ECTU Central Office SOP_TM_02: Agreements

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Authorship and Approval			
Name and Designation	Author/Reviewer/ Approval/ Authorisation	Date	Signature
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Tanya Tharakan, QA Manager	QA Authorisation	18 Oct 2023	See email approval retained on 18 Oct 2023

Document Revision History		
Version No.	Effective Date	Summary of Revisions
1.0	12 Jun 2012	Initial creation
2.0	02 Feb 2015	Sections 3.1 and 3.2 added. Working checklist deleted. Section 4.0 updated
3.0	13 Mar 2017	Amended after scheduled review to section 3.1 regarding change of contact for agreement advice
4.0	27 Mar 2019	Updated at scheduled review. Document moved to new SOP template. Minor amendments to wording in section 1 and 2. Document reformatted and renumbered throughout. Co-enrolment agreement reference added to section 3.3. Reference to ACCORD GS003 and POL008 added to section 4
5.0	28 Jul 2021	SOP Author and reviewer have been updated. Research Contracts renamed to Research Contracts, Governance

		and Integrity Team (RCGI). Additional comment on process for validated questionnaires when authors or license holders cannot be reached. Addition of data sharing agreements. Signposting to RCGI procedures for new projects or contract amendments
6.0	14 Nov 2023	SOP has been transferred onto the new SOP template. This includes the addition of Section 3 Responsibilities, which has had a knock-on effect to the numbering of subsequent sections. Minor clarifications were made in sections 4.1 and 4.2. Section 4.3 on initiating an agreement was added, replacing the previous section 4.4. U o E Contract Office. Section 4.4 Agreements Types (formerly 4.3) was updated, including clarifications regarding material transfer agreements and questionnaire licenses, as well as the addition of service level agreements.

1.0 PURPOSE

This Standard Operating Procedure (SOP) describes the procedure for obtaining, managing and implementing agreements for a clinical trial.

2.0 SCOPE

This SOP applies to all studies with a designated ECTU Trial Manager or designee who will be responsible for the management of all agreements for a clinical trial.

3.0 RESPONSIBILITIES

The Trial manager or designee will be responsible for

- Liaising with the Research Contracts, Governance and Integrity Team (RCGI) and/or Sponsor representative regarding agreements
- Ensuring all the relevant agreements are in place and signed
- All signed agreements are filed in the Trial Master File (TMF)

4.0 PROCEDURE

4.1 Agreements for CTIMP and Medical Device Trials

4.1.1 Agreements must be in place for Regulated trials (Clinical Trials of Medicinal Products CTIMPs) and Medical Device Trials.

4.1.2 The funding application for the trial will have details of what is involved in the trial, which will give an indication of what agreements need to be set up specifically for each trial. The trial manager is responsible for confirming with the Research Contracts, Governance and Integrity (RCGI) team and/or Sponsor representative what agreements are required.

4.2 Agreements for non-CTIMP Trials

4.2.1 Agreements may not always be required for non-CTIMPs and the legal team will make a decision on a case by case basis.

4.2.2 The Trial Manager is responsible for confirming what agreements, if any, are required with the RCGI team and/ or sponsor representative.

4.3 Initiating an Agreement

4.3.1 The Trial Manager is responsible for liaising with the RCGI team and/ or Sponsor representative to coordinate the drafting of agreements and subsequent review and signature by all relevant parties.

4.3.2 Advice on legal agreements can be sought in the first instance from the RCGI team at ERO.contracts@ed.ac.uk.

4.3.3 For all new clinical studies requiring support from the University of Edinburgh RCGI team, a new clinical studies request form should be submitted to ERO.contracts@ed.ac.uk alongside a checklist of materials, including the submitted ethics application. The new clinical studies request form can be found on the RCGI SharePoint Document Library: Setting up research contracts (sharepoint.com).

4.3.4 For any new agreements, a request form needs to be completed and submitted to ERO.contracts@ed.ac.uk. Request forms for a variety of agreement types can be found on the RCGI SharePoint Document Library: Setting up research contracts (sharepoint.com).

4.3.5 Third parties may provide their own agreements for review and these should always be submitted to the RCGI team for review.

4.4 Types of Agreement

The agreements required will include, but are not limited to:

- **Co-sponsorship agreement**
  This is required in all Regulated trials co-sponsored by NHS Lothian (NHSL) and the University of Edinburgh.

- **Site agreement**
  This is required in all multi-centre Regulated trials.

