinar

Friday 10 May

If you can not hear us speaking / background music, you will need to also dial in via a phone:

0207 4849 444 PIN code: 93916827#

Four Nations NHS/HSC Compatibility Programme

UK Local Information Pack Webinar



Four Nations Programme Aims

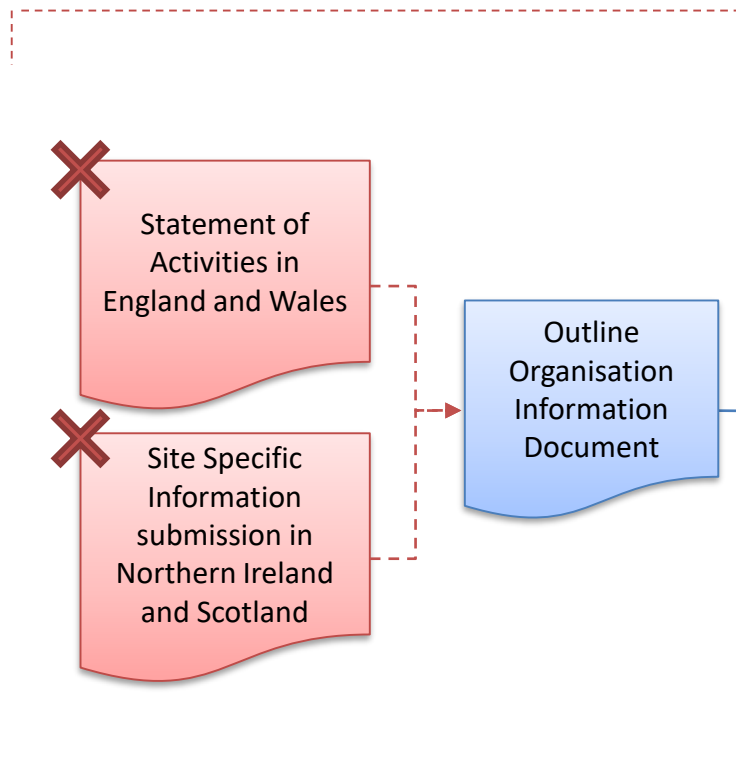
- Continue to **streamline** processes
- Maintain **compatible** systems across the UK
- Support **cross border** research
- Make it **easier** to do research across the UK

Introduction of a UK Local Information Pack

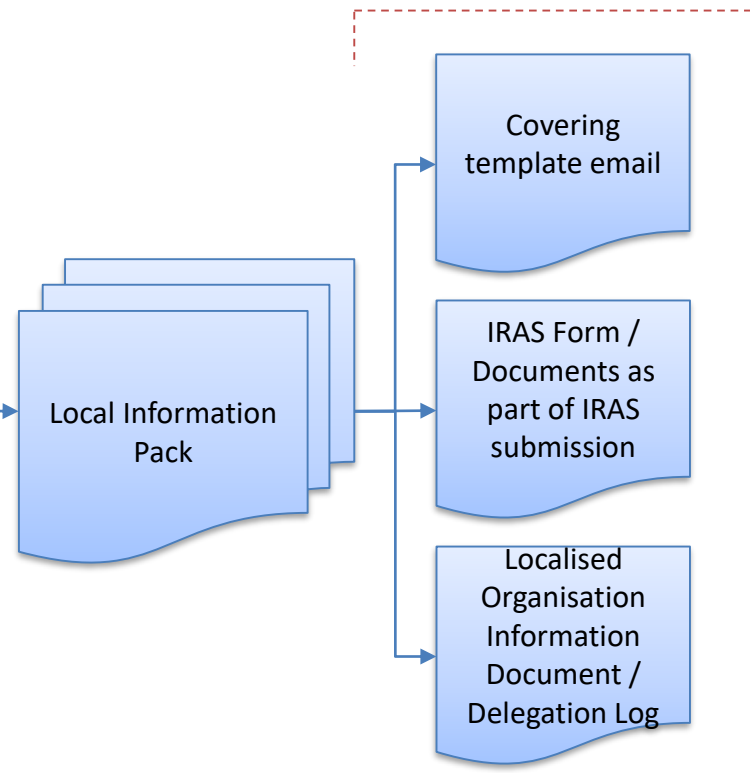
- Implementation outside IRAS on 5 June 2019
- A consistent set of documents for study set up across England, Northern Ireland, Scotland and Wales
- Part of the Local Information Pack is an Organisation Information Document, this replaces:
 - *Statement of Activities in England and Wales*
 - *Site Specific Information Form in Northern Ireland and Scotland*

What makes up the Local Information Pack?

