

Guidance Document for the Commercial Organisation Information Document

(Version 1.3)

What is the Commercial Organisation Information Document?

The commercial Organisation Information Document has two main functions:

1. The outline Organisation Information Document is completed by the sponsor or authorised delegate and submitted with the IRAS application. It provides key information to facilitate the regulatory review of the submission and forms the basis from which localised Organisation Information Documents are created.
2. Following submission of the outline Organisation Information Document, it is localised¹ and shared by the sponsor or authorised delegate with participating NHS / HSC organisations as part of the UK Local Information Pack. Taken together with the documents in the pack, the localised Organisation Information Document provides the participating NHS / HSC organisation with the basis for a conversation with the sponsor or authorised delegate, to allow arrangements to be made to undertake the study locally.

In many cases, arriving at a final localised Organisation Information Document for a participating NHS / HSC organisation will be a collaborative endeavour between the sponsor or authorised delegate and the participating NHS/HSC organisation, including local research team members, the research management function supporting them, and where applicable the relevant Clinical Research Network. As such, the final localised Organisation Information Document for an organisation may require changes from the outline version submitted in IRAS, in order to appropriately reflect the final understanding between the sponsor or authorised delegate and the participating NHS / HSC organisation. Changes should be made and agreed collaboratively.

We welcome your feedback on the use of the UK Local Information Pack. If you would like to provide feedback, please take the [UK Local Information Pack Survey](#).

How do I complete my Organisation Information Document?

Questions marked with an asterisk* must be completed prior to submission of

¹ There are circumstances in which the Organisation Information Document may be shared with participating NHS/HSC organisations without first being localised, e.g. for low risk studies when sharing the document with a large number of potential participating NHS / HSC organisations. Please see 'How do I Localise my Organisation Information Document?' below for further detail.

the IRAS Form.

Questions marked with a caret[^] are completed by the participating NHS / HSC organisation, after the Local Information Pack is shared and where relevant.

Remaining questions may be answered on the localised Organisation Information Document either by the Sponsor or authorised delegate prior to sharing the Local Information Pack, or by the participating NHS / HSC organisation (or collaboratively between the two) after the Local Information Pack is shared, as appropriate.

To provide an answer in the form, click in a box with the grey text (click here to enter text), select the relevant option if presented with a drop-down list Select an item or click in the box if presented with a check-box .

Please read the question specific guidance where present in the Organisation Information Document itself. The following sections are intended to supplement that question specific guidance:

Version Control and File Naming

The version control within the footer of the Organisational Information Document is for completion by the sponsor or authorised delegate, although once the document is localised the participating NHS / HSC organisation may iterate the localised section to reflect changes to the localisation.

An appropriate file name should be chosen by the sponsor or authorised delegate to facilitate ease of identification of the correct document.

The below guidance provides standards to support file naming and version control.

For an IRAS application with **a single** outline Organisation Information Document i.e. where all participating NHS / HSC organisations are undertaking the same activities.

FILE NAME:

OUTLINE_DD_MMM_YYYY_Organisation_Information_Document_Commercial_v1_0.docx

FOOTER VERSION:

OUTLINE DD_MMM_YYYY V1.0

Changes made during the review process will result in an update to the date and version of file name and footer version.

For an IRAS application with **more than one** outline Organisational Information Document, please use the file name and footer to help provide clarity as appropriate to the activities covered by the outline documents for that study.

