Standard Operating Procedure

Management Approval Process

Document Control Sheet

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Revision History:

Version:	Date:	Summary of Changes:	Responsible Officer:
Appendix 2a	No date	This was previously a guidance document so has been changed to a SOP and updated to reflect current practice	Natalie McLuckie Amanda Kiddell
V02.0	02/09/22	Recognise changes with Appendix 2a did not result in a change to date. Revisions at this time were substantial so a full change in version number. Changes relating to update to documents e.g. OID, National Processes, change to RDI, update to reflect new appendices and WIs.	Natalie McLuckie

Approvals: this document was formally approved by:

Name & Title / Group:	Date:	Version:
RDI Project Team	30/08/2018	v01.0
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Local Information Appendix	Z:\Project Team\Proforma\Blank Proformas\Local Information Proformas\Non-commercial - Local Information Appendix v1.0 04.07.19.docx

Management Approval Timesheet	..\..\..\..\..\Project Team\Proforma\Blank Proformas\MA Time Sheet 2021-02-25 v9.rtf
Checklist for Info Gov	..\..\..\..\..\Project Team\Proforma\Blank Proformas\Checklist for Info Gov v1.0.docx
Email Template for Reviewers	..\..\..\..\..\Project Team\Proforma\Email Templates\Projects for review.docx
Email Template for R&D Management Approval	..\..\..\..\..\Project Team\Proforma\Email Templates\R&D Management Approval Email.docx

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BACKGROUND

Research and Development Management Approval for projects is a key component of Research Governance. The UK Policy Framework for Health and Social Care Research 2017 requires all projects to have a favourable ethics opinion and management approval before a project can commence.

The following procedure explains the review process for R&D management approval.

PURPOSE

To describe the procedure for sending a Research & Development project for review.

SCOPE

All Research & Development projects being undertaken within NHS Ayrshire and Arran.

RESPONSIBLE PERSONNEL

Lead R&D Facilitator
R&D Assistant
Support Accountant

ABBREVIATIONS

CTA – Clinical Trial Agreement
CTRE – Current Target Recruitment End
DP - Data Protection
IRAS - Integrated Research Application System
NIHR – National Institute for Health Research
NRSPCC - NHS Research Scotland Permissions Co-ordinating Centre
PA – Personal Assistant
PI – Principal Investigator
R&D - Research & Development
R&D MA – Research & Development Management Approval
RGL – Regulatory Green Light
SOP - Standard Operating Procedure
SReDA - Scottish Research Database Application
OID – Organisation Information Document

WHO

The Lead R&D Facilitator is responsible for processing Management Approval.

WHEN

Projects will be sent for review when all relevant documentation has been received in the RDI Office.

HOW

1. On receipt of all required documentation (Appendix 1) from NRSPCC (including single and multicentre studies) the project will be issued with a R&D number from SReDA and added to the Proposed Studies Spreadsheet – 'Study No. given' tab.

2. Project related paperwork will be saved into the relevant folders within the electronic project file (if there is a record in the proposed electronic folder then it should be moved into the electronic project number file).

3. When the outline OID is received the Lead R&D Facilitator completes sections 6 – 11 as best they can and will email the document to the PI to check and complete what is left of sections 6 – 11. If there is no local PI identified the Lead R&D Facilitator will email the study contact named at section 4 of the OID to request for the OID to be localised.

4. The Lead R&D Facilitator will also issue the Local Information Appendix (Appendix 2) to be completed along with the OID when sent to the PI / study contact to be localised.

5. Management Approval Timesheet will be completed electronically by the Lead R&D Facilitator (Appendix 3).

6. If there is an agreement for the study, follow Work Instruction 1 or 2.

7. For agreements with budgets attached:

    - The Lead R&D Facilitator will compare the local NIHR Costing template against the one that is reviewed and agreed by the Generic Reviewer. It will be the same version number and date and all the costings will be the same unless there are specific activities being added or not occurring locally.
    - The Lead R&D Facilitator will then compare the NIHR Costing Template to the Finance Appendix in the CTA to ensure that the costings match.
    - The Lead R&D Facilitator will send the agreed NIHR Costing Template and the agreed CTA to the Support Accountant for review.

8. If there is a requirement to transfer Material out of the organisation the Sponsor will provide a Material Transfer Agreement to be signed.

9. Reviewers in relevant service areas will be identified by the Lead R&D Facilitator.

10. If the application includes named NHS Ayrshire & Arran staff the Lead R&D Facilitator should confirm that the staff members are aware of the study.

11. The project documentation is issued electronically to reviewers along with the Checklist for Information Governance (Appendix 4) by the Lead R&D Facilitator using template e-mail (Appendix 5).

