Standard Operating Procedure

Amendments

NHS Ayrshire and Arran
SOP Amendments SOP 7. Version 05.1
Date: 06/06/2024

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Final 1	29/04/2008	First version	Archie MacDonald
03.0	20/01/2010	Updated to reflect national changes	Amanda Kiddell
04.0	04/07/2018	Updated to reflect new R&D processes	Amanda Kiddell
04.1	08/09/2020	Minor updates	Amanda Kiddell
05.0	27/09/2021	Updated to reflect new R&D processes and include footnotes	Colin Irving/Marie Frew
05.1	06/06/2024	Minor updates	Colin Irving/Marie Frew

Approvals: this document was formally approved by:

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Karen Bell, Head of Research & Development & Innovation	23/5/24	05.1
RDI Team	23/5/24	05.1

Dissemination Arrangements:

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RDI Team	Access on shared drive	23/5/24	05.1

Linked Documentation:

Document Title:	Document File Path:
Checklist for Information Governance	..\..\..\..\..\..\Project Team\Proforma\Blank Proformas\Amendment Checklist for Information Governance v1.0.docx
Checklist for Finance	Z:\Project Team\Proforma\Blank Proformas\Amendment Checklist for Finance.docx

Template Email to Reviewers	Z:\Project Team\Proforma\Email Templates\Amendments for review.doc
Follow up Template Email to Reviewers	Z:\Project Team\Proforma\Email Templates\Amendments for review follow-up.doc
Amendment Objection Letter	W:\Project Team\Proforma\Letters\Amendment Letters\Amendment Objection letter v2.doc
Amendment Approval Letter	W:\Project Team\Proforma\Letters\Amendment Letters\Amendment Approval Letter v4.doc
Email template for Acknowledgement of minor/non-substantial amendments	W:\Project Team\Proforma\Email Templates\Amendment - acknowledgement of a MINOR Amendment v2.docx

BACKGROUND

An amendment is any change to a research study following initial regulatory approvals. There is a national procedure in place for the processing of amendments which NHS Ayrshire & Arran follow. Please refer to 'Standard Operating Procedure for the Processing of Notices of Amendment to Multi-NHS Organisation Research Studies in the UK' and 'NRS-SOP-019'.

All amendments for multi-centre studies must come to the RDI office via NRSPCC. The RDI office can only accept amendments direct from the Sponsor/delegate if it is a single site study.
Amendments will be categorised as one of three categories; A, B or C.
A Category A amendment needs to be approved by NHS, a Category B amendment only needs to be approved by those NHS sites that are affected by the changes and a Category C amendment does not need to be approved by NHS and can be implemented immediately.

Category A and B amendments will be notified with a 35 calendar day implementation date. After this date continued NHS permission may be presumed by the Sponsor, if no objection has been raised, and the amendment can be implemented at site assuming all necessary regulatory approvals are in place.

PURPOSE

To describe the processing and review of Notice of Amendment applications for category A and B amendments to assess the impact on the cost and resource capability for the Health Board.

SCOPE

Lead R&D Facilitator
R&D Co-ordinator
R&D Assistant

RESPONSIBLE PERSONNEL

Head of Research, Development and Innovation
Senior Research Advisor
Lead R&D Facilitator
R&D Co-ordinator
R&D Assistant

ABBREVIATIONS

A&A – Ayrshire & Arran
DB - Database
FDS – Full Document Set
HRA – Health Research Authority
IRAS – Integrated Research Application System
MHRA – Medicines & Healthcare Products regulatory Agency
NRS – NHS Research Scotland
NRSPCC – NHS Research Scotland Permissions Coordinating Centre
RDI – Research, Development & Innovation
REC – Research Ethics Committee
PIC – Participant Identification Centre
SReDA – Scottish Research Database Application
WI – Work Instruction

PROCEDURE
WHO?

The R&D Co-ordinator/Assistant will process all amendments received within the RDI team.

WHEN?

This process will take place when the amendment notification and supporting documents are received from NRSPCC or Sponsors/Delegates if it is a single site study.

HOW?

Category A & B Amendments

1. On receipt of notification email from NRSPCC the R&D Co-ordinator/Assistant will pick this up for processing.

2. The R&D Co-ordinator/Assistant will download the amendment document set from SReDA and save in the shared drive along with the notification email.

3. The R&D Co-ordinator/Assistant will process the amendment and send for review to the appropriate service areas that the amendment affects using Appendix C and following Work Instruction 1 for category A amendments and follow Work Instruction 2 for category B amendments

4. The R&D Co-ordinator/Assistant will add the amendment to the amendment spreadsheet to monitor that reviews are received on time

and the 35 day implementation date is not breached. Reviewers are given 6 calendar days to review.

5. The R&D Co-ordinator/Assistant will email any outstanding reviewers (Appendix D) the day after the 6 day due date and continue to correspond with them until all issues and/or queries are resolved.

