**R&D: RECEIPT OF RESEARCH**

**STUDY AMENDMENTS**

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# FOREWORD

## The Academic & Clinical Central Office for Research & Development (ACCORD) is a joint office comprising clinical research management staff from NHS Lothian (NHSL) and the University of Edinburgh (UoE).

## ACCORD will receive research study amendments into the R&D or ACCORD generic mailboxes ([R&DOffice@nhslothian.scot.nhs.uk](mailto:R&DOffice@nhslothian.scot.nhs.uk) or [ACCORD@nhslothian.scot.nhs.uk](mailto:ACCORD@nhslothian.scot.nhs.uk)), either directly from the research team or from the NHS Research Scotland Permissions Coordinating Centre (NRS PCC).

## Amendments will be classified by the Amendment Tool as either ‘substantial’ or ‘non-substantial’ and as category ‘A’, ‘B’ or ‘C’, and given an implementation date;

* **Category A**– applies to all NHS sites and approval must be given by R&D.
* **Category B**– only applies to some NHS sites. If it is relevant to NHSL, R&D approval will be required. If it is not relevant to NHSL or substantial, it will be treated as a non-substantial Category C amendment.
* **Category C**– If the amendment has been categorised as substantial Category C, this will require approval. If it is categorised as a non-substantial Category C amendment, it will only be acknowledged.

## Amendments to an Investigator’s Brochure, a Summary of Product Characteristics (SPC) and/or to an Investigational Medicinal Product Dossier (IMPD), whether substantial Category A or C, will be acknowledged only.

## This work instruction will be followed by the R&D Amendments Officer or by any R&D personnel delegated the task of receipting amendments.

# INSTRUCTIONS FOR RECEIPTING AMENDMENTS

## **R&D Amendment Tracker**

### All Category A, B, and C amendments that require NHSL R&D approval will be tracked using the R&D Amendments Tracker on the R&D shared drive (*Research & Development/Admin/AMENDMENTS/Amendments – Files Currently in Use*).

### Add all amendment details in the appropriate tab of the Amendments Tracker on receipt of the amendment documentation. These details can be found in the study folder on SReDA, on the R&D shared drive, and in the e‑mail sent from NRS PCC.

### If there is something outstanding e.g. Research Ethics Committee (REC) favourable opinion (FO) and/ or MHRA authorisation letter, add the amendment details to the ‘Non-Commercial Amendments’ or ‘Commercial Amendments’ tab.

### If all documents have been received, add the amendment details to the ‘Non-Commercial all docs recd’ or ‘Commercial all docs recd’ tab and mark as ready for review.

### All amendments will be assigned a priority level ‘3’ except for amendments with R&D numbers that end in ‘TMF’ and Urgent Public Health (UPH) amendments which will be a priority level ‘1’. Amendments will be changed to priority level ‘2’ when there has been contact from the research team seeking an update on progress.

## **Amendments to ‘Proposed’ Studies**

### Check SReDA to confirm that the study is ‘Active or ‘In Follow-Up’ or ‘Suspended’ in Lothian.

### If the project status in SReDA is ‘Proposed’, send an e-mail to the R&D Governance Reviewer (detailed on SReDA in the local information tab under ‘R&D Officer’), advising them of the amendment.

### If the ‘R&D Officer’ has not yet been assigned on SReDA, the notice of amendment should be sent to the R&D Coordinators for information.

### Create a folder in the R&D shared drive (see study specific amendment folder called ‘Pre-MA’). Download and appropriately name all the files that have been sent from NRSPCC for this amendment (NRS-GUI-009 NRS Permissions CC – Document Standard Naming Convention). File the e-mail from NRS PCC and the e-mail to the R&D Governance Reviewer in the folder.

### If the study status is ‘Not Set’, find the project folder on the R&D shared drive, create a ‘Pre-MA’ folder for this specific amendment and save the email. Notice of amendment should be sent to the R&D Coordinators for information.

### Amendments for studies set to ‘Proposed’ or ‘Not Set’ **do not** need to be added to the amendment tracker.

## **Receipt of Single-Centre Study Amendments**

### Verify that the study is single-centre by entering the R&D reference number (e.g. YYYY/1234) into SReDA. If there is no NRS number listed, this means that the study is single-centre.

### On receipt of a research study amendment directly from the research team, create a folder on the R&D shared drive in the study specific amendment folder and save the e‑mail to this folder.

### You can check the Amendment Tool to see if the amendment has been classified as substantial (SA) or non-substantial (NSA) and if there is a number or date associated with the amendment.

### Save the documents from the e-mail to the R&D shared drive and re‑name using the NRS naming convention (NRS-GUI-009) e.g. SA01, NSA01.

### The amendment folders should be numbered numerically; if this has not been done already, sort folders and add the correct amendment numbers.

### If single-centre, issue an acknowledgement of receipt e-mail to the researcher using Amendment E-mail Template (Appendix 1, section 4.1 or 4.2).

### If the study has an NRS reference number (e.g. NRSYY/123456), the study is multi-centre and we can only accept the amendment when received from NRS PCC. Use Amendment E-mail Template (Appendix 1, section 4.3) to e-mail the research team and advise that we will be unable to process the amendment until it has been received from NRS PCC. Save this e-mail correspondence in the appropriate study specific amendment folder in the R&D shared drive.

## **Receipt of Multi-Centre Study Amendments**

### On receipt of an amendment from NRS PCC, use the NRS reference or IRAS project code to find the R&D number on SReDA.

### Create a folder in the study specific amendment folder on the R&D shared drive (as named by NRS PCC) and save all the documents from SReDA there, together with the e-mail from NRS PCC.

### Check the project file on the R&D shared drive and the R&D Amendment Tracker (*Research & Development/Admin/Amendments/Amendments – Files Currently In Use*) to make sure the amendment has not already been processed e.g. on occasion NRS PCC will advise us that previously missing documents have been received so you will not need to save all the documents, only the new ones.

### If a researcher has sent us the amendment directly, some information will already be on the R&D shared drive, so check the naming conventions are correct (NRS-GUI-009). Add the date if it is not included already e.g. SA01 - 01.05.22 - Cat A.

### The amendment folders should be numbered numerically. If this has not been done already, please sort folders and add the amendment numbers.

### 

# REFERENCES

NRS-GUI-009 NRS Permissions CC – Document Naming Convention

# APPENDIX 1

## **E-Mail Template: Acknowledgement of a Substantial Amendment (e-mail the PI)**

Dear

**Study Title