STANDARD OPERATING PROCEDURE FOR SPONSOR AGREEMENT FOR RESEARCH PROJECTS INVOLVING HUMANS, THEIR TISSUE AND/OR DATA

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1. PURPOSE

This document describes the procedure used for securing Sponsor Agreement for research in NHS Fife and complies with the principles of Good Clinical Practice (GCP).

It is the responsibility of all researchers using this SOP to ensure they are using the latest version of it. The latest version is available via the Research & Development (R&D) page on the NHS Fife Intranet or, for guidance, contact the R&D Office (fife-uhb.randd@nhs.net)

2. APPLICABILITY

This SOP applies to Medical Director(s), R&D staff, Chief Investigators (CIs) and major collaborators.

3. POLICY

3.1 Under the UK Policy Framework for Health and Social Care Research (2017) all research taking place in the NHS must have an explicitly recognised Sponsor. This is the individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance a study. A group of individuals and/or organisations may take on sponsorship responsibilities and distribute them by agreement among the members of the group, provided that, collectively, they make arrangements to allocate all the responsibilities in the research governance framework that are relevant to the study.

3.2 Acting as Sponsor means taking on full legal liability for the design, conduct and management of the research, and also responsibility for securing the arrangements to initiate, manage and finance a study (these functions can be carried out by another person or organisation under the Sponsor's control). It is therefore extremely important that all risks and implications are considered before taking on the role.

Because of the possible legal and financial implications, NHS Fife is unlikely to take on sponsorship of high risk interventional studies and will not sponsor Clinical Trial of an Investigational Medicinal Product (CTIMPs) as covered by the Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031) or any legislation that replaces it. Other studies will be considered in terms of the risks and responsibilities involved in taking on the role of Sponsor.

3.3 It is important to obtain explicit agreement of sponsorship as early as possible in the approval process, preferably prior to the preparation of a grant application. A Research Ethics Committee (REC) will not give an opinion on a study without an agreed Sponsor. Likewise, Local Management Approval cannot be granted unless the study has a Sponsor.

3.4 The design of any study applying for sponsorship from NHS Fife must adhere to all the required guidelines and legislation, including (but not limited to) UK Policy Framework for Health & Social Care Research, The General Data Protection Regulation (GDPR), the Human Tissue Act 2004 or the Human Tissue (Scotland) Act 2006 as appropriate, the Principles of Good Clinical Practice, relevant NHS Fife Policies, SOPs and Work Instructions and any applicable Equality and Diversity policies and appropriate financial management requirements. These aspects of the proposal will be reviewed by the Assistant R&D Director, Senior Research Advisor and R&D Research Coordinator who will, where necessary, ask the CI to amend the proposal.

3.5 The responsibilities of a Sponsor in terms of monitoring are more detailed than those for an organisation hosting a research study (see R&D SOP30 - Procedure for Monitoring Research for more details).

3.6 When a study is brought to the attention of the R&D Department and the CI is an NHS Fife employee or is based in NHS Fife, and/or there is not yet a recognised Sponsor, discussions will begin on who is the most appropriate person or body to act as Sponsor. Where no other organisation is involved, such as a funder or a university, then NHS Fife sponsorship will be considered.

3.7 The identification of NHS Fife as a possible Sponsor can be made either by the CI, who will discuss it with the R&D Research Coordinator, or by the R&D Research Coordinator when first informed of the detail of the study.

3.8 Final agreement to Sponsor a study is provided by the Medical Director and, in the case of joint or co-sponsorship, by the person with the appropriately delegated responsibility in the collaborating organisation.