FILE NAME:

OUTLINE_ALL_ACTIVITIES_DD_MMM_YYYY_Organisation_Information_Document_Commercial_v1_0.docx

OUTLINE_FOLLOW_UP_ACTIVITIES_DD_MMM_YYYY_Organisation_Information_Document_Commercial_v1_0.docx

FOOTER VERSION:

OUTLINE all activities DD_MMM_YYYY V1.0

OUTLINE follow up activities DD_MMM_YYYY V1.0

Prior to sharing the Local Information Pack with a participating NHS / HSC organisation, the file name and footer version should be amended to reflect the fact that the document is now specific to the participating NHS / HSC organisation and no longer an outline (but please see “How do I localise my Organisation Information Document?” below for information on when further localisation may not be appropriate). For example:

FILE NAME:

ALL-ACTIVITIES_DD_MMM_YYYY_V1.0_[NHS ORGANISATION NAME]_DD_MMM_YYYY_V1.0

FOLLOW_UP_ACTIVITIES_DD_MMM_YYYY_V1.0_[NHS ORGANISATION NAME]_DD_MMM_YYYY_V1.0

FOOTER VERSION:

All activities DD_MMM_YYYY V1.0 – [NHS ORGANISATION NAME] DD/MMM/YYYY V1.0

Follow up activities – [NHS ORGANISATION NAME] DD_MMM_YYYY V1.0

Changes made during the process of setting up the participating NHS / HSC organisation to deliver the study will result in an update to the localised elements of the date and version in the file name and to the footer date and version.

Where localised Organisation Information Documents are being shared for separate sites within one legal entity (e.g. different hospitals within one NHS Trust or Board are being set up as separate sites), this should be reflected in the file names and footer versions. For example:

FILE NAME:

ALL-ACTIVITIES_DD_MMM_YYYY_V1.0_[NHS ORGANISATION NAME]_[HOSPITAL NAME]_DD_MMM_YYYY_V1.0

FOLLOW_UP_ACTIVITIES_DD_MMM_YYYY_V1.0_[NHS ORGANISATION NAME]_[HOSPITAL NAME]_DD_MMM_YYYY_V1.0

FOOTER VERSION:

All activities DD_MMM_YYYY V1.0 – [NHS ORGANISATION NAME]
[HOSPITAL NAME] DD_MMM_YYYY V1.0

Follow up activities – [NHS ORGANISATION NAME] [HOSPITAL NAME]
DD_MMM_YYYY V1.0

To change the version and date in the footer please:

1. Double click on footer text
2. Make changes to the version and date information
3. Click close footer in the tool bar.
4. Click save

Study Information

Questions 1-2

To be completed by the sponsor or authorised delegate prior to IRAS submission.

Please provide your IRAS ID and full title of your study.

Question 3. Contact details of person acting on behalf of sponsor for questions relating to study set up.

Please enter the contact details for the person who is the sponsor's main point of contact (or the point of contact for the party delegated to act on behalf of the sponsor) for all correspondence on setting up the study at this participating NHS / HSC organisation. This contact may be the Sponsor, a Study Manager or a Clinical Research Associate. Where a Contract Research Organisation (CRO) has been delegated to handle set up on behalf of the sponsor, the contact at the CRO may be named here. Where a Sponsor or their authorised delegate has more than one point of contact for setting-up a participating NHS / HSC organisation (e.g. different departments dealing with contracting and supplies) a main point of contact should be named as the individual who will coordinate the conversation with the participating NHS / HSC organisation on behalf of the sponsor or authorised delegate.

Where the contact is the same for all participating NHS / HSC organisations to be covered by localised versions of the same outline Organisation Information Document, this question should be answered in the outline version prior to IRAS submission. Where different contacts may be applicable to different organisations falling under the same outline Organisation Information Document (e.g. because of different regional/national scope of individuals concerned with study set-up) this question may be answered when localising the Organisation Information Documents after IRAS submission.

Question 4. Are all participating NHS / HSC organisations undertaking the same protocol activities?

To be completed by the Sponsor or authorised delegate prior to IRAS submission.

Many research studies take place at more than one participating NHS / HSC organisation (by “participating NHS / HSC organisation” we refer to the legal entity). Where this is the case, each participating NHS / HSC organisation might be required to undertake the same research procedures, e.g. identify, consent, treat and follow-up research participants. In such cases this question should be answered ‘yes’ and only one outline Organisation Information Document should be submitted with your IRAS application.

