27 April 2026

Requirements for University of Bristol researchers when completing the Organisation Information Document

Please ensure the steps below are followed when completing the HRA Organisation Information Document (OID) to ensure that specific University of Bristol sponsorship requirements are met.

*This document refers to Organisation Information Document template version 2.0 and will be updated from time-to-time.*

1) Complete the OID in line with University requirements and HRA guidance document (appended to this document). This guidance contains useful information for the completion of each question.
2) Please note that Participant Identification Centres (PICs) are not set up using the OID.
    - If PICs are sub-contracted by, and refer participants to, participating NHS / HSC organisation(s), a model non-commercial PIC agreement (mNC-PICA site to PIC) should be used.
    - If the PIC directs participants directly to the University, a model non-commercial PIC agreement (mNC-PICA sponsor to PIC).
3) It is expected that the OID will form the agreement between the University (as the Sponsor) and the participating NHS / HSC organisation (except clinical trials or clinical investigations as defined in IRAS). Where this is the case, all appendices should be completed. If the OID does **not** form the agreement between the parties Appendix 1 **only** should be completed.
4) Appendix 1:
    - The relevant section highlighted in yellow should be selected throughout. For the avoidance of doubt, the University acts as a single Sponsor.
    - Clause 3.2
        - Non-NHS/HSC organisations (e.g. GP practices), obtain evidence of the insurance/indemnity cover before the OID is finalised.
        - NHS/HSC organisations state that we assume they are members of an NHS indemnity scheme but should flag to the University if this is not the case prior to signing (*so they can be asked for evidence of alternative cover*).
    - **REMOVE** the last clause of section 3 concerning no-fault compensation copied below (unless required by NHS REC/HRA and provision of such cover is confirmed by the Insurance Officer. Please contact the Research Governance Team for further information.):

        *[OPTION FOR NON-NHS SPONSORS ONLY] The sponsor/co-sponsors/joint-sponsors agree/s that in respect of any personal injury or death of any participant as a result of participation in the study, it/they will provide no-fault compensation and will be insured to pay out on any such claims.*

    - Clauses 9.6.1: select the appropriate option for the study
    - Note all clauses and ensure the University complies with these, in particular: 2, 4, 6 and 7 (if anyone other than University employees and medical/dental students will access Site confidential information then the PI should contact DREI's Research Contracts Team for further advice https://www.bristol.ac.uk/red/contracts/).
5) Appendix 2
    - Note the optional wording at top of section A. This needs to be considered carefully and please note the need to notify the Site promptly when the target is reached.
    - Quarterly invoices in arrears are recommended and should be emailed to purchasing-invoices@bristol.ac.uk
    - Notes 1 and 2 should be noted each time (DREI's Research Contracts Team can advise further as required).

6) Appendix 4: clause 5.l.i. – enter email address for contact within the study team, e.g. Chief Investigator or generic mailbox, to which personal data breaches can be reported. The study team must then onward report these to the Research Governance team via the Quality Events process.
7) Appendix 5: select yes where identifiable and/or pseudonymised data is being transferred from participating NHS / HSC organisation to University.
8) Appendix 6: select yes.
9) Please contact the Research Governance Team to arrange signature of the declaration on page 6 (Question 18) **prior** to submission on IRAS.

# Guidance Document for the Non-Commercial Organisation Information Document

**(Version 2.0 28 April 2026)**

## What is the Non-Commercial Organisation Information Document?

The Non-Commercial Organisation Information Document has three 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 localised by the Sponsor or authorised delegate[1] and shared 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.

3. For non-commercial studies that are not clinical trials or clinical investigations, the agreed final Organisation Information Document (taken together with the documents in the Local Information Pack and the exchange of correspondence) forms the agreement between the participating NHS / HSC organisation and the Sponsor, once confirmed by the participating NHS / HSC organisation. For all other non-commercial studies, it is expected that the model Non-Commercial Agreement (mNCA) is used as the agreement (although the localised Organisation Information Document is still needed in the Local Information Pack, for the information it contains).

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

[1] There are circumstances in which the Organisation Information Document may be shared with participating NHS / HSC organisations without first being localised, for example 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.

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 may require changes from the outline version submitted in IRAS and the localised version shared with the NHS / HSC organisation, 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.