IRAS Form Submission



Local Information Pack Contents



What makes up the Local Information Pack?

Commercial studies

[Covering email in standard template format](#)

IRAS Form

Protocol

Patient information sheet and consent form

Localised Organisational Information Document (commercial)

Model Clinical Trial Agreement

Industry Costing Template or Tool

Other documents to help support study set up

For England and Wales – HRA and HCRW Initial Assessment Letter/or Approval letter

What makes up the Local Information Pack?

Non-commercial studies

[Covering email in standard template format](#)

IRAS Form

Protocol

Patient information sheet and consent form

Localised Organisational Information Document (non-commercial)

IRAS Schedule of Events or SOECAT

Model Non-commercial Agreement, *if being used as agreement*

Other documents to help support study set up

For England and Wales – HRA and HCRW Initial Assessment Letter/or Approval letter

Participating Identification Centres

- PICs do not require a Local Information Pack
- Use of Model PIC agreements as subcontract
 - *Subcontract between participating NHS/HSC organisation and PIC*
 - *Sets out agreed arrangements*
 - *Includes data processing agreement for GDPR*
 - *Commercial and non-commercial versions available*

Organisation Information Document

- An Organisation Information Document provides information to the participating NHS/HSC organisation(s) to support the set up of research
- There are [commercial and non-commercial versions](#)
 - *In IRAS Help*
 - *For non interventional, non commercial studies can be used as an agreement*

Commercial organisation information document

The screenshot shows a web browser window displaying the IRAS Help page for 'Preparation & submitting application'. The left-hand navigation menu is expanded to show 'Site specific information', which includes 'Organisation Information Document'. The main content area contains the following text:

Organisation Information Document

The Organisation Information Document replaces:

- the Statements of Activities, which have been used for non-commercial studies, in England and Wales; and
- the NHS/HSC Site Specific Information (SSI) Form in Scotland and Northern Ireland.

The Organisation Information Document will be a key component of the UK Local Information Pack for commercial and non-commercial research projects.

There are different templates for the Organisation Information Document according to whether the study is a commercial or non-commercially sponsored project. You should use the appropriate template to create the 'outline Organisation Information Document(s)' for the project:

- Organisation Information Document for commercially sponsored projects – [template](#) and [guidance](#)
- Organisation Information Document for non-commercially sponsored projects – [template](#) and [guidance](#)
- Organisation Information Document for data processing only (non-commercially sponsored projects) – [template](#).

Note that this document is intended for use as the data processing agreement between sponsor and participating NHS / HSC organisation where neither a national template agreement or Organisation Information Document are appropriate (i.e. for use between University Sponsor and Participating NHS / HSC organisation, which share a Joint Research Office and hence do not need to use the Local Information Pack to set up their 'own' organisation, for studies that are not clinical trials or clinical investigations).

The outline Organisation Information Document should give information that will be common to all participating NHS/HSC organisations that are undertaking the same activities within the study. In some studies, some NHS/HSC organisations will undertake different activities to others. In this scenario you will need to create and submit an outline Organisation Information Document for each group of NHS/HSC organisation undertaking the same activities.

The outline Organisation Information Document(s) must be electronically submitted as part of the IRAS Form application. This means you must attach the outline Organisation Information Document(s) to the IRAS Form checklist prior to e-submission of the application.

