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#

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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

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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*

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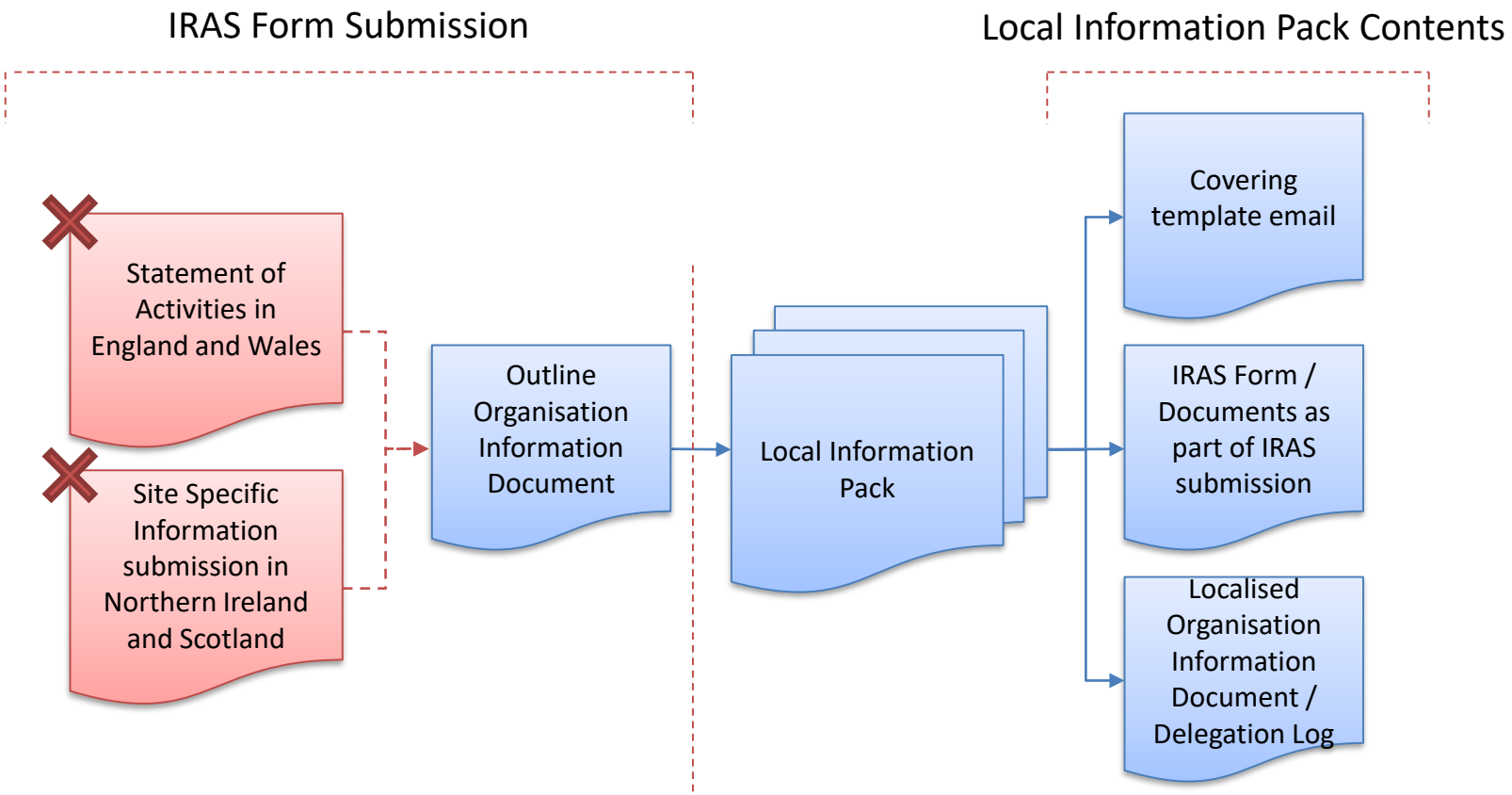
What makes up the Local Information Pack?



