UNIVERSITY OF ABERDEEN

NHS Grampian

Standard Operating Procedure: Generation of Contracts for Clinical Trials of Investigational Medicinal Products

SOP Number: UoA-NHSG-SOP-028 **Version No:** 1

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Issue Date: 26/08/2013

Review Due Date: 26/08/2016

Document History:

Version No.	Description of Changes	Date Approved
1	New joint SOP with NHS Grampian, originally a guidance document with code UoA-NHSG-GD-001	26/8/13

This SOP will be reviewed at least every 3 years from initial and subsequent issue dates.

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1. PURPOSE/INTRODUCTION

1.1 For the purpose of this SOP "Trial" shall mean a Clinical Trial of an Investigational Medicinal Product (CTIMP). This SOP describes the procedure for issuing and completing agreements required for Trials.

'Trial Agreement' is a term used throughout this SOP to describe a document used between the Trial sponsor and an outside party, to define the terms and conditions associated with the specific Trial-related tasks delegated to that outside party by the sponsor of the Trial.

2. SCOPE

2.1 This SOP applies to non-commercial Trials that are sponsored or co-sponsored by the University of Aberdeen (UoA) and/or NHS Grampian (NHSG).

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 Supply Agreements

3. RELATED DOCUMENTATION

SOP-UoA-NHSG-004	Applying for Sponsorship, Project Risk Assessment and Insurance Approval
SOP-UoA-NHSG-022	Selection and Management of Contracted Third Parties
UoA-NHSG-TMP-072	Trial Agreement Guidance Checklist

To create a new agreement record using Inteum *(100621)*
To record an agreement amendment using Inteum *(100513)*

4. REFERENCES

Scottish Executive Health Department Research Governance Framework for Health and Community Care

UK Medicines for Human Use (Clinical Trials) Regulations 2004
Current versions of these documents can be accessed via the Research Governance Website:http://www.abdn.ac.uk/medical/researchgovernance/clinicalresearch

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4.1 Abbreviations and Definitions

BDO	Business Development Officer
CI	Chief Investigator
NCM	Non Commercial Manager
NHSG	NHS Grampian
QAM	Quality Assurance Manager
R&D	Research & Development
R&I	Research & Innovation
RFS	Research Financial Services
RGM	Research Governance Manager
SOP	Standard Operating Procedure
TM	Trial Manager
TMF	Trial/Project Master File
UoA	University of Aberdeen

5. RESPONSIBILITIES

5.1 Chief Investigator

5.1.1 It is the responsibility of the Chief Investigator (CI), or a delegated individual e.g. the Trial Manager (TM), to liaise with the University of Aberdeen Business Development Officer (BDO) from the Research and Innovation (R&I) section, to arrange for the legal and administrative management of the Trial.

5.1.2 It is the CI's responsibility to ensure that activities covered by Trial Agreements are not implemented until the relevant Trial agreements are executed and that any necessary regulatory or ethical approvals or amendments are in place. For Site Agreements, local recruitment to the trial may not proceed until relevant Research & Development (R&D) approval is granted for the site.

5.1.3 It is the responsibility of the CI to ensure that all contracted third parties or collaborators receive a copy of the approved Trial protocol and any subsequent amendments.

5.2 Business Development Officer

5.2.1 It is the responsibility of the BDO to oversee the preparation of Trial Agreements and to arrange internal approval of these through liaison with the CI, TM, Research Governance Manager (RGM), NHS Grampian Non Commercial Manager (NCM), clinical trials pharmacist and Research Financial Services (RFS) as required. The BDO will receive support from specialised contracts officers (Contracts Co-ordinators) in R&I when necessary.

5.2.2 The BDO, or Contracts Co-ordinator where agreed, is responsible for maintaining a file for each Trial agreement using a unique identifier code ("Agreement File") on the University's Inteum agreements database ("Inteum Database"). The Contracts Co-ordinators are responsible for maintaining a set of version controlled agreement templates for the contracting of Trials.

5.3 Authorised Signatories

5.3.1 Final authorisation of Trial agreements is the responsibility of the authorised signatories of the University of Aberdeen (UoA) and NHS Grampian (NHSG).

6 PROCEDURE

6.1 Identification of Required Agreements

Following confirmation of funding the BDO, with input from the following where required: CI, TM, Contracts Co-ordinator, representative from RFS, the NCM and RGM, will identify the contracts required for the Trial. The BDO will document the contracts required e.g. by email or on R&I's Inteum database.

Trial Agreement Type	Normally to be in place before:
Funding Agreement	Any other Trial Agreements are signed
Co-sponsorship Agreement	Trial recruitment at any site can commence
Site Agreements	Site recruitment at that site
Technical or Drug Supply Agreement	Commencement of recruitment at any site
Laboratory agreement	External laboratories receive any trial samples
Collaboration agreement	Collaborator received any trial data

6.2 Generic Procedure for Preparing, Negotiating and Filing all Trial Agreements

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 6.3.