In other cases, different participating NHS / HSC organisations may be required to undertake different sub-sets of the overall set of research procedures that make up the study, e.g. some participating NHS / HSC organisations may identify and consent participants, while others treat and follow-up. In such cases one outline Organisation Information Document should be submitted for each planned scenario. Localised Organisation Information Documents are then produced, to be shared as part of your Local Information Packs, on the basis of the relevant outline.

It is important to note that the number of outline Organisation Information Documents to be submitted in the IRAS application for any one study is determined by the number of planned scenarios, not by the number of participating NHS / HSC organisations.

It is also important to note that the way NHS / HSC services are provided in the different UK nations may be relevant to the number of outline Organisation Information Documents needed for studies taking place in more than one UK nation. For example, if you are planning a study in Scotland or Wales and have different research activities being undertaken in hospitals and in GP practices, you would still need only one outline Organisation Information Document where those GP practices are within the same Health Boards as the hospitals (because in Scotland and Wales it is common, although not universal, for GPs and hospitals to be part of the same Health Board and hence different participating NHS / HSC organisations are not undertaking different procedures). If you were to look to open the same study in England as well as in Scotland and Wales, you would likely need three outline Organisation Information Documents: one to cover the Scottish/Welsh scenario where each participating NHS organisation (i.e. the Health Board consisting of the hospitals and GPs) undertakes all procedures, a second to cover NHS Trusts in England that reflects only those procedures to be undertaken in hospitals and a third to cover GP practices in England that reflects only those procedures to be undertaken at GP practices.

For the avoidance of doubt, organisations that only process data to identify potential participants, who will be recruited at a separate legal entity, are not participating NHS / HSC organisations. Such Participant Identification Centres (PICs) should not be set up using the Local Information Pack and hence separate outline Organisation Information Documents are not needed to reflect only PIC activities as part of the IRAS application. PICs should be sub-contracted from the participating NHS / HSC organisations to which they will refer. A national template PIC subcontract and further guidance is available [here](#).

Participating NHS / HSC Organisation Information

Question 5. Name of Participating NHS / HSC Organisation:

Please enter the name of the **LEGAL ENTITY** (as listed in Part C of the IRAS form or as added by amendment), e.g. NHS Health Board, NHS Trust, HSC Trust, NHS Foundation

Trust, independently contracted GP Surgery, etc. For studies taking place in primary care it is, in some cases, appropriate to name the region within which the primary care organisations sit (e.g. Part C of the IRAS form allows the applicant to name LCRNs within which individual primary care providers sit). Further information on site set-up in primary care is available [here](#).

This question should not be answered in the outline Organisation Information Document prior to the IRAS submission. Instead, it should be answered in localising Organisation Information Documents prior to sharing with participating NHS / HSC organisations (although there are circumstances in which it may be appropriate to leave the answer to this question blank at the time of sharing the pack, for completion by the participating NHS / HSC organisation afterwards, e.g. when sharing with a very large number of organisations. Please see ‘How do I share my Organisation information Pack?’ for more detail).

Question 6. Locations

Whereas question 5 asks for the participating NHS / HSC organisation, i.e. the legal entity, question 6 asks for detail on the locations within that entity where you plan to undertake research activities. This is not seeking a list of departments (e.g. pharmacy, pathology, medical imaging, etc.) but instead seeking clarity on whether you plan to use specific hospitals or units within the organisation.

Many NHS / HSC Trusts, Boards, etc. consist of multiple hospitals geographically distinct from each other, albeit within the same legal entity.

Scottish Health Boards, for example, typically consist of multiple hospitals and GP surgeries.

Many participating NHS / HSC organisations will have one or more facility dedicated for research use (e.g. a clinical research facility).

This question asks that the sponsor or authorised delegate clarify at which locations (e.g. hospital/s, GP surgeries, CRFs, etc.) they intend to undertake which activities.