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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

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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

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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*

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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*

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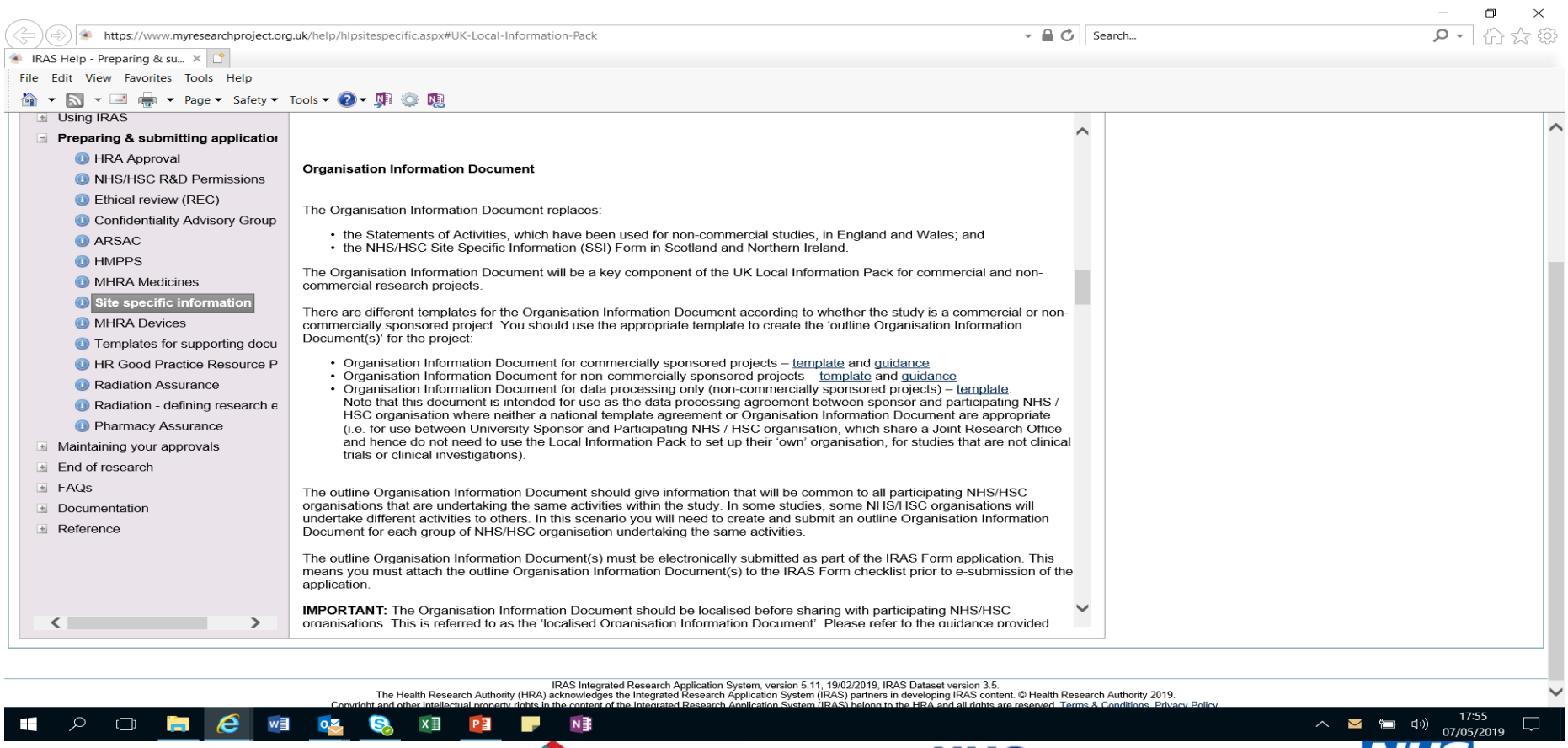
Commercial organisation information document