4. RESPONSIBILITIES

4.1 Chief Investigator:

- To ensure sponsorship is in place prior to submission to Research Ethics Committees, relevant Health Boards and others as required by the project
- To ensure adherence to Sponsor SOPs

4.2 R&D Research Approvals Team (Assistant R&D Director, Senior Research Advisor and R&D Research Coordinator)

- To risk assess the protocol and relevant study documentation as required to ensure NHS Fife carries out its responsibilities as Sponsor organisation.
- To liaise with NHS Fife Service Manager(s) and CI regarding required contracts/agreements

4.3 R, D&I Director:

- To review and risk assess research projects on request of R&D Research Approvals Team in areas of expertise outside the scope of the R&D Research Approvals Team.

4.4 NHS Fife Medical Director or appropriately senior delegate

- To authorise Sponsor approval as the Sponsor's representative on behalf of NHS Fife.
- To sign documents as the Sponsor's representative such as study Agreements or other financial or legal documents relating to the study.

- To authorise the study on the Integrated Research Application System (IRAS) on behalf of the NHS Fife

5. PROCEDURE

5.1 Sponsorship Request

5.1.1 As soon as the CI or delegate has a proposal that will require sponsorship, they must contact the NHS Fife R&D Department via the R&D Research Coordinator (fife-uhb.fiferesearchapprovals@nhs.net) to request study sponsorship and must send the following as available:

- Study protocol, using the appropriate template (see R&D WI36)
- Adverts
- Participant Information Sheet (PIS)
- Informed Consent Form (ICF)
- Invitation letter
- GP letter
- Study Questionnaire.
- Draft emails
- Draft IRAS Form (if available)
- IRAS Checklist (if available)

The above list is an example and is not exhaustive.

5.1.2 All documents must be sent as WORD documents and must be version controlled and include a version number and date (see R&D WI37 - Version Control of Clinical Research Study Documentation).

Each version must be considered a draft until sponsorship has been confirmed, to ensure that the documents included with the IRAS application are Version 1.

5.2 Sponsorship Review

5.2.1 Upon receipt of the complete document set (as determined by the IRAS Checklist), the R&D Research Coordinator must allocate an R&D Reference Number ([Year]-[next consecutive number] to the study, register the study on the Sponsor database, and add it to the Study Approval Tracker in S:\Research\PROJECTS\1 PROJECT TRACKING.

5.2.2 The R&D Research Coordinator must review all study documents to ensure NHS Fife can comply with and support the requirements of the study, discuss any required amendments to the documents with the CI or delegate and complete a Research Sponsorship Checklist for Non-CTIMPs (Doc Ref 06-01).

5.2.3 If the proposed study involves medication the R&D Research Coordinator will consult the MHRA algorithm to confirm whether it is a CTIMP (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/317952/Algothrim.pdf). If the project is confirmed as a CTIMP, the applicant must be advised that NHS Fife cannot act as Sponsor.

5.2.4 All documents pertaining to the application must be reviewed by the R&D Research Coordinator, Assistant R&D Director, Senior Research Advisor and Quality & Performance Lead who will decide whether or not to recommend that NHS Fife can act as Sponsor.

This review will consist of a documented Risk Assessment, including an assessment of appropriate insurance requirements and a review of the feasibility, safety and funding of the study as well as the legal implications for the Sponsor (See R&D SOP07). If necessary the R&D Research Coordinator will contact the CI/Delegate to request further information or clarification.

5.2.5 If sponsorship is agreed, the R&D Research Coordinator will prepare a Sponsorship Agreement and Chief Investigator Declaration (Doc Ref 06-02) for signature by the CI and Medical Director to detail the responsibilities delegated to the CI.

5.2.6 The CI must read, sign and return to the R&D Research Coordinator the original of the Sponsorship Agreement and Chief Investigator Declaration and a copy of this will be returned by the R&D Research Coordinator to the CI for inclusion in the Study Master File.

5.2.7 Once the Sponsorship Agreement and Chief Investigator Declaration has been received, the R&D Research Coordinator must advise the CI that the IRAS forms can be authorised when ready.

5.2.8 Once the CI authorisation is in place, the CI must request authorisation of the IRAS application by transferring the form to the NHS Fife Medical Director or appropriately senior delegate for authorisation as the Sponsor's representative.

