SOP-QA-4 V6

Title: Applying for sponsorship

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Document History

Version	Description of update	Date Effective
4	Scope and responsibilities clarified Revised procedure at 3. Abbreviations added at 4 RGM changed to RGT at 2, 3.1, 3.2, 3.3, 3.11, 3.12	1-8-20
5	Minor updates made throughout SOP Update to Application for CTA process added at 3.5 – 3.10	9-8-23
6	Reference to DPIA at 3.1, 4 and 5	15-11-23

1. Scope

1.1 This SOP applies to any researcher requesting sponsorship for a high-risk interventional study involving human participants, Clinical Trial of an Investigational Medicinal Product (CTIMP) or Medical Device Clinical Investigation (MDCI), following successful grant application. Other types of studies may require sponsorship - contact the Research Governance Team (RGT).

1.2 ⚠ All high-risk interventional studies, CTIMPs and MDCIs must have sponsorship and appropriate insurance cover in place before the study commences and before application to Research Ethics Committee (REC), NHS Research & Development (R&D) and the Medicines and Healthcare products Regulatory Agency (MHRA), as applicable. The decision to grant sponsorship and insurance cover shall be taken by Sponsor on a case by case basis.

2. Responsibilities

Research Governance Manager	Review the protocol and relevant study documentation to assist CSOG in considering sponsorship. Risk assess high risk studies, CTIMPs and MDCIs. Confirm indemnity provision for each study.
Business Development Team	Confirm funding and coordinate contracts/agreements where required.
Chief Investigator (CI)	Liaise with RGT prior to submission to REC, R&D and MHRA.
CSOG	Risk assess high risk studies, CTIMPs and MDCIs.

3. Procedure

Applying for sponsorship

3.1 The CI, or delegate, shall inform the RGT of a planned CTIMP, MDCI or High Risk Interventional Study as early as possible. Documents sent to the RGT (researchgovernance@abdn.ac.uk) shall be version controlled at all times.

- Full IRAS dataset
- Outline Organisation Information Document
- SOECAT or Schedule of Events, as applicable
- Evidence of funding
- Evidence of peer review relevant to the protocol
- Completed Data Protection Impact Assessment (DPIA) requirement form
- Short CV of CI (and any co-investigators where requested)
- Evidence of current (within past two years) Good Clinical Practice (GCP)/Good Research Practice (GRP) training for CI
- Investigator Brochure (IB), Summary of Product Characteristics (SmPC/SPC) or Investigational Medicinal Product Dossier (IMPD) as applicable
- Copies of all documents relevant to participation:
  - Advert
  - Participation Information Sheet
  - Letter of invite
  - Informed Consent Form
  - Patient diary
  - Questionnaires
  - Letter to GP
  - Draft emails

3.2 Upon receipt of the complete set of required documents, the RGT shall register the trial on the Sponsor log and notify the investigator of the unique identification number.

Risk Assessment

3.3 All documents pertaining to the sponsorship application shall be reviewed and risk assessed by the RGT, using the University of Aberdeen and NHS Grampian risk assessment document. Identification shall be made as to whether the proposed research falls under MHRA Clinical Trial/Medical Device legislation.

- An assessment shall be made of insurance requirements.
- If the trial falls out with the terms of UoA clinical research policy, the RGT will refer the study to the UoA insurer to confirm insurance cover.
- If UoA cannot obtain insurance for the trial, the RGT shall inform the CI.
- Research & Innovation (R&I) shall advise on any costs that may be incurred for which funding must be in place.
- R&I shall be contacted regarding any required contracts and agreements.
- The Clinical Trials Pharmacist shall be contacted regarding any study involving a medicinal product and provided with all relevant documentation to review, before. providing written confirmation agreeing capacity and capability.
- The RGT shall provide advice and guidance on any amendments required, prior to review by the Clinical Studies Oversight Group (CSOG), and liaise with the investigator

to ensure study documents identify and mitigate potential risks to participants and to trial integrity.

- The study shall be provisionally graded by the Research Governance Manager (RGM) according to MHRA guidelines.
- The study shall be referred to CSOG for a full risk assessment, confirmation or change of MHRA classification and Sponsorship approval. This shall include review of the protocol by a CSOG statistician. CSOG shall liaise with the RGT regarding any comments or queries concerning the trial; these will be directed to the investigator for clarification.
- Discussion, and any decisions regarding sponsorship, shall be recorded.
- CSOG shall confirm or decline sponsorship.

The Investigator may appeal the decision through CSOG.

Confirmation of sponsorship arrangements

3.4 Following confirmation of sponsorship from CSOG, the RGM shall inform the investigator, sign the relevant IRAS forms, and permission shall be given to apply for a Clinical Trial Authorisation (CTA) from MHRA, if required.

3.5 Applications for CTA is now combined with REC review and must be made using the Combined review process through new IRAS. Where there are exceptions the RGT will advise prior to submission. Further information is available on the HRA website (Combined Review).

3.6 The RGT shall send the completed Risk Assessment Document and the study protocol to the QA Manager and the Research Monitors to highlight areas for audit and monitoring.

3.7 The RGM shall liaise with R&I and NHSG R&D to complete a Co-sponsorship Agreement detailing the delegated tasks that the CI must follow to maintain sponsorship and insurance.

3.8 The Co-sponsorship agreement shall be signed by the CI and Co-sponsors to confirm the delegation of responsibilities between Co-sponsors and the CI.

3.9 A risk-based monitoring plan shall be prepared by the Monitors in liaison with the RGM and Quality Assurance Manager, to oversee study related activities, ensure the continuing safety of trial participants and ensure compliance with the agreed protocol and the principles of GCP.

3.10 Evidence of trial registration on ISRCTN or clinicaltrials.gov must be provided to RGT before Sponsor greenlight will be issued.

Amendments

3.11 Review of sponsorship arrangements and risk for all research projects is ongoing while the project is active. It is the CI's responsibility to forward details of all amendments to the RGT for review, classification and approval prior to submission to REC, R&D or the MHRA.

3.12 The RGT may refer the project back to CSOG for risk assessment and review of sponsorship depending on the nature of the amendment.

4. Abbreviations and definitions

CI	Chief Investigator
CSOG	Clinical Studies Oversight Group
CTA	Clinical Trial Authorisation
CTIMP	Clinical Trial of an Investigational Medicinal Product
DPIA	Data Protection Impact Assessment
GCP	Good Clinical Practice
GRP	Good Research Practice
IB	Investigator Brochure
IMPD	Investigational Medicinal Product Dossier
IRAS	Integrated Research Application System
MHRA	Medicines and Healthcare products Regulatory Agency
R&D	Research and Development (NHS Grampian)
R&I	Research and Innovation (University of Aberdeen)
REC	Research Ethics Committee
RGM	Research Governance Manager
RGT	Research Governance Team
SPC (or SmPC)	Summary of Product Characteristics

5. Related documentation and references

SOP-QA-10	Applying for REC ethical opinion
TMP-QA-96	DPIA requirement