Title: Generation of contracts

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Document History

<table>
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<tr>
<th>Version</th>
<th>Description of update</th>
<th>Date Effective</th>
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<tr>
<td>1</td>
<td>Change of number for Q-Pulse</td>
<td>2-10-15</td>
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<tr>
<td>2</td>
<td>Include reference to electronic copies of Trial Agreements at 3.5</td>
<td>30-3-16</td>
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<td>3</td>
<td>Reformatted and inclusion of device trials at 1.3</td>
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1. Scope

1.1 This SOP applies to non-commercial research projects which are sponsored or co-sponsored by the University of Aberdeen (UoA) and/or NHS Grampian (NHSG).

1.2 This SOP covers the following Trial Agreement types, as required:

- Funding Agreements
- Co-Sponsorship Agreements
- Site Agreements
- Collaboration Agreements
- Medicinal Product Supply Agreements
- Laboratory Service Agreements
- Material Transfer Agreements (MTA)

1.3 For the purpose of this Standard Operating Procedure (SOP) ‘Trial’ shall mean a Clinical Trial of an Investigational Medicinal Product (CTIMP) or clinical investigation of a medical device. This SOP describes the procedure for issuing and completing agreements required for Trials.

1.4 ‘Trial Agreement’ is a term used throughout this SOP to describe a document used between the Trial Sponsor and/or an outside party, to agree the contractual terms associated with the specific Trial-related tasks and responsibilities.

1.5 This SOP may also be used by staff from other NHS areas, or organisations, with prior agreement.

2. Responsibilities

Chief Investigator (CI) Liaise with the Sponsor to arrange legal, financial and administrative management of the trial (may be delegated to Trial Manager).

Business Development Officer (BDO) Maintaining a file for each Trial Agreement.

Authorised signatory Final authorisation of Trial Agreements.

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Key to symbols Ⓡ = Important point to note ⚠️ = Warning
3. Procedure

3.1 Following confirmation of funding the Business Development Officer (BDO) in Research & Innovation (R&I) with input from the following where required: CI, Trial Manager, Contracts Co-ordinator, representative from Research Financial Services (RFS), the Non-commercial Manager and Research Governance Manager (RGM), shall identify the contracts required for the Trial. The Trial Agreements required for each Trial will be recorded on the UoA Inteum Database.

<table>
<thead>
<tr>
<th>Trial Agreement Type</th>
<th>To be in place prior to:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Funding Agreement</td>
<td>Any other Trial Agreements are signed</td>
</tr>
<tr>
<td>Co-sponsorship Agreement</td>
<td>Trial recruitment at any site can commence (N.B. recruitment cannot commence until all required approvals are in place)</td>
</tr>
<tr>
<td>Site Agreement</td>
<td>Site recruitment at that site (N.B. recruitment cannot commence until all required approvals are in place)</td>
</tr>
<tr>
<td>Collaboration Agreement</td>
<td>Collaborator receives any trial data or samples</td>
</tr>
<tr>
<td>Medicinal Product Supply Agreement</td>
<td>Sign off of Dispensing Authorisation Form (Green Light)</td>
</tr>
<tr>
<td>Laboratory/ Service Agreement</td>
<td>External laboratories or other third parties sub-contracted, for the Trial, to either UoA and or NHSG receiving any trial samples</td>
</tr>
<tr>
<td>Material Transfer Agreement</td>
<td>Before trial materials are transferred to the third party</td>
</tr>
</tbody>
</table>

Generic procedure for preparing, negotiating and filing all Trial Agreements

3.2 The generic procedure for preparing, negotiating and filing Trial Agreements is detailed below. In addition, specific steps for the different Trial Agreements types are described in section 3.10.

3.3 The BDO, with support from the Contracts Co-ordinator where necessary, will draft the Trial Agreements based on the appropriate template. The BDO shall seek approval of the draft agreement (or specified clauses) from any of the CI, Trial Manager, RGM, Non-commercial Manager, Clinical Trials Pharmacist (CTP) and/or RFS as necessary to ensure consistency with the trial protocol and associated trial documents. Where required, the Contracts Co-ordinator shall conduct a consistency review to ensure the Trial Agreements do not conflict.

3.4 The BDO or Contracts Co-ordinator shall issue the draft Trial Agreement to the other party (or to the Trial Manager to issue to the other party) for review. Any negotiation of the Trial Agreement will be led by the BDO. The BDO shall seek advice and/or approval of any changes to the Trial Agreement from the CI, Trial Manager, RGM, Non-commercial Manager, CTP and by RFS, as required.