12. The Lead R&D Facilitator will add the project details and names of reviewers to the Proposed Studies Spreadsheet – 'Out for Review' tab.

    - Reviewers are given 5 calendar days to respond to the review email
    - If a response is not received after 4 days the Lead R&D Facilitator will phone the reviewer for a response.

13. When reviews are received they are filed electronically in the project file and recorded in the Proposed Studies Spreadsheet – 'Out for Review' tab.

14. If there have been issues raised by reviewers the Lead R&D Facilitator must liaise with the researcher and the reviewer raising the issues (via NRSPCC if necessary and applicable), until they are resolved.

15. If all reviews are favourable and all necessary paperwork has been received (including Scottish Assessment Tool from NRSPCC) the following will happen:

    15.1 When using the OID as an agreement the Localised OID is sent to the Medical Director's PA to issue an authorisation email. When received the Lead R&D Facilitator will save the authorisation email to the R&D Approval folder and add the date of authorisation to the final page of the OID. The R&D MA letter is then prepared and e-mailed to the Medical Director's PA for signature. They will email the signed R&D MA letter when ready (this should all be logged on the 'Correspondence sent for signature' spreadsheet).

    15.2 When using a separate Agreement the R&D MA letter is prepared and e-mailed to the Medical Director's PA for signature. They will email the signed R&D MA letter when ready (this should all be logged on the 'Correspondence sent for signature' spreadsheet). The date of the R&D MA letter is the date of signature that should be used on the Agreement against the Medical Director details.

16. The signed email copy of the R&D MA letter, Medical Director email authorisation, OID and Agreement (if the OID is not being used as the agreement) is then:

    - Filed electronically in the R&D Approval folder of the project file

- Emailed to the PI, Sponsor, all reviewers and any other relevant contacts (Appendix 6)
- R&D MA letter should be saved within the project record on SReDA (documents tab – local documents)

17. All contact between R&D staff and internal/external personnel relating to the study must be recorded on the MA Timesheet (Appendix 3) and all correspondence should be filed electronically.

18. The SReDA clocks (see NRS-GUI-001 v5 Jan 2014) must be updated to reflect the progress of the study throughout and the clock stopped once the R&D Management Approval has been issued (R&D approval must be issued within 15 days of receipt of the full document set).

19. Once R&D MA has been issued the record on the Proposed Studies spreadsheet should be updated to reflect this and moved to the top of the sheet underneath `Approved and awaiting RGL & CTRE`. Once these dates have been received the records can be deleted.

20. All approved projects should be marked as complete on the 'Out for Review' tab on the Proposed Studies spreadsheet.

21. The study record on SReDA should be updated on the relevant tabs – see MA Timesheet.

OTHER RELATED PROCEDURES
N/A

REFERENCES
NRS-GUI-001 v5 Jan 2014

APPENDICES
Work Instruction 1 – Non-commercial and Clinical Trial Agreements
Work Instruction 2 – Agreements with Universities
Appendix 1 – List of documentation required
Appendix 2 – Local Information Appendix
Appendix 3 - Management Approval Timesheet
Appendix 4 – Checklist for Info Gov
Appendix 5 – E-mail template for reviewers
Appendix 6 – R&D Management Approval Email

Work Instruction 1

Non-Commercial and Clinical Trial Agreements

WI NUMBER	1
VERSION	01.0
AUTHOR	Natalie McLuckie
APPROVED BY	*Dr Karen Bell, Head of RDI*
DATE APPROVED	02/09/2022
EFFECTIVE DATE	02/09/2022
REVIEW DATE	02/09/2024

Version History Log

Version	Effective Date	Details of significant changes

The most up-to-date version of the agreement (reviewed and agreed by the Generic Reviewer) will be added to SReDA by NRSPCC. Once this is available start populating with local information as follows:

1. **Front Page – should have the following information:**

   Ayrshire and Arran Health Board, Eglinton House, Ailsa Hospital, Dalmellington Road, AYR, KA6 6AB

   Agreement date on the front page should be the date of the last signatory (this will be the last thing to be completed by Sponsor or R&D – whoever is the last to sign).

2. **Signatory on behalf of NHS Organisation:**

   Dr Crawford McGuffie, Medical Director

Clinical Trial Agreements:
- will have a section for the PI to also sign
- if there is Pharmacy involvement there may also be a section for them to complete, mostly for Cancer studies (they will need to tick boxes and enter contact info)

3. **Schedule 1:**

   Normally have to enter PI name and address and Employer
   Also check that the number of participants to be recruited match what is on the authorised OID Question 11.

