ECTU Central Office SOP ECTU_TM_02: Agreements

<table>
<thead>
<tr>
<th>Version No:</th>
<th>4.0</th>
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<td>Effective Date:</td>
<td>27th March 2019</td>
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### Authorship and Approval

<table>
<thead>
<tr>
<th>Name and Designation</th>
<th>Author/Reviewer/Approval</th>
<th>Date</th>
<th>Signature</th>
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<tbody>
<tr>
<td>Claire Battison, Trial Manager</td>
<td>v3.0 Author/Reviewer</td>
<td>27th February 2019</td>
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<td>Gina Cranswick, Trial Team Manager (Operations)</td>
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<td>13th March 2019</td>
<td>Signature on file</td>
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### Document Revision History

<table>
<thead>
<tr>
<th>Version No</th>
<th>Date</th>
<th>Summary of Revisions</th>
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<tbody>
<tr>
<td>1.0</td>
<td>12th June 2012</td>
<td>Initial creation/New document</td>
</tr>
<tr>
<td>2.0</td>
<td>2nd Feb 2015</td>
<td>Sections 3.1 and 3.2 added. Working checklist deleted. Section 4.0 updated</td>
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<tr>
<td>3.0</td>
<td>13th March 2017</td>
<td>Amended after scheduled review to section 3.1 regarding change of contact for agreement advice</td>
</tr>
<tr>
<td>4.0</td>
<td>27th March 2019</td>
<td>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</td>
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1. PURPOSE

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

2. SCOPE

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

3. PROCEDURE

3.1 Agreements for CTIMP and Medical Device Trials

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

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

3.1.3 The funding application for the trial will have details of what is involved in the trial and what agreements need to be set up specifically for each trial. Advice on legal agreements can be sought in the first instance from the Research Support Office Contracts Team https://www.ed.ac.uk/research-support-office/about-us/contracts-governance-integrity-team.

3.2 Agreements for non-CTIMP Trials

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

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

3.3 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 Research Contracts 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.

- **Sample shipping/analysis**
  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
a collaborators/co-applicant agreement. A short ‘project plan’/technical agreement document with the lab and counter-signed by the lab lead is recommended, although the detail (i.e. cost per sample etc.) should correspond with 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.

- **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 Research Contracts but details of the license agreement including proof of payment for any fees should be retained.

### 3.4 Document Retention

3.4.1 Final, signed copies of agreements (except questionnaire licenses) will be retained by the legal team but copies must be held in the TMF and ISF.

3.4.2 All agreements should be signed and filed in the TMF/ISF before the first participant is recruited.

### 3.5 Amendments to Agreements

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

3.5.2 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. RELEVANT DOCUMENTS AND REFERENCES

- ACCORD Policy POL008 Co-enrolment
- ACCORD SOP GS001 R&D Management Approval
- ACCORD SOP GS003 Sponsorship Approval
- [http://www.accord.scot/research-access/resources-researchers](http://www.accord.scot/research-access/resources-researchers)