Organisational Information Document ('OID') Completion

Document No.:	CR017 v4.0
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Issue Date:	08 JUL 2025
Effective Date:	22 JUL 2025

1 Introduction

1.1 The Academic & Clinical Central Office for Research & Development (ACCORD) is a joint office comprising clinical research management staff from NHS Lothian (NHSL) and the University of Edinburgh (UoE).

1.2 As part of the Four Nations Compatibility Programme, Site Specific Information Forms have been replaced by Local Information Packs (LIPs). The LIP consists of a Schedule of Events Cost Attribution Template (SoE[CAT]) and an Organisational Information Document ("OID"). The OID requires research site details to be completed, e.g. identification of local study team members and local study locations. The OID also contains appendices that the Sponsor and Site can elect to use as a Site agreement for non-commercial studies other than clinical trials and clinical investigations (i.e. for studies that do not match with any of the top four Integrated Research Application System (IRAS) project filter options for study type).

2 Purpose

2.1 To describe the procedure for completing and submitting OIDs for UoE and/or NHSL sponsored studies that elect to use OID appendices as a Site agreement.

3 Scope

3.1 This SOP applies to UoE/NHSL Research Governance staff involved with the oversight of studies, including reviewing OIDs.

3.2 This SOP also applied to Edinburgh Research Office ("ERO") personnel and study team members regarding the completion and submission of OIDs.

4 Responsibilities

4.1 The ACCORD Sponsor Reviewer as defined by GS003 (Sponsorship Approval), is responsible for overseeing the completion of the outline OID by the study lead ("Study Lead") (for example, Trial Manager/CI/study team delegate).

4.2 The ERO Contracts Representatives will oversee the authorisation of the localised OID and the Sponsor reviewer will provide advice to the Study Lead, as necessary, in regards to the localisation process.

4.3 The Study Lead is responsible for populating the outline OID and ensuring the Site localises and authorises the OID.

5 Procedure

5.1 Outline OID

5.1.1 During the Sponsorship review (including new study and amendment scenarios), when the Sponsor Reviewer becomes aware of a study that will require an OID to be used as an agreement with participating sites, the Sponsor reviewer will instruct a member of the study team (Study Lead) to advise the ERO Contracts team of this requirement and that they should provide the short-form title of the study, the name of the Chief Investigator (CI), a copy of the IRAS form along with the completed ERO contract request form for clinical studies. The information will be provided via the ERO.contracts@ed.ac.uk address.

5.1.2 A representative of ERO Contracts team will return an acknowledgement email and provide an ERO Contracts reference number, with request to cite the reference number in future correspondence.

5.1.3 The Sponsor Reviewer will provide the Study Lead with access to a template appropriate OID, including pre-populated fields;

- Legal name(s) of Sponsor/Co-Sponsors

5.1.4 When providing a template OID, the Sponsor Reviewer will ensure the most recent version of the OID issued by the Health Research Authority (HRA) is provided.

5.1.5 The Sponsor Reviewer will subsequently request that the Study Lead complete all required fields of the OID this is all the parts marked with an asterisk. This will become

known as the outline OID. Required fields will be inclusive of appendices, as the OID will be used as a site agreement.

5.1.6 The Study Lead will return the completed outline OID to the Sponsor Reviewer once all required fields are completed. The Sponsor Reviewer will verify that the information is complete and that the selections in the Appendices are correct and consistent with the default positions documented in the template OID. The Sponsor reviewer should also amend the highlighted text in yellow in appendices 1 and 3 to correspond to the Sponsorship model (e.g. co-sponsor) and appendix 4 to confirm whether the study involves PICs (participant identification centres) before completing the following details:

- Name, Job Title and Organisation Name of the Sponsor Reviewer, and add the text "Approved at outline stage, to be authorised by Sponsor once localisation is completed and agreed."

The Sponsor Reviewer will liaise with the Study Lead if changes are required.

5.1.7 The Sponsor Reviewer may also consult with the ERO Contracts Representative as required regarding decisions concerning OID Appendix selection. Once complete, the Sponsor Reviewer will advise the Study Lead that the outline OID can be submitted as part of the IRAS submission.

5.2 OID Localisation

5.2.1 The Study Lead will email the participating Sites the agreed outline OID and liaise directly with the Site to "localise" the OID (i.e. make it Site-specific).

5.2.2 To ensure no changes are made to the details already included in the outline OID, the Study Lead may choose to send the Site the outline OID formatted with editing restrictions.

