



# 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](#)

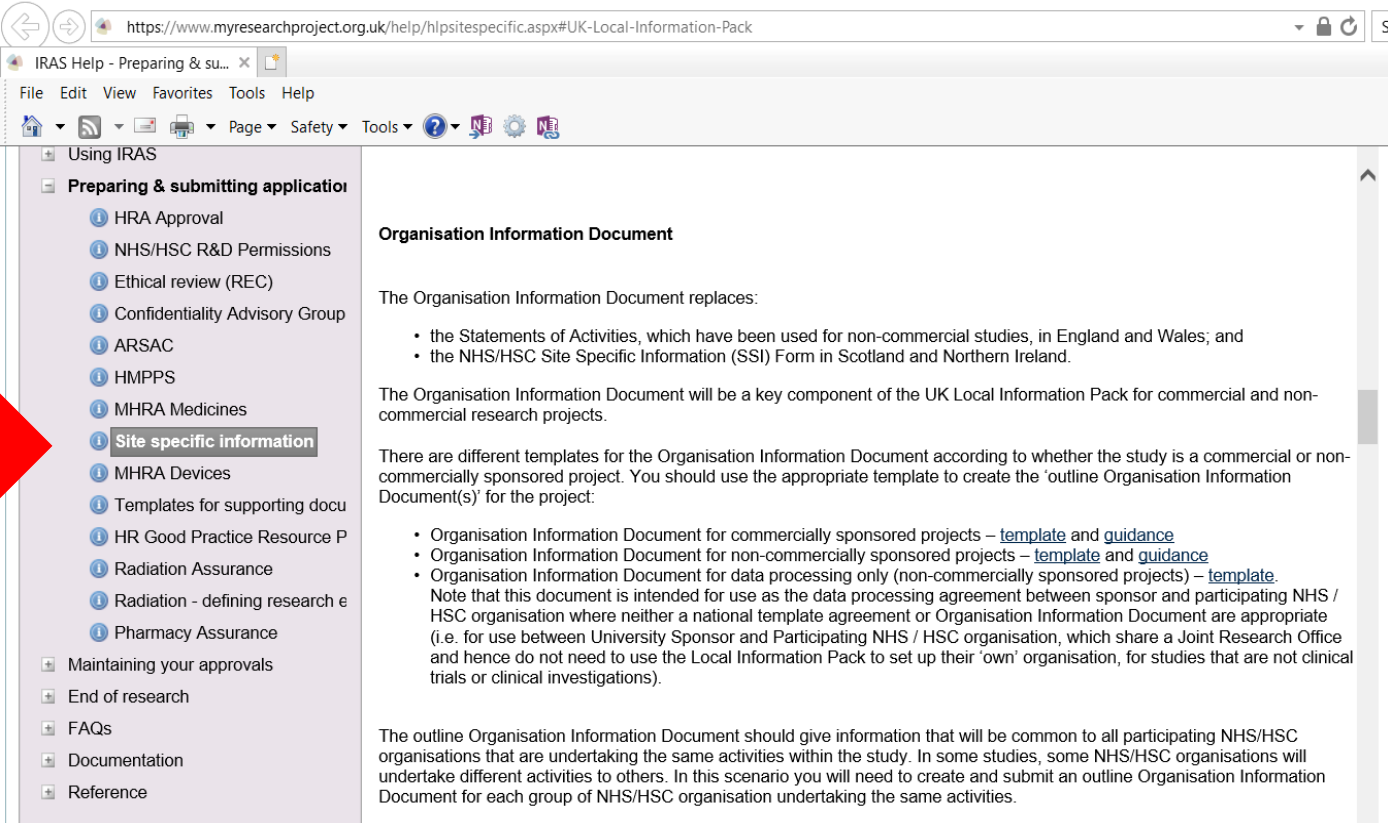
# Organisation Information Document

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

# Templates can be found in IRAS



The screenshot shows a web browser window with the URL <https://www.myresearchproject.org.uk/help/hlpsitespecific.aspx#UK-Local-Information-Pack>. The browser title is "IRAS Help - Preparing & su...". The page content is organized into a left-hand navigation menu and a main content area.