## How do I complete my Organisation Information Document?

Questions/items marked with an asterisk* (Questions 1-3, 5, 8 and 12-15 and 18, as well as items throughout the appendices as applicable) must be completed prior to submission of the IRAS Form. The question for Appendix 1 should be answered by the Sponsor or their authorised delegate prior to IRAS submission in all cases. Only if the localised Organisation Information Document is to be used as the agreement between the parties should the Sponsor or authorised delegate check the relevant check-boxes at the top of each subsequent appendix. In all cases the Sponsor authorisation at question 18 should be completed prior to submission of the outline Organisation Information Document in IRAS.

Items 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), or select the relevant option if presented with a drop-down list.

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, that is where all participating NHS / HSC organisations are undertaking the same activities:
>
> **FILE NAME:**

OUTLINE_DD_MMM_YYYY_Organisation_Information_Document_NonCommercial_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_NonCommercial_v1_0.docx

OUTLINE_FOLLOW_UP_ACTIVITIES_DD_MMM_YYYY_Organisation_Information_Document_NonCommercial_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 (for example 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 1-3

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

Please provide your IRAS ID and full title of your study. Please provide the legal name of the Sponsor, co-Sponsors or joint-Sponsors (this is critical where the document is used as the agreement for the study and is referenced in Clause 2.3. of Appendix 1: General Provisions).

### Question 4. 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 Clinical Trials Unit (CTU) or Contract Research Organisation (CRO) has been delegated to handle set up on behalf of the Sponsor, the contact at the CTU or 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 (for example 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 (for example 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 5. 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, for example 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 or Wales, you would likely need three outline Organisation Information Documents: one to cover the Scottish / Welsh scenario where each participating NHS organisation (that is, 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 on the IRAS website.

## Participating NHS / HSC Organisation Information

### Question 6. 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 modification), for example NHS Health Board, NHS Trust, HSC Trust, NHS Foundation Trust, independently contracted GP Surgery, et cetera. For studies taking place in primary care it is, in some cases, appropriate to name the region within which the primary care organisations sit (for example Part C of the IRAS form allows the applicant to name LCRN region in England within which individual primary care providers sit, in Scotland and Wales the Health Board can be named). 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, such as when sharing with a very large number of organisations. Please see 'How do I share my Organisation information Pack?' for more detail).

### Question 7. Locations

Whereas question 6 asks for the participating NHS / HSC organisation, that is the legal entity, question 7 asks for detail on the locations within that entity where you plan to undertake research activities. This is not seeking a list of departments (for example pharmacy, pathology, medical imaging, et cetera) but instead seeking clarity on whether you plan to use specific hospitals or units within the organisation.

Many NHS / HSC Trusts, Boards, et cetera 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 (for example a clinical research facility).

This question asks that the Sponsor or authorised delegate clarify at which locations (for example 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 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 8. 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.

Not all participating NHS / HSC organisations need to have a Principal Investigator in place to take responsibility for research activity at that organisation. Depending on the activities to be undertaken at the organisation, and who will undertake them, it may instead be appropriate for the participating NHS / HSC organisation to have a Local Collaborator. Or it may be that the Chief Investigator should 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 site 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 site to undertake research procedures (the role of the Local Collaborator is to facilitate the presence of Sponsor / CTU 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 site, select Chief Investigator.

The following definitions expand upon the above:

<u>Principal Investigator</u>

- 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 NSH / 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 9. Contact details of person responsible for research activities at this participating NHS / HSC organisation as indicated in question 8 (if known).**

Many but not all participating NHS / HSC organisations will be expected to have a Principal Investigator or Local Collaborator (see above) 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, for example 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, for example via the relevant Research Network.

In some study types, it is more likely that the Sponsor or authorised delegate has not been able to engage with all of its participating NHS / HSC organisations in advance of sharing the Local Information Pack and have therefore not been able to identify a Principal Investigator or local collaborator at each organisation. In such instances it is appropriate that the sharing of the Local Information Pack serves as the request by the Sponsor or authorised delegate to the participating NHS / HSC organisation for support in identifying an appropriate person to fulfil the role.

Where the Principal Investigator (or Local Collaborator) is not known at the 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.

