# How to complete an Organisation Information Document - commercial

This bite size presentation provides a high level overview for completing a Organisation Information Document for Commercial studies.

It should be read in conjunction with the full guidance available on IRAS

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# Organisation Information Document

An Organisation Information Document facilitates discussion to support the set up of research with participating NHS/HSC organisation(s)

It confirms:

- Who the Investigator is
- Which locations/ sites are being used within an NHS/HSC Organisation
- Who the sponsor contact is

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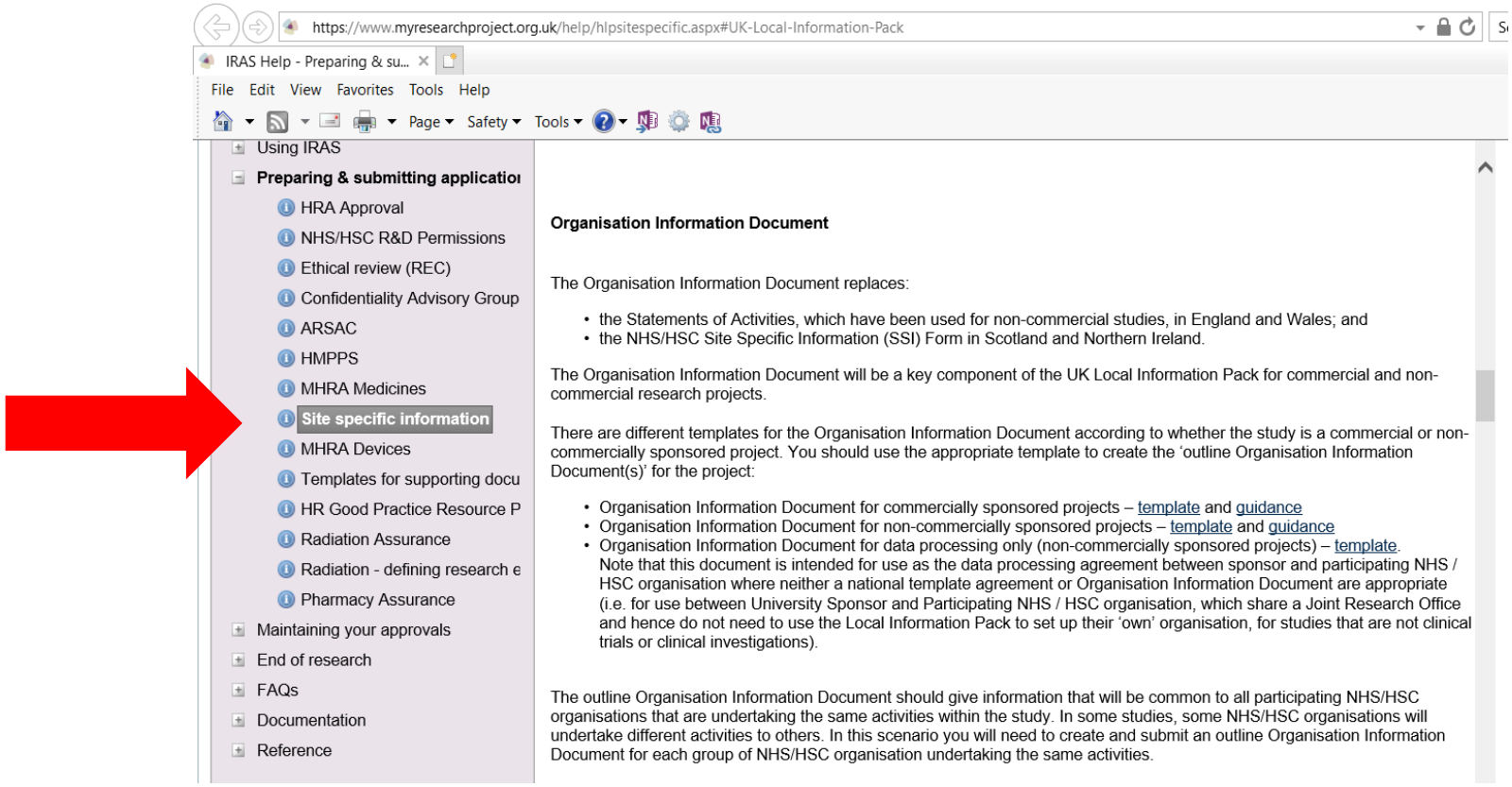
# Templates can be found in IRAS