IMPORTANT: The Organisation Information Document should be localised before sharing with participating NHS/HSC organisations. This is referred to as the 'localised Organisation Information Document'. Please refer to the guidance provided

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Non- Commercial organisation information document

The screenshot shows a web browser window displaying the IRAS Help website. The address bar shows the URL: <https://www.myresearchproject.org.uk/help/hlpsitespecific.aspx#UK-Local-Information-Pack>. The page title is "IRAS Help - Preparing & submitting application". The left sidebar contains a navigation menu with the following items: "Using IRAS", "Preparing & submitting application" (expanded), "Maintaining your approvals", "End of research", "FAQs", "Documentation", and "Reference". Under "Preparing & submitting application", the following items are listed: "HRA Approval", "NHS/HSC R&D Permissions", "Ethical review (REC)", "Confidentiality Advisory Group", "ARSAC", "HMPPS", "MHRA Medicines", "Site specific information" (highlighted), "MHRA Devices", "Templates for supporting documents", "HR Good Practice Resource Pack", "Radiation Assurance", "Radiation - defining research activities", and "Pharmacy Assurance". The main content area is titled "Organisation Information Document". It contains the following text: "The Organisation Information Document replaces:" followed by a bulleted list: "the Statements of Activities, which have been used for non-commercial studies, in England and Wales; and the NHS/HSC Site Specific Information (SSI) Form in Scotland and Northern Ireland." Below this, it states: "The Organisation Information Document will be a key component of the UK Local Information Pack for commercial and non-commercial research projects." It then explains: "There are different templates for the Organisation Information Document according to whether the study is a commercial or non-commercially sponsored project. You should use the appropriate template to create the 'outline Organisation Information Document(s)' for the project." This is followed by a bulleted list: "Organisation Information Document for commercially sponsored projects – [template](#) and [guidance](#)", "Organisation Information Document for non-commercially sponsored projects – [template](#) and [guidance](#)", and "Organisation Information Document for data processing only (non-commercially sponsored projects) – [template](#)". A note follows: "Note that this document is intended for use as the data processing agreement between sponsor and participating NHS / HSC organisation where neither a national template agreement or Organisation Information Document are appropriate (i.e. for use between University Sponsor and Participating NHS / HSC organisation, which share a Joint Research Office and hence do not need to use the Local Information Pack to set up their 'own' organisation, for studies that are not clinical trials or clinical investigations)." The text continues: "The outline Organisation Information Document should give information that will be common to all participating NHS/HSC organisations that are undertaking the same activities within the study. In some studies, some NHS/HSC organisations will undertake different activities to others. In this scenario you will need to create and submit an outline Organisation Information Document for each group of NHS/HSC organisation undertaking the same activities." It then states: "The outline Organisation Information Document(s) must be electronically submitted as part of the IRAS Form application. This means you must attach the outline Organisation Information Document(s) to the IRAS Form checklist prior to e-submission of the application." Finally, it includes an "IMPORTANT:" note: "The Organisation Information Document should be localised before sharing with participating NHS/HSC organisations. This is referred to as the 'localised Organisation Information Document'. Please refer to the guidance provided".

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Changes to IRAS Form Submission

- An **outline** Organisation Information Document is part of the IRAS Form submission
 - *Document is partially completed by Sponsor at IRAS submission*
- IRAS Schedule of Events/Schedule of Events Cost Attribution Template (SoECAT)
 - *For non-commercial studies*
 - *A change for Northern Ireland and Scotland (new)*
 - [Guidance is available in IRAS help](#)

Localised Organisation Information Document

- The **outline** Organisation Information Document is **localised** for each participating site (Sponsor)
 - *Complete information that is known*
 - *May only be partially complete at this point*
 - *Will vary for different studies*

Sharing the Local Information Pack

- For sites in England, Northern Ireland and Wales
 - *Sponsor emails the Local Information Packs to each participating NHS/HSC organisation*
- For sites in Scotland
 - *Sponsor emails the Localised Organisation Information Documents and Delegation Logs to NRS coordinating function in who make available to participating NHS organisations.*
- Complete the appropriate email template
 - *Multiple templates will be required for cross border studies*

