**Template email for commercial sponsors to share the Local Information Pack with participating HSC organisations in Northern Ireland**

**Guidance**

This email is provided for use by sponsors for the purpose of sharing the local information pack with HSC organisations in Northern Ireland. The local information pack should be shared with the principal investigator or local collaborator (where and as applicable) and the R&D office of the participating HSC organisation (who will then share the information with the relevant clinical research network where applicable).

Contact details for the R&D office of participating HSC R&D Offices can be found at <https://rdforum.nhs.uk/rd-contacts-directory/>.

**Template email**

**From:** Sponsor organisation

**To:** PI/LC (if and as applicable) at participating HSC organisation; R&D office at participating HSC organisation

**Subject:** IRAS [Insert IRAS ID]. Provision of local information pack to [Insert Participating HSC organisation].

**Body of email:**

Dear all,

**RE: IRAS [Insert IRAS ID], [Insert study Title]. Provision of local information pack.**

Please find attached the local information pack for [Insert Participating HSC organisation] in relation to the above referenced study. Please now begin the arranging of capacity and capability.

[Please record N/A against any documents which are not applicable. Only attach current versions if any documents have been superseded]

| **Document** | **Version (where applicable)** | **Date (where applicable)** |
| --- | --- | --- |
| IRAS Form or StudyProjectInfromation.pdf document (for studies using combined review) |  |  |
| Protocol and any amendments |  |  |
| Participant information and consent documents (without local logos/ headers) |  |  |
| Relevant model agreement |  |  |
| NIHR Industry Costing Template or confirmation that the NIHR Industry Costing Tool has been accepted |  |  |
| Delegation log if applicable to this study type – or indication of when the delegation log will be shared.  When sharing the delegation log list any known members of the research team. Delegation logs are completed and signed during study set up. |  |  |
| Pharmacy Technical Review Form (for Pharmacy Assurance) if applicable |  |  |
| Research Exposure Form (for Radiation Assurance) if applicable |  |  |
| IRAS Part B section 3 and the PRA ARSAC form. (For studies involving ionising radiation and/or radioactive substances, using combine review) |  |  |
| Any other documents that the sponsor wishes to provide to the site to support the set up and delivery of the study |  |  |

Arranging of capacity and capability

Please contact the representative of the sponsor organisation at [insert appropriate sponsor contact details for discussion of arranging of capacity and capability] if you need to discuss any points related to the arranging of capacity and capability at your organisation.

[Insert any specific points/actions that need to be communicated that HSC organisations need to know in order to arrange capacity and capability]

If you have any questions, please do not hesitate to contact us using the details provided above.

Kind regards

[Sponsor organisation]