6. If issues/queries cannot be resolved or are still outstanding at the 35 day implementation date the R&D Co-ordinator/Assistant will issue an Amendment Objection letter (Appendix E). If an amendment is received late and the 35 day implementation date has already passed or is very close, an objection letter will be issued immediately.

7. Substantial Amendment only - When all reviewers have approved, the R&D Co-ordinator/Assistant will check that the regulatory approvals are in place. If the regulatory approvals have been received an Amendment Approval Letter (Appendix F) will be prepared and sent to the Medical Director's office for signature. If the Regulatory approvals are not in place the R&D Co-ordinator/Assistant will follow this up with the trial centre and colour code the spreadsheet according to the "Key".
   Non-substantial Amendment only – When all reviewers have approved, the R&D Co-ordinator/Assistant will issue the non-substantial acknowledgement email (Appendix G). Non-substantial amendments are not required to be submitted to ethics.

8. Update the "Correspondence sent for signature" spreadsheet with the date that the letter was sent to the Medical Director's office and then also with the date that the signed letter is returned.

9. The signed letter will be saved in the relevant amendment folder within the project file.

10. The signed letter will then be issued and the spreadsheet updated and colour coded following "Key" on spreadsheet.

11. Update ReDA on the Add Amendment box in the "Post Approval" tab.

NOTE: If the amendment requires a change to the clinical trial agreement, then this must be completed prior to approval of amendment.

Category C Amendments

1. On receipt of email from NRSPCC, input NRS number into SReDA to find project ID.

2. Go to documents tab and find folder with the amendment number that matches the amendment number on the notification email.

3. Create a folder in the shared drive under the project for the amendment (name it the same as the SReDA folder) and save all documents from SReDA into it including the notification email.

4. Check all the documents are there for the amendment against the ethics letter and read the documents to see if any information needs to be updated.

5. Cat C amendments need to go to Pharmacy and any Research Nurses if they are involved in the study for their information as they don't always get updated directly from the trial centre and Pharmacy need to update their own study files with the correct information.

6. Cat C amendments should be recorded on the Amendment spreadsheet and followed until Ethics/MHRA authorisation is received if applicable. Use colour code following "Key" on spreadsheet.

7. The RDI team do not need to do anything else as the NHS do not need to review or approve Category C amendments.

Single Centre Amendments

1. Check that the project does not have an NRS number and therefore definitely single-centre. Save email and documents to amendment folder under the relevant project file in the shared drive.

2. Check that a FDS has been received including the Amendment Tool and all documents pertaining to the amendment. A full document set does not need to include regulatory approvals (i.e. ethics and MHRA). If not a FDS, request missing documents. If you do have FDS, calculate the 35 day implementation date and inform the researcher.

3. Continue to follow steps 3 – 11 for category A and B amendments above.

Work Instruction 1 – Category A amendment process

1. Input NRS number into SReDA to find project ID.

2. Go to documents tab and find folder with the amendment number that matches the amendment number on the notification email.

3. Create a folder in the project file in the shared drive (name it the same as the SReDA folder) and save all documents from SReDA into it.

4. Check all the documents are there and read to find out what the changes are and check who the original reviewers of the project were, and the appropriate service areas that the amendment affects.

5. Complete the Amendments Checklist for Information Governance (Appendix A) to see if they need to review it. Once complete save into the project file.

6. Complete the Amendments Checklist for Finance (Appendix B) to see if they need to review it. Once complete save into the project file.

7. Copy email template (Appendix C) into a new email. Add in Project No and Amendment no. into Subject line. Attach documents i.e. Amendment Tool, Summary of Changes, Protocol, Information Sheets & Consents etc.

8. Put in the title of the document that explains the changes in the email content. Take out the statement in bold if you have this, if you don't have a document explaining changes insert summary there.

9. Change the REC/MHRA approval section as appropriate for the amendment.

10. Calculate the 6 calendar day due date and insert into email.

11. Send email to reviewers and copy in the PI and any A&A Research nurses then save email in the project file.

12. Under the projects folder, open the spreadsheet entitled "Amendments for review" and add in details of amendment. Put a box around the whole amendment entry to separate from the other entries. **NB Days to Implementation date will be automatically calculated**

13. When reviewers reply always save the emails in the project file within the relevant amendment and any issues raised should be followed up on until the reviewer is happy to approve. The spreadsheet should then be updated with the date that the reviewer approved the amendment.

Work Instruction 2 – Category B amendment process

1. First check if the amendment affects Ayrshire & Arran or is it just for information.

2. If it affects Ayrshire and Arran – treat the same as Category A amendment and continue to follow steps in WI1.

3. If it does not affect Ayrshire & Arran – treat as a Category C amendment.

OTHER RELATED PROCEDURES

Standard Operating Procedure for the Processing of Notices of Amendment to Multi-NHS Organisation Research Studies in the UK NRS-SOP-019

REFERENCES

N/A

FOOTNOTES

PIC study amendments usually only apply to the recruiting sites and we then issue for information, however, this would change if the amendment affected how the PIC sites work and the amendment directly affects them.

DB study amendments are issued for information only.

Generic review studies do not require any R&D approval or oversight so these are just saved in the project file.

