

Four Nations NHS/HSC Compatibility Programme

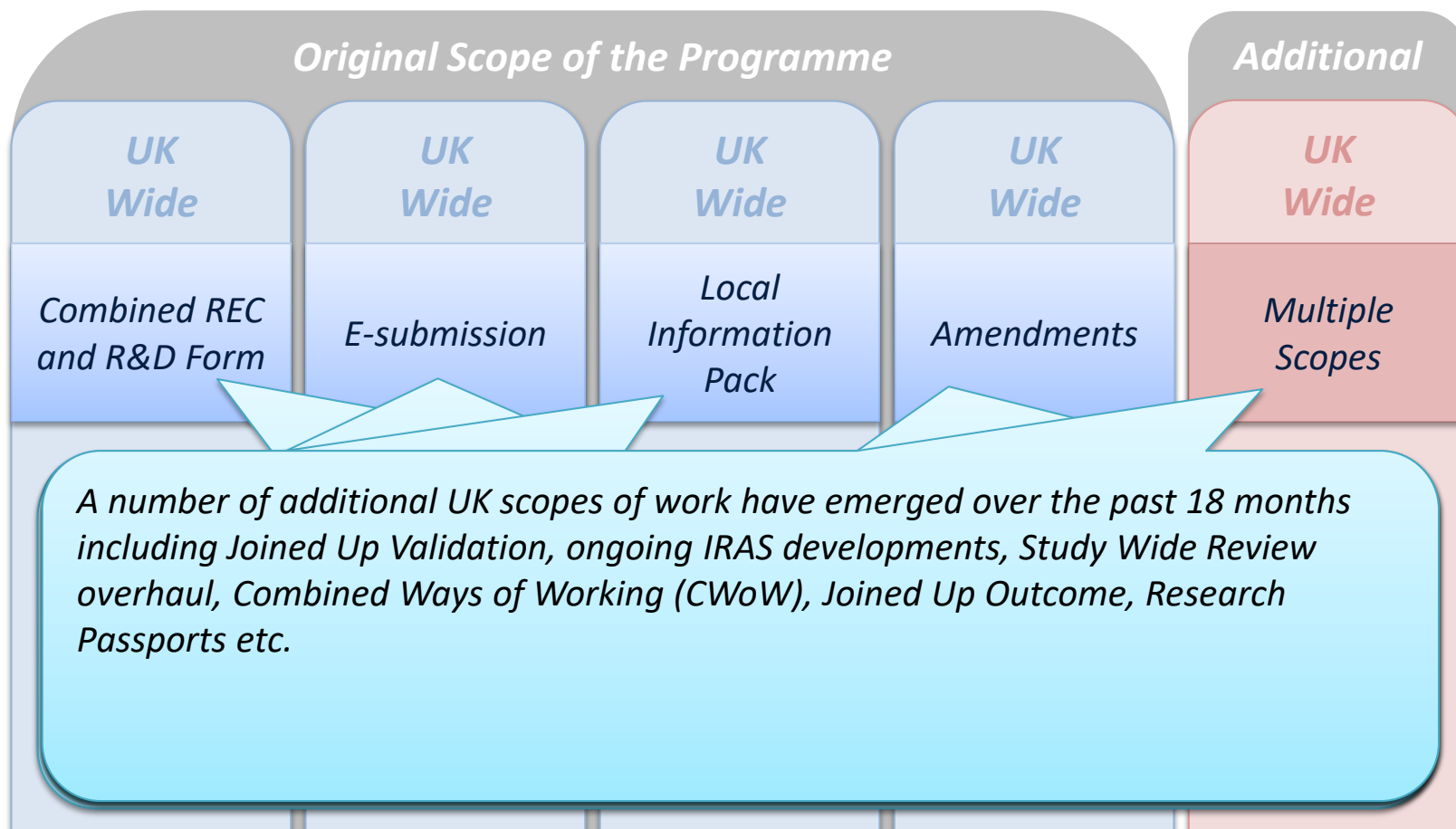
UK Local Information Pack



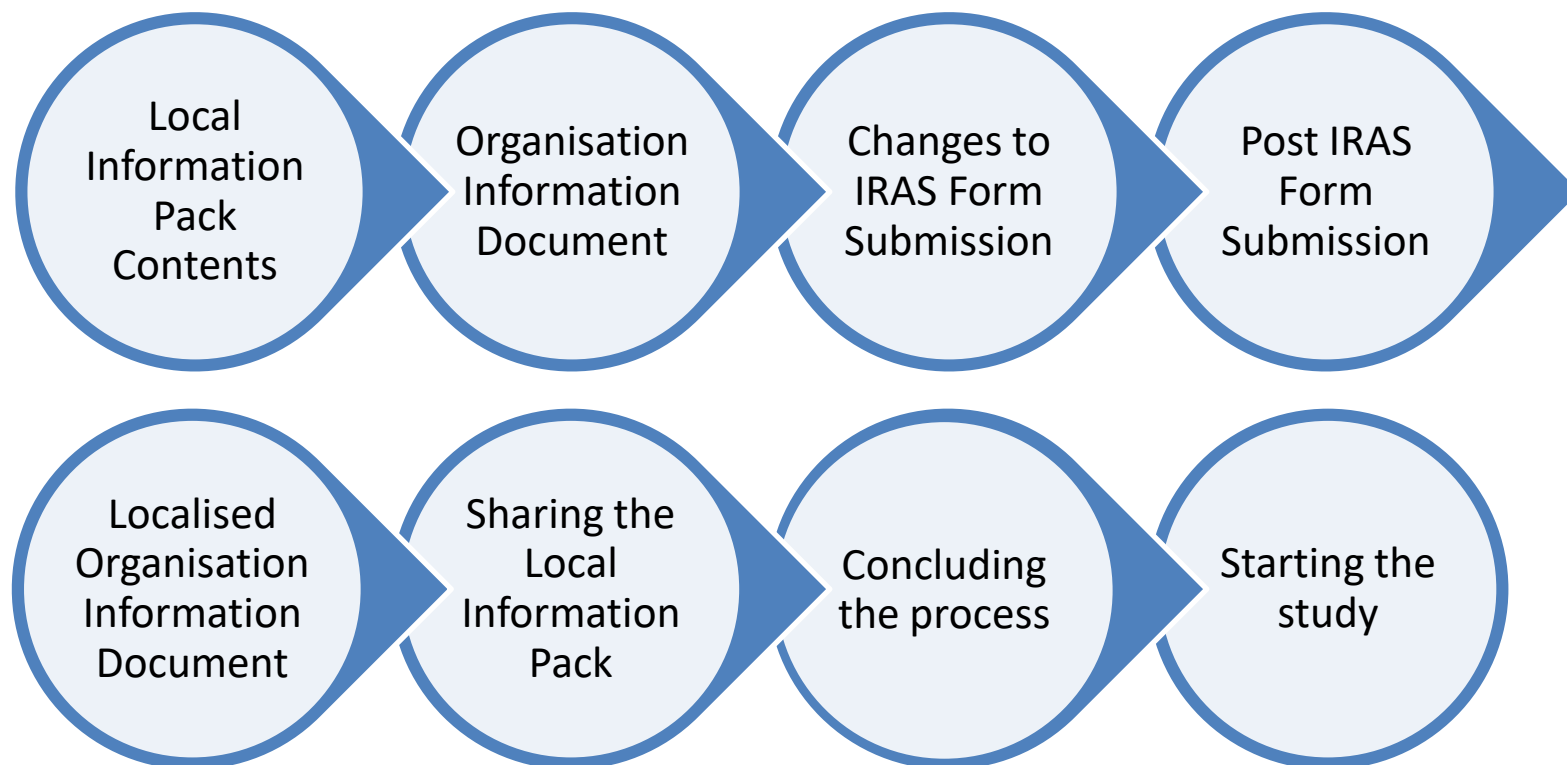
Four Nations Programme Aims

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

Four Nations Programme Scope



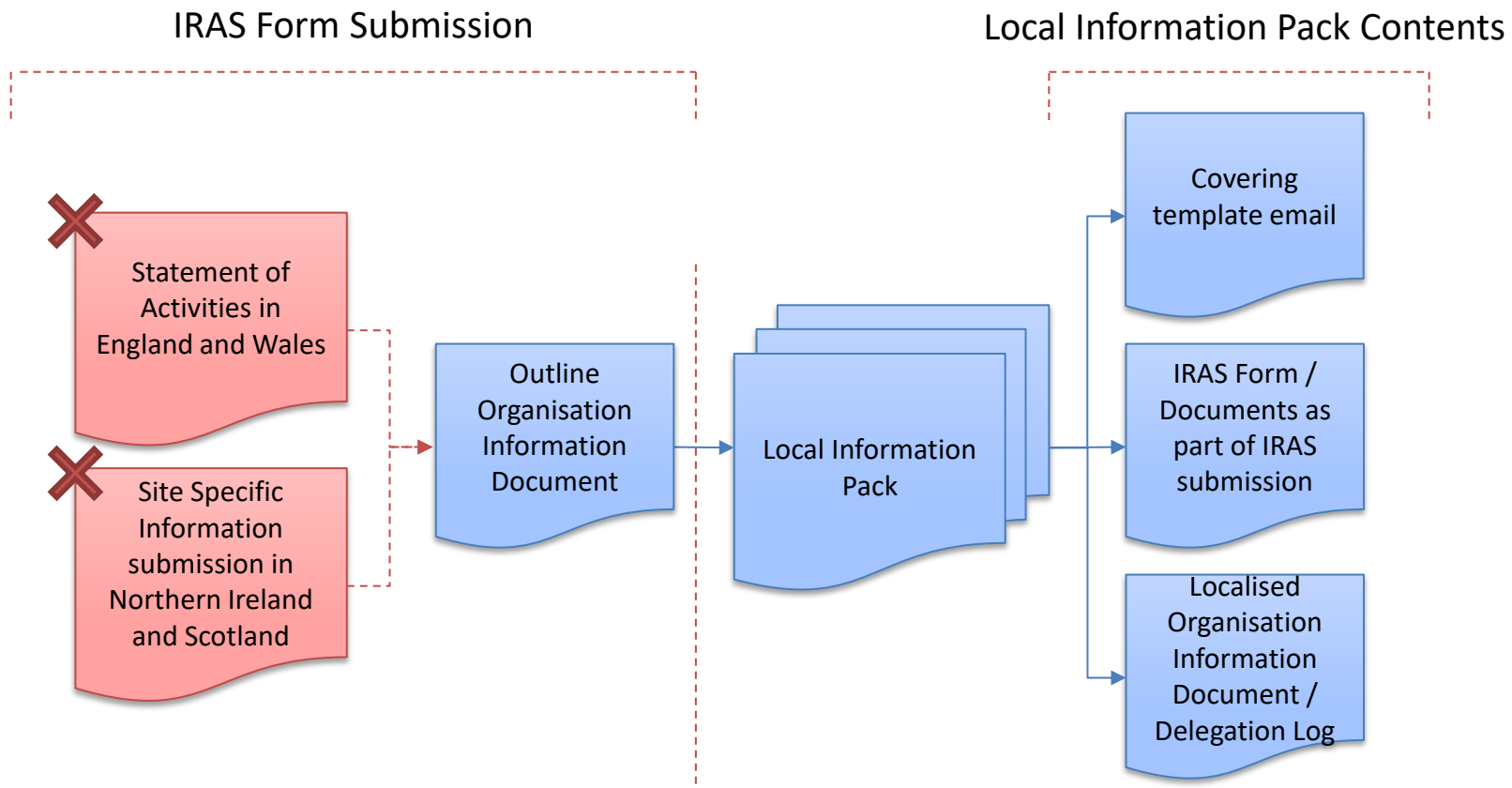
Session Overview



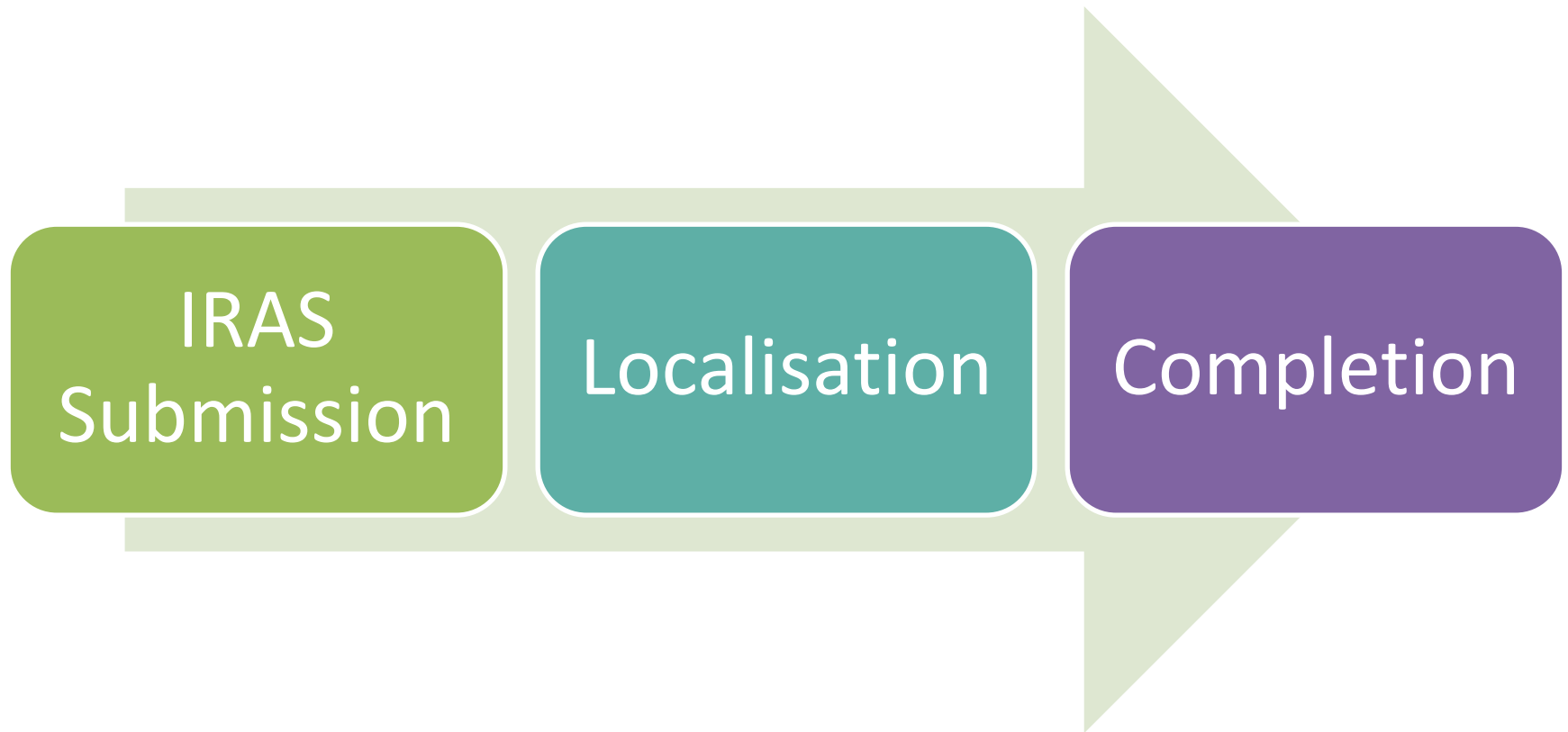
Introduction of a UK Local Information Pack

- 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?



Stages of completion



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

Delegation Log (This is required for all interventional studies requiring a principal investigator. The sponsor must indicate if this is being provided at a later date ie SIV)

Other documents to help support study set up (e.g. CRF Information, Pharmacy Manual etc.)

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*

Delegation Log (This is required for all interventional studies requiring a principal investigator. The sponsor must indicate if this is being provided at a later date ie SIV)

Other documents to help support study set up (e.g. CRF Information, Pharmacy Manual etc.)

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

Participant 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](#)
 - *For non interventional, non commercial studies can be used as an agreement*

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*
 - [Guidance is available in IRAS help](#)

Localised Organisation Information Document

- The **outline** Organisation Information Document is **localised** for each participating site (Sponsor)
 - *Again, will only be partially complete at this point*
- Delegation Log may be included, or provided later ie at Site Initiation Visit
 - [Guidance and template is available in IRAS help](#)

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 Log (as required) 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*

Summary of stages of completion



IRAS Submission

- Outline
- Part completed
- * Questions completed
- If sites are undertaking different activities, more than one will be required



