Organisational Information Document (OID)

&

Model Agreement for Non-Commercial Research (mNCA)

for Imperial College sponsored studies

The **Organisation Information Document** is a document that provides information on participating NHS/HSC organisations in the UK. It is required as part of the UK Local Information Pack for both commercial and non-commercial research. An outline Organisational Information Document for each site type should be completed as part of your submission.

All college sponsored studies funded by a non-commercial organisation with NHS Trust study costs will require a **SoECAT and Organisational Information Document (OID)**.

Single Centre Study - The exception when an OID is not required is when the study is for a clinical trial or investigation and when ICHT is the ONLY site. When both criteria are met then a Model Agreement for Non-Commercial Research (mNCA) will be required, and no OID.

<u>Multi-centre studies</u> for a clinical trial or investigation, **ICHT JRO** contracts team expects to receive the localised non-commercial OID (with Appendix 1 indicating an OID is **NOT** to be used as the formal Agreement between ICL and ICHT site) and with an accompanying localised mNCA and localised SoECAT.

Details of the above can be found on the **OID and mNCA Contracts Flowchart (pdf)** on <u>JRO Post-Award webpage</u> under OID, mNCA and Trust Funding Letter section.

N.B. Commercially sponsored trials will be run through the NHS Trust JRO team via <u>Model</u> Agreements not JRO Contracts.

The internal process for the OID and mNCA in the Faculty of Medicine can be found by clicking on the OID and mNCA Process Map (PDF) on JRO Post-Award webpage under OID & mNCA section.

Please note, when there is NO STUDY or ACTIVITY taking place in any NHS Trust, yet Trust staff are working on an Imperial College Project under an Honorary Contract, then an ICHT FUNDING LETTER can be used to reimburse for salary between organisations.

Please click on <u>JRO Post-Award webpage</u> under OID, mNCA and Trust Funding Letter section.

Contract Agreement or Offer Letter

When an award is made to the college, the PI/Study Team will generate an Outline OID using the generic template for review by the **Research Governance and Integrity Team (RGIT)** as part of the original HRA/REC submission.

• The OID Word template and guidance for use with the OID can all be downloaded from the <u>HRA link – Prepare study documentation</u> (click link).

A '<u>Local information pack'</u> (click link) is then prepared for each participating site and this will include the localised version of either the mNCA or OID. The site will then notify the PI/study team if they require changes to the document before this can be signed off.

In Appendix 2 of the OID: Finance Provisions - The PI/Study team must complete this section with the following details:

- The Trust shall submit invoices to <u>apinvoices@imperial.ac.uk</u> (or address below), quoting the sponsor's account number [Insert Project Code] and purchase order number [Insert PO Number e.g. 1234567], which will be sent by [Insert Name and Email of Dept Contact].
- Payments to be made by cheque or BACS Transfer **are not** possible and this section should be **removed**.

Once a final draft of the **Outline OID** has been approved for sponsorship by the <u>RGIT</u> (click link), the PI should submit to the HRA, along with IRAS checklist for "Initial Assessment".

The **Process Map for OID & mNCA** can be found by clicking on the <u>JRO Post-Award webpage</u> under OID, mNCA and Trust Funding Letter section.

- Once the initial assessment has been received from the HRA, the PI/Study Team
 must check with their Dept Admin team to confirm there is a budget per site as per
 the application form, and review "Appendix 2: Finance Provisions" have been
 completed correctly to ensure payments to Trusts will be made, as per section
 above.
- A Local Document Pack is submitted to sites. (Localised OID forms part of this pack)
- During the negotiation phase, budgets may need to be reconfirmed for each site, in case there have been any budget adjustments for each site.
- Any queries to be discussed with the section/divisional manager in terms of budget adjustment.

- The PI and participating NHS site will need to authorise the OID before the NHS
 Trust site issue a Capacity and Capability Approval to the PI and attach an
 authorized version of the OID.
- ICHT JRO will send a fully executed OID with P-code and PI name to the Dept Name and Contact in "Appendix 2: Finance Provisions" and request to raise a PO if not already raised and included in the OID.
- For other NHS Trusts, a request should be made to the PI/Study team to raise a PO to send to the other Trust.

IMPORTANT - For ALL Trust sites, the PI/Study Team or Dept Admin **MUST ENSURE** a copy of the OID is sent to the <u>RGIT</u> and to the <u>JRO Grants team</u> for audit and assurance purposes. Failure to do so will be prone to investigation by the auditor who may disallow any costs without suitable backup documentation.

Amendments to agreement

Any significant amendments to the OIDs which will have an impact on the budget and/or duration of the project will need to have funder and/or department & JRO approval.

Examples being:

- A significant increase in participants which will require a budget amendment; and a top up of existing purchase orders.
- A significant decrease in participants which will require a budget amendment; and the cancellation/amendment of existing purchase orders (and possibly re-raise of new ones)
- Change in the research plan where an NHS investigative test may longer be required. Hence a reduction in commitment to NHS cost.
- No cost (or cost) extension which falls outside the overall project period will require funder approval.