**Organisation Information Document – commercially sponsored** **studies**

**(Template version 1.0)**

## Guidance on using this document

Please use this document to create the outline Organisation Information Document/s that you will submit with your IRAS Form. In most instances, the Organisation Information Document should be localised before sharing with participating NHS / HSC organisations.

Questions marked with an asterisk\*(Questions 1, 2, 4 and 7) must be completed prior to submission of the IRAS Form.

Questions marked with a caret **^** (Questions 9 and 10) are completed by the participating NHS / HSC organisation, after the local information pack is shared and where relevant.

Remaining questions may be completed on the localised Organisation Information Document either by the sponsor or authorised delegate, or by the participating NHS / HSC organisation (or collaboratively between both parties), 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 or click in the box if presented with a check-box [ ] .

A separate guidance document is provided and should be consulted prior to completion of this document. Please also read the question specific guidance where present.

## Study Information

|  |  |
| --- | --- |
| **1.\* IRAS Project ID** | Enter IRAS Project ID |
| **2.\* Full Title of the Study** | Enter full title of study |
| **3. Contact details of person acting on behalf of sponsor for questions relating to study set up.** Please enter details of the person who is the sponsor’s main point of contact for all correspondence on setting up the study at this NHS / HSC organisation. This contact may be the Sponsor, a Study Manager or Clinical Research Associate. Where a Contract Research Organisation (CRO) has been delegated to handle set up on behalf of the sponsor, the contact at the CRO should be named here. |
| **Name** | Enter name |
| **Telephone Number** | Enter telephone number |
| **Email Address** | Enter email address |
| 4.\* Are all participating NHS / HSC organisations undertaking the same protocol activities?  |
| Select yes or no |
| If ‘No’ give a brief outline of the activities taking place at NHS / HSC organisations that you will use this Organisation Information Document with. Additional outline Organisation Information Documents may be required for participating NHS / HSC organisations undertaking different activities.  |
| If no, give details |

## Participating NHS / HSC Organisation Information

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| **5. Name of Participating NHS / HSC Organisation:** Please enter the name of the participating NHS / HSC organisation.  |
| Enter name of participating NHS / HSC organisation |
| **6**. **Location/s**: Please provide detail below where it is planned to undertake the research only at specified locations within the participating NHS / HSC organisation (i.e. hospital(s), GP Practice(s) and/or Research Unit(s)). It is not intended that the level of detail provided here captures individual departments within the participating NHS / HSC organisation. |

| Location (enter in boxes below) | Activity (enter in boxes below) |
| --- | --- |
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| 7\*. What is the role of the person responsible for research activities at the participating NHS / HSC organisation?* Principal Investigators are expected to be in place at participating NHS / HSC organisations where locally employed staff take responsibility for research procedures. In this scenario Principal Investigator should be selected even for single centre studies where the Chief Investigator will also be the Principal Investigator.
* Where this is not the case, local collaborators are expected to be in place where central study staff will be present at participating organisation to undertake research procedures (the role of the Local Collaborator is to facilitate the presence of sponsor/CRO research staff).
* Where existing data is being provided for research purposes without additional research procedures and without the presence of central research team members at the participating organisation, select Chief Investigator.
 |
| Select role |
| 8. Contact details of person responsible for research activities at this participating organisation as indicated in question 7 (if known). If known, please enter the details of the person you have spoken to about their role in this study at this participating NHS / HSC organisation. If unknown, please leave blank and that person can be identified and listed here during the setup of the study.  |
| Name | Enter name |
| Post | Enter post |
| Employing Organisation | Enter organisation |
| Email Address | Enter email address |
| Telephone | Enter telephone number |
| **9**^**. The participating NHS/ HSC organisation confirms (by checking the 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**](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/)**.** | [ ]  |
| **10**^**. The participating NHS / HSC organisation has considered and mitigated any conflict/s of interest declared by the Principal Investigator.**  | Select from drop down |
| If yes, please detail conflict of interest |  |