This question should not be answered in the outline Organisation Document prior to the IRAS submission. Instead, it should be answered in localising Organisation Information Documents prior to sharing with participating NHS / HSC organisations. In the unlikely event that the sponsor or authorised delegate is unclear which hospitals, GP surgeries, research facilities it will use at a participating NHS / HSC organisation at the time of sharing the Local Information Pack, the answer may be left blank for completion in collaboration with the participating NHS / HSC organisation after the Local Information Pack has been shared.

Question 7. What is the role of the person responsible for research activities at the participating NHS / HSC organisation?

To be completed by the sponsor or authorised delegate prior to IRAS submission.

Most NHS / HSC organisations participating in commercially sponsored studies will be expected to have a Principal Investigator, with responsibilities for that participating NHS / HSC organisation as outlined in the [UK Policy Framework for Health and Social Care](#). There may however be instances where a Local Collaborator is appropriate, or where the Chief Investigator may be named as the person responsible for research associated activities at the participating

NHS / HSC organisation, even when the Chief Investigator is not the Principal Investigator for that organisation (because there is no need for a Principal Investigator). As set out in the question specific guidance:

- Principal Investigators are expected to be in place at participating NHS / HSC organisations where locally employed staff take responsibility for research procedures. In this scenario Principal Investigator should be selected even for single centre studies where the Chief Investigator will also be the Principal Investigator.
- Where this is not the case, Local Collaborators are expected to be in place where central study staff will be present at the participating organisation to undertake research procedures (the role of the Local Collaborator is to facilitate the presence of sponsor / CRO research staff).
- Where existing data is being provided for research purposes without additional research procedures and without the presence of central research team members at the participating organisation, select Chief Investigator.

The following definitions expand upon the above:

Principal Investigator

- Where locally employed staff take responsibility for research procedures at the participating NHS / HSC organisation you select Principal Investigator. The term “locally employed” includes those with an honorary contract.
- A Principal Investigator takes responsibility for the conduct of the research at the participating NHS / HSC organisation.
- There is usually one Principal Investigator for each participating NHS / HSC organisation. However, there may be studies for which the identification of two Principal Investigators at the same organisation is more appropriate, for example where a study involves both adult and paediatric participants two Principal Investigators with clearly demarked responsibilities may be needed to reflect the fact that there are two distinct ‘research sites’ within the one participating NHS / HSC organisation (where the study is genuinely being set up as two “sites” then two Local Information Packs are shared with the NHS / HSC organisation). There may also be instances where one Principal Investigator has responsibility for more than one participating NHS / HSC organisation.
- In the case of a single-site study, the Chief Investigator and the Principal Investigator will normally be the same person.
- In the case of a multicentre study the Chief Investigator may also be the Principal Investigator at their own participating

organisation.

- Where research procedures are delegated from the Principal Investigator to other members of the local study team they are recorded in a delegation log.

Local Collaborator

- Where locally employed staff do not take responsibility for research procedures at the participating NHS / HSC organisation and where central study staff will be present at the participating NHS / HSC organisation to undertake research procedures select Local Collaborator.
- The role of the Local Collaborator is to support practical arrangements for the presence of research staff. Their role may involve anything from booking a room for central study team staff to use, circulating information about the study, facilitating data base searches or negotiating appointments with people within their organisation.

Chief Investigator

- The Chief Investigator has overall responsibility for the research.
- In a multi-site study, the Chief Investigator is responsible for the central study team and has co-ordinating responsibility for research at all participating organisations.
- Where the involvement of a participating NHS / HSC organisation in a study is limited to providing existing data for research purposes without additional research procedures and without the presence of central research team members at the participating NHS / HSC organisation, Principal Investigators and local collaborators need not be identified and you select Chief Investigator.

Question 8. Contact details of person responsible for research activities at this participating NHS / HSC organisation as indicated in question 7 (if known).

Most participating NHS / HSC organisations in commercially sponsored studies will be expected to have a Principal Investigator and in most cases it will be expected that this individual has been identified by or to the sponsor or their authorised delegate in advance of the Local Information Pack being shared.

