**Email Templates for ICHT Confirmation of CCC**

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Appendix 1 - Email template to notify Sponsor valid HRA pack has been received

**Email Subject: (enter Documas Ref); (enter short study title); (enter name of PI)**

Dear colleague,

Thank you for your email providing the study documents. I can confirm receipt of all documents as per the HRA initial assessment letter/HRA approval letter (delete as appropriate) dated (insert date).

If you have any questions, please do not hesitate to contact me.

Best wishes,

Appendix 2 – CCC (without study amendments) email template

**Email Subject: (enter Documas Ref); (enter short study title); (enter name of PI)**

Dear

Study Title:

Documas No.:

REC Reference No.:

Initial study capacity and capability confirmation

**I can confirm that Imperial College Healthcare NHS Trust has the capacity and capability to deliver the above referenced study. This means the project may start at Imperial College Healthcare NHS Trust sites once the sponsor gives the green light to begin.**

The capacity and capability is confirmed based on the following HRA approval:

|  |  |
| --- | --- |
| **Documents** | **Date** |
| HRA Approval |  |

Before you commence your research, please note that you must be aware of your obligations to comply with the minimum requirements for compliance with the UK policy framework indicators – Researcher teams (9.6) and Research sites (9.14) (Details of the requirements to be met can be found in the on the UK policy framework for health and social care on <https://www.hra.nhs.uk/>

Under the UK policy framework regulations, Serious Adverse Event Reports and amendments to the protocol or other supporting documents must be forwarded to the Research Governance and Integrity Team.

In accordance with the UK Policy Framework for health and social care, research projects carried out in the Trust will be randomly chosen by the Research Governance and Integrity Team for auditing.

Appendix 3 – CCC (with study amendments) email template

**Email Subject: (enter Documas Ref); (enter short study title); (enter name of PI)**

Dear

Study Title:

Documas No.:

REC Reference No.:

Initial study capacity and capability confirmation up to amendment

**I can confirm that Imperial College Healthcare NHS Trust has the capacity and capability to deliver the above referenced study. This means the project may start at Imperial College Healthcare NHS Trust sites once the sponsor gives the green light to begin.**

The capacity and capability is confirmed based on the following approvals:

|  |  |
| --- | --- |
| **Documents** | **Date** |
| **Initial approvals** | |
| HRA Approval |  |
| **Substantial Amendment** | |
| HRA confirmation of amendment assessment |  |
| NRES – favourable opinion |  |
| MHRA |  |

Before you commence your research, please note that you must be aware of your obligations to comply with the minimum requirements for compliance with the UK policy framework indicators – Researcher teams (9.6) and Research sites (9.14) (Details of the requirements to be met can be found in the on the UK policy framework for health and social care on <https://www.hra.nhs.uk/>

Under the UK policy framework regulations, Serious Adverse Event Reports and amendments to the protocol or other supporting documents must be forwarded to the Research Governance and Integrity Team.

In accordance with the UK Policy Framework for health and social care, research projects carried out in the Trust will be randomly chosen by the Research Governance and Integrity Team for auditing.

Appendix 4 – CCC email template for PIC site

**Email Subject: (enter Documas Ref); (enter short study title); (enter name of PI)**

Dear

Study Title:

Documas No.:

REC Reference No.:

Initial study capacity and capability confirmation up to amendment

**I can confirm that Imperial College Healthcare NHS Trust has the capacity and capability to deliver the above referenced study as a PIC site. This means participants referral to the research site(s) may now start at Imperial College Healthcare NHS Trust sites.**

The capacity and capability is confirmed based on the following approvals:

|  |  |
| --- | --- |
| **Documents** | **Date** |
| **Initial approvals** | |
| HRA Approval |  |
| HRA confirmation of amendment assessment |  |
| NRES – favourable opinion |  |
| MHRA |  |

Before you commence your research, please note that you must be aware of your obligations to comply with the minimum requirements for compliance with the UK policy framework indicators – Researcher teams (9.6) and Research sites (9.14) (Details of the requirements to be met can be found in the on the UK policy framework for health and social care on <https://www.hra.nhs.uk/>

Under the UK policy framework regulations, Serious Adverse Event Reports and amendments to the protocol or other supporting documents must be forwarded to the Research Governance and Integrity Team.

In accordance with the UK Policy Framework for health and social care, research projects carried out in the Trust will be randomly chosen by the Research Governance and Integrity Team for auditing.