SOP-QA-5 V3

Title: Sponsorship review and risk assessment	
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Document History

Version	Description of update	Date Effective
1	Change of number for Q-Pulse	2-10-15
2	Reformatted & removal of 'Applying for sponsorship section'	1-4-17
3	Updated references to RGT CSOG member review changed to 14 days at 3.14 3.18-3.20 removed Updated abbreviations at 4 Updated Related Documentation and references at 5 Inclusion of interventional studies & clarification of process at Appendix 1	5-8-20

1. Scope

1.1 This SOP applies to all research and Sponsor staff participating in, or supporting, research projects sponsored or co-sponsored by University of Aberdeen (UoA) and/or NHS Grampian (NHSG).

1.2 ⚠ Interventional and non-interventional research projects must have a protocol prepared which is compliant with the principles of Good Clinical Practice (GCP).

2. Responsibilities

Chief Investigator (CI)	Request approval of the sponsorship arrangements and provide the appropriate documentation for risk assessment through the Research Governance Team (RGT).
Research Governance Team	Assess all studies and identify those for referral to the Clinical Studies Oversight Group (CSOG) or insurer.
CSOG	Undertake full risk assessments on studies referred by RGT and confirm sponsorship arrangements.

3.Procedure

Confirmation of indemnity arrangements

3.1 Studies involving UoA staff, facilities or premises: If the study falls within a specific exclusion or endorsement of the UoA insurance policies, or if deemed appropriate, the RGT shall refer the study to the UoA insurer to confirm insurance cover. The UoA insurer has confirmed that Clinical Trials of an Investigational Medicinal Product (CTIMPs) do not need to be referred to them unless they fall within an exclusion or endorsement of the policy.

3.2 The UoA insurer has deemed the NHS REC (responsible for giving ethical approval to the study) is the body responsible for determining whether cover for non-negligent harm is required for a particular study. UoA has non-negligent harm insurance cover within its Clinical Trials policy; as such, providing a study does not fall within a specific exclusion or endorsement of the UoA insurance policies, individual studies do not need to be referred to the insurer individually to confirm cover.

3.3 In the event a study-specific premium is requested by the UoA insurer, the Research Governance Manager (RGM) shall confirm who is responsible for paying such a premium. UoA does not have central funds to cover additional premium costs; payment of these costs must be arranged by the CI. Wherever possible, studies which are likely to require an additional insurance premium, shall be identified at the grant application stage to allow the costs of the premium to be included in the funding application.

3.4 For studies which involve both UoA and NHSG, the RGT shall provide appropriate wording for the indemnity sections of the IRAS forms reflecting the roles and contributions of each party.

Research Governance Team initial review

3.5 The RGT shall assess the study documentation and Sponsor Registration Form (SRF). Following this review, the RGT shall:

- Assess the study as low risk with no significant issues and confirm sponsorship arrangements to the CI by issuing sponsorship documentation; **or**
- Request specific amendments to study documentation, or procedures, before confirming sponsorship arrangements and issuing sponsorship documentation; **or**
- Refer the study to CSOG for a full risk assessment.

3.6 The RGT shall refer all CTIMPs, surgical trials and medical device clinical investigations to CSOG for a full risk assessment. Other studies shall be referred on a case by case basis, where deemed appropriate by the RGM. For further guidance see: SOP-QA-4 - Applying for sponsorship.

Full Risk Assessment procedure

3.7 Provision of documents for CSOG review:

- The RGT shall send the Protocol, Risk Assessment Proforma (RAP) and other documentation, as appropriate, to two CSOG members on a rotational basis. If deemed appropriate, one member may be selected based on their expertise.
- For CTIMPs and medical device clinical investigations, two reviews are required, for other studies one review may be acceptable.

3.8 CSOG member risk assessment:

- CSOG members shall assess the risk associated with the proposed study and send the completed RAP to the RGT, ideally within 14 days. For CTIMPs, if the reviewer is unable to complete the assessment within this timeframe the project shall be assigned to another CSOG member.
- The CSOG review shall include an assessment of participant and researcher safety, reputational risk to both UoA and NHSG, project management procedures, including Data Monitoring Committee, Trial Steering Committee and Trial Management

Committee arrangements and whether additional monitoring should be implemented (see SOP-QA-28 – Monitoring).

3.9 Procedure when minor issues identified:

- The CSOG reviewer shall record any minor issues identified on the RAP form.
- The RGT shall liaise with the CI regarding any recommended amendments.
- If the RGT identifies any further issues and the project shall be referred back to the CI and/or CSOG at the next scheduled meeting.

When all issues have been addressed, the RGT shall confirm sponsorship of the study, subject to ethical, regulatory and NHS R&D approval and any additional caveats of sponsorship.

3.10 Procedure when significant issues identified:

- The CSOG reviewer shall record any significant issues identified on the RAP form.
- The RGT shall liaise with the CI to address the issues raised.
- The CI's responses shall be assessed by the RGT who shall either confirm sponsorship of the study or refer the study back to CSOG for further assessment.

When all issues have been addressed the RGT shall confirm sponsorship of the study, subject to ethical, regulatory and NHS R&D approval and any additional caveats of sponsorship.

3.11 Procedure when CSOG reviewers disagree in their assessment of risk:

- If the two CSOG reviewers reach different conclusions on their assessment of risk, the RGM shall ask them to liaise, in order to attempt a resolution.
- If no resolution can be found, the RGM shall refer the study to one of the CSOG Convenors for a resolution.
- If a resolution still cannot be found, the project shall be referred to the entire CSOG at the next scheduled meeting.