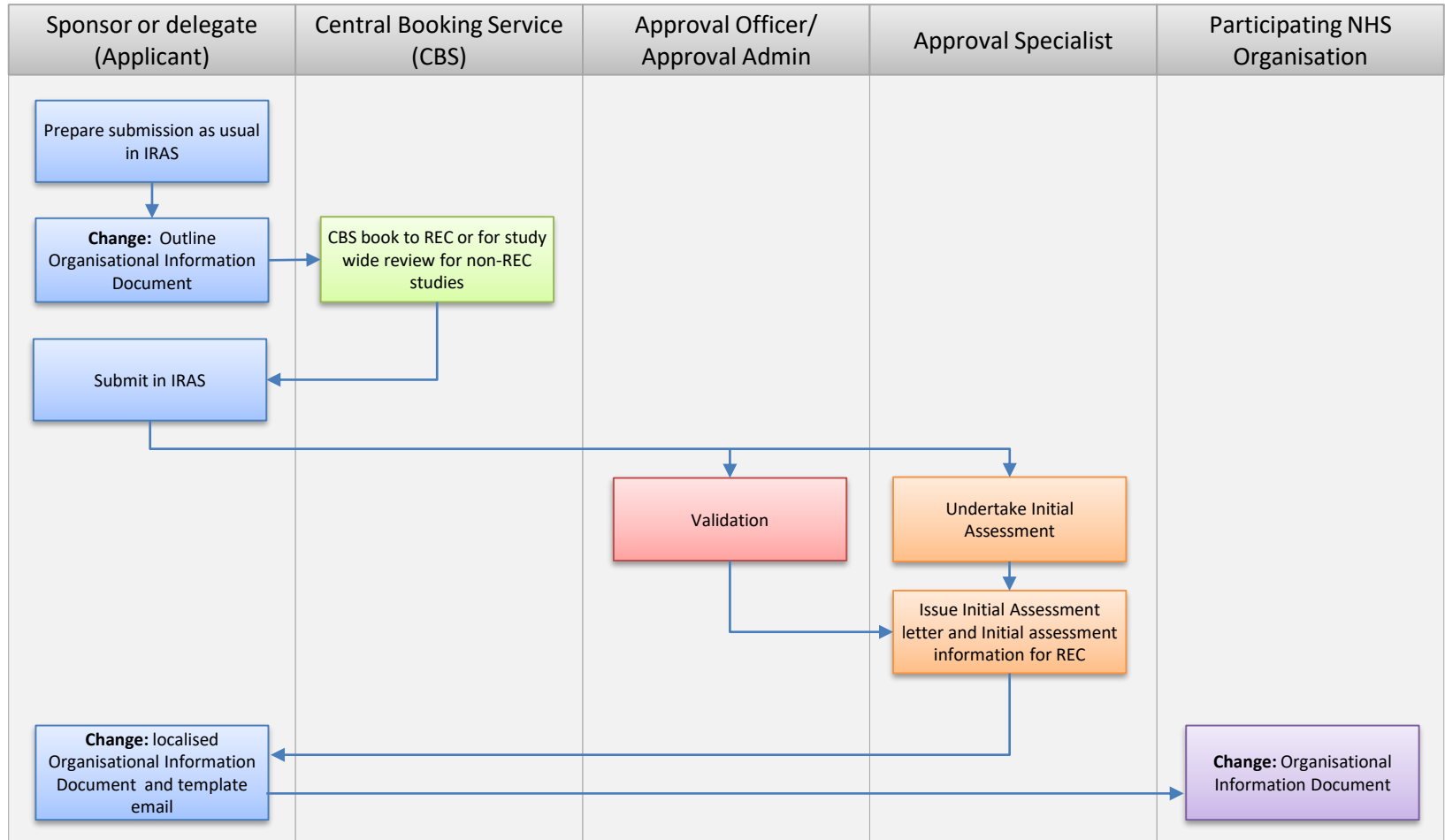
Concluding the process

- Sponsor **agrees** and finalises the localised Organisation Information Document with PI, local research team, networks/specialty groups **AND** R&D at the same time
 - *In England, Northern Ireland and Wales NHS/HSC provides confirmation of capacity and capability using a model agreement or the Localised Organisation Information Document according to study type*
 - *In Scotland NHS provides NHS permission*