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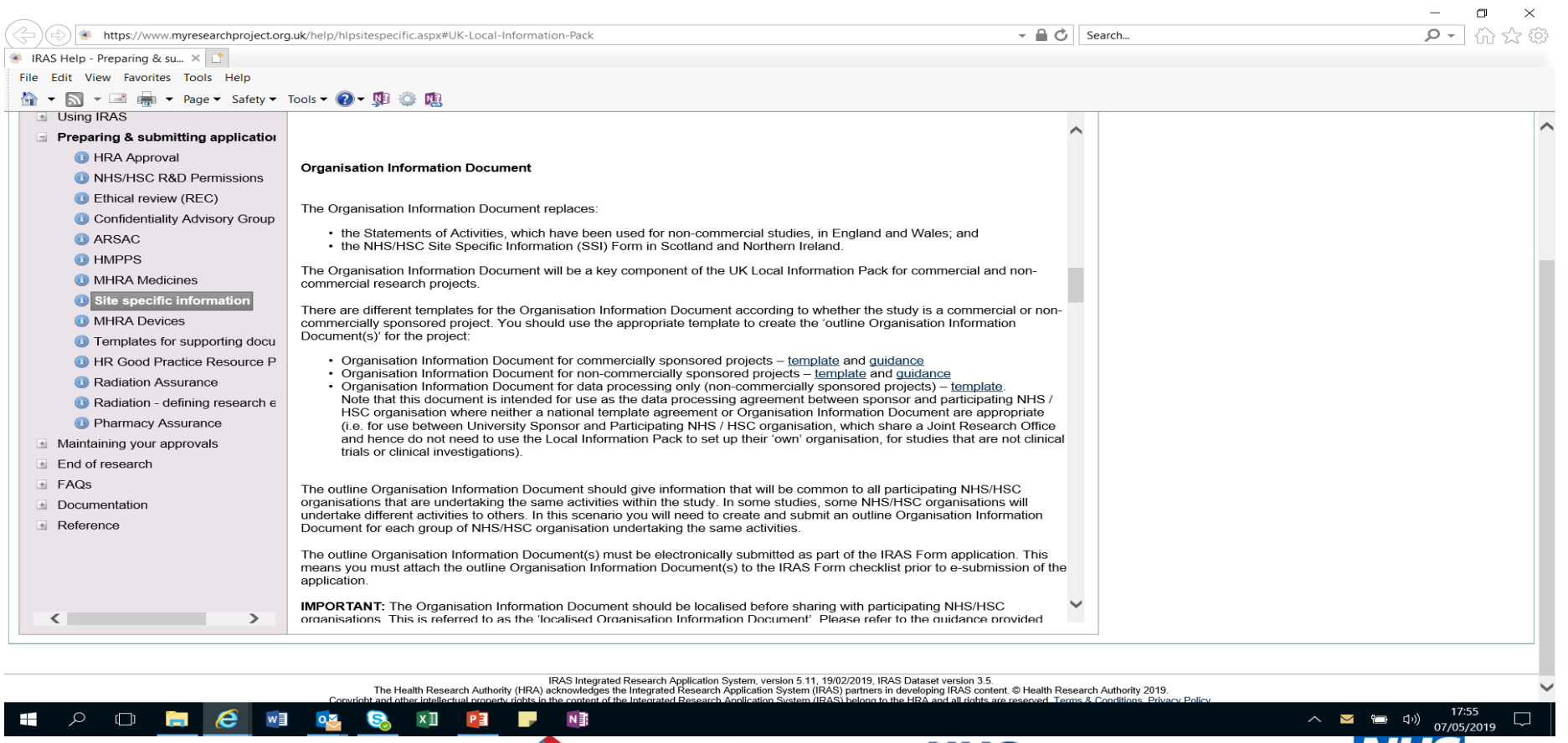
Non- Commercial organisation information document



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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*

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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*

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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*

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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*

