Guidance Document for the Non-Commercial Organisation Information Document

(Version 1.1)

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[1] 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.

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) 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.

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 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.

[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. If potentially applicable please consult with your national coordinating centre to discuss whether such an approach may be appropriate for your study.

How do I complete my Organisation Information Document?

Questions/items marked with an asterisk* (Questions 1-4, 7, and 11-14) must be completed prior to submission of the IRAS Form.

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 by their authorised delegate, or by the participating NHS / HSC organisation (or collaboratively between the two), 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:

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 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 (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 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 tin Scotland 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, you would likely need three outline Organisation Information Documents: one to cover the Scottish scenario where each participating NHS / HSC 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.

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 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. Given that the expectation for interventional studies is that the sponsor or their authorised delegate will have had early feasibility conversations with all relevant parties at their participating NHS / HSC organisations, it is likely that this question will be left unanswered only for some non-trial/investigation studies, or otherwise only in exceptional cases.

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.

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 / 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 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 8. Contact details of person responsible for research activities at this participating NHS / HSC organisation as indicated in question 7 (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, 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 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 9. 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 10. 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 11. 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, etc.

Question 12. 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 (e.g. the Principal Investigator) will receive this training, this should be detailed below.

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 13. 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**, etc.

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 14. 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 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, etc. 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.

Appendices

Each appendix has a box at its top with check-boxes 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 (i.e. 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 in all cases. Only if the localised Organisation Information Document is to be used as the agreement between the parties should the sponsor then check the relevant check-boxes 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 (i.e. not one of the top four IRAS study categories). The mNCA should be used for clinical trials and clinical investigations. Where the localised Organisation Information Document is used as the agreement between the parties, 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 forms part of that agreement (all subsequent appendices are optional, dependent on the nature of the study and the activities at the participating organisation).

Appendix 2 - Finance Provisions

Any funding, resources and/or equipment to be provided by the sponsor or authorised delegate to the participating NHS / HSC organisation should be detailed here. Where such transfer is to take place and the localised Organisation Information Document is used as the site agreement, the outline Organisation Information Document should be partially completed by the sponsor or authorised delegate before submitting as part of the IRAS application.

Remittance details should be completed by each participating NHS / HSC organisation and shared directly with the sponsor or authorised delegate, to facilitate payment. If funds, resources and/or equipment are to be provided by the sponsor or authorised delegate to the participating NHS / HSC organisation but the sponsor intends to use a separate agreement, this should be clearly stated.

Appendix 3 – Material Transfer Provisions

This appendix allows the sponsor and participating 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.

The sponsor should use the options boxes at the top of the page to make clear whether or not it wishes these provisions to form part of the agreement (where the Localised Organisation Information Document is being used as the agreement) and, if it does not, whether it has made alternative provisions for agreement for the transfer of any human biological material (any other agreements with participating organisations that are to be proposed by the sponsor, including material transfer agreements, should be submitted as templates as part of the IRAS application).

Appendix 4 – Data Processing Agreement

Where a study involves the processing of personal data for research purposes by a participating organisation on behalf of the sponsor, the sponsor may elect to make use of these GDPR compliant provisions for agreement with its participating organisation/s, where the Localised Organisation Information Document is itself used in place of any other study agreement.

For the avoidance of doubt, the data processing provisions are intended to form a legally binding contract between sponsor and participating organisation. This is to meet the requirements of the GDPR generally and of GDPR Article 28 (3) specifically.

Appendix 5 – Data Sharing Agreement

Where a study involves the transfer of personal data (i.e. data about living persons that has not been anonymised/pseudonymised and safeguarded such that it can no longer be used to identify those persons) from the participating organisation to the sponsor or one or more agent/s of the sponsor, you should make use of these provisions where the Organisation Information Document is itself used as the study agreement.

Appendix 6 – Intellectual Property Rights

Where a study requires the protection of background intellectual property rights (i.e. 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 include this appendix as part of the agreement, when it is intended to use the localised Organisation Information Document as the agreement.

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?

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 information is known to the sponsor or authorised delegate, it should be completed prior to sharing. 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.

In some circumstances it is appropriate to provide Organisation Information Documents to participating NHS / HSC organisations without first undertaking any localisation. This may be the case, for example, when setting up a low risk study with a large number of participating organisations. If potentially applicable please consult with your national coordinating centre to discuss whether such an approach may be appropriate for your study.

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.

Authorisation when using this Organisation Information Document as an agreement

Where the Organisation Information Document forms the agreement between the sponsor and a participating organisation in England or Wales or Northern Ireland with no additional agreement e.g. 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 organisation in Scotland with no additional agreement e.g. 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 / HSC 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).

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

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

Whilst 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 a requirement of GDPR (Article 28 (3)) that data processors (i.e. participating NHS / HSC organisations) are legally bound in specific ways to their data controllers (i.e. 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 making 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 on how agreement should be recorded and at what juncture is not provided, as this is a matter between partner organisations. Formal, legal agreement must be in place before the participating 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 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 or contact the lead R&D office for advice.

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