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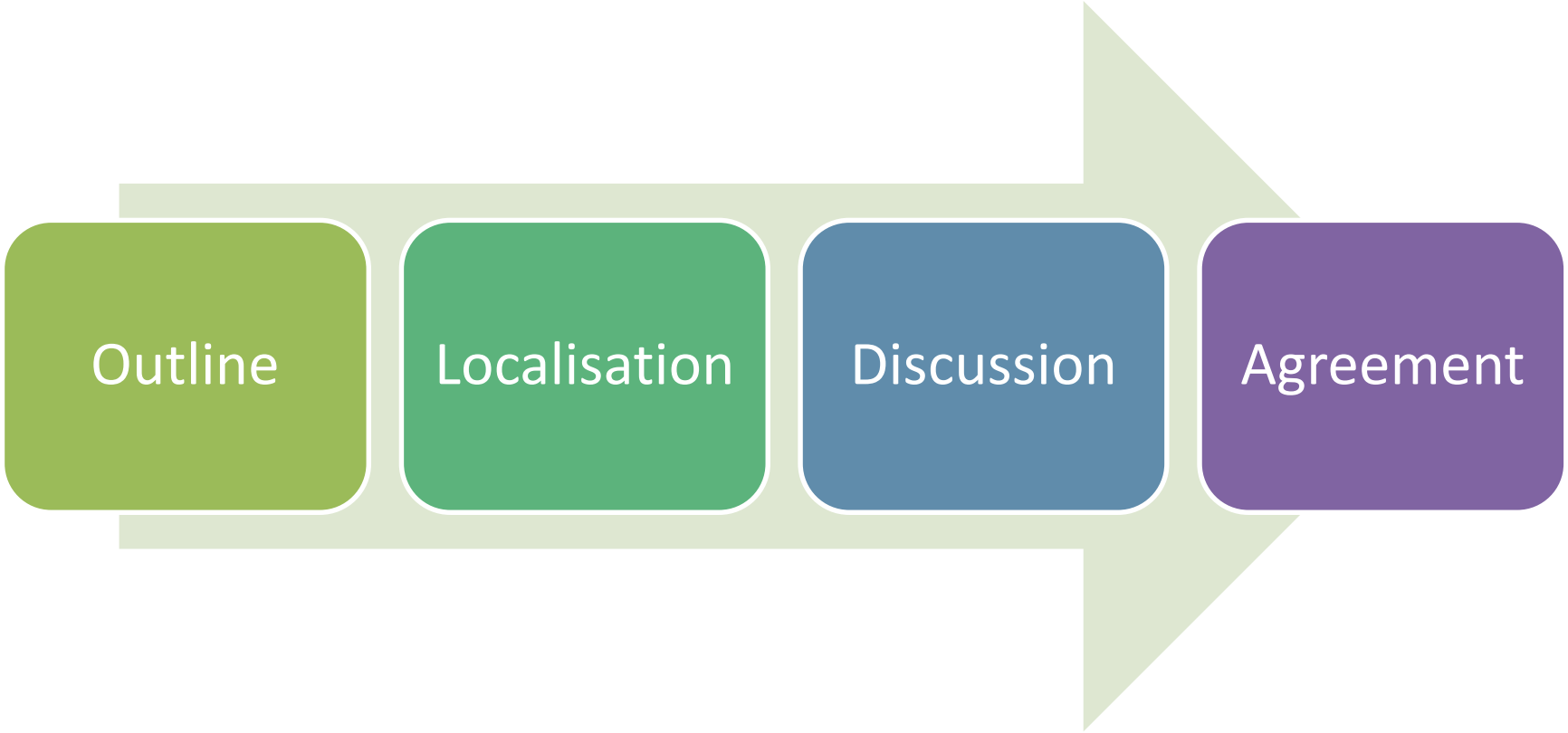
# There are 4 stages of completion

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# Stage one: Outline

- An outline Organisation Information Document is submitted as part of the IRAS submission
- An outline Organisation Information Document required for each site type
  - If all research sites are undertaking the same activities only one outline document is required

# Stage one: Outline

- Complete all questions marked with an Asterix *
- These include Questions 1, 2, 4 and 7
- Ensure you version control the document
- Attach **outline** document to the IRAS checklist