It would be extremely unusual in an interventional study for the sponsor or authorised delegate to have not had early feasibility conversations with the participating NHS / HSC organisation prior to sharing the local information pack. Whilst unusual, such instances are not impossible, e.g. a rare disease study, where it is impossible to know in advance of admission which organisation an individual may present to and where study treatment needs to commence rapidly after admission. Even in such cases sponsors would usually

be expected to have undertaken as much engagement with potential participating NHS / HSC organisations as possible, e.g. via the relevant Research Network.

In the rare cases where the Principal Investigator (or Local Collaborator) is not known at time of sharing of the Local Information Pack, the answer to this question may be left blank to indicate to the participating NHS / HSC organisation that the sponsor or authorised delegate requires support to identify an appropriate person.

Question 9. The Participating NHS / HSC Organisation confirms (by use of the drop-down box) that the Principal Investigator, where one is required, is aware of and has agreed to discharge their responsibilities in line with the [UK Policy Framework for Research and Social Care](#)

Questions 9 and 10 are for completion by the participating NHS / HSC organisation after the localised Organisation Information Document has been shared with them and prior to finalisation.

Question 10. The Participating NHS / HSC Organisation has considered and mitigated any conflict/s of interest declared by the principal investigator.

As above.

How do I submit my outline Organisation Information Document?

The outline Organisation Information Document should be electronically submitted as part of your IRAS application, by uploading to the IRAS Form checklist tab prior to submission.

To upload your outline Organisation Information Document please use the row allocated for this purpose in the checklist tab. Please follow the guidance at the top of the tab to add additional rows, as required, should you need to upload more than one outline Organisation Information Document.

How do I localise my Organisation Information Document?

Once the outline Organisation Information Document/s has/have been submitted in IRAS the sponsor or nominated delegate may begin to localise versions to share with participating NHS / HSC organisations as part of their Local Information Packs (where there is only one participating NHS / HSC organisation per outline Organisation Information Document, it is permissible to have localised prior to IRAS submission but care should be taken not to do so where there is a possibility of adding more participating NHS / HSC organisations).

Localised Organisation Information Documents should be based upon the outline version/s submitted in IRAS. Fields marked with an asterisk should have already been completed by this stage. Fields marked with a caret should be completed by the participating NHS / HSC organisation after the Local Information Pack is shared. All other fields should be completed either by the sponsor or authorised delegate prior to sharing, by the participating NHS / HSC organisation after sharing, or collaboratively between the two after sharing.

Where the sponsor or authorised delegate knows the answers to the unmarked

questions in advance of sharing the Local Information Pack, it should provide the answers in the localised Organisation Information Document when sharing the pack. It is likely that, in many cases, conversations between sponsor or authorised delegate and participating NHS / HSC organisation prior to sharing the Local Information Pack will be directed towards addressing these questions.

There are however circumstances in which the answers to some or all of these questions are not known when the Local Information Pack is shared. It is particularly likely that no answers are known when there has been little or no opportunity to discuss the study with participating NHS / HSC organisations in advance. Such studies are likely to involve a large number of participating NHS / HSC organisations and have minimal capacity and capability requirements and/or be of a type where it is difficult to identify the participating NHS / HSC organisations in advance. As such, there are circumstances where it is appropriate for the sponsor or their nominated delegate to not further localise the outline document prior to sharing as part of the Local Information Pack/s.

Where the answer/s to one, some or all of the unmarked questions are not known by the sponsor or authorised delegate at the time of sharing the Local Information Pack/s, these questions may be left blank for completion by participating NHS / HSC organisation and/or collaboratively with the sponsor or authorised delegate. In most cases the file name and footer version should still be localised prior to sharing of the Local Information Pack/s but in instances where there are many participating NHS/HSC organisations it may be appropriate to not localise the unmarked questions, or to localise the file name or footer version.

