Standard Operating Procedure 1

Sponsorship

Document Control Sheet

Title:	Sponsorship
Document Status:	Final
Document Type:	Standard Operating Procedure
Version Number:	v03.1
Document location:	Shared drive and EDGE
Author:	Dr Karen L Bell, Head of Research, Development & Innovation Carolina Borda-Nino, Head of Research, Development & Innovation
Owner:	Dr Karen L Bell, Head of Research, Development & Innovation Carolina Borda-Nino, Head of Research, Development & Innovation
Approved By:	Karen Bell and Carolina Borda-Nino
Date Effective From:	1st August 2023
Review Frequency:	Two years
Next Review Date:	1st August 2025

Revision History:

Version:	Date:	Summary of Changes:	Responsible Officer:
v03.1	01/08/2023	Formatting changes, minor updates to peer review and appendices	Karen Bell and Carolina Borda-Nino
v03.0	20/08/2021	changing from R&D to R,D&I, updates on personnel involved, clarification of all the	Karen Bell

		steps for the process, updates on Appendices to reflect processes	
v02.0	01/05/2020 05/01/21 07/06/21	Revision of document to incorporate Peer Review process and RGL process Revision of document to clarify information, correct typos, add in abbreviations. Email Address and contacts updated in Appendix 1	Karen Bell
v01.0	08/02/2019	Development of SOP	Karen Bell

Approvals: this document was formally approved by:

Name & Title / Group:	Date:	Version:
Karen Bell, Head of Research, Development & Innovation	18/7/23	v03.1
Carolina Borda-Nino, Head of Research, Development & Innovation	18/7/23	v03.1

Dissemination Arrangements:

Intended audience:	Method:	Date:	Version:
RDI Project Team	Access on shared drive and EDGE	18/7/23	v03.1

Linked Documentation:

Document Title:	Document File Path:

NB. This document is uncontrolled when printed. The contents of this document are subject to change, any paper copy is only valid on the day of printing. To ensure you have the most up to date version of this document please use the link to access the document directly from AthenA or contact the Author.

BACKGROUND

Best practice indicates that all non-IMP research studies should be conducted according to the 19 principles of good practice (UK Policy Framework for Health and Social Care Research 2017). It sets out the standards and requirements for the conduct of all clinical and non-clinical research undertaken by NHS staff, using the resources of the NHS research and any research undertaken by any external organisation within the NHS that might have an impact on the quality of those services.

All health and social care research is required to have a Sponsor. The Sponsor takes on overall responsibility for proportionate, effective arrangements being in place to set-up, run and report a research project. The Sponsor is normally expected to be the employer of the Chief Investigator (CI) for non-commercial research. The employer or funder is not automatically the

Sponsor and there is a requirement to explicitly accept the responsibilities of being the Sponsor.

PURPOSE
To provide a procedure for the explicit acceptance by NHS Ayrshire & Arran of the responsibilities of Sponsor for individual projects.

SCOPE
Research, Development & Innovation (RDI) Team
Study Team

RESPONSIBLE PERSONNEL
Medical Director
Head of Research, Development & Innovation
Senior Research Advisor
Lead R&D Facilitator
R&D Assistant

ABBREVIATIONS
NHS A&A – NHS Ayrshire & Arran
CI - Chief Investigator
GCP - Good Clinical Practice
HEI - Higher Education Institute
HRA - Health Research Authority
IMP - Investigational Medicinal Product
IRAS - Integrated Research Application System
MHRA - Medicines and Healthcare Products Regulatory Agency
RDI – Research, Development & Innovation
RGL – Regulatory Green Light
SOP - Standard Operating Procedure

PROCEDURE

WHO?
The Head of RDI and the Senior Research Advisor are responsible for assessing project applications for Sponsorship. The Lead R&D Facilitator and R&D Assistant will provide support for this process depending on staff availability.

WHEN?

On receipt of an application from a Chief Investigator requesting that NHS Ayrshire & Arran accept the role of Sponsor for a non-IMP study, projects will be reviewed for Sponsorship when all relevant documentation has been received by Research, Development & Innovation.

HOW?