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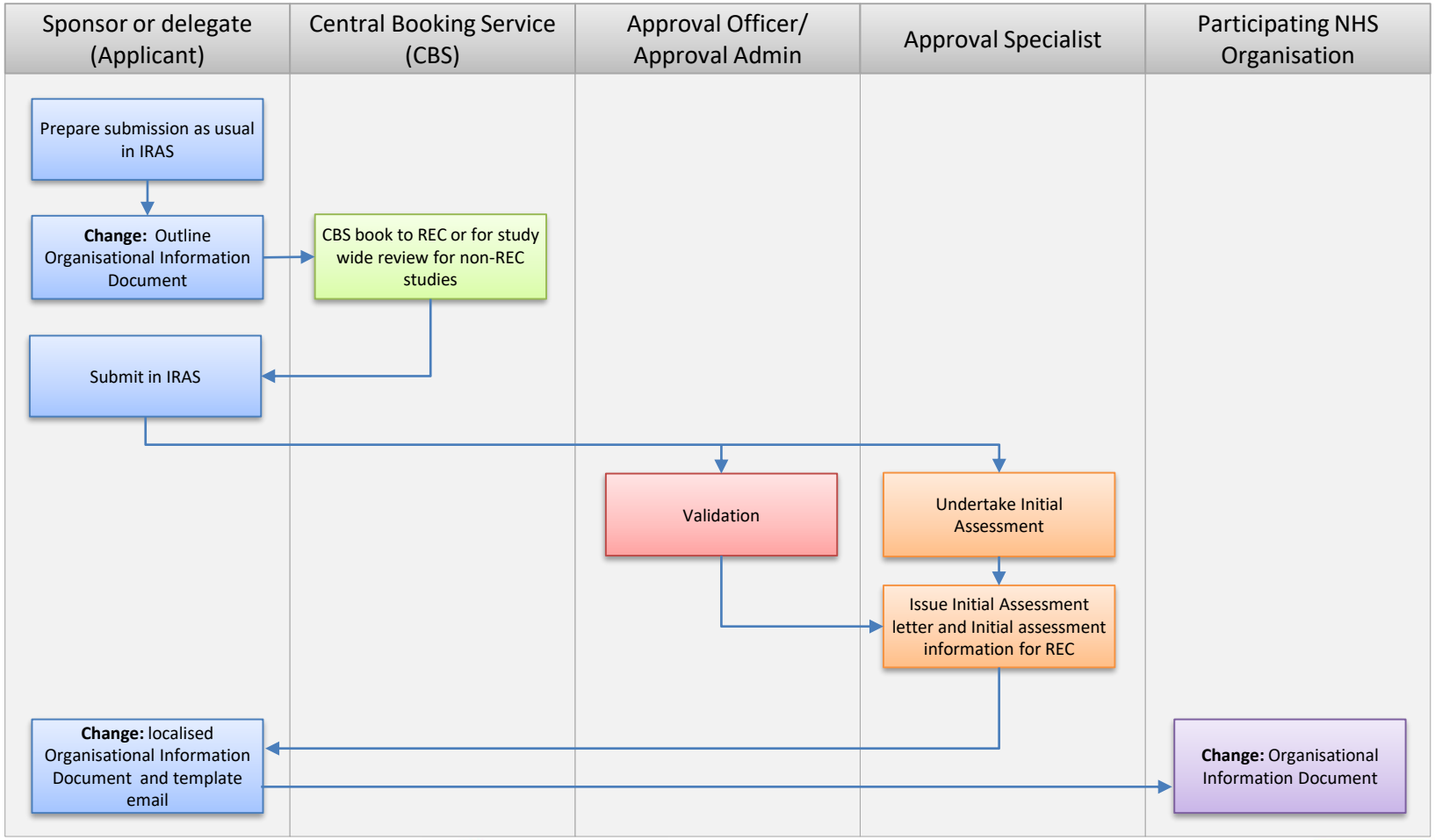
Starting the study

- 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



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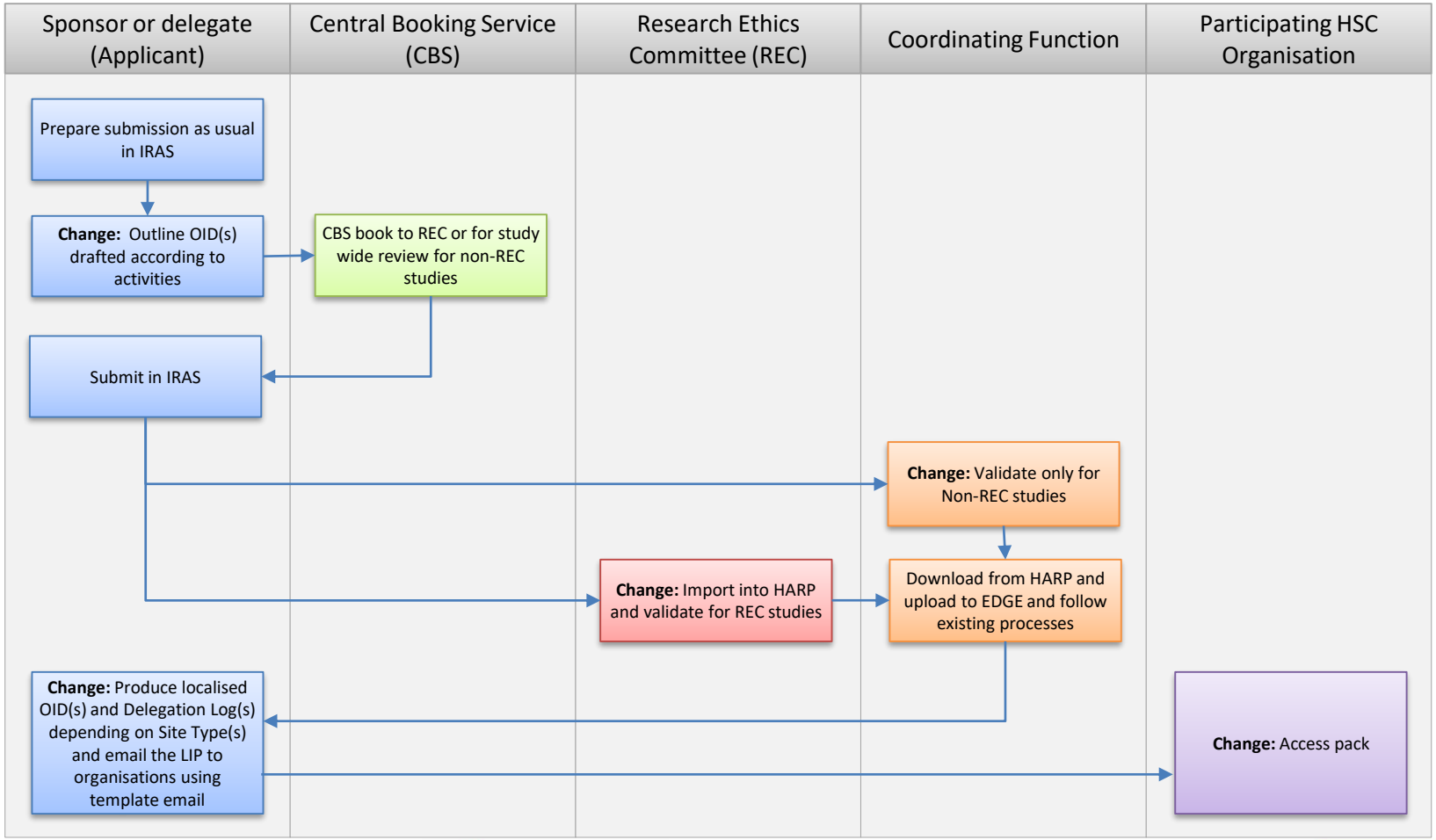
Local Information Pack – NI



