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| **SUBJECT: SITE INITIATION AND PROVISION OF LOCAL INFORMATION PACK – INSERT STUDY ACRONYM / IRAS NUMBER**  Dear INSERT NAME OF PI | |
| **Study Title:** | INSERT FULL STUDY TITLE | |
| **Sponsor R&D Reference:** | INSERT SPONSOR R&I REFERENCE | |
| **Chief Investigator:** | INSERT CI NAME | |
|  |  | |
| **Local Principal Investigator:** | INSERT PI NAME | |
| **Site Name/Number:** | INSERT SITE NAME/NUMBER | |

Congratulations, your site has been selected to take part in the INSERT STUDY ACRONYM study.

In anticipation of receiving local R&D management approval for your site's participation in the INSERT STUDY ACRONYM study, I would be grateful if the items listed below could be forwarded to me at your earliest convenience. This will start our internal ‘**Green for Go’** process.

* Site address and name of hospital where the study will take place.
* CV (signed and dated) and current GCP certificate for your local PI.
* Name and contact details (email address, postal address and telephone number) for the person who will act as the main site contact for set up.
* Insert any others as necessary

When all set up actions are completed, and all requirements are in place, your site will receive “Green for Go” to start.

**Please note: Recruitment and therapy cannot commence prior to receiving the Green for Go email.**

Please find attached the local information pack for NAME OF HEALTH BOARD in relation to the INSERT STUDY ACRONYM study. Please now begin arranging of capacity and capability in line with the information provided in the initial assessment letter and/or HRA and HCRW Approval letter

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| **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 or StudyProjectInformation.pdf document (for studies using combined review) |  |  |
| Protocol and any amendments |  |  |
| Participant information and consent documents (without local logos/ headers) |  |  |
| Relevant model agreement |  |  |
| Schedule of events or SoECAT |  |  |
| 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 | *For example GP Letter* |  |
| *Questionnaire* |  |
| *Patient diary* |  |
| *Sample Manual* |  |

Please contact (insert name of PM) if you need to discuss any points related to the arranging of capacity and capability at your organisation.

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

Kind regards