6.2.1 The BDO or Contracts Co-ordinator will draft the Trial Agreement (or template, as relevant) and will ensure the draft is approved by the CI, TM, RGM, NCM, Clinical Trials Pharmacist and by RFS, as required. The BDO or Contracts Co-ordinator will ensure the Trial Agreement is consistent with the other Trial Agreements.

6.2.2 The BDO or Contracts Coordinator will issue the draft Trial Agreement to the other party for review. Any negotiation of the Trial Agreement will be led by the BDO. The BDO will seek advice and approval of any changes to the Trial Agreement from the CI, TM, RGM, NCM, Clinical Trials Pharmacist and by RFS, as required.

6.2.3 The Trial agreement will receive final approval following signature by the authorised signatories of each contracting party. The BDO or Contractor Co-ordinator will manage the signature process. Hard copies of the final Trial agreement will be issued to the third party for signature. In general, the Co-Sponsors will be the last parties to sign the agreement.

6.2.4 The BDO or Contract Coordinator will distribute the hard copies of the executed agreement to each party. Electronic copies will be circulated to the CI and/or TM, RFS and others, as required and will be uploaded to the Inteum database. The University hard copy of the agreement will be retained within the R&I office and the NHS Grampian copy will be retained by NHS Grampian R&D.

6.2.5 The BDO may use the guidance checklist to confirm details to be included in the Trial Agreement. When used, a copy of the checklist will be logged on the Inteum Database in the Agreement File.

6.2.6 Any request to amend the Trial agreements must be referred initially to the BDO. The BDO will liaise with the Contracts Co-ordinator, if required, to draft any required amendments and then follow the procedure described in section 6.2 above. It is the CIs responsibility to ensure contractual amendments are not implemented until any associated regulatory or ethical amendments are approved. The BDO will contact the sponsors' provider of Clinical Trials Insurance to notify them of unusual Trials to ensure that cover will be in place. See Risk Assessment SOP UoA-NHSG-SOP-004.

6.3 Specific Steps for Different Trial Agreement Types

6.3.1 Funding Agreements

6.3.1.1 The BDO will check and approve the contract with the Trial funder (Funding Agreement) with support from colleagues in RFS and NHS Grampian Research & Development (NHS R&D).

6.3.1.2 Where necessary, the BDO will outline any key or unusual terms and conditions of the Funding Agreement to the CI.

6.3.2 Co-Sponsorship Agreements

6.3.2.1 The BDO or Contracts Co-ordinator will draft either a Co-Sponsorship Agreement or a Co-Sponsorship Site Agreement when the co-sponsor is also recruiting participants to the Trial.

6.3.2.2 The RGM will prepare the Schedule 2: Delegation of Responsibilities. Any costs to be passed to the co-sponsor will be included in a finance schedule or, when these are not known at the time, will be agreed at a later date through an amendment.

6.3.2.3 Any costs to be passed to the co-sponsor will be included in a finance schedule or, when these are not known at the time, will be agreed at a later date through an amendment.

6.3.3 Site Agreements

6.3.3.1 A template Trial Site Agreement will be prepared as per clause 6.2.

6.3.3.2 The RGM will prepare the Schedule 2: Delegation of Responsibilities.

6.3.3.3 The CI or TM will confirm the following as required for each site: name, contact, nominal recruitment target, recruitment review processes, archiving and sample handling obligations.

6.3.4 Collaboration Agreements

6.3.4.1 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.

6.3.5 Investigational Medicinal Product ("IMP") Supply Agreements

6.3.5.1 The BDO will alert the UoA/ NHSG Quality Assurance Manager (QAM) as soon as 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 UoA-NHSG-022.

6.3.5.2 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.

6.3.5.3 Where the third party's template agreement is used, review and negotiation of the third party's terms of service may also be required in conjunction with the supply agreement and will be led by the BDO.

6.3.5.4 The CI, TM, a clinical trial pharmacist and where appropriate the NCM and RGM must check and approve the draft Drug Supply Agreement and/or Technical Agreement.

6.3.6 Third Party Laboratory Service Agreements

6.3.6.1 The BDO will alert the University / NHS Grampian Quality Assurance Manager as soon as a third party laboratory 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 UoA-NHSG-022.

6.3.6.2 Where deemed necessary, the University / NHS Grampian Quality Assurance Manager will provide an Analytical Protocol which will form a Schedule to the agreement.

6.3.7 Material Transfer Agreements

Where clinical samples are to be collected for analysis in accordance with a specific Trial protocol, the BDO will assess whether a separate Material Transfer Agreement is required or a clause addressing handling of Trial samples should be included within one of the other Trial agreements. In either case, the material transfer provision must be place before any samples are transported.