FACILITATING A REGULATED OR COMPLEX RESEARCH PROJECT

DOCUMENT NO.:	**FA001 v7.0**
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ISSUE DATE:	**26 MAY 2023**
EFFECTIVE DATE:	**09 JUN 2023**

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 The ACCORD Sponsor Representatives acts as a main point of contact for clinical investigators planning research in Lothian, and may provide assistance at any stage of the study, but typically will be involved from grant application, and subsequently help with protocol design, research contracts, investigational product supply and research approvals.

2 PURPOSE

2.1 To describe how ACCORD provides support to investigators, while ensuring sponsor obligations are met and that the relevant policies, procedures, guidelines and regulations are adhered to.

3 SCOPE

3.1 This SOP applies to ACCORD research governance staff, including Clinical Research Facilitators and Research Governance Co-ordinators. This SOP applies to all Clinical Trials of Investigational Medical Products (CTIMPs) and any clinical research for which a Combined Risk Assessment is deemed appropriate, including Global Health clinical research (e.g. First in Human studies and other invasive, experimental, or complex research involving one or more research sites).

4 RESPONSIBILITIES

4.1 The Lead Sponsor Representative, is responsible for;

- Providing support to investigators from initial point of contact until R&D approval for NHSL is in place.
- Initiating the Combined Risk Assessment procedure with the ACCORD Quality Assurance (QA) team.

- Raising their own studies at the Early Projects meeting, and for resolution of any issues that have been identified at the meeting.
- Discussing any matters arising and status updates, at the Sponsorship meeting, in relation to their own studies.
- Identifying which parts of the Facilitation Checklist (FA001-T03/FA001-T07) apply to specific studies and complete the checklist as necessary.
- Handover of studies to the Senior Clinical Trials Monitor, or designee.

4.2 The QA Manager, or designee, is responsible for arranging the Combined Risk Assessment meeting at the request of the Lead Sponsor Representative

4.3 The Senior Clinical Trials Monitor is responsible for ensuring all study specific documentation received from the Lead Sponsor Representative is filed in the Trial Master File (TMF)/Sponsor File.

5 PROCEDURE

5.1 Identifying Studies for Facilitation

5.1.1 All clinical research for which a Combined Risk Assessment as per SOP GS002 is deemed appropriate (e.g. Regulated studies, First in Human studies and other invasive, experimental, or complex research involving one or more research sites) will be collectively known as 'Facilitated Studies'. These projects requiring sponsorship by NHSL and/or UoE, should be reviewed by ACCORD governance staff at the point of applying for funding and assigned a Lead Sponsor Representative at the time of Sponsorship Review as per SOP GS003 (Sponsorship Approval), or SOP GH001 (Global Health Sponsorship).

5.2 Managing Studies for Facilitation

5.2.1 All new studies for facilitation will be taken to the Early Projects meeting, unless otherwise agreed, to ensure that key people are aware of the study and have the opportunity to identify any potential issues.

5.2.2 The Lead Sponsor Representative will also provide an update on Risk Assessed projects assigned to them at monthly Sponsorship meetings.

5.2.3 The Facilitation Checklist (FA001-T03/FA001-T07), or relevant parts of the appropriate checklist, will be completed for Facilitated Studies by the Lead Sponsor Representative.

5.2.4 Each section of the Facilitation Checklist should be completed. Where sections have not been completed, justification must be provided. Additional information must be added to the "Details" column (e.g. where indicating "REC Approval Obtained" the date of favourable opinion should be detailed).

5.2.5 Items must not be removed from the checklist - if specific items on the checklist are not applicable to the study, this should be indicated on the checklist, with the rationale provided in the "Details" section.

5.2.6 Where appropriate for a specific trial, additional items may be added to the checklist or existing items edited to suit the circumstances of a specific trial.

5.2.7 The Lead Sponsor Representative will save Facilitation documentation electronically in the appropriate study specific Sponsorship Review folder on the ACCORD SharePoint site.

