**Sponsorship and Insurance Approval email**

***Author guidance notes***

\*Please ensure all the information in green have been deleted before sending the email.

Dear [Investigator name inserted here],

**Please read the whole email for details on what is required now sponsorship is in place**  
Please find attached the insurance certificate (insurance cert if only for College not Trust studies) and sponsorship letter. Please now request signatures on your IRAS form using the authorisations tab/upload documents to the checklist tab. Then book your study for REC/HRA review using the [online booking service](https://www.hra.nhs.uk/about-us/committees-and-services/online-booking-service/) or via CWOW in IRAS.

**Please forward the fully signed IRAS form to the Trust DRM Team as soon as possible to initiate the CCC process.**

* All Faculty of Medicine (FOM) studies using identifiable (includes pseudonymised) data must be registered on [DART](https://apps.powerapps.com/play/ad6f060e-b289-49c4-b46d-633730e1adb3?tenantId=2b897507-ee8c-4575-830b-4f8267c3d307) (any queries contact [FOM GDPR Office](mailto:fom.gdpr@imperial.ac.uk)).  This is only relevant to College sponsored studies (not Trust ones), if so, copy them in.
* If your study requires registration on **clinicaltrials.gov or ISRCTN** contact the [QAF](mailto:a.zicari08@imperial.ac.uk) (Quality Assurance Facilitator) to register it. Registrations need to be implemented before (and not later than 6 weeks of) recruiting the first patient and the HRA will automatically register CTIMPs on ISRCTN. Copy in the [QAF](mailto::a.zicari08@imperial.ac.uk) as required, copy in [RGIT@imperial.ac.uk](mailto:RGIT@imperial.ac.uk) for all sponsor letters.
* If your study involves human tissue, ensure the EDGE **Sample Storage Form tab is completed** so tissue is brought under the HTA licence at the end of the study.
* As your study uses the OID as an agreement then please ensure it is now **localised** for all sites and any financial information has been entered into the appendix 2 and approved by the budget holder (as given on your RGIT form). Delete if an mNCA will be used or no OID required (i.e. ICHT sponsored ICHT site study).
* Please ensure that any other required agreements are in place with the JRO contracts team as required.

**Before your project can start at ICHT, following HRA approval, capability and capacity (CCC) must be confirmed at site** - liaise with the DRM cc’d aboveto facilitate this process. This is only for studies taking place at ICHT, therefore copy in the relevant DRM and Feasibility Team Lead (contact details from will RGIT\_TEMP\_009) For any other site, please liaise with the Organisation’s [R&D dept](https://rdforum.nhs.uk/rd-contacts-directory/) directly.

Any changes made to the documents must be agreed by RGIT prior to submission. Please send all documents where changes are requested by the REC or HRA to me.

You can now contact all sites involved in the study to start the approval process. Their clocks for approval will not start until they have received the local information pack from you.  **Please use a set email when sending out the** [UK local information pack](https://www.myresearchproject.org.uk/help/hlpsitespecific.aspx#UK-Local-Information-Pack-Sharing).  Some of this information is only relevant for NHS sites.  For studies with non-NHS sites the wording will be different and should include the below sentence:

For non-NHS sites study start is contingent on all contracts and necessary approvals being in place

Best Wishes,

[Insert Name]

[Insert Signature]