## Timescales

### Question 10. Predicted Start and End Dates of the Study at this Participating NHS / HSC Organisation

Where all participating NHS / HSC organisations to be covered under the one outline Organisation Information Document are to share the same start and end dates, the Sponsor or authorised delegate may complete their section in the outline prior to IRAS submission. In other cases it will be appropriate to only complete this section in localising the Organisation Information Documents prior to sharing with each participating NHS / HSC organisation, thereby proposing dates specific to each organisation to reflect, for example, staging / staggering of study set-up.

Alternatively, this may be left blank when the Local Information Pack is shared to allow for agreement during study set up at the Participating NHS / HSC Organisation.

For many study types the detailed dates requested will not be applicable (N/A) and this may be stated in answer.

## Participant Numbers

### Question 11. How many research participants are expected at this participating NHS / HSC organisation?

It is likely that different participating NHS / HSC organisations will have different recruitment targets and in such cases this section should not be completed in the outline Organisation Information Document prior to the IRAS submission. Instead, where early feasibility conversations have taken place, or the Sponsor otherwise has a target in mind, this should be completed when localising the Organisation Information Document for sharing. In some cases, it will be appropriate to leave this section blank in the shared localised Organisation Information Document, to allow for recruitment targets to be agreed and recorded after the Local Information Pack has been shared.

For studies not directly involving human participants, this section should indicate the number of samples or data-sets to be obtained.

It is important that it is made clear whether the number of participants indicated is per month, per year, overall etc.

## Study Set-Up and Delivery Arrangements at Participating Organisations

### Question 12. The following are needed at the participating NHS / HSC organisation to deliver the study:

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

This section allows the Sponsor or authorised delegate to indicate any specific expectations or requirements that will be needed to successfully set up and deliver

the study at the participating NHS / HSC organisations. This may be specific equipment, particular patient / participant groups, service support, nursing time, et cetera. This may also be used to set out any requirements on the participating NHS / HSC organisation relating to remote monitoring and / or auditing and / or access requirements. For example, where the participating NHS / HSC Organisation will be expected to complete remote monitoring forms and / or provide copies of staff signature and delegation logs, such expectations should be made clear here.

This section also provides an opportunity for the applicant to highlight where staff members external to the participating NHS / HSC organisation will be coming to the site. Even where it is not known at the time of sharing the Local Information Pack who will be visiting site, where it is known that such access will be required for a particular purpose, providing clarity on this to the participating NHS / HSC organisation at this time may allow for preparatory work to commence.

**Question 13. The following training will be provided by the Sponsor for local research team members.**

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

Where only specific team members (for example the Principal Investigator) will receive this training, this should be specified.

The Sponsor or authorised delegate should, where appropriate, use this opportunity to clarify which research team members need to have received the relevant training before the study may commence and what arrangements there are to provide training to research team members who join the team later.

**Question 14. The Sponsor expects that local research team members will have the following skills and where they do not have those skills that they will undertake the relevant training before undertaking the relevant study activities.**

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

Whilst it would not be usual for the Sponsor or authorised delegate to expect study specific training additional to that which it will provide. This section does however allow Sponsors to state, for example, that when they expect training in Good Clinical Practice for appropriate team members where the study is a Clinical Trial of an Investigational Medicinal Product, they will accept UK nationally recognised GCP training, training recognised on the Transcelerate mutual recognition scheme, et cetera.

The Sponsor or authorised delegate should, where appropriate, use this opportunity to clarify which research team members need to have received any applicable training before the study may commence.

**Question 15. The following funding / resources / equipment, etc. is to be provided to this participating NHS / HSC organisation.**

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

The Sponsor should answer this question whether this Organisation Information Document is to be used as the agreement between participating NHS / HSC organisation or not. Where the document is intended as the agreement, further detail should be

provided in Appendix 2.

This question is intended to supplement the IRAS Schedule of Events / SoECAT that also forms part of the Local Information Pack, by clarifying what research funding, resources, equipment, et cetera will be provided to the participating NHS / HSC organisation, as well as allowing the Sponsor or authorised delegate to describe the arrangements and / or conditions applicable to this.

Although the question should be answered prior to IRAS submission, it may be appropriate to further localise the answer prior to sharing the localised Organisation Information Document (for example all participating NHS / HSC organisations may require access to a specific piece of equipment, which should be set out in answering question 12. If all but one participating NHS / HSC organisations already has such access and the Sponsor or authorised delegate therefore intends to loan the equipment to only one organisation, this should be stated only in the document localised for that organisation).

