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| --- | --- | --- | --- |
| Form number | **51.021A** | Version  | **4.0** |
| Title | **Amendment Type Confirmation Email template** |

Throughout this form, yellow highlighted text is used to indicate where optional text has been provided. The email template should retain the relevant option, delete those not relevant or include additional research study specific text. For example where research study is sole sponsored by NHSGGC, retain “Sponsor” and delete any reference to “Co-Sponsor”. Once the text has been entered, removed or retained (as appropriate) yellow highlights should be removed and the completed email template should be sent to the Chief Investigator by the Sponsor Research Co-ordinator (or delegate such as Project Manager or Senior Research Administrator). Furthermore the email should be cc’d to the wider Sponsor/Co-Sponsor teams such as Project Manager, Pharmacy, Monitors, CTU etc. (as applicable)

1. **Sponsor/Co-Sponsor confirmation of amendment type email template for Non-substantial amendment**

**E-Mail SUBJECT: Confirmation of amendment type – insert name/ acronym, amendment number and R&I ref**

Dear insert name of CI

|  |  |
| --- | --- |
| **Study Title:** |  |
| **Sponsor/Co-Sponsors:** |  |
| **Sponsor/Co-Sponsor NHSGGC R&I ref:** |  |
| **Chief Investigator:** |  |
| **Amendment number**  |  |

Thank you for submitting the above amendment to the NHSGGC R&I office for Sponsor/Co-Sponsor review.

This amendment has been reviewed on behalf of the Sponsor/ Co-Sponsor and I can confirm that the changes proposed are **non-substantial** updates/clarifications and do not require to be submitted to the REC, HRA and/or MHRA. However, I would recommend that the REC/HRA is notified of this amendment and that details regarding this amendment are included in the next substantial amendment to the REC/HRA and/or MHRA (if applicable).

**You should now submit the amendment and documents through the IRAS Identity Gateway and all sites will be notified.**

I have attached the locked pdf tool and the supporting documents reviewed on behalf of the Sponsor/Co-sponsor.

Please do not hesitate to contact me should you have any queries.

Sent on behalf of insert name and email of Research Co-ordinator

Kind regards,

Insert name and email signature of Sender

1. **Sponsor/Co-Sponsor confirmation of amendment type email template for Substantial amendment**

SUBJECT: Confirmation of amendment type – insert name/acronym, amendment number and R&I ref of study

Dear insert name of CI

|  |  |
| --- | --- |
| **Study Title:** |  |
| **Sponsor/Co-Sponsors:** |  |
| **Sponsor/Co-Sponsor NHSGGC R&I ref:** |  |
| **Chief Investigator:** |  |
| **Amendment number**  |  |

Thank you for submitting the above amendment to the NHSGGC R&I office for Sponsor/Co-Sponsor review.

This amendment has been reviewed on behalf of the Sponsor/ Co-Sponsor and I can confirm that it is substantial and should, therefore, be submitted to the REC, HRA and/or MHRA (if applicable).

I have attached the locked pdf tool and the supporting documents reviewed on behalf of the Sponsor/Co-sponsor.

Please do not hesitate to contact me should you have any queries.

Sent on behalf of insert name and email of Research Co-ordinator

Kind regards,

Insert name and email signature of Sender

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