Localisation

- Sponsor completes with known information
- Will differ across studies



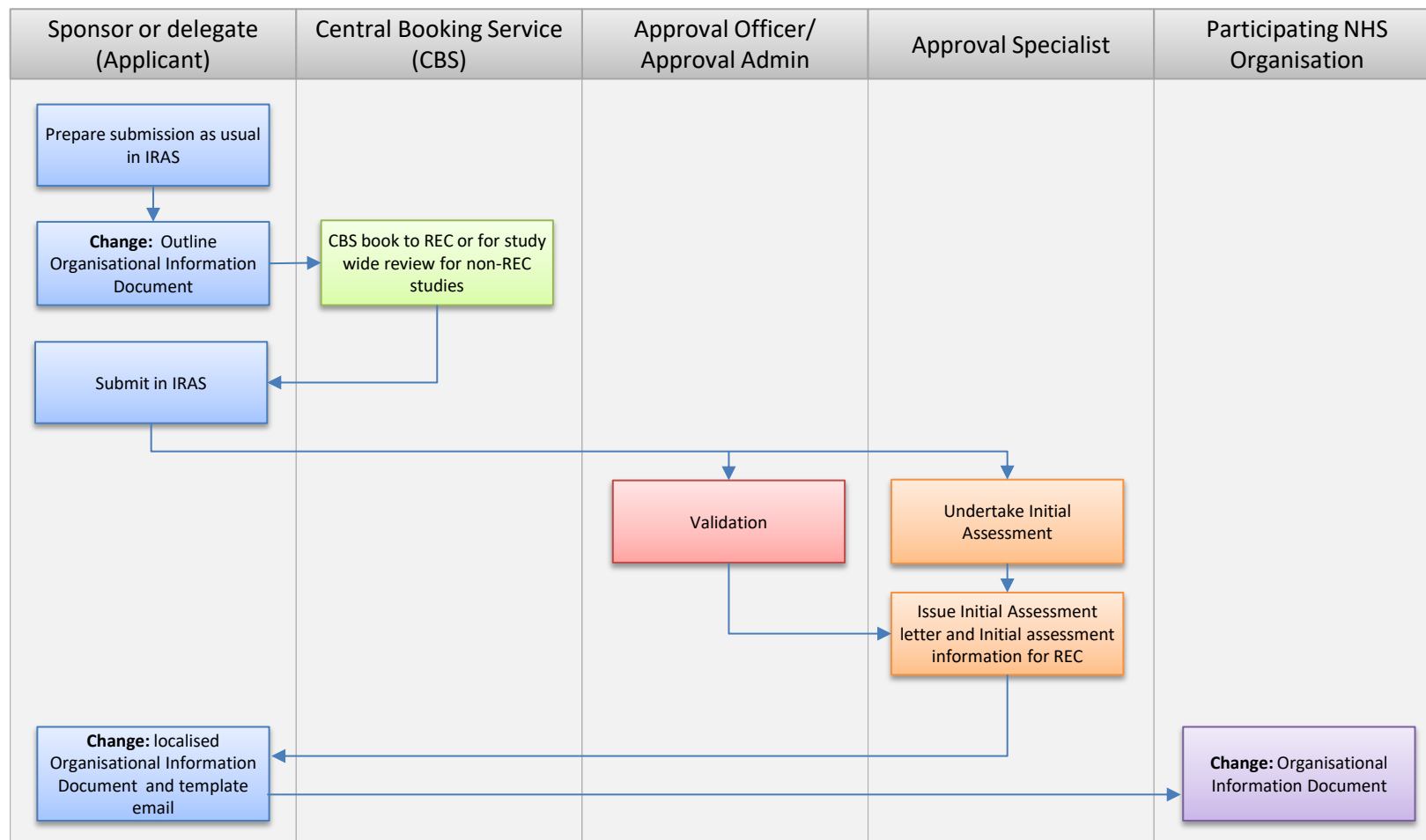
Agreement

- Finalise together
- ^ completed by site

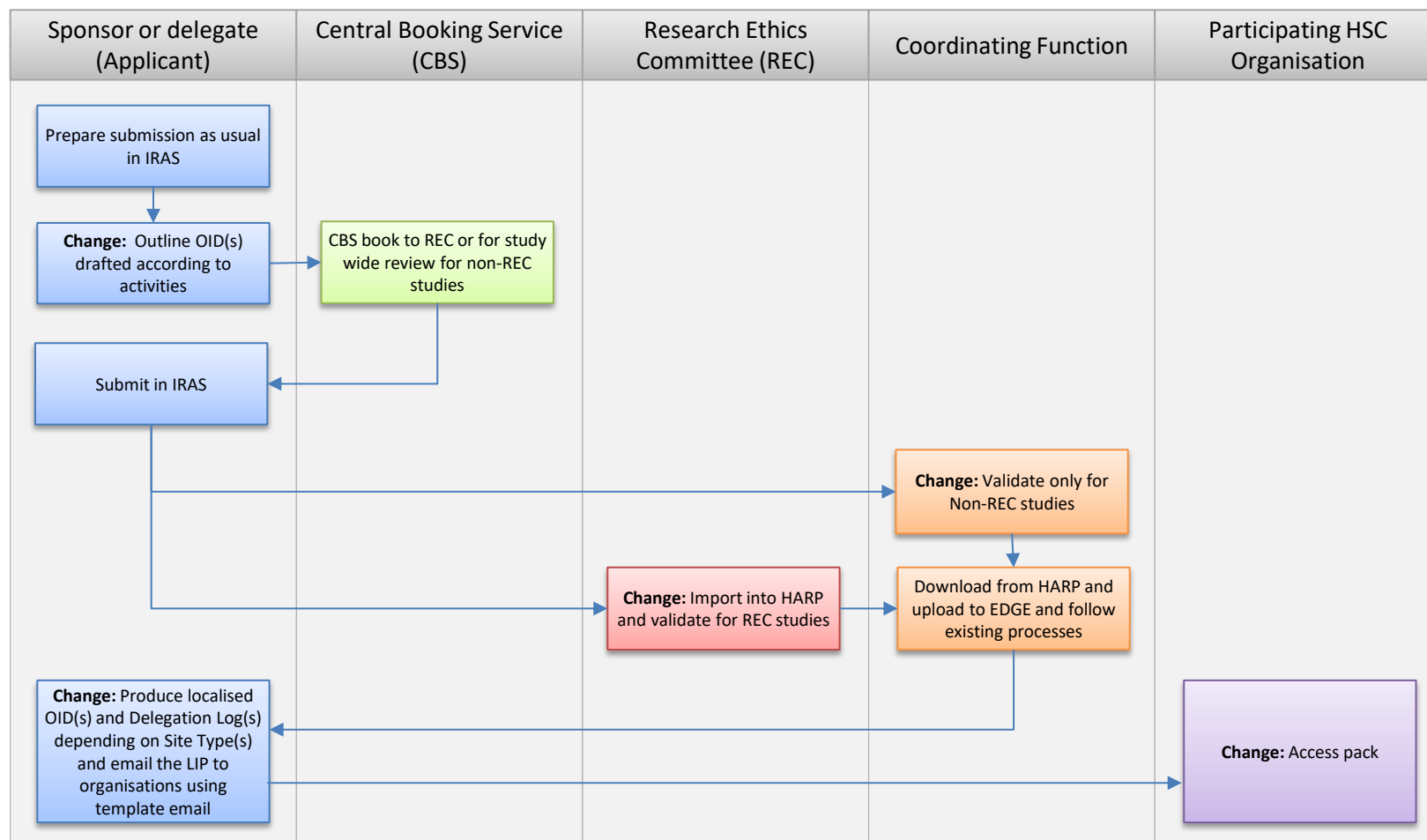
Starting the study

- 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.*

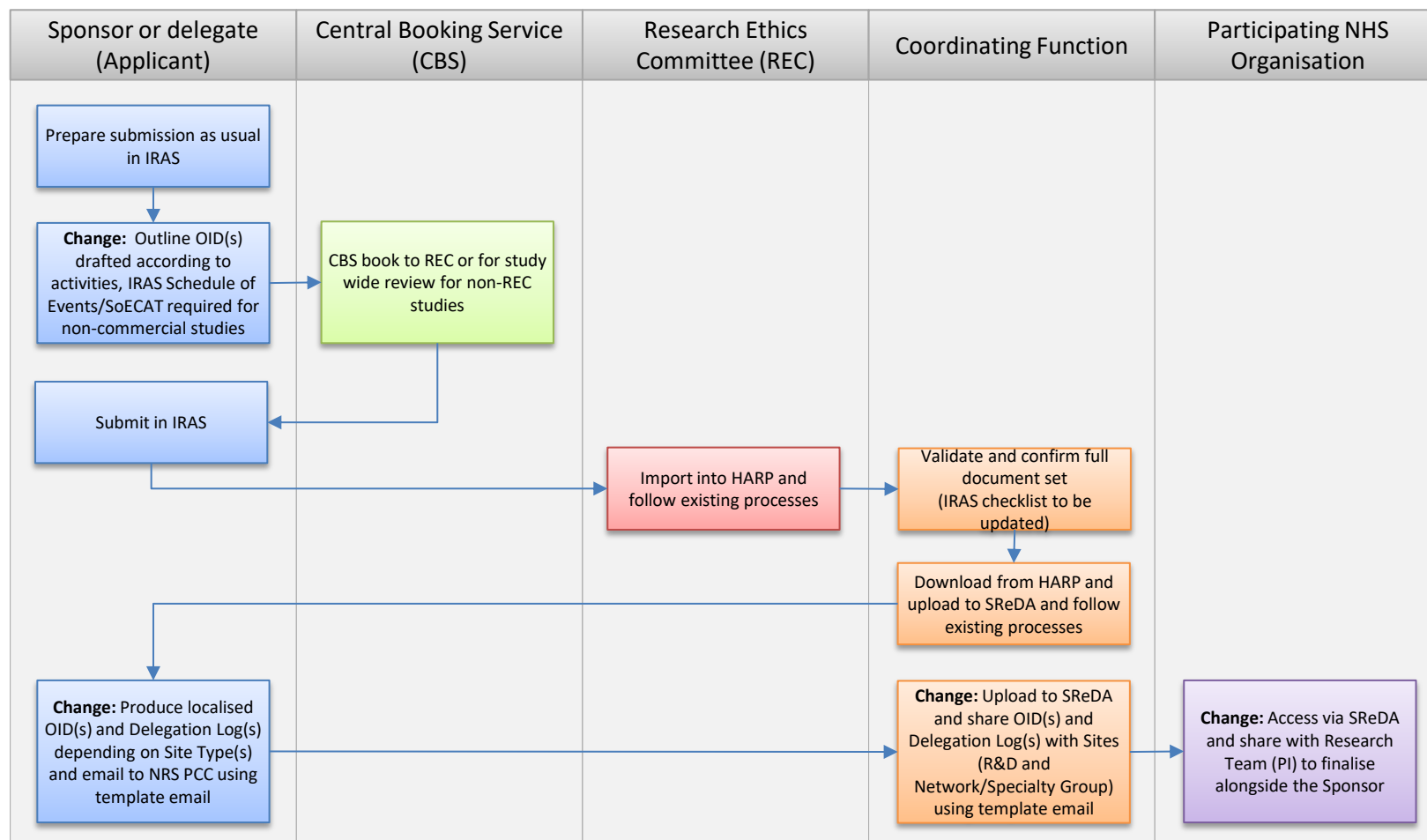
Local Information Pack – England/Wales



Local Information Pack – NI



Local Information Pack – Scotland



Summary of stages of completion



IRAS Submission

- Outline
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Localisation

- Sponsor completes with known information
- Will differ across studies



Agreement

- Finalise together
- ^ completed by site



Health and
Social Care



Ymchwil Iechyd
a Gofal Cymru
Health and Care
Research Wales



NHS RESEARCH SCOTLAND



Health Research
Authority

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 to coordinating function in Scotland
- Finalise localised Organisation Information Document in a facilitative manner

Role of the Coordinating Function – Summary

- Carry out Validation/Initial Assessment
 - *All nations validate*
 - *England and Wales do an Initial Assessment*
- In Scotland the coordinating function receive localised Organisation Information Documents and make available through national IT system

Role of the participating NHS/HSC Organisation – Summary

- Finalise localised Organisation Information Document in a facilitative manner with sponsor

Transitional Arrangements

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

Non NHS SSI Form



- for CTMIPs and Medical Device studies
- from 5 June being replaced by a simple non-NHS/HSC Site Assessment Form
- reviewed by REC

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](#)