4. **Financial Arrangements:**

   If it has been populated send this to Management Accountant, Lesley Douglas as soon as possible for her to agree to.
   Also enter the payment details (if necessary) this can be found in Project Team / Projects / CTA – MTA info / CTAs / bank details.

5. **Notices:**

   Dr Karen L Bell, Head of RDI, NHS Ayrshire and Arran, 60 Lister Street, University Hospital Crosshouse, Kilmarnock KA2 0BB

Once the local details are complete email copy to the study contact for their review and save this version to the Correspondence – Agreement folder within the project folder.

Always check with the contact if they want to start signature process first (sometimes they will have this information on the original email but not always).

Update the ‘Agreements sent for signature’ tracker within the 2022 Projects folder.

When the agreements are sent to the Medical Director for sign-off update the ‘Agreements sent for signature’ tracker

Work Instruction 2

Agreements with Universities

WI NUMBER	2
VERSION	01.0
AUTHOR	Natalie McLuckie
APPROVED BY	*Dr Karen Bell, Head of RDI*
DATE APPROVED	02/09/2022
EFFECTIVE DATE	02/09/2022
REVIEW DATE	02/09/2024

Version History Log

Version	Effective Date	Details of significant changes

The most up-to-date version of the agreement (reviewed and agreed by the Generic Reviewer) will be added to SReDA by NRSPCC. Once this is available start populating with local information as follows:

1. Board name on the front page (Ayrshire and Arran Health Board) and the full Board name and address on the second page (Ayrshire and Arran Health Board, constituted pursuant to the National Health Service (Scotland) Act 1978 (as amended) and having its headquarters at Eglinton House, Ailsa Hospital, Dalmellington Road, AYR, KA6 6AB) - this can be found in Project Team / Projects / CTA – MTA info / CTAs / Address for CTAs.

2. One of the clauses at the beginning will have the PI name to be entered (normally highlighted for completion).

3. As well as the usual Board signatory there will be a part for the PI to sign (normally the Investigator declaration).

4. The number of patients to be recruited may also be within one of the clauses again this is normally highlighted for completion and should be checked. If you can't find it within the document ask the contact if it is necessary.

Once the local details are complete email copy to the study contact for their review and save this version to the Correspondence – Agreement folder within the project folder.

Always check with the contact if they want to start signature process first (sometimes they will have this information on the original email but not always).

Update the 'Agreements sent for signature' tracker within the 2022 Projects folder.

When the agreements are sent to Medical Director for sign-off update the 'Agreements sent for signature' tracker.

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 RDI Team, 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.

If you require further information and guidance please contact the research and development team – 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

Non-commercial Local Information Appendix

R&D Number:		**IRAS Number:**	
Project Title:			
Principal Investigator:			
NHS A&A Site: e.g. Uni Hospital Crosshouse, Biggart Hospital, Ayrshire Central			

Please complete the following questions:

1. Which other department(s) do you intend to use for interventions/procedures (clinical / non-clinical)?
   Must state the total number per patient and how many are standard of care

Department	**Location**	**Activity**	**Who will conduct intervention/procedure**	**Total no. of interventions received per participant**	**If routinely given as per standard care, how many of the total would have been routine?**
Eg. Ophthalmology	University Hospital Ayr	Questionnaire Completion EXAMPLE ONLY	Research Nurse EXAMPLE ONLY	3	2

EXAMPLE ONLY	EXAMPLE ONLY			EXAMPLE ONLY	EXAMPLE ONLY

2. Will this be the same PI / Local Collaborator **and** study team in each location? (Y/N)_____
    a. If not, please complete this form for **each** location.

3. Who is the contact for recruitment data – (who will be able to provide monthly recruitment figures for this site, **this must be a Study Centre contact**)? Please provide name and email address.
    _____

4. Give details of how potential participants will be identified locally and who will be making the first approach to them to take part in the study.
    _____
    _____
    _____
    _____
    _____
    _____
    _____
    _____

5. Please provide the following information for the site research team. Please add further pages as needed to capture all of your research team.

Name	**Job Title**	**Role in Study** e.g. PI, Sub I, Research nurse, etc.	**Employing Organisation**	**If not employed by NHS A&A, which type of contract does the person have with NHS A&A**[1]

Notes:

1 - Honorary Clinical / Research Contract / NHS-NHS Proforma/ Letter of Access/ None

Declaration by PI or Local Collaborator

- The information in this form is accurate to the best of my knowledge.
- I am aware of and have agreed to discharge my responsibilities in line with the UK Policy Framework for Research and Social Care.
- I have considered and mitigated any conflicts of interest that I may have.