5.2.8 The Lead Sponsor Representative will initiate the Combined Risk Assessment procedure with the ACCORD Quality Assurance team as detailed in SOP GS002 (Combined Risk Assessment).

5.3 Facilitation Checklist Sign-Off

5.3.1 All sections of the Facilitation Checklist must be completed prior to sign-off ('Facilitation Checklist sign – off' section of the form) by the Lead Sponsor Representative, except in the case of exceptional circumstances (see section 5.4.6). The Lead Sponsor Representative may liaise with ACCORD colleagues and trial representatives, as necessary, to obtain information required to complete the form.

5.4 Regulatory Release by the Sponsor

5.4.1 Where applicable, the Lead Sponsor Representative will provide written authorisation to start the trial, known as the 'Regulatory Checks Complete' confirmation.

5.4.2 Once all sections of the Facilitation Checklist (FA001-T03/FA001-T07) have been completed (and prior to the Regulatory Checks Complete confirmation), the Lead Sponsor Representative will liaise with the appointed Clinical Trials Monitor to discuss the status of the trial and conduct formal handover. When the handover is concluded, the Lead Sponsor Representative and the Clinical Trials Monitor will both sign the 'Regulatory Checks' section of the Facilitation Checklist.

5.4.3 Formal handover will occur in tandem with the Lead Sponsor Representative (in agreement with the Clinical Trial Monitor) providing confirmation of Regulatory Checks Complete to the Chief Investigator.

5.4.4 A template email (FA001-T05 Regulatory Checks Complete) should be used as the written authorisation to start the trial to the Chief Investigator. The

content of the template should be edited to meet the requirements of the individual study. The Trial Manager (where appropriate) and Clinical Trials Monitor should be notified of the confirmation of Regulatory Checks.

5.4.6 A copy of the Regulatory Checks email to the CI must be filed in the TMF/Sponsor File/ and SharePoint.

5.4.7 In exceptional circumstances, confirmation of Regulatory Checks Complete may be provided prior to sign-off of the Facilitation Checklist (e.g. where an agreement may be outstanding) however there is still the requirement that the "Approvals" section of the Facilitation Checklist (FA001-T03/FA001-T07) is completed confirming appropriate approvals are in place. Such instances should only occur following discussion and agreement with the Quality Assurance Manager and/or Senior Clinical Trials Monitor. The rationale and justification
for this decision must be documented on the Facilitation Checklist. The Facilitation Checklist must be completed and signed off as soon as possible there after by the Lead Sponsor Representative and provided to the appointed Clinical Trials Monitor prior to Sponsor Authorisation To Start (SATO) being issued.

5.4.8 Where an IMP/ /device is from clinical trial stock and requires shipment to site, the Clinical Trials Monitor, or designee, will provide authorisation to ship the IMP/device to the site ('Regulatory Green Light') following CM001 (Site Initiation and Sponsor Authorisation)

5.5 Following Study Handover to the Clinical Trial Monitor

5.5.1 The appointed Clinical Trials Monitor will ensure that a hard copy of the Facilitation Checklist (FA001-T03), and relevant facilitation documentation, is retained in the TMF and/or Sponsor File.

5.5.2 The Clinical Trials Monitor will liaise with the trial team to discuss monitoring arrangements and Sponsor's Authorisation to Open (SATO) trial sites as per CM001 Site Initiation and Sponsor Authorisation.

6 REFERENCES AND RELATED DOCUMENTS

- FA001-T03 Facilitation Checklist
- FA001-T05 Regulatory Checks Complete Template Email
- FA001-T07 Global Health Facilitation Checklist
- GH001 Global Health Sponsorship
- CM001 Site Initiation and Sponsor Authorisation

- GS002 Combined Risk Assessment
- GS003 Sponsorship Approval
- Medicines for Human Use (Clinical Trials) Regulations 2004, as amended
- UK policy framework for health and social care research
- ICH-GCP E6(R2) Guidelines