3.5 The Trial Agreement shall receive final approval following signature by the authorised signatories of each contracting party. The BDO or Contractor Co-ordinator shall oversee the signature process. Hard copies, or electronic copies, of the final Trial Agreement shall be issued to the third party for signature. In general, the Co-sponsors/Sponsor shall be the last parties to sign the agreement.

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3.6 The BDO, Contract Co-ordinator or Trial Manager shall distribute the fully signed copies of the executed Trial Agreement to each party. Copies shall be circulated to the CI and/or Trial Manager, RFS and others, as required and shall be uploaded to the Inteum database. For hard copies of Trial Agreements the UoA hard copy of the agreement shall be retained by R&I and the NHSG hard copy of the agreement shall be retained within the NHSG R&D office.

3.7 The BDO will liaise with the Contracts Co-ordinator, if required, to draft any required amendments to the Trial Agreements and then follow the procedure described in section 3.6 above.

3.8 It is the CI’s responsibility to ensure contractual amendments are not implemented until any associated regulatory, ethical and R&D amendments are approved, as required.

3.9 Where necessary, the BDO or RGM shall contact the Sponsor’s provider of Clinical Trials Insurance to notify them of the amendment to ensure that cover will be in place (see SOP-QA-4 – Applying for sponsorship).

### Specific steps for different Trial Agreement types

**3.10 Funding Agreements**
- The BDO will check and approve the contract with the Trial funder (Funding Agreement) with support from colleagues in RFS.
- Where necessary, the BDO will outline any key or unusual terms and conditions of the Funding Agreement to the CI and others as required.

**3.11 Co-sponsorship Agreements**
- The BDO or Contracts Co-ordinator will draft either a Co-sponsorship Agreement or a Co-Sponsorship Site Agreement.
- The RGM, or delegate, will propose the Schedule 2: Delegation of Responsibilities.

**3.12 Site Agreements**
- The RGM, or delegate, shall prepare the Schedule 2: Delegation of Responsibilities.
- The CI or TM shall confirm the following as required for each site: Principal Investigator name, R&D contact, nominal recruitment target, recruitment review processes, archiving and sample handling obligations.

**3.13 Collaboration Agreements**
- Where the collaborating institution is also undertaking site recruitment activities the BDO, with input from Contracts Co-ordinators, CI, TM and others as required, will assess whether it would be appropriate to have either a Collaborative Site Agreement or a separate Site Agreement and Collaboration Agreement with the same institution and implement accordingly.
- Where the collaborating institution is to receive trial samples for analysis, the BDO and QAM shall agree whether an Analytical Protocol should be put in place with that institution, in which case this will form part of the Collaboration Agreement.

**3.14 Investigational Medicinal Product (IMP) Supply Agreements**
- Where dedicated, supply of the Investigational Medicinal Produce (IMP) is required to be contracted for the trial, the BDO shall alert the Quality Assurance Manager (QAM) or delegate once a third party IMP supplier is identified (this may happen as early as the grant

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application stage). Assessment of the third party supplier will be made in accordance with SOP-QA-16 - Selection and management of contracted third parties for CTIMPs.

- The BDO or Contracts Co-ordinator will draft the Drug Supply Agreement and/or Technical Agreement or will review a draft agreement if this is sent by the supplier.
- Where the third party’s template agreement is used, review and negotiation of the third party’s commercial and technical terms may also be required in conjunction with the supply agreement and will be led by the BDO.

3.15 Third party Service Agreements
- The BDO/CI or delegate will alert the QAM or delegate once a third party is identified (this may happen as early as the grant application stage); assessment of the third party supplier will be made in accordance with SOP-QA-16 - Selection and management of contracted third parties for CTIMPs.
- The QAM or delegate shall review and approve an Analytical Protocol, which where necessary, will form a Schedule to the agreement.
- Where a third party provides their own contract template the QAM or delegate will assess whether a separate Analytical Protocol is also required.

3.16 Material Transfer Agreements (MTAs)
Where clinical samples are to be collected for analysis in accordance with a specific Trial protocol, the BDO will assess whether a separate MTA is required or whether clauses addressing handling of Trial samples should be included within one of the other Trial agreements.

4. Abbreviations and definitions

CTP  Clinical Trial Pharmacist
IMP  Investigational Medicinal Product
MTA  Material Transfer Agreement
R&D  Research & Development (NHS)
R&I  Research & Innovation (UoA)
RFS  Research Financial Service (UoA)

5. Related documentation and references

SOP-QA-4   Applying for sponsorship
SOP-QA-16  Selection and management of contracted third parties for CTIMPs
TMP-QA-18  Analytical Protocol template