# **Joint Research Office and Research Governance and Integrity Office**

# **NON-COMMERCIAL STUDY PROCESS**

# **College Sponsored Multi Centre Studies (or study with Imperial College London sponsor and one non-ICHT site)**

For **all** multi-centre ICL sponsored studies, which require ICHT as a site, the type of study (as determined by the category of study selected in filter Question 2 of the IRAS form) impacts on the required documentation by ICHT.

**For a clinical trial or investigation (i.e. the 5 types of trials listed on the left),** ICHT JRO contracts team expects to receive the localised non-commercial OID (with Appendix 1 indicating OID **NOT** to be used as the formal Agreement between ICL and ICHT site) with an accompanying localised mNCA and localised SoECAT/SoE.

**The OID** for sponsorship review (not localised) will be drafted by the PI/study team and reviewed/signed off by RGIT. Review will encompass basic information, the \* section, and appendix 1 (including highlighted yellow sections) only.

**The mNCA** will be completed by the CI/CI’sstudy team and ICL JRO contracts team and sent to ICHT JRO contracts team for review/approval/sign off. The minimum requirement for HRA submission is for the template mNCA RGIT\_GUID 009a to be provided along with the OID. RGIT team will provide this template to the CI/research team at the sponsorship review stage. The draft mNCA can be finalised in parallel with the HRA review for site set up.

*SoECAT/SoE* will be provided by the PI team following the usual process for these (with ICHT JRO).

**For other studies (i.e. those listed on the right),** the RGIT will provide the non-commercial OID (with Appendix 1 indicating OID **IS** to be used as the formal agreement), plus the localised SoeCAT/SOE as per the usual process with ICHT JRO. The OIDs for sponsorship review (not localised) will be drafted by the CI/CI’s study team and reviewed/signed by the RGIT.

Where funding is being provided to sites this should be indicated in Appendix 2 – Finance Provisions – by selecting yes from the drop down for the question Are there funds / resources / equipment, etc. being provided to this participating NHS / HSC organisation by the Sponsor? This information is the minimum information (along with the \* questions) required for Appendix 2 for HRA submission of this OID (aka the outline OID).

* IF YES IS SELECTED TO THE DROPDOWN MENU IN APPENDIX TWO (FINANCE SECTION) the CI will be advised to send the OID to the ICL Grants team or finance approver, in case further information needs to be added for study set up at sites (this should not delay the sponsorship process). It is the CI’s responsibility to liaise with the appropriate parties regarding costings and this will be communicated to the CI in the [RGIT\_TEMP\_057\_Sponsorship-and-Insurance-Approval-email.docx](https://www.imperial.ac.uk/media/imperial-college/research-and-innovation/research-office/public/RGIT_TEMP_057_Sponsorship-and-Insurance-Approval-email_-V10_31.01.2023.docx) email. OIDs should be localised with correct financial information, signed off by the appropriate budget holder prior to submission to site.
* Appendices 3 – 6 (including any modifications to highlighted yellow sections) should be completed as applicable to the study.
* Further sign off from RGIT is not required for localisation stage (or following an amendment) unless any key sections of the OID have been updated (i.e. \* sections of the OID or Appendices). If updates to the finances in Appendix 2 are made at localisation stage, or following an amendment the RGIT will obtain confirmation from the relevant Grants Manager of the update finances.

#  **College Sponsored Single Centre Studies (ICHT only site)**

**For a clinical trial or investigation (i.e. the 5 types of trials listed on the left),** ICHT expects an mNCA and **no** OID. The mNCA will be completed by the CII/CI’s study team and ICL JRO Contracts team and sent to ICHT JRO Contracts team for review/approval/sign off. The mNCA does not need submitting to the HRA for approval. RGIT team will provide template mNCA RGIT\_GUID 009b to the CI/research team at the sponsorship review stage. The draft mNCA can be finalised in parallel with the HRA review for site set up.

**For other studies (i.e. those listed on the right),** ICHT expects an OID. These will be drafted by the CI/CI’s study team and the RGIT will review and sign off on the outline OID as sponsor. This will not be the localised OID The Trust will be notified when the study has sponsorship approval and can access the OID on Documas.

Where funding is being provided to sites this should be indicated in Appendix 2 – Finance Provisions – by selecting yes from the drop down for the question Are there funds / resources / equipment, etc. being provided to this participating NHS / HSC organisation by the Sponsor? This information is the minimum information (along with the \* questions and appendices) required for approval of Appendix 2 of the OID

IF YES IS SELECTED TO THE DROPDOWN MENU IN APPENDIX TWO (FINANCE SECTION) the CI will be advised to send the OID to the ICL Grants team or finance approver, in case further information needs to be added for study set up at sites (this should not delay the sponsorship process). It is the CI’s responsibility to liaise with the appropriate parties regarding costings and this will be communicated to the CI in the [RGIT\_TEMP\_057\_Sponsorship-and-Insurance-Approval-email.docx](https://www.imperial.ac.uk/media/imperial-college/research-and-innovation/research-office/public/RGIT_TEMP_057_Sponsorship-and-Insurance-Approval-email_-V10_31.01.2023.docx) email. OIDs should be localised with correct financial information, signed off by the appropriate budget holder prior to submission to site.

* Further sign off from RGIT is not required for localisation stage (or following an amendment) unless any key sections of the OID have been updated (i.e. \* sections of the OID or Appendices). If updates to the finances in Appendix 2 are made at localisation stage, or following an amendment the RGIT will obtain confirmation from the relevant Grants Manager of the update finance.
* Appendices 3 – 6 (including any modifications to highlighted yellow sections) should be completed as applicable to the study.

*SoECAT/SoE* are not necessary for ICL Sponsored studies with a single ICHT site.

**List of documents required by ICL JRO Contracts Team to draft an mNCA:**

Protocol

IRAS Form

ICL funding code List of documents required by ICHT JRO Contracts Team to review OID or mNCA: IRAS application form, Protocol and proposed OID/mNCA

**Participant Identification Centres (PICs)**

PICs should be set up by through a sub-contracting arrangement between the site and the PIC, containing appropriate data processing arrangements which should be put in place by using the relevant PIC agreement available at [IRAS Help - Preparing & submitting applications - Templates for supporting documents (myresearchproject.org.uk)](https://www.myresearchproject.org.uk/help/hlptemplatesfor.aspx#PIC-contracting)

**Contacts for this process**

**ICHT JRO Contracts Team:**

imperial.admin\_trustresearchcontracts@nhs.net

**ICL RGIT Sponsorship Team:**

rgit@imperial.ac.uk

**ICL JRO Contracts Team:**

Relevant person can be located via [JRO Contacts | Research and Innovation | Imperial College London](https://www.imperial.ac.uk/research-and-innovation/support-for-staff/joint-research-office/about-us/jro-contacts/)