5.2.3 The participating site will be invited to add/agree participating NHS / Health and Social Care (HSC) Organisation Information (sections 6-9); Timescales (section 10); and any other Site-specific details.

5.2.4 The Study Lead will ensure that all sections marked with an asterix on the OID have been completed and agreed with Site. If money is payable to the Site, the Study Lead will ensure *Appendix 2: Finance Provisions* is completed.

5.2.5 If the Study Lead requires assistance with the localisation of the OID for example with finance provisions, the Study Lead will email the Sponsor Reviewer with specific queries.

5.2.6 Once the OID has been localised by the Site and is considered complete by the Study Lead, the Study Lead will ensure that any tracked changes on the OID are accepted and editing restrictions are ended, if applicable.

5.2.7 The Study Lead will invite the Site to authorise the OID by completing and dating the Authorisation section (all in Microsoft Word) and return as Word document to Study Lead. The Site may insist upon authorising the OID subsequent to Sponsor authorisation (the procedure in section 5.2.9 of this SOP), to which the Study Lead may acquiesce if agreed by ERO Contracts.

5.2.8 The Study Lead will email (using an UoE email address) the part-authorised OID to ERO Contracts team at ERO.contracts@ed.ac.uk with the following email message:

"Dear Contracts team,

Please find attached an OID part-authorised by the Site. I have checked that the information contained within the OID is correct and in line with our agreed process. On that understanding, please arrange for the OID to be fully-authorised on behalf of the Co-Sponsors and returned to me.

I will then forward to the Site to complete the process."

Include "Request to authorise OID_site name [ ]_study name [ ], together with ERO reference number" in the subject header of email.

5.2.9 On receipt of the part-authorised OID from the Study Lead, the ERO Contracts Representative will:

- Replace Name, and Job Title of the Sponsor Reviewer with that of the Head of RCGI, and delete the text *"Approved at outline stage, to be authorised by Sponsor once localisation is completed and agreed."*
- Authorise on behalf of Sponsor by completing date of authorisation.
- Convert the now fully-authorised OID into a pdf.
- Reply to Study Lead's email attaching a copy of the pdf of the fully-authorised OID.

PLEASE NOTE: In exceptional circumstances, the Study Lead can authorise on behalf of the Sponsor, however ONLY with prior written agreement from the ERO Contracts team.

5.2.10 Once Study Lead will retain the fully authorised OID and email a copy of the fully-authorised OID to Site.

6 References and Related Documents

- http://www.nhsresearchscotland.org.uk/services/uk-wide-working

7 Document History

Version Number	Effective Date	Reason for Change
1.0	01 MAY 2020	New SOP
2.0	05 FEB 2021	Change to process at 5.1.3 and 5.2.9 to ensure that Sponsor has had oversight of information entered by Sites into the outline OID before authorisation.
3.0	13 JUN 2023	Update to process at section 5.1.1 outlining the Study Lead will now be prompted by the Sponsor Reviewer to send an ERO contract request form, whilst advising to contact ERO. Minor administrative changes throughout.
4.0	22 JUL 2025	Minor updates throughout to reflect current process.

8 Approvals

Sign	Date
Jo-Anne Robertson (04-Jul-2025 13:52 GMT+1) AUTHOR: Jo-Anne Robertson, Research Governance Manager, UoE, ACCORD	04-Jul-2025
Kenneth Scott Kenneth Scott (04-Jul-2025 13:56 GMT+1) APPROVED: Kenneth Scott, NRS Generic Review Manager, NHSL, ACCORD	04-Jul-2025
Gavin Robertson (04-Jul-2025 14:43 GMT+1) AUTHORISED: Gavin Robertson, QA Coordinator, NHSL, ACCORD	04-Jul-2025

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Final Audit Report 2025-07-04

Created:	2025-07-04 (British Summer Time)
By:	Roisin Ellis (v1relli8@exseed.ed.ac.uk)
Status:	Signed
Transaction ID:	CBJCHBCAABAABHh_DAgewT6S0Q675El2YgdfKAqX6sDW

"CR017 Organisational Information Document Completion v4.0" History

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2025-07-04 - 1:56:37 PM GMT+1- IP address: 62.253.82.242

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Signature Date: 2025-07-04 - 1:56:39 PM GMT+1 - Time Source: server- IP address: 62.253.82.242

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2025-07-04 - 2:43:06 PM GMT+1- IP address: 90.247.173.187

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