3.12 Review of studies provided with sponsorship since the last CSOG meeting:

- CSOG shall review all studies given sponsorship approval since its previous meeting. This is so that the group can assess whether the risk assessment process has been applied appropriately to each study, including those not referred to CSOG members for full risk assessment.
- If deemed appropriate, any study which has not been through the full risk assessment process shall be identified and entered into that process.
- If CSOG identifies any issues with sponsorship arrangements the project shall be referred back to the CI for further clarification or amendment.
- When all issues have been addressed the RGT shall confirm sponsorship of the study, subject to ethical, regulatory and NHS R&D approval and any additional caveats of sponsorship.

3.13 RGM Referral of active studies to the CSOG:

- If the RGT identifies any issues during the conduct of an active study that may affect sponsorship arrangement, eg after assessment of proposed amendments to the study, CSOG will reassess the study for risk (See SOP-19 – Amendments).
- The RGM shall liaise with the CI to address the identified issues and either reconfirm or withdraw sponsorship.

3.14 CSOG assessment of studies presented for appeal:

- CSOG shall review all appeals from CIs of studies rejected for sponsorship.
- The RGM shall liaise with the CI to confirm the outcome of the appeal process.

CSOG Pharmacovigilance Assessment Procedure

3.15 At each scheduled meeting, CSOG shall review reports generated by the RGT of Suspected Unexpected Serious Adverse Reactions (SUSARs), Serious Adverse Events (SAEs) or serious breaches occurring in active studies sponsored by UoA and/or NHSG (see SOP-QA-22 – Adverse Events in CTIMP, SOP-QA-25 – Deviations and Breaches and SOP-QA-39 Adverse Events in Medical Device Trials).

3.16 The review shall include confirmation that the correct pharmacovigilance or serious breach procedure has been followed (particularly with respect to the reporting of events within the appropriate timeframes) and if not, shall determine appropriate CAPA. The review shall enable UoA and NHSG to identify any changes in risk during the conduct of a trial which may affect sponsorship arrangements.

CSOG Monitoring/Audit Report Procedure

3.17 At each scheduled meeting, the Quality Assurance Manager (QAM) shall provide an overview of monitoring and audit reports, highlighting any significant or systematic issues that have been identified.

3.18 The RGM shall liaise with the QAM, Research Monitors and CI, as appropriate, to ensure that any issues identified have been addressed. In exceptional circumstances, the RGM may refer the issues back to CSOG for further assessment, especially if there may be a change in risk which might affect sponsorship arrangement.

Studies involving NHSG investigators /UoA investigators with honorary NHSG contracts or NHSG facilities

3.19 For studies sponsored by third parties, and which involve NHSG/honorary NHSG employees, approval for the involvement of the NHSG employee(s) in the study shall be confirmed via the NHSG R&D Management process.

4. Abbreviations and definitions

CAPA	Corrective Action and Preventive Action
CI	Chief Investigator
CSOG	Clinical Studies Oversight Group
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
IRAS	Integrated Research Application System
QAM	Quality Assurance Manager
R&D	Research and Development
R&I	Research and Innovation
RAP	Risk Assessment Proforma
REC	Research Ethics Committee
RGM	Research Governance Manager
RGT	Research Governance Team
SAE	Serious Adverse Event
SRF	Sponsor Registration Form
SUSAR	Suspected Unexpected Serious Adverse Reaction

5. Related documentation and references

SOP-QA-5 Appendix 1	Sponsorship arrangements for different types of clinical research studies
SOP-QA-4	Applying for sponsorship
SOP-QA-19	Amendments
SOP-QA-22	Adverse Events in CTIMPs
SOP-QA-25	Deviations and Breaches
SOP-QA-28	Monitoring
SOP-QA-39	Adverse Events in Medical Device Clinical Investigations
TMP-QA-7	Sponsor registration form
TMP-QA-16	Sponsor Risk Assessment

Appendix 1 Sponsorship arrangements for different types of clinical research studies.

Chief Investigator	CTIMPs, Medical Device Clinical Investigations, Surgical Trials & high risk interventional studies		
	Where NHSG facilities used and/or NHSG-employed staff are on research team		Where no NHSG facilities used and/or no NHSG-employed staff on research team
	Participants: NHS patients, tissue, data or staff	**Participants: Healthy Volunteers**	**Participants: Healthy Volunteers**
UoA employee	Co-sponsorship	Co-sponsorship	UoA sponsorship or co-sponsorship with a third party.
NHSG employee where no UoA involvement in study (UoA input is limited to pharmacovigilance oversight)	NHSG sponsorship	NHSG sponsorship	N/A
NHSG employee with UoA honorary contract where UoA has input in to study (except where UoA input is limited to oversight of pharmacovigilance)	Co-sponsorship	Co-sponsorship	N/A
Commercial company	Commercial company	Commercial company	Commercial company
Other e.g. employee of another University	Other	Other	Other

	All Other Studies		
UoA employee	UoA sponsorship	UoA sponsorship	UoA sponsorship
NHSG employee	NHSG sponsorship	NHSG sponsorship	N/A
NHSG employee with UoA honorary contract	NHSG sponsorship	NHSG sponsorship	N/A
UoA postgraduate student (Supervisor should be named as CI)	UoA sponsorship	UoA sponsorship	UoA sponsorship
UoA undergraduate student (Supervisor should be named as CI)	UoA sponsorship (UoA supervisor is always required either alone or alongside NHSG supervisor)	UoA sponsorship (UoA supervisor is always required either alone or alongside NHSG supervisor)	UoA sponsorship
Commercial company	Commercial company	Commercial company	Commercial company