

SOP-QA-13 V6

Title: Generation of contracts

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Document History

Version	Description of update	Date Effective
5	Business Development Officer now Research Development Executive Contracts Advisor title change and clarification on role	09-08-23
6	R&I now Research Innovation & Enterprise (RI&E) Updates regarding funding and agreement with PPI parties at 3.1 Updates to amendments at 3.7 Removal of schedule 2 at 3.11 Addition regarding two-way agreement at 3.13 Addition regarding sharing personal data with third parties at 3.15	01-10-26

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 SOP 'Trial' shall mean a Clinical Trial of an Investigational Medicinal Product (CTIMP) or Medical Device Clinical Investigation (MDCI). This SOP describes the procedure for issuing and completing agreements required for Trials. To demonstrate best practice the principles of this SOP may also be applied to studies other than CTIMPs and MDCIs.
- 1.4 'Trial Agreement' is a term used throughout this SOP to describe a document used to agree the contractual terms associated with the specific Trial-related tasks and responsibilities.

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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).
Contracts Advisor	Legal review of Trial Agreements
Research Innovation & Enterprise (RI&E)	Maintaining a file for each Trial Agreement.
Authorised signatory	Final authorisation of Trial Agreements.

3. Procedure

- 3.1 Following confirmation of funding, the Research Development Executive (RDE) in Research Innovation & Enterprise (RI&E) with input from the following where required: CI, Trial Manager, RI&E Contracts Advisor, representative from RI&E Research Finance (RF) team, the Non-commercial Manager and Research Governance Manager (RGM), shall identify the contracts required for the Trial. The Trial Agreements required for each Trial shall be recorded on the UoA Inteum Database.

Trial Agreement Type	To be in place prior to:
Funding Agreement	Any other Trial Agreements are signed
Co-sponsorship Agreement	Trial recruitment at any site (NB recruitment cannot commence until all required approvals are in place)
Site Agreement	Site recruitment at that site (NB recruitment cannot commence until all required approvals are in place)
Collaboration Agreement	Collaborator receives any funding, trial data or samples
Medicinal Product Supply Agreement eg Drug Supply, Technical Agreement.	Sign off of Dispensing Authorisation Form (Green Light)
Laboratory/ Service Agreement	External laboratories or other third parties sub-contracted, for the Trial, to either UoA and or NHSG receiving any trial samples or data
Side Letter Agreements with PPI parties	PPI party receives any funding

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 Contracts Advisor, with support from the RDE as necessary, will draft the Trial Agreements based on the appropriate template. The RDE or Contracts Advisor 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 RF as necessary to ensure consistency with the trial protocol and associated trial documents. Where required, the Contracts Advisor shall conduct a consistency review to ensure the Trial Agreements do not conflict.
- 3.4 The RDE or Contracts Advisor 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

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Agreement will be led by the RDE or Contracts Advisor. The RDE or Contracts Advisor 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 RF, as required.

- 3.5 The Trial Agreement shall receive final approval following signature by the authorised signatories of each contracting party. The RDE or Contracts Advisor 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.
- 3.6 The RDE, Contract Advisor 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, RF 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 RI&E and the NHSG hard copy of the agreement shall be retained within the NHSG R&D office.
- 3.7 The RDE or Contracts Advisor, will draft any required amendments to the Trial Agreements following the procedure outlines in sections 3.4 - 3.6 above.
- 3.8 It is the CIs 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 RDE 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 RDE and or Contracts Advisor will check and approve the contract with the Trial funder (Funding Agreement) with support from colleagues in RF.
- Where necessary, the RDE or Contracts Advisor 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 Contracts Advisor will draft either a Co-sponsorship Agreement.

3.12 Site Agreements

- The RGM, or delegate, will propose the Schedule 2: Delegation of Responsibilities.
- The CI or Trial Manager 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 to receive trial samples for analysis, the Contracts Advisor or RDE, and Quality Assurance Manager (QAM) shall agree whether an Analytical Protocol should be put in place with that institution, and whether this will form part of the Collaboration Agreement or not. Consideration should be given to receipt of any personal data and whether this is included in the collaboration agreement or a separate two-way agreement after discussion with Contracts Advisor or RDE.

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3.14 Investigational Medicinal Product (IMP) Supply Agreements

- Where dedicated supply of the Investigational Medicinal Product (IMP) is required to be contracted for the trial, the RDE shall alert the QAM, or delegate, once a third party IMP supplier 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 third parties and in line with any policies that may apply.
- The Contracts Advisor 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 RDE or Contracts Advisor.

3.15 Third party Service Agreements (eg Drug Supply, Technical, Laboratory Service Agreements)

- The RDE/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 shall be made in accordance with SOP-QA-16 - Selection and management of third parties.
- Where necessary, the QAM or delegate shall review and approve an Analytical Protocol, which will form a Schedule to the agreement.
- Consideration will be taken if any identifiable personal data will be shared with said third party as this will need to be reflected in any agreement as well as any trial documentation and patient facing information.
- Where a third party provides their own contract template the QAM or delegate will assess whether a separate Analytical Protocol is also required.

4. Abbreviations and definitions

CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
CTP	Clinical Trial Pharmacist
IMP	Investigational Medicinal Product
MDCI	Medical Device Clinical Investigation
QAM	Quality Assurance Manager
R&D	Research & Development (NHS)
RI&E	Research Innovation and Enterprise (UoA)
RDE	Research Development Executive
RF	Research Finance (UoA)
RGM	Research Governance Manager

5. Related documentation and references

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

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