7 DOCUMENT HISTORY

Version Number	Effective Date	Reason for Change
1.0	25 APR 2011	New procedure
2.0	18 JUL 2016	New title and SOP template, with additional section on responsibilities. References to documents associated with Clinical Investigational Agents (FA001-T01 and FA001-T02) and the Quality and Safety Checklist (FA001-T04) removed. Reference to Sponsorship Approval SOP added to section 5.1.1. Other minor changes made throughout procedure.
3.0	22 JUN 2018	Addition of section 5.3 (Regulatory Release by the Sponsor). Inclusion of a new regulatory release email template (FA001-T05). Reference to SOP
		CM001 at section 5.4. Reference to the UK policy framework for health and social care research, replacing the Research Governance Framework for Health and Community Care (Scotland 2006 2nd ed). Other minor changes made throughout procedure.
4.0	29 JUL 2020	Addition of EudraCT Upload Planning form (FA001-T06). Renaming of FA001-T05. Minor clarifications and administrative changes throughout.
5.0	08 JUN 2021	Section 5.4.3 updated to clarify that the Regulatory Checks Complete email to the CI and formal handover to Monitor must occur in tandem. Section 5.4.4 updated to remove reference to co-sponsor representative being informed of confirmation of Regulatory Checks. Updates made throughout FA001-T03
6.0	08 JUN 2021	FA001-T07 Global Health Facilitation Checklist added prior to effective date

7.0	09 JUN 2023	Minor clarifications in sections 5.2.6, 5.3.1 and 5.4.2, following review of ACCORD processes. FA001-T06 (Summary Result Upload Planning) removed from references as made obsolete in March 2023. Updates also made to FA001-T03 (v9.0), FA001-T05 (v3.0) and FA001-T07 (v2.0)

8 APPROVALS

Sign	Date
Paul Dearie Paul Dearie (May 25, 2023 11:58 GMT+1) AUTHOR: Paul Dearie, Clinical Research Facilitation Manager, UoE, ACCORD	May 25, 2023
Elizabeth Craig Elizabeth Craig (May 25, 2023 10:15 GMT+1) APPROVED: Elizabeth Craig, Senior Clinical Trials Monitor, NHSL, ACCORD	May 25, 2023
L. Mackenzie AUTHORISED: Lorn Mackenzie, QA Manager, NHSL, ACCORD	May 25, 2023

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Final Audit Report 2023-05-25

Created:	2023-05-25
By:	Roisin Ellis (v1relli8@exseed.ed.ac.uk)
Status:	Signed
Transaction ID:	CBJCHBCAABAAnUl2JRCCqgac-cE4NEg9K6mEIaQ7ny8l

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2023-05-25 - 8:52:41 AM GMT

Document emailed to Paul Dearie (paul.dearie@ed.ac.uk) for signature
2023-05-25 - 8:55:12 AM GMT

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2023-05-25 - 8:55:12 AM GMT

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2023-05-25 - 8:55:12 AM GMT

Email viewed by Lorn Mackenzie (lorn.mackenzie@nhslothian.scot.nhs.uk)
2023-05-25 - 8:59:40 AM GMT

Document e-signed by Lorn Mackenzie (lorn.mackenzie@nhslothian.scot.nhs.uk)
Signature Date: 2023-05-25 - 8:59:54 AM GMT - Time Source: server

Email viewed by elizabeth.a.craig@nhslothian.scot.nhs.uk
2023-05-25 - 9:15:16 AM GMT

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Document e-signed by Elizabeth Craig (elizabeth.a.craig@nhslothian.scot.nhs.uk)
Signature Date: 2023-05-25 - 9:15:35 AM GMT - Time Source: server

Email viewed by Paul Dearie (paul.dearie@ed.ac.uk)
2023-05-25 - 10:58:26 AM GMT

Document e-signed by Paul Dearie (paul.dearie@ed.ac.uk)

Signature Date: 2023-05-25 - 10:58:34 AM GMT - Time Source: server

Agreement completed.

2023-05-25 - 10:58:34 AM GMT