**Question 16. 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 16 and 17 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 17. The Participating NHS / HSC Organisation has considered and mitigated any conflict/s of interest declared by the principal investigator.**

As above.

## Sponsor Authorisation

**Question 18. Authorised on behalf of Sponsor by:**

In all cases (that is, whether or not it is intended to use the localised Organisation Information Document as the agreement), Sponsor authorisation should be obtained prior to submission of outline Organisation Information Documents in IRAS. It is not intended that this confirmation involves wet-ink signatures, or the passing of hard copies between the Sponsor and participating NHS / HSC organisation. The authorisation on behalf of the sponsor should be provided by an individual empowered by the sponsor organisation to authorise IRAS submissions (it would not be usual for the Chief Investigator or other research team member to be formally authorised this role by the sponsor).

## Appendices

Each appendix has a box at its top with drop-down options to allow the Sponsor or their authorised delegate to indicate whether the localised Organisation Information Document is to be used as the agreement between the parties (that is, where the study is neither a clinical trial or investigation) and, if so, which appendices form part of the agreement. The question for appendix 1 should be answered by the Sponsor or their authorised delegate prior to IRAS submission in all cases. Only if the localised Organisation Information Document is to be used as the agreement between the parties should the Sponsor select from the drop-down options at the top of each subsequent appendix.

For the avoidance of doubt – the Organisation Information Document should be used as the agreement between Sponsor or authorised delegate and the participating NHS / HSC organisation for non-commercial studies that are not clinical trials or investigations (that is, not one of the top four IRAS study categories). The model Non-Commercial Agreement (mNCA) should be used for clinical trials and clinical investigations. Where the localised Organisation Information Document is used as the Agreement between the parties, by incorporation into an exchange of correspondence it forms a legally binding contractual Agreement consisting of the invoked appendices and the information agreed between the parties in the main body of the document.

### Appendix 1 – General Provisions

Where the localised Organisation Information Document is to be used as the Agreement between Sponsor and participating NHS / HSC organisation (i.e. non-commercial studies that are not clinical trials or investigations) this appendix always forms part of that Agreement (all subsequent appendices are optional, dependent on the nature of the study and the activities at the participating NHS / HSC organisation).

### Appendix 2 - Study Set Up Arrangements

Where the Organisation Information Document is to be used as the Agreement between Sponsor and participating NHS/HSC organisation the Sponsor or authorised delegate should state whether any funding, resources and / or equipment are to be provided by the Sponsor or authorised delegate to the participating NHS / HSC organisation. Where there is to be such provision, it should be detailed here.

The outline Organisation Information Document should be partially completed by the Sponsor or authorised delegate before submitting as part of the IRAS application.

Where applicable, remittance details should be completed by each participating NHS / HSC organisation after the Local Information Pack is shared and provided directly to the Sponsor or authorised delegate, to facilitate payment.

### Appendix 3 – Material Transfer Provisions

This appendix allows the Sponsor and participating NHS / HSC organisation to agree the transfer of human biological material, including relevant material under the Human Tissue Act 2004/2006 (as applicable), and is in line with the guidance for Sponsors and participating organisations in the UK-wide study-wide governance criteria on the use of material transfer agreements.

Where the Organisation Information Document is being used as the Agreement, the Sponsor or authorised delegate should use the options boxes at the top of the appendix to make clear whether or not human biological material is to be transferred and hence whether or not this appendix is to form part of the Agreement.

### Appendix 4 – Data Processing Agreement

Where the Organisation Information Document is being used as the Agreement and the study involves the processing of personal data for research purposes by a participating NHS / HSC organisation on behalf of the Sponsor, the Sponsor or authorised delegate should indicate that these GDPR compliant provisions are to form part of the agreement with its participating NHS / HSC organisation/s.

For the avoidance of doubt, this data processing agreement is intended to form a legally binding contract between Sponsor and participating NHS / HSC organisation. This is to meet the requirements of the GDPR generally and of GDPR Article 28 (3) specifically.

If the participating NHS / HSC organisation will not be receiving referrals from Participant Identification Centres (PICs) for the study, the yellow highlighted text at 5b should be deleted prior to sharing with the participating NHS / HSC organisation (this may be removed before submitting the outline Organisation Information Document in IRAS, where no organisations to come under the document will use PICs). Similarly, where the participating NHS / HSC organisation will be sub-contracting data processing to PICs but each such PIC sub-contract must be agreed individually in advance by the Sponsor, the yellow highlighted text should be removed. The yellow highlighted text should be retained, and the highlight removed, only where the Sponsor is authorising the participating NHS / HSC organisation to sub-contract with PICs without the Sponsor approving each individual sub-contract in advance (albeit that the participating NHS / HSC organisation will notify the sponsor of new PICs in advance of activating their PIC activity).