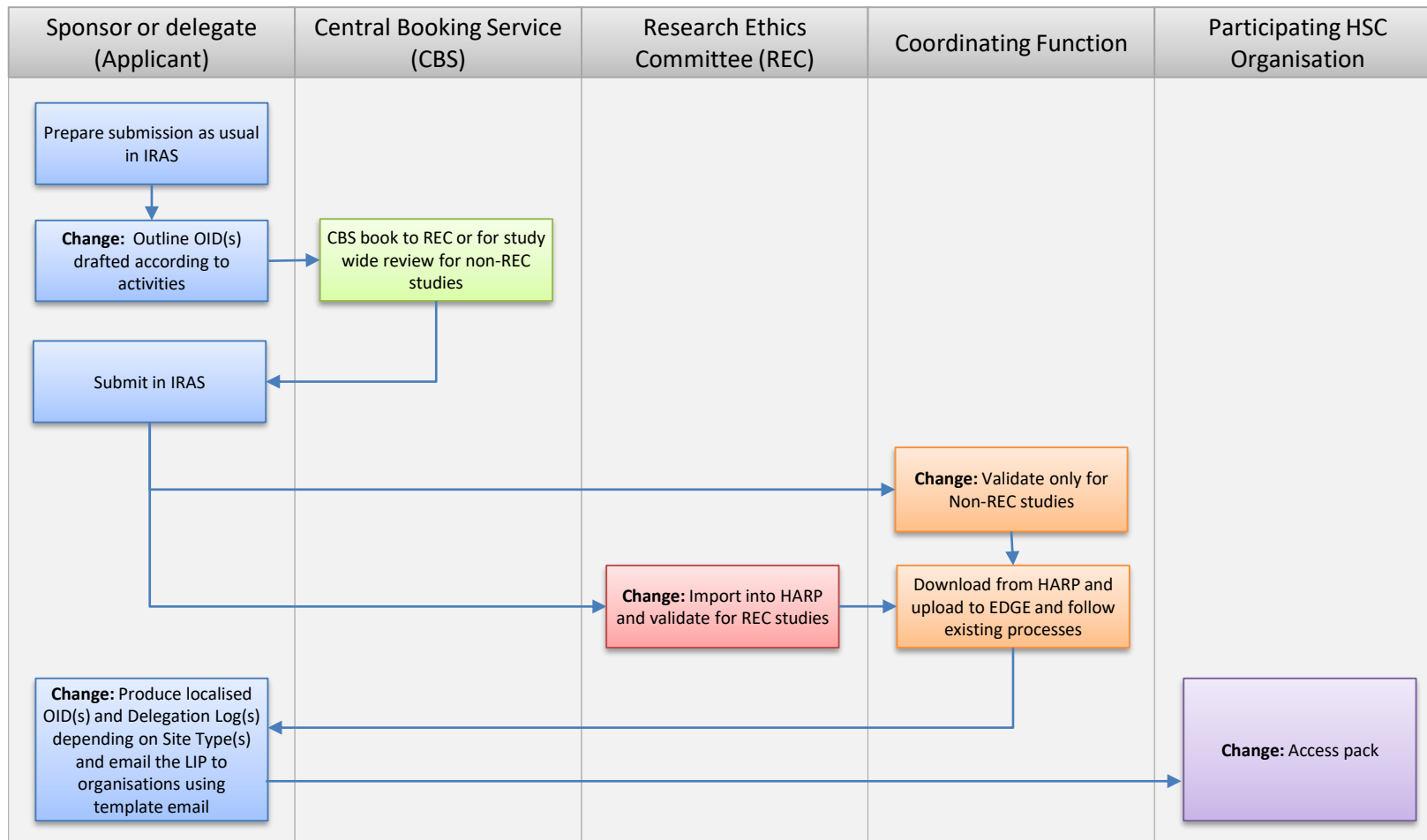
Starting the study

- England, Northern Ireland and Wales
 - *Confirmation of capacity and capability means that the organisation will take part and is ready to do so when the sponsor says start. For CTIMPs this will be after Site Initiation Visit etc.*
- Scotland
 - *When the NHS study delivery team is ready to start they do so. For CTIMPs this will be after Site Initiation Visit etc.*