**Left-hand navigation menu:**

- Using IRAS
  - Preparing & submitting application
    - HRA Approval
    - NHS/HSC R&D Permissions
    - Ethical review (REC)
    - Confidentiality Advisory Group
    - ARSAC
    - HMPPS
    - MHRA Medicines
    - Site specific information**
    - MHRA Devices
    - Templates for supporting docu
    - HR Good Practice Resource P
    - Radiation Assurance
    - Radiation - defining research e
    - Pharmacy Assurance
  - Maintaining your approvals
  - End of research
  - FAQs
  - Documentation
  - Reference

**Main content area:**

### 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.

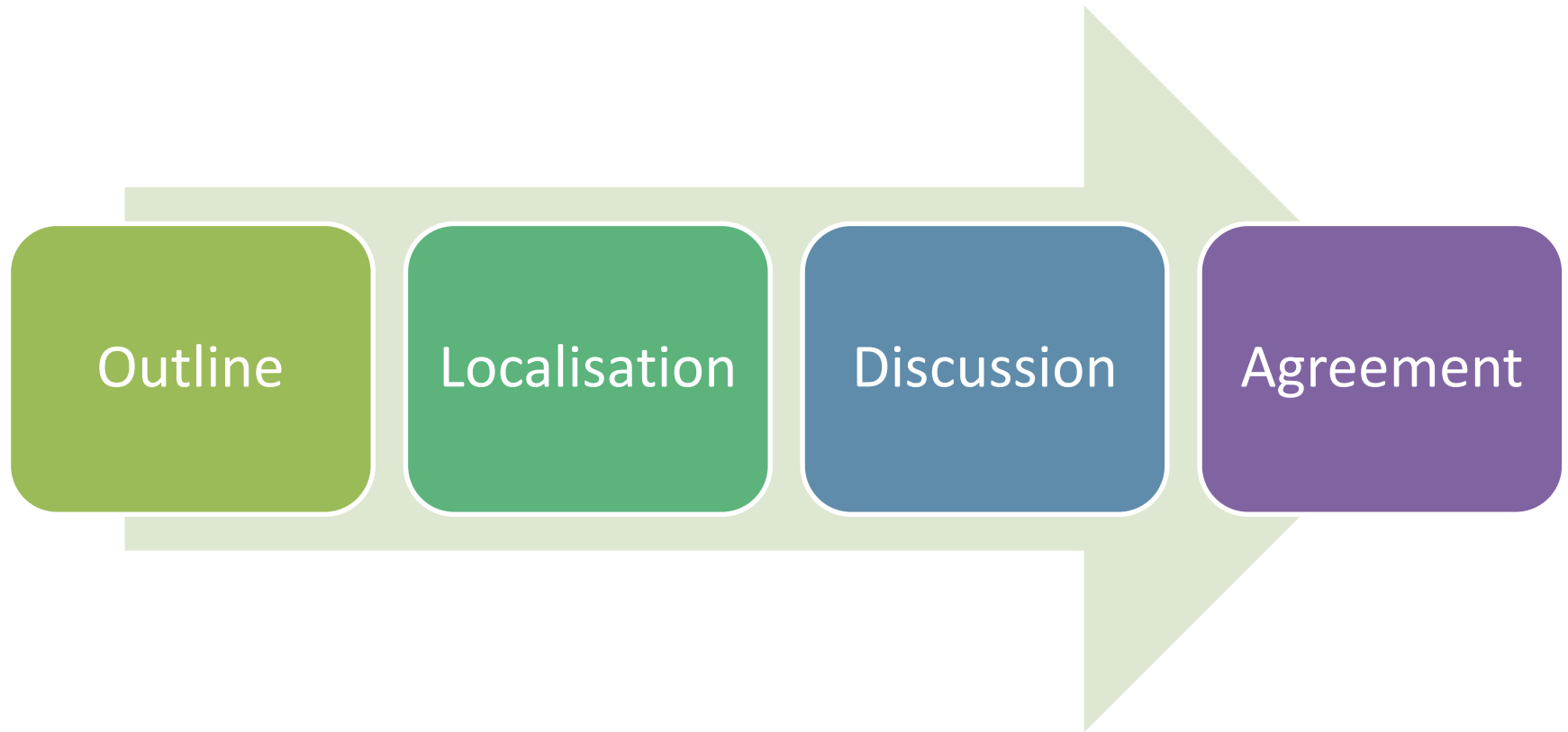
There are different templates for the Organisation Information Document according to whether the study is a commercial or non-commercially sponsored project. You should use the appropriate template to create the 'outline Organisation Information Document(s)' for the project:

- 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.

# There are 4 stages of completion



# 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*

# Stage two: Localisation

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



**Outline**

**Localisation**





# 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!



# 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!

# 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

# 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