1. Following contact from a CI advising that they plan to undertake a study that will require Sponsorship from NHS Ayrshire & Arran the Lead R&D Facilitator/R&D Assistant will provide the Information on R&D Management Approval Process and the List of Documents required for sponsorship consideration (Appendix 1 & 2 to the CI). The Lead R&D Facilitator /R&D Assistant will check with the CI that the study does not involve an IMP. If there is any uncertainty about whether the study qualifies as an IMP study, the CI will be advised to approach the MHRA Clinical Trials Helpline. RDI will be provided with copies of the correspondence and the outcome of the correspondence. If the study is deemed to be an IMP study, NHS A&A will advise that it will not take on the role of Sponsor. If the study is not an IMP study the rest of the SOP will be followed.

2. On receipt of the documents from the CI, the Lead R&D Facilitator /R&D Assistant will check that all the documents have been provided and that the fields in the documents have been completed. If the documents are complete they will be provided to the Head of RDI or Senior Research Advisor if the Head of RDI is not available to review.

3. A student should not normally take on the role of Chief Investigator at any level, however there is an exception to this in the UK Policy Framework for Health and Social Care Research 2017. NHS Ayrshire & Arran expect that an HEI would normally take on the role of Sponsor for student projects.

4. The Head of RDI or Senior Research Advisor if the Head of R&D is not available to review will review the documents to ensure that all fields are completed correctly. The Sponsor Checklist for Non-IMP studies (Appendix 3) will be completed as part of the review process.

5. If the project has external funding then it will be assumed that a review of the proposal was undertaken as part of the funding process. If the study does not have external funding, the Head of RDI or Senior Research Advisor if the Head of RDI is not available to review will discuss peer review with CI and this will be arranged. The Peer review form will be sent to identified appropriate Peer Reviewers and completed (Appendix 4).

6. The CI will be advised to link with Information Governance and Finance to ensure that the proposed study is compliant with data protection requirements and that sufficient funding is in place to cover the study activities.

7. Once the above reviews have taken place, Steps 4-6, and all issues have been addressed, the Head of RDI or Senior Research Advisor if the Head of RDI is not available to review will advise the Lead R&D Facilitator /R&D Assistant that Sponsorship has been agreed.

8. The Lead R&D Facilitator /R&D Assistant will then advise the CI of the process on requesting Sponsor sign-off of the IRAS forms by the Medical Director.

9. The project application will be reviewed by the appropriate Ethics Committee and also reviewed for R&D management approval process.

10. Following a favourable ethics opinion and R&D Management approval being granted, the Head of RDI or Senior Research Advisor if the Head of RDI is not available to review will review the RGL checklist for Sponsorship and will advise if the RGL can be granted and the study is able to commence. (Appendix 5).

11. If the Chief Investigator requires to make any amendments to the study after Sponsorship has been agreed then the Chief Investigator would need to submit these to the Head of RDI or Senior Research Advisor if the Head of RDI is not available to review in the first instance for the Sponsor to determine if the amendment is a substantial or non-substantial amendment and for Sponsor approval. The Head of RDI or Senior Research Advisor if the Head of RDI is not available to review will refer to the HRA guidance on classification of amendment type.

OTHER RELATED PROCEDURES

REFERENCES

UK Policy Framework for Health and Social Care Research 2017

APPENDICES

Appendix 1 - R&D Management Approval Process
Appendix 2 - Documents Required for Sponsorship Consideration
Appendix 3 - Sponsor Checklist for Non-IMP studies
Appendix 4 - Peer Review Assessment Form
Appendix 5 - RGL Sponsorship Checklist

Appendix 1

R&D Management Approval Process

Research cannot be undertaken within NHS Ayrshire and Arran without formal written R&D Management Approval.

In order to obtain this you must register online with IRAS at the following site *https://www.myresearchproject.org.uk* and then contact the relevant member of the R&D team listed below who will assist you with your application.

Prior to your project being considered for R&D Management Approval you must submit the completed IRAS form and all supporting documents electronically through the IRAS system by uploading the documents and phoning the Central Booking system.

What do applicants have to do?

1. Complete the IRAS Form
2. Upload all supporting documents to the checklist tab for the IRAS form and enter details for the documents in the rows (including subtitles, version numbers and dates, as appropriate)
3. Make sure the application is ready to submit and passes the verification step. The IRAS Form e-submission tab gives guidance on this
4. Book in the application for review using the Central Booking Service. If the study requires Research Ethics Committee (REC) review, the service will book the REC meeting slot at the same time as enabling e-submission. For non-REC studies the service will enable e-submission. Applicants will receive a confirmation email from the Central Booking Service
5. Add the booking information to the first page of the IRAS Form
6. Click the “E-submit application” button to submit the application.