Name..... Signature ……..... Date.....
(PLEASE PRINT)

Appendix 3

MANAGEMENT APPROVAL TIME SHEET

Project ID: | NRS No:

Short Title:

Chief Investigator:
Principal Investigator:

Recruitment Activity Contact:
(not required for NEFs unless Lesley needs figures)

Sponsor:
Funder:

R&D Approval Date: | R&D End Date:

Outline OID Rcvd (date for SReDA): | Full document set:
Localised OID Rcvd: | Governance Report:
Local Info Appendix Sent:
Local Info Appendix Completed:
Localised OID Completed:

Days to approve: | SReDA docs last updated:

Adopted (extended review) ☐	Database ☐
Eligible ☐	Tissue Bank ☐
Lesley needs figures ☐	Bio Bank ☐
Date added to accrual sheet (excluding PICs):	Date added to accrual sheet:

Commercial: ☐

Date added to Accrual sheet (excludes PIC studies) :

Recruitment section on SReDA completed (if under £1000 per patient fee - should not be added to CSO report):

SReDA minimum dataset completed including: ☐

Study Details
- Comment on front page with date MA issued
- Stakeholders (including RAC)
- Project status and start and end dates (local information)
- Add each location (if just NHS A&A then let Amanda know)

Governance
- Update clocks
- Report reminders (attention of box to be left blank)

Recruitment
- Targets and Dates Tab ensure 'recruitment status' is changed to recruiting and update 'date of status change' using approval date (for EF / extended review only. Non consenting e.g. Tissue Banks / Databases that are eligible / extended review should be set to 'No longer recruiting' with date of approval. NEF should be left to 'not set')
- Recruitment Totals Tab record RGL and CTRE.

- Recruitment Totals Tab add RN initials to screening and recruitment info (if applicable)
- Recruitment Totals Tab record Recruitment Source (NEF – N/A / Eligible – Manual Gathering / Cancer – Edge)

Documents

- Add MA to local documents

Documentation	Yes	N/A	Version	Date	Notes
Localised OID					
IRAS Form					
Protocol					
PBPP					
Confirmation of Sponsor					
Financial Agreement					
Copy of REC approval letters					
Clinical Trials Authorisation (MHRA)					
Clinical Trials Agreement / OID as Agreement (*delete as appropriate*)					

Notes section for letters of access, research passports, MTAs, CTAs etc:

Date	Action

Amendments (Post-Approval)

Amendment No. / Date	Amendment in relation to:	Date of R&D Approval

Appendix 4

Checklist for Information Governance

Questions	Guidance notes	YES	NO	NOTES
Are potential participants identified by anyone who would not normally have access to their personal information?	Participants should be identified by those already responsible for their care and those who support those staff e.g. admin support for the clinicians, Or identified by someone incorporated into the team who is bound by obligations of confidentiality (where necessary) e.g. A&A research nurses Q. A27-1 / A27-2 / A29	☐	☐	
Will any personal information be given to researchers outside of the care team without the consent of the individual?	See Q. 11 of R&D / SSI form Informed Consent Q. A30 Q. A40 / A41 / A42	☐	☐	
Will any personal information be disclosed outside of NHS Ayrshire & Arran?	Q. A38 Storage of data – Q. A36 / A45 Security of data – Q. A37	☐	☐	
Will personal information be entered onto a website?		☐	☐	
Will there be audio or video recordings taken by NHS Ayrshire & Arran staff?		☐	☐	
Will personal information be sent by fax?	Q. A37	☐	☐	
Misc: PIC specific questons	Q. A73-1 / A73-2 / A73-3			

Information Governance review required: YES NO
(delete as appropriate)

Additional related comments:

Appendix 5

Email Template for Reviewers

Dear Colleagues

PRINCIPAL INVESTIGATOR/LOCAL COLLABORATOR: Please note that it is your responsibility to discuss the above project with the service clinical team and clinical director. There is no need for you to review.

Please find attached the above project that has been submitted to the R&D office for management review.

Can you let me know using the voting buttons above if you are happy to approve or if you have issues with the study and the impact it will have on the service area.

There is a strict time limit placed against this review process due to the performance measures set by the Scottish Government (click here to access NRS PCC site). Please therefore return your comments to me by **enter date 5 days from now.**

Thank you for your time and expertise on helping us with this review process.

Appendix 6

Email Template for R&D Management Approval

Dear ....

Please find attached R&D Management Approval, authorised OID and Medical Director email authorisation for NHS Ayrshire and Arran

Can the following dates be confirmed (when available):

- **Recruitment Activity Contact**
- **The estimated date you expect recruitment to the study to finish**
- **The date that the Sponsor gives the Regulatory Green Light to start recruiting to the study**

This information ensures that we maintain an accurate database of research activity and can meet the mandatory reporting requirements of the Chief Scientist Office