**Template email for commercial sponsors to share the Local Information Pack with participating NHS organisations in England and Wales**

**Guidance**

This email is provided for use by sponsors for the purpose of sharing the local information pack with NHS organisations in England and Wales. The local information pack should be shared with the principal investigator or local collaborator (where and as applicable), the R&D office of the participating NHS organisation and, if a NIHR portfolio study, the LCRN of participating NHS organisations in England.

Contact details for the R&D office of participating NHS R&D Offices can be found at <http://www.rdforum.nhs.uk/content/contact-details/>.

Contact details for the LCRN can be found at <https://www.nihr.ac.uk/funding-and-support/study-support-service/study-support-service-contacts/>.

This template email has been developed in accordance with the HRA guidance on NHS site set up in England and Wales - <https://www.hra.nhs.uk/planning-and-improving-research/best-practice/nhs-site-set-up-in-england/>.

**Template email**

**From:** Sponsor organisation

**To:** PI/LC (if and as applicable) at participating NHS organisation; R&D office at participating NHS organisation; Participating LCRN for English NHS organisation (if a NIHR portfolio study)

**Subject:** IRAS [Insert IRAS ID]. Provision of local information pack to [Insert Participating NHS 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 NHS organisation] in relation to the above referenced study. Please now begin the arranging of capacity and capability in line with the information provided in the initial assessment letter and/or HRA and HCRW Approval letter

[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 Only attach current versions if any documents have been superseded]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)** |
| Localised Organisation Information Document |  |  |
| HRA and HRCW Initial Assessment Letter (or HRA and HCRW Approval letter if application is already approved by the HRA and HCRW) |  |  |
| IRAS Form |  |  |
| 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 |  |  |
| 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 NHS 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]