- **IMP/ Device supply agreement**
  This is required in all Regulated trials where the IMP/device is sourced from an external company. The IMP/device supply agreement may contain specific instruction and detail that should be included in the site agreement (i.e. requirements for how site store and handle the IMP/device etc.).
  In certain cases, there may be a series of agreements (drug supply agreement, distribution agreement, technical agreement and QP-QP agreement). In these situations, ensure that the RCGI team are kept aware of all agreements even if they are not directly involved in them (i.e. distribution agreements may be arranged via the procurement team) so that terms and conditions can be considered together.

- **Material transfer agreement**
  This is required in all Regulated trials where samples are being shipped and/or analysed off site (i.e. the samples are being removed from the site at which they were taken). Where samples are being analysed by a collaborating party or within NHS Lothian/University of Edinburgh, then this may be incorporated within Schedule 4 Material Transfer Provision of the Site Agreement or within the collaborators/co-applicant agreement.

- **Collaboration/ Co-applicant agreement**
  This may be required for multi-centre trials where investigators from multiple organisations have been involved in the design of the research and funds are due to be allocated to their

departments from the grant for their individual input (e.g. for Statistical support, Health Economics, Medical expertise etc.). This is separate to a site agreement.

- **Service Level agreement**
  This is required for any external parties providing a service for the study. This may include, but is not limited to, central laboratories, independent monitors, couriers or clinical research facilities.

- **Co-enrolment policy/ agreement**
  Sponsor guidance should be sought in the first instance regarding any proposed co-enrolment between studies as a formal agreement may be required. For NHSL/ UoE studies sponsored by ACCORD, refer to policy POL008 Co-enrolment and Co-enrolment Checklists POL008-F01 (CTIMP-CTIMP) and POL008-F02 (CTIMP-Non CTIMP).

- **Pharmacy agreement**
  This is required for studies involving independent community pharmacies.

- **Questionnaire licenses**
  In many cases, permission to use a validated questionnaire instrument within a trial constitutes a formal agreement. In most cases this is negotiated directly between licensing bodies and the Trial Office staff involved in a trial without recourse to the RCGI team but details of the license agreement including proof of payment for any fees and approval letter should be retained. If a license agreement requires to be reviewed and signed, the RCGI team should be contacted. Licensed companies or authors should be contacted initially. In the event of non-response the named author should be approached. If authors or license holders cannot be reached, evidence of efforts to contact should be kept on file and the questionnaire cited in any publications according to original citation. Flagging these instances of non-contact to the Sponsor is advised as there are a small number of 'black-listed' measures that should not be used because of known issues with licensing.

- **Data Sharing and Data Access**
  If a study involves either receiving or sending datasets to a third party, or accessing a dataset held by a third party it is likely that the RCGI team will need to put in place a formal agreement. There are specific forms held on the RCGI team SharePoint site to cover different scenarios. A copy of this form should be retained within the TMF.

4.5 Document Signature and Retention

4.5.1 The RCGI team have moved to a validated electronic signature process (e.g. using Adobe Sign or DocuSign) and copies of the finalised electronically signed documents should be held in the TMF and ISF. The RCGI team will coordinate signatures by the University of Edinburgh and by the Lothian Health Board. RCGI may ask the trial manager to distribute the partially signed agreement to external signatories. If this is the case, a copy of the fully signed agreement should be returned to RCGI at ERO.Contracts@ed.ac.uk.

4.5.2 All agreements should be signed and filed in the TMF/ ISF before the first participant is recruited. The trial manager should also send a copy of all fully executed agreements to the Sponsor for their files.

4.6 Amendments to Agreements

4.6.1 The Trial Manager is responsible for arranging review and amendment of agreements by the RCGI team if required.

4.6.2 All amendments to trial agreements must be reviewed and approved by all the relevant parties and copies of signed versions should be retained in the TMF/ ISF.

4.6.3 Any proposed amendment should be submitted to the RCGI team with an Amendment of Existing Agreement form available on the RCGI SharePoint Document Library, accompanied by the contract reference code in the email subject line.

5.0 RELEVANT DOCUMENTS AND REFERENCES

- ACCORD Policy POL008 Co-enrolment
- Co-enrolment Checklists - POL008-F01 (CTIMP-CTIMP) and POL008-F02 (CTIMP-Non CTIMP)
- ACCORD SOP GS001 R&D Management Approval
- ACCORD SOP GS003 Sponsorship Approval
- http://www.accord.scot/research-access/resources-researchers
- RCGI SharePoint Document Library: Setting up research contracts (sharepoint.com)