NB. The Central Booking Service asks questions relating to the application in order to assign the application to the correct reviewers. Please make sure that the person making the call to the Central Booking Service understands the study.

Please follow the Step-by-Step Guide on IRAS

Supporting documents:
You should enter the details for all of the supporting documents that you are submitting in the ‘Checklist’ tab for the application form in IRAS.

***** The Organisation Information Document (OID) *****

This replaced the SSI form as of 5th June 2019. Guidance is available on IRAS https://www.myresearchproject.org.uk/help/hlpsitespecific.aspx#UK-Local-Information-Pack

It is the Sponsors responsibility to localise the OID and email it along with the relevant delegation log for the site (if applicable) to NRS Permissions CC (NRSPCC) who will then make the Local Information Pack available to participating NHS sites in Scotland (there is no need to supply documents already electronically submitted as part of the IRAS Form application as they will be made available to participating NHS sites in Scotland via NRSPCC).

The Sponsor should email the localised OID(s) after the IRAS Form submission is validated. If there is more than one localised OID, then they should be sent via a single email to NRSPCC.

IMPORTANT: The Sponsor is expected to use a template email when sending the localised OID to NRSPCC. This can be accessed via https://www.myresearchproject.org.uk/help/hlpsitespecific.aspx#UK-Local-Information-Pack under *Participating NHS Organisation in Scotland*, the email template is at the bottom of the paragraph.

Documents to be submitted:

IRAS Submission:

IRAS form
Protocol / Proposal (must include version numbers and dates)
Final versions of supporting documentation (must include version numbers and dates):
- questionnaires
- participant information sheet
- letter of invitation
- consent form
- GP letter

All ethics correspondence including final ethics favourable opinion letter
Abbreviated CV of Chief Investigator, Principal Investigator and all named local co-investigators (should be signed and dated)
Copy of grant application and final award letter (**if applicable**)
Clinical Trials Authorisation (MHRA Letter) (**Clinical trials only**)
Costing Template (**Commercial Projects only**)
Evidence of Insurance/Indemnity (**Non-NHS Sponsors only**)
Clinical Trials Agreement (CTA) or site agreement (**if applicable**)

UK Local Information Pack:
Covering email using standard template format (mentioned above)
Localised OID (Organisation Information Document)
Delegation Log (**Clinical trials only**)
Schedule of Events / Schedule of Events Cost Attribution Tool (SoECAT) (**Non-commercial studies only**)

Please note that for commercial trials there is a £700 +VAT charge for processing R&D Management Approval and a 25% levy on all other income.

For further information and guidance please contact:
RandDProjectTeam@aapct.scot.nhs.uk

To ensure your study meets the requirements of the Data Protection Act 2018, GDPR, Caldicott Principles and the Common Law of Confidentiality please refer to the *Guidance on Data Protection, Caldicott and Confidentiality for Researchers* *http://athena/kmeh/kmeh/igs/Pages/DataProtectionandResearch.aspx*

The UK policy framework for health and social care sets out the principles of good practice in the management and conduct of health and social care research in the UK https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/

APPENDIX 2

Documents required for Sponsorship Consideration in NHS Ayrshire and Arran

Project Title:
RDI Ref/IRAS No.:
Chief Investigator:

Documents required

Documents	Included			Comments
	Yes	No	N/A	
Abbreviated CV for each member of research team (template available)				
Protocol				
IRAS form				
Peer Review (if no secured external funding award, template available)				

If applicable to the study the undernoted documents are also required:

Documents	Included			Comments
	Yes	No	N/A	
Participant Information Sheet				
Participant Consent Form				
GP Letter				
Letter of invitation				
Questionnaire				
Collaboration agreement				
Funding award Letter				

All documents must include version numbers and dates.
Please note NHS Ayrshire and Arran will not consider sponsorship of studies involving Investigational Medicinal Products.

