Title: Applying for sponsorship

Effective Date: 1-4-17
Review Date: 1-4-20

Author: Patricia Burns, Research Governance Manager
QA Approval: Richard Cowie, QA Manager
Approver: Prof Maggie Cruickshank, R&D Director
Approver: Prof Steve Heys, Head of School

Document History

<table>
<thead>
<tr>
<th>Version</th>
<th>Description of update</th>
<th>Date Effective</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Change of number for Q-Pulse and addition of associated documents</td>
<td>2-10-15</td>
</tr>
<tr>
<td>2</td>
<td>Revised title, purpose and introduction. Removal of use by other NHS areas at 1.</td>
<td>11-4-16</td>
</tr>
<tr>
<td></td>
<td>Revised associated documents and responsibilities.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Revised procedure at 3.1</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Reformatted and reference to government website for guidance.</td>
<td>1-4-17</td>
</tr>
</tbody>
</table>

1. Scope

1.1 This SOP applies to any researcher requesting sponsorship for a high-risk interventional study involving human participants, CTIMP or medical device trial, following successful grant application.

1.2 ⚠ All high-risk interventional studies, device trials and CTIMPs must have sponsorship and appropriate insurance cover in place before the study commences and before application to Research Ethics Committee (REC), NHS R&D and the MHRA. 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.

Business Development Team
Confirm indemnity provision for each study (with RGM).

Chief Investigator
Liaise with RGM 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 Research Governance Manager (RGM) of a planned CTIMP, device trial or High Risk Intervventional Study as early as possible.
Documents sent to RGM (researchgovernance@abdn.ac.uk) shall be version controlled at all times.

- Full IRAS dataset
- Evidence of peer review relevant to the protocol and funding
- Short CV of Chief Investigator and any co-investigators

Uncontrolled when printed. Please ensure that you are working on the most up to date version of this SOP.

Key to symbols ⚠ = Important point to note ⚠ = Warning
- Evidence of current (within past two years) GCP training for trial staff
- Investigator Brochure (IB), Summary of Product Characteristics (SPC) or Investigational Medicinal Product Dossier (IMPD) as applicable
- Evidence of involvement of Clinical Trial Pharmacy
- 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 RGM 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 by the RGM, or delegate, and identification made as to whether the proposed research falls under MHRA clinical trial legislation.

- An assessment shall be made of insurance requirements.
- The RGM shall forward the protocol to Research & Innovation (R&I) to advise if:
  - University of Aberdeen (UoA) insurance is sufficient for the trial,
  - If trial specific insurance must be obtained.
- R&I will advise on any costs that may be incurred for which funding must be in place.
- If the trial falls outwith the terms of UoA clinical research policy R&I will refer the study to the UoA insurer to confirm insurance cover.
- If UoA cannot obtain insurance for the trial, the RGM shall inform the CI.
- R&I shall be contacted in regard to any required contracts and agreements.
- The Research Governance Team shall provide advice and guidance on any amendments required, prior to review by 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 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.
- CSOG shall liaise with the RGM 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 CTA from MHRA.

Uncontrolled when printed. Please ensure that you are working on the most up to date version of this SOP.

Key to symbols

- Important point to note
- Warning
3.5 ️ Before submission to MHRA a EudraCT number must be obtained and included on the application. Go to [https://eudract.ema.europa.eu/](https://eudract.ema.europa.eu/) and follow the on-screen instructions.

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.

3.5 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.

3.6 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.

3.7 A risk based monitoring plan shall be prepared, in liaison with the 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.

**Amendments**

3.8 The review of sponsorship arrangements 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 RGM for review, classification and approval prior to submission to an NHS REC, R&D or the MHRA if required.

3.9 The RGM may refer the study back to CSOG for risk assessment and review of sponsorship. The RGM 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**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CESP</td>
<td>Common European Submission Platform</td>
</tr>
<tr>
<td>CSOG</td>
<td>Clinical Studies Oversight Group</td>
</tr>
<tr>
<td>CTA</td>
<td>Clinical Trial Authorisation</td>
</tr>
<tr>
<td>CTIMP</td>
<td>Clinical Trial of Investigational Medicinal Product</td>
</tr>
<tr>
<td>CV</td>
<td>Curriculum Vitae (Resume)</td>
</tr>
<tr>
<td>EudraCT</td>
<td>European Clinical Trials Database</td>
</tr>
<tr>
<td>GCP</td>
<td>Good Clinical Practice</td>
</tr>
<tr>
<td>IB</td>
<td>Investigator Brochure</td>
</tr>
<tr>
<td>IMPD</td>
<td>Investigational Medicinal Product Dossier</td>
</tr>
<tr>
<td>IRAS</td>
<td>Integrated Research Application System</td>
</tr>
<tr>
<td>MHRA</td>
<td>Medicine and Healthcare products Regulatory Authority</td>
</tr>
<tr>
<td>R&amp;D</td>
<td>Research and Development (NHS Grampian)</td>
</tr>
<tr>
<td>R&amp;I</td>
<td>Research and Innovations (University of Aberdeen)</td>
</tr>
<tr>
<td>REC</td>
<td>Research Ethics Committee</td>
</tr>
<tr>
<td>SPC (or SmPC)</td>
<td>Summary of Product Characteristics</td>
</tr>
</tbody>
</table>

**5. Related documentation and references**

| SOP-QA-10     | Applying for REC ethical opinion |
| TMP-QA-7      | Sponsor registration form |

Uncontrolled when printed. Please ensure that you are working on the most up to date version of this SOP.

Key to symbols ️ = Important point to note ⚠️ = Warning