If SReDA status for the study is pre-approval or suspended (COVID) do not process the amendment but create an amendment folder in the project file (name it the same as SReDA folder) and save the email notification and documents in it. Advise Lead R&D Facilitator and update the proposed studies spreadsheet. (These are then dealt with during the R&D Management Approval process).

If an amendment includes an extension to the end date or closure of a study the R&D Co-ordinator/Assistant must notify the Lead R&D facilitator to allow EDGE to be updated.

HRA approval is not required in Scotland.

Once all amendments on the spreadsheet for the year have been finalised then this should be saved in the relevant project year folder.

APPENDICES:

Appendix A – Checklist for Information Governance
Appendix B – Checklist for Finance
Appendix C – Template Email to Reviewers
Appendix D – Follow-up Template Email to Reviewers
Appendix E – Amendment Objection Letter
Appendix F – Amendment Approval Letter
Appendix G – Email template for acknowledgement of minor/non-substantial amendments

Appendix A: Checklist for Information Governance

Amendment Checklist for Information Governance

Amendments	YES	NO
1) Does the amendment involve a change to the collection of personal information:- • Collecting more information than before or • Identifiable information where before it was previously anonymous		
2) Does the amendment involve a change to the method of processing information:- • A different method of storage, or • A change to the transfer of data, or • A change to the destruction of data		
3) Does the amendment involve a change to the recruitment process?		
4) Does the amendment involve any change to the consent process?		
5) Further Comments:		

Appendix B: Checklist for Finance

Amendment Checklist for Finance

Amendments	YES	NO
1. Is the amendment 'Information only'?		
2. Is the amendment Patient Letters only?		
3. Is the amendment GP Letters only?		
4. Is the amendment Flyers or Posters only?		
5. Does the amendment notify of a change of CI, PI or Participating Site only?		
6. Further Comments:		

Appendix C: Template Email to Reviewers

Dear Colleague

Project ID and Full Title

As original reviewer of the above study, please find attached amendment that now requires further review.

A summary of the amendment can be found on the document/s entitled *****. The other attachments are supporting documents for the amendment.

(**If this is not available please provide a summary paragraph in the email detailing the purpose of the amendment**).

This amendment has MREC* and MHRA* approval.

I would be grateful if you could provide me with a response by **(please insert date 6 calendar days from date of issue)** in order that I may process the amendment.

If you require any further information, please do not hesitate to contact me. I appreciate your assistance and look forward to hearing from you in due course.

Kind regards

XXXX

Appendix D: Follow-up Template Email to Reviewers

Dear Colleague

Project ID and Full Title

Further to my email of XXXX (please see below) regarding the amendment for the above study.

I have not yet received a response and would be grateful if you could let me know as soon as possible if you are happy with this or if you have any objections.

I appreciate your assistance and look forward to hearing from you.

Kind regards

XXXX

Appendix E: Amendment Objection Letter

Research, Development & Innovation Office
58 Lister Street
University Hospital Crosshouse
Kilmarnock
KA2 0BB

XXXX

Date	XXXX
Your Ref	
Our Ref	CM/KLB/XXX RDI No
Enquiries to	Karen Bell
Extension	25850
Direct line	01563 825850
Fax	01563 825806
Email	Karen.Bell2@aapct.scot.nhs.uk

Dear XXXX

RDI No & Title

NHS Ayrshire and Arran have received documentation for amendment number XXXX for the above study.

We note that the implementation date has been set as XXXX, however, we (add in objection) and we require further time to process. We are treating this as a priority and hope to give approval as soon as possible.

Please be advised not to implement this amendment at this site until you receive notification that all issues have been resolved and continued RDI permission has been issued.

Please contact the RDI Office if you have any queries.

Yours sincerely

Dr Crawford McGuffie
Medical Director

Appendix F: Amendment Approval Letter

Research, Development & Innovation Office
58 Lister Street
University Hospital Crosshouse
Kilmarnock
KA2 0BB

Date
Your Ref
Our Ref CM/KLB/XX RDI NO

Enquiries to Karen Bell
Extension 25850
Direct line 01563 825850
Fax 01563 825806
Email Karen.bell2@aapct.scot.nhs.uk

Dear XXXX

Title:
IRAS ref:
Amendment ref:
RDI ref:

I have received the undernoted documentation, relating to proposed changes to the above study:

- XXXX
- XXXX
- XXXX

I can confirm that the above amendment has been approved.

Please contact the RDI Office if you have any queries. On behalf of the department, I wish you every success with the project.

Yours sincerely

Dr Crawford McGuffie
Medical Director

Appendix G

Email template for acknowledgement of a MINOR/NON-SUBSTANTIAL Amendment

Dear Colleagues

RDI No and Title

I have received the documents below relating to a minor amendment to the above study:

- XXXX
- XXXX
- XXXX

I can confirm that the above amendment has been acknowledged and given continued RDI permission.

A letter is no longer issued for non-substantial amendments. Please retain this email for your records.

Kind regards

XXXX