Where the PIC arrangements for the study alter after a localised Organisation Information Document is agreed, this may require clause 5b in this appendix to be varied with individual participating NHS / HSC organisation (for example if the sponsor chooses to add the identification of potential participants by the use of PICs only after the study has commenced).

**Appendix 5 – Data Sharing Agreement**

Where the Organisation Information Document is being used as the Agreement and the study involves the transfer of personal data or pseudonymised data from the participating NHS / HSC organisation to the Sponsor or one or more agent/s of the Sponsor, the Sponsor or authorised delegate should indicate that this appendix forms part of the Agreement. The data sharing terms are designed to safeguard not only personal data leaving the NHS / HSC but also to safeguard data that has been rendered no longer personal data to the recipient (for example, to place obligations on the Sponsor and its agents to not attempt to re-identify data that has been pseudonymised).

**Appendix 6 – Intellectual Property Rights**

Where the Organisation Information Document is being used as the Agreement and where a study requires the protection of background intellectual property rights (that is, rights held by a party prior to the Agreement), or there is potential for the generation of new intellectual property to arise as a result of the study, the Sponsor or their authorised delegate should indicate that this appendix forms part of the Agreement.

## How do I submit my outline Organisation Information Document?

The outline Organisation Information Document/s 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/s 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 (questions 1-3, 5, 8 and 12-15 and 18 and asterisked questions throughout the appendices) should have already been completed by this stage. Fields marked with a caret in Appendix 2 and in the authorisations section should be completed by the participating NHS / HSC organisation after the Local Information Pack is shared. All other fields (questions 6, 7, 9, 10 and 11) 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 questions 6, 7, 9, 10 and 11 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 questions 6, 7, 9, 10 and 11 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 questions 6, 7, 9, 10 or 11, 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 9 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 or Local Collaborator (as applicable and where named) at each participating NHS / HSC organisation. Where, exceptionally, the answer to question 9 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 Letter 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 or 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 Regional Research Delivery Network. Where, exceptionally, the answer to question 9 has been left blank, the research office will contact the applicant to discuss identifying an appropriate individual.

## Authorisation when using this Organisation Information Document

## as an Agreement

Where the Organisation Information Document forms the Agreement between the Sponsor and a participating NHS / HSC organisation in England or Wales or Northern Ireland, with no additional agreement (for example a mNCA) to be put in place, agreement of the parties to the information in the documents confirms that the participating NHS / HSC organisation has the capacity and capability to deliver the study and intends to commence the study locally on the date stated.

Where the Organisation Information Document forms the agreement between the Sponsor and a participating NHS organisation in Scotland, with no additional agreement (such as a mNCA) to be put in place, agreement of the parties to the information in the documents is provided before or simultaneously with the participating NHS organisation issuing NHS Permission.

It is not intended that this confirmation involves wet-ink signatures, or the passing of hard copies between the Sponsor and participating NHS / HSC organisation. Instead, Sponsors are expected to accept confirmation by email from an individual empowered by the participating NHS / HSC organisation to agree to the commencement of research (including any budgetary responsibility, where the study involves the transfer of funds). Similarly, the authorisation on behalf of the sponsor should be provided by an individual empowered by the sponsor organisation to confirm on behalf of the sponsor, for example the person signing off the IRAS form (it would not be usual for the Chief Investigator or other research team member to be formally authorised this role by the sponsor).

Where additional information has been added to the Organisation Information Document subsequent to the IRAS application and / or sharing of the localised version (for example bank transfer details, name of PI, etc.), or information originally provided has been updated, such email confirmation should include copies of the final localised Organisation Information Document that forms the agreement.

## What happens with localised Organisation Information Documents once finalised?

When the localised Organisation Information Document is being used as the agreement between the Sponsor and participating NHS / HSC organisation, the finalised version should be provided by the participating NHS / HSC organisation to the Sponsor or their authorised delegate by email (see above section on Authorisation). Copies of the Agreement should then be held by participating NHS / HSC organisation and Sponsor in line with their relevant policies, including in any site file or equivalent.