5.2.9 The Medical Director or an appropriately senior delegate will be required to sign other documents as the Sponsor's representative such as Clinical Trial Agreements (CTAs) or other financial or legal documents relating to the study.

5.2.10 The R&D Research Coordinator must inform the CI that any changes made to IRAS form following signature will negate the signatures. The CI must contact the R&D Research Coordinator and provide an explanation of what changes were made. The IRAS form will only be re-authorised by the Medical Director once the R&D Research Coordinator has checked to ensure sponsorship remains appropriate.

5.3 Following Authorisation of IRAS

5.3.1 If any study agreement is required the R&D Research Coordinator will seek appropriate legal advice and will advise the CI of the requirement to prepare a model standard agreement using the template available from the IRAS system (https://www.myresearchproject.org.uk/help/hlptemplatesfor.aspx.)

5.3.2 The R&D Quality & Performance Lead must prepare a Monitoring Plan (see R&D SOP30) for review and signature by the CI, Assistant R&D Director and

R, D&I Director or an appropriately senior delegate as the Sponsor's representative.

5.4 Shared Sponsorship

5.4.1 If another organisation is involved in the study, such as a funder or university, and either they, the R&D Research Coordinator, Assistant R&D Director or the Medical Director feel that sponsorship responsibilities should be shared, the R&D Research Coordinator will coordinate discussions to agree how this will be arranged.

5.4.2 Sponsorship can be shared in two ways:

- Joint sponsorship means that each organisation takes responsibility for certain aspects of the study such as the design or management of it.
- Co-sponsorship means that both bodies are jointly responsible for all aspects of the study.

Joint sponsorship is the preferred option and the division of responsibilities will depend on the position(s) of the various members of the study team.

5.5 Studies not Appropriate for Sponsorship by NHS Fife

5.5.1 If the study is not considered appropriate for NHS Fife sponsorship the R&D Research Coordinator and Senior Research Advisor will work with the CI to identify other possible Sponsors or to redesign the research in such a way that NHS Fife would be able to act as Sponsor.

6. ASSOCIATED DOCUMENTS

Doc Ref 06-01 - Research Sponsorship Checklist for Non-CTIMPs
Doc Ref 06-02 - Sponsorship Agreement and Chief Investigator Declaration
R&D SOP07 - Assessment of Risk Associated with Research Studies Sponsored by NHS Fife
R&D SOP30 – Monitoring of Clinical Research Sponsored by NHS Fife.

7. ABBREVIATIONS

CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
IRAS	Integrated Research Application System
REC	Research Ethics Committee
SOP	Standard Operating Procedure

8. REFERENCES

UK Policy Framework for Health and Social Care Research (2017)
https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/

9. DOCUMENT HISTORY

Version Number:	Edited by (job title):	Effective Date:	Details of Revisions Made:
1	Julie Aitken, R&D Trials Facilitator David Chinn, Senior Research Advisor and R&D Coordinator	31/10/2014	New (adapted from NHS Forth Valley SOP 13, Version 1a (as part of the East of Scotland Node)
2	Julie Aitken R&D Trials Facilitator	14/09/2017	Amended for consistency with NHS Fife SOP template. Further details added to clarify the procedure to be followed. SOP title amended to clarify Sponsor 'Agreement' rather than 'Approval'. Job titles for R&D Research Co-ordinator and Assistant R&D Director updated.
3	Aileen Yell R&D Research Coordinator	23/07/2020	Format updated in line with current SOP template and minor changes to text for clarity. Reference to Research Governance Framework updated to UK Policy Framework for Health and Social Care Research. Reference to Doc Ref 06-03 removed as not required for this SOP.

10. APPROVAL

APPROVED BY	Date
Professor Alex Baldacchino, Research, Development & Innovation Director, NHS Fife Signature: 	23 June 2020