*Do not submit localised versions with IRAS application*

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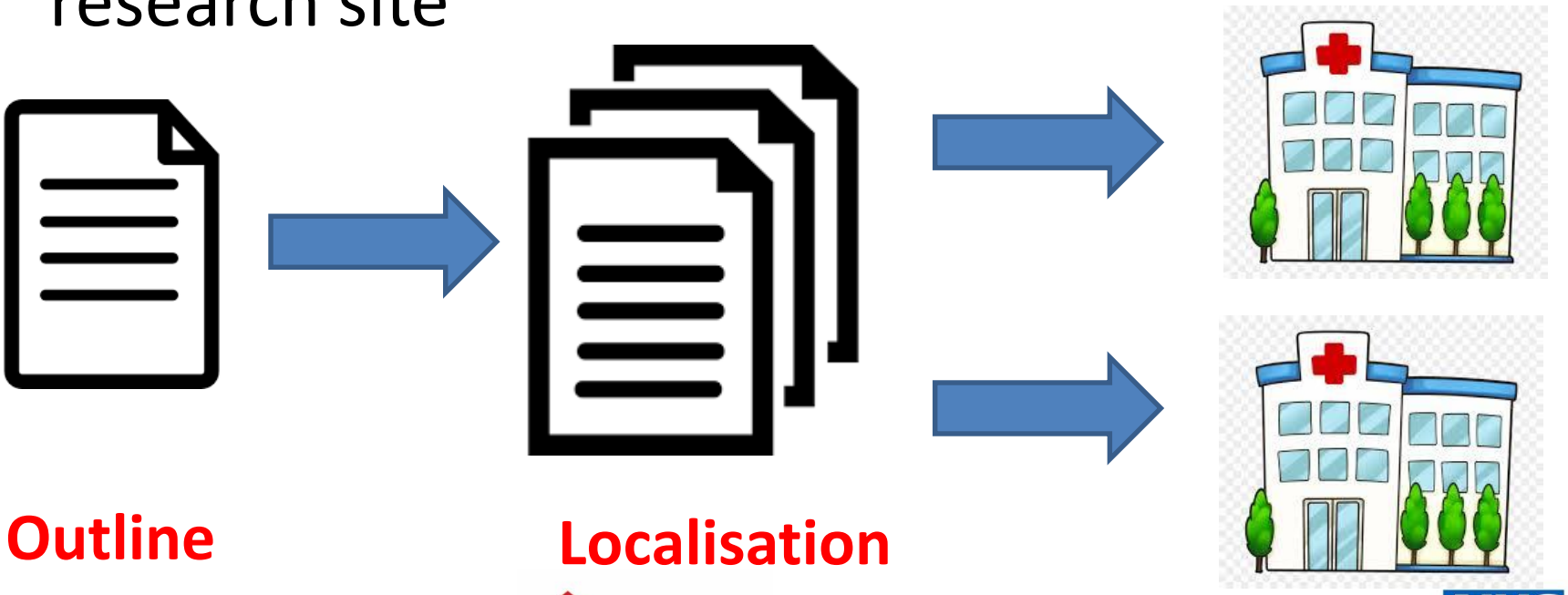
# Stage two: Localisation

Outline Organisation Information Document needs to be localised by the sponsor for each research site



**Outline**

**Localisation**

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# Stage two: Localisation

- Questions 3,5 6 and 8 are completed by the sponsor prior to sharing with a site
- For some studies, not all information will be known and will be completed in discussion with the research site
- The version control should be updated when localising

# Completing the document – it is a conversation not an application!


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# Stage three: Discussion

- After sharing with a site the Organisation Information Document is discussed and agreed, completing or updating any of the information to reflect activities at the site
- Remember for Scotland, the Organisation Information Document is shared via the NRSPCC. Use the template emails!

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# Stage four: Agreement

- Question marked ^ are completed by delegated representatives of the research site (R&D/I team)
- Completed documents are exchanged with the sponsor at the time of contract exchange and filed in the site file.

# 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

- Discuss and agree information
- Complete together

## Agreement

- ^ completed by site
- Stored in the site file

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# Completed Document

Completed Organisation Information Documents do not need to be submitted to coordinating functions or REC

Completed documents should be filed in the site file

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