SOP-QA-4 V4

Title: Applying for sponsorship

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Document History

Version	Description of update	Date Effective
1	Change of number for Q-Pulse and addition of associated documents	2-10-15
2	Revised title, purpose and introduction. Removal of use by other NHS areas at 1. Revised associated documents and responsibilities. Revised procedure at 3.1	11-4-16
3	Reformatted and reference to government website for guidance.	1-4-17
4	Scope and responsibilities clarified Revised procedure at 3 RGM changed to RGT at 2, 3.1, 3.2, 3.3, 3.11, 3.12 Abbreviations added at 4	1-8-20

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, following successful grant application. Other types of studies may require sponsorship, please contact the Research Governance Team (RGT).

1.2 ⚠ All high-risk interventional studies, Medical Device Clinical Investigations and CTIMPs 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. Confirm indemnity provision for each study.
Business Development Team	Confirm funding and coordinate contracts and agreements where required.
Chief Investigator	Liaise with RGT prior to submission to REC, R&D and MHRA.
CSOG	Risk assesses high risk studies and CTIMPs.

3. Procedure

Applying for sponsorship

3.1 The Chief Investigator (CI), or delegate, shall inform the RGT of a planned CTIMP, Medical Device Clinical Investigation 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
- Short CV of CI and any co-investigators
- 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 (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 database 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) will 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 all relevant documentation shall be provided for review. Written confirmation from the Clinical Trial Pharmacist agreeing capacity and capability shall be required.

- 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 trial 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 in the minutes.
- 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 Before submission to MHRA a EudraCT number must be obtained and included on the application. Go to https://eudract.ema.europa.eu/ and follow the on-screen instructions. Confirmation of the EudraCT number shall be given to the RGT once received.

3.6 Applications for Clinical Trials Authorisation must be made using the Common European Submission Platform (CESP). Further information is available on the MHRA website.

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

3.8 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.

3.9 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.

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

Amendments

3.11 The 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 an NHS REC, R&D or the MHRA, if required.

3.12 The RGT may refer the study back to CSOG for risk assessment and review of sponsorship. The RGT may need to refer research projects back to CSOG for further risk assessment and review of sponsorship depending on the nature of the amendment.

4. Abbreviations and definitions

CESP	Common European Submission Portal
CI	Chief Investigator
CSOG	Clinical Studies Oversight Group
CTA	Clinical Trial Authorisation
CTIMP	Clinical Trial of an Investigational Medicinal Product
CV	Curriculum Vitae (Resume)
EudraCT	European Union Drug Regulating Authorities Clinical Trials Database
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
QAM	Quality Assurance Manager
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-7	Sponsor registration form