In the time between sharing with the participating NHS / HSC organisation and agreeing the content with them prior to research starting at the organisation, if the information changes or if corrections are necessary, updates to the information provided may be made by the participating NHS / HSC organisation in conversation with the sponsor or their authorised delegate.

How do I share my localised Organisation Information Document with Participating NHS / HSC Organisations?

Your localised Organisation Information Document should be shared as part of your Local Information Pack and will only be considered to have been formally shared if part of a complete and valid pack, under the appropriate standard template email.

How you share your Local Information Packs with participating NHS / HSC organisations, and when you may do so, depends on which UK nation the participating NHS / HSC organisation is in:

For participating NHS / HSC organisations in Scotland or Northern Ireland you may share your Local Information Packs upon validation of your IRAS application. You may share all of your packs immediately following validation, or you may share them over time, as appropriate to how you wish to time setting up your participating NHS / HSC organisations.

To share a Local Information Pack for a participating NHS / HSC organisation in **Scotland**, you should email the localised Organisation Information Document to

the [NRS Permissions Coordinating Centre](#) who will share each pack with the research office at the participating NHS / HSC organisation. The research office will then share the pack with the local Principal Investigator or Local Collaborator (as applicable and where named) and the appropriate network or specialty group as relevant. Where, exceptionally, the answer to question 8 has been left blank, the research office will contact the applicant to discuss identifying an appropriate individual.

To share a Local Information Pack for a participating NHS / HSC organisation in **Northern Ireland**, you should email (using the standard cover email template) the [research office](#) and Principal Investigator/Local Collaborator (as applicable and where named) at each participating NHS / HSC organisation. Where, exceptionally, the answer to question 8 has been left blank, the research office will contact the applicant to discuss identifying an appropriate individual.

For participating organisations in **England** or **Wales** you may share your Local Information Packs once you have received your HRA and HCRW Initial Assessment Letter, or Approval if no Initial Assessment Letter is issued. You may share all of your packs immediately thereafter, or you may share them over time, as appropriate to how you wish to time setting up your participating NHS / HSC organisations.

To share a Local Information Pack for a participating NHS / HSC organisation in **England** or **Wales**, you should email (using the standard cover email template) the [research office](#) and Principal Investigator / Local Collaborator (as applicable and where named) at each participating NHS / HSC organisation. If your study is on the NIHR portfolio, you should copy in your [Local Clinical Research Network](#). Where, exceptionally, the answer to question 8 has been left blank, the research office will contact the applicant to discuss identifying an appropriate individual.

What happens with localised Organisation Information Documents once finalised?

The final localised Organisation Information Document should be shared (by email) by the participating NHS/HSC organisation with the Sponsor or their authorised delegate and copies held by both parties (including in any site file, or equivalent as per relevant policies). Where changes have been made to the information provided by the Sponsor in the document and these have not previously been agreed with the Sponsor, the email should clarify what these changes are. In this way both participating NHS/HSC organisation and Sponsor are clear as to the practical arrangements agreed in the document.

Accessing help and support completing this document

Advice and support may be obtained from your Lead NHS R&D Office (as identified at IRAS question A 68-1) in the first instance, with advice and support also available from clinical research networks where applicable to the study.

Additional advice and support may be obtained from your Lead National

Coordinating Centre:

England: hra.approval@nhs.net

Northern Ireland: Contact the HSC R&D Office (details of offices are available via the [HSC website](#)) or the Gateway (phone: (028) 7161 1126; email: research.gateway@hscni.net).

Scotland: For further guidance on seeking NHS R&D Permission in Scotland please refer to the [NHS Research Scotland Permission Coordinating Centre website](#).

Wales: For support in working with NHS organisations in Wales email: HCRW.approvals@wales.nhs.uk.

Change History

Version 1.3, 25 September 2019

- Guidance updated to include sections on questions 9 and 10 in the Organisation Information Document.
- Addition of section on “What happens with localised Organisation Information Documents once finalised?”
- Other minor edits