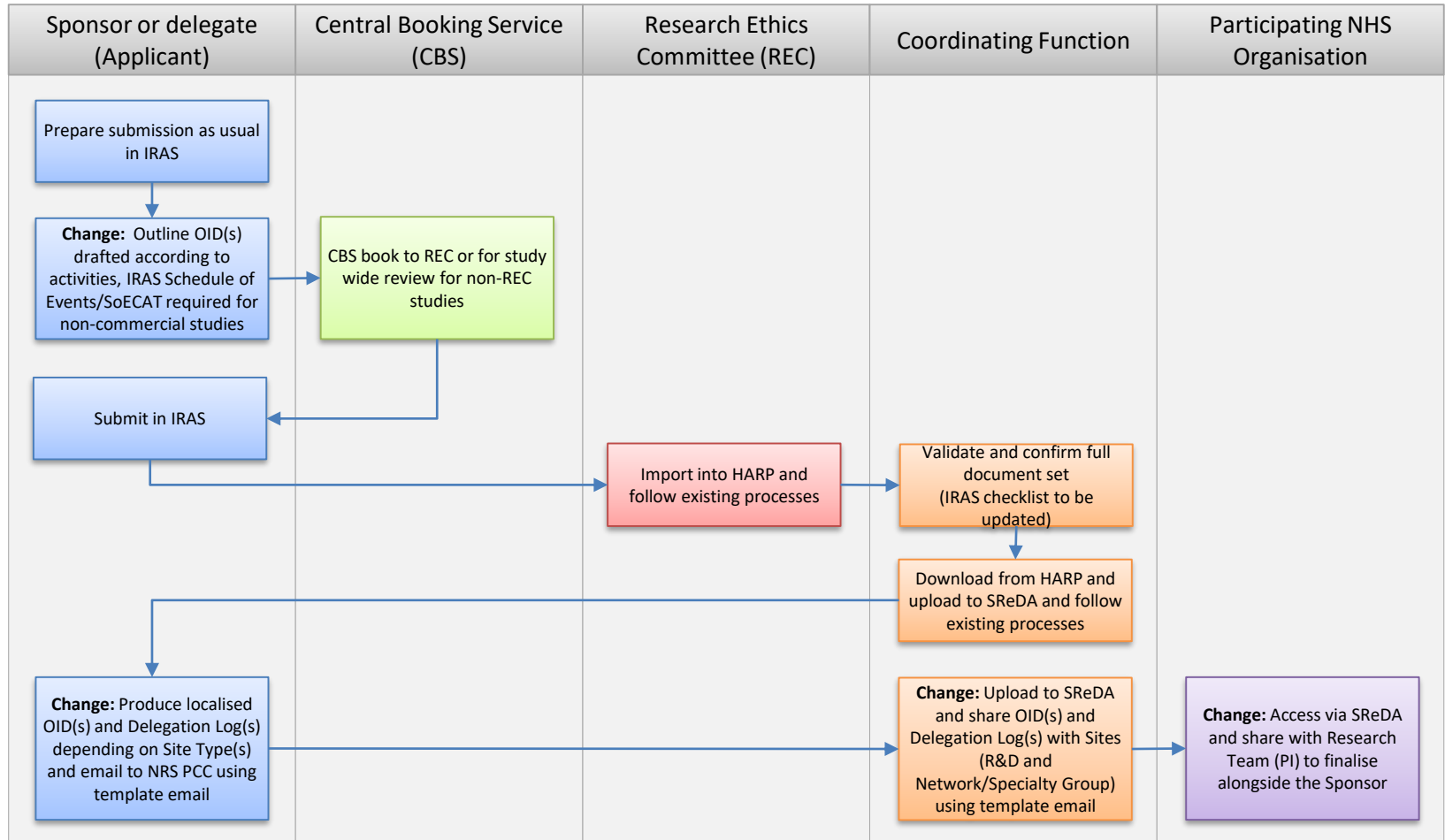
Local Information Pack – England/Wales



Local Information Pack – NI



Local Information Pack – Scotland



Role of the Sponsor – Summary

- Complete Local Information Pack documentation
- Distribute Local Information Packs to all sites in England, Northern Ireland and Wales
- Send localised Organisation Information Documents and Delegation Logs to coordinating function in Scotland
- Finalise localised Organisation Information Document in a facilitative manner

Transitional Arrangements

- Studies submitted before 5 June use Statement of Activities or Site Specific Information Form
- Studies from 5 June use Organisation Information Document
- [Guidance available on IRAS help](#)

Further Support

- Each country to schedule local support as necessary
- [Guidance is available on IRAS help](#)
- [Q&A's are available on the Four Nations Compatibility Programme website](#)
- [UK Operational Leads contact information](#)