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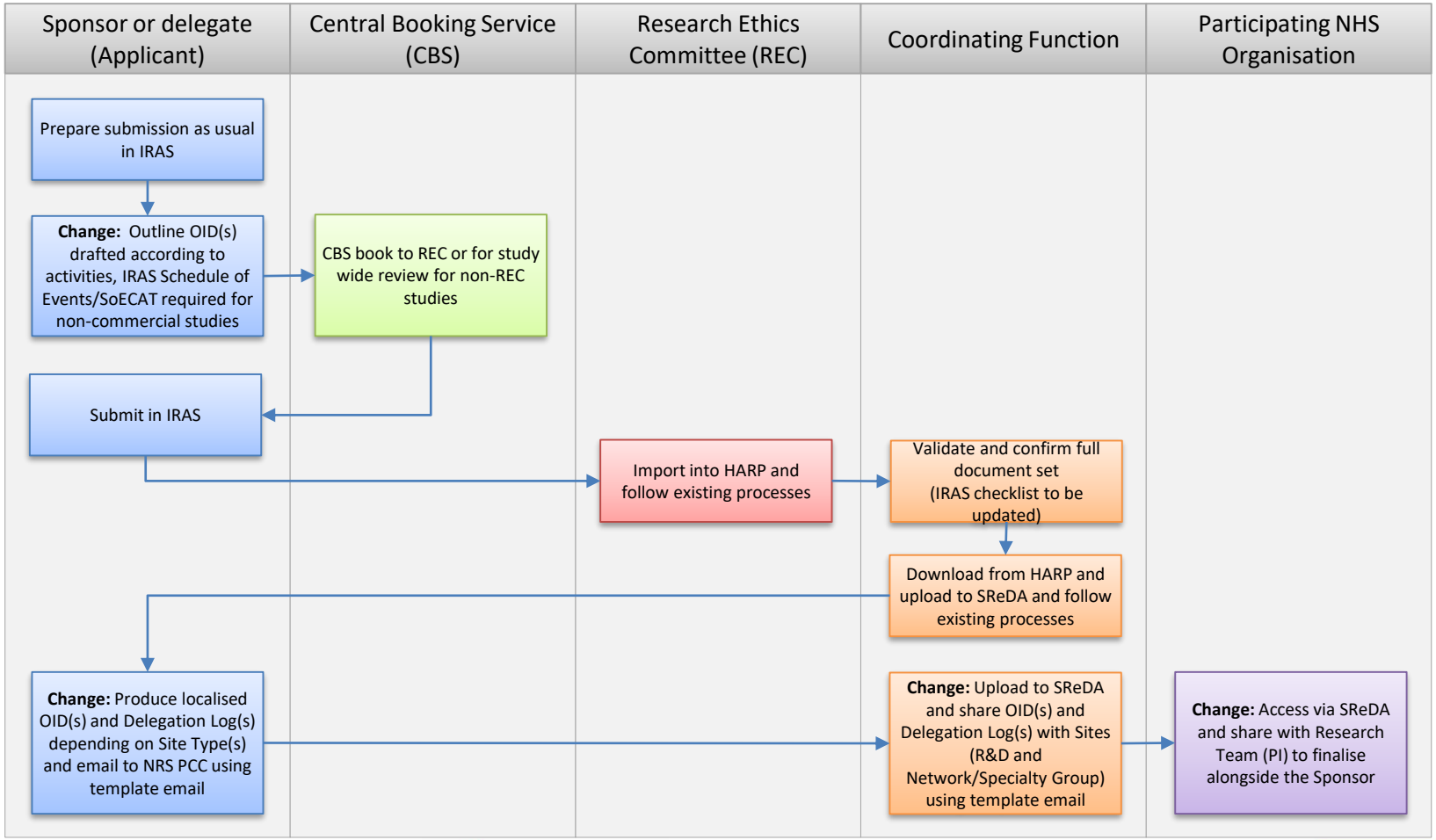
Local Information Pack – Scotland



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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

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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

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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

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