When a separate agreement is being used, the final localised Organisation Information Document should still be emailed to the Sponsor or their authorised delegate by the participating NHS / HSC organisation 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, even

where a separate legal agreement exists.

## Organisation Information Document (Data Processing Agreement ONLY) – Non-commercially Sponsored projects

It is not expected that all close partnerships between universities and participating NHS / HSC organisations (particularly those served by a Joint Research Office) will elect to use Local Information Packs, including localised Organisation Information Documents, to set up their 'own' organisation. It is however a requirement of GDPR (Article 28 (3)) that data processors (that is, participating NHS / HSC organisations undertaking research on behalf of a separate Sponsor organisation) are legally bound in specific ways to their data controllers (their Sponsor). As such, where the study is not a clinical trial or clinical investigation, and hence mNCA is not used, there remains a requirement for a contractual data processing agreement to be in place. To save the need for such university / NHS JRO partnerships to make use of the full non-commercial Organisation Information Document, a stand-alone non-commercial Organisation Information Document (Data Processing Agreement ONLY) has been developed.

The document consists of three elements; a study information section, which should be used to identify the study and the parties to the agreement; data processing clauses derived from those in the UK template mNCA, and; authorisation boxes for the parties to record their agreement. As with the full non-commercial Organisation Information Document, it is not intended that agreement requires the use of wet-ink signatures or exchange of hard copies. Further guidance is not provided on how agreement should be recorded and at what juncture, as this is a matter between partner organisations. Formal, legal agreement must be in place before the participating NHS / HSC organisation commences processing data for the purpose of the study on behalf of the Sponsor.

## 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:** approvals@hra.nhs.uk

**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.approvals@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, 9 June 2019:

- Appendix 4 – Data Processing Agreement:
    - Guidance added on inclusion or deletion of yellow highlighted text relating to use of PICs.

### Version 1.4, 6 July 2019

- Minor changes to reflect replacement of check-boxes in the Organisation Information Document with drop-down option boxes.
- "Authorisation when using this Organisation Information Document as an Agreement"
    - Clarification on suitable persons to authorise the Organisation Information Document on behalf of the sponsor.

### Version 1.5, 18 September 2019

- Updated to reflect incorporation of questions 16, 17 and 18 in the main body of the document (to be completed whether or not the document is to be used as the agreement – unlike in previous version where the questions were answered only when the document was to be used as the agreement).
- Addition of section on 'What happens with localised Organisation Information Documents once finalised?'
- Other minor edits

### Version 1.6, 12 November 2020

- Updated to include a new link for feedback and new contact details, where they have changed.

### Version 1.7, March 2024

- Removed details for providing feedback.
- Renaming of 'Finance Provisions' to 'Study Set Up Arrangements' in line with changes made to the Organisation Information Document.
- Updated email address for Northern Ireland Gateway
- Other minor edits.

### Version 1.8, April 2024

- Corrected clause numbering in Appendix 1.

### Version 2.0, April 2026

- Replacement of the term "amendment" with "modification" throughout, to align with system-wide changes as a result of the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025.

- Alignment of the definitions of Agent and Confidential Information across the suite of model agreements.

- Addition of defined terms in Appendix 1: Collaboration Agreement, Personal Data Breach.

- Addition of Clause 2.8 in Appendix 1 to specify that the investigator overseeing the conduct of the Study at the Participating NHS / HSC Organisation will be aware of and understand the implications on the Participating NHS / HSC Organisation of any Protocol modifications to ensure they can be implemented.

- Correction of the reference to the National Health Service (Scotland) Act 1978 in Clause 3 of Appendix 1.

- Clarification in Clause 8 of Appendix 1 regarding the relationship and order of precedence between the Organisation Information Document as an agreement and a Collaboration Agreement.

- Alignment of the termination clauses across the suite of model agreements.

- Clarification in Appendix 4 that Clause 1 relates to Processing by the Participating NHS / HSC Organisation for the purpose of the Study.

- Addition of Clause 5.j in Appendix 4 in line with GDPR requirements.

- Addition of Clause 5.l in Appendix 4 to manage Personal Data Breaches.

- Clarification in Clause 2 of Appendix 5 that Personal Data and / or Pseudonymised Data can be used as permitted in the approved consent form.