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| **SUBJECT: INSERT STUDY ACRONYM / IRAS NUMBER – AMENDMENT NOTIFICATION INSERT NUMBER AND DATE** Dear INSERT STUDY ACROMYN Investigators and site teams |
| **Study Title:** | INSERT FULL STUDY TITLE  |
| **Sponsor R&I Reference:** | INSERT SPONSOR R&I REFERENCE  |
| **Chief Investigator:** | INSERT CI NAME  |
|  |   |
| **Amendment Number:** | INSERT AMENDMENT IDENTIFIERS |

**\*\* Please disseminate this email to all members of your study team \*\***

Please find attached documents relating to a substantial / non-substantial (delete as applicable) INSERT CATEGORY amendment for the INSERT STUDY ACRONYM study.

Please note: the 35 day implementation date as assigned at amendment submission is INSERT DATE HERE. Please let me know if you are unable to process the amendment by this date.

The changes are:

LIST CHANGES AS PART OF THE AMENDMENT- REFER TO AMENDMENT TOOL

Please find attached:

LIST ALL ATTACHMENTS FOR THIS AMENDMENT

**ACTIONS REQUIRED by the local PI / Point of Contact:**

* Acknowledge receipt of this email
* Liaise with your local R&I team for local approval to implement at your site.
* Ensure that all staff participating at your site are aware and have been informed of the changes relating to this amendment.
* Ensure that all amendment documentation and this email is available in the PI Study Site File and available to all study staff.

WHERE A CHANGE TO THE eCRF IS NEEDED PRIOR TO IMPLEMENTATION PLEASE ALSO INCLUDE THE TEXT BELOW (DELETE IF NOT APPLICABLE)

Note that a change to the eCRF is needed prior to implementation of this amendment. Please proceed with your local amendment approval process but await further instruction in order to implement the changes in relation to this amendment.

Any queries about this amendment please get in touch.

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