APPENDIX 3

Sponsor Checklist for non IMP studies

Project ID: _____ ____

a) Is this study a non-IMP trial or does it fall within the Medicines for Human Use (Clinical Trials) Regulations 2004?	☐
b) The research proposal respects the dignity, rights, safety and well-being of participants and the relationship with care professionals?	☐
c) Has ethical approval been granted by the relevant ethics committee?	____
d) An appropriate process of independent expert review has demonstrated that the research proposal is worthwhile, of high scientific quality and good value for money?	☐
e) Appropriate arrangements are in place for the registration of a trial[1]?	☐
f) The chief investigator, and other members of the research team, including those at collaborating sites if appropriate, have the necessary expertise and experience and have access to the resources needed to conduct the proposed research successfully?	☐
g) The arrangements and resources proposed will allow the collection of high quality, accurate data and the systems and resources proposed are those required to allow appropriate data analysis and data protection?	☐
h) Arrangements proposed for the work are consistent with the Research Governance Framework?	
i) Organisations and individuals involved in the research agree the division of responsibilities between them?	☐
i) Evidence of the arrangements for the management and monitoring of the study?	☐
k) Arrangements are in place for the sponsor and other stakeholder organisations to be alerted if significant developments occur as the study progresses, whether in relation to the safety of individuals or to scientific direction[2]	☐
l) Agreement has been reached about compensation in the event of harm to research participants and if any organisation, or the sponsor itself, offers compensation without proof of negligence, it has made the necessary financial arrangements;	☐

[1] QA50 of the IRAS form provides information on registration of the trial. Indicate in the notes section if there is any other information provided about trial registration

[2] These include adverse events, serious adverse events, suspected unexpected serious adverse events

m) Are there arrangements for the conclusion of the study including appropriate plans for disseminating the findings? | |

Notes:

Is NHS Ayrshire and Arran able to take on the role of Sponsor for Study ID No. XXX?

Email sent to Medical Director to advise an IRAS authorisation notification will be received and that Sponsor authorisation can occur.

Date sent _____

Date __/__/__

Name (print) _____

Name (signature) _____

Designation: _____

Please use the MA timesheet for A&A Sponsored Studies.
Z:\Project Team\Proforma\Blank Proformas\MA Time Sheet- A&A Sponsored studies v1.0.rtf

APPENDIX 4

PEER REVIEW ASSESSMENT FORM

Under the terms of the UK Policy Framework for Health and Social care Research all research conducted In the NHS must be subject to independent, expert peer review. We are therefore grateful for your assistance in reviewing the attached project. This form is provided as a guide; please include any additional comments that you feel are appropriate. Your (unattributed) comments may be sent to the applicant to enable them to refine their proposal.

Project Title:	**RDI Project ID:**

1. Does the research have clearly stated hypotheses or research question – please describe?
2. Please comment on the study design and methodology, as described, for conducting the research – e.g. is this clear, comprehensive, appropriate etc.? Is the data to be collected in the research necessary to achieve the research aims?
3. Are the objectives clearly stated and is it likely that they can be achieved?
4. Is the research built on a robust evidence-based, e.g. strong literature review, background etc

5. Does the research address questions that need to be answered, and please describe why this is / is not the case?
6. Has there been any attempt to link the research with changes in clinical care or service provision?
7. Is the stated sample size appropriate, and has it been sufficiently justified?
8. Is the sample representative of the target population?
9. Do you feel that the project presents 'value for money' in terms of use of NHS resources versus potential benefits?
10. Does the results dissemination plan contribute to a positive research impact?
11. Do you foresee any risks associated with the study?
12. Are there any other suggestions or comments you wish to make regarding the study, including any suggestions that you feel may improve its design, conduct or likelihood of achieving its objectives?

13. In your opinion is the proposal worthwhile to be undertaken?

12. Please indicate the outcome of your review by ticking one of the following boxes:

- ☐ Project can be carried out with no modifications
- ☐ Project can be carried out with minor modifications
- ☐ Project should be reconsidered only after major modifications
- ☐ Project should not be carried out

Additional comments:

Reviewer's Name	
Title	
Organisation	
Signature	
Date	

APPENDIX 5

Regulatory Green Light (RGL) Checklist

Project ID: IRAS:

Title:

RGL Checklist	Comments	Yes	No	N/A
R&D Management Approval		☐	☐	☐
Ethics Favourable Opinion		☐	☐	☐
Finance		☐	☐	☐
Training		☐	☐	☐
CVs		☐	☐	☐
Letter's of Access		☐	☐	☐
Equipment		☐	☐	☐
Logo on PIS		☐	☐	☐
Logo on Consent Form		☐	☐	☐
Steering Group		☐	☐	☐
		☐	☐	☐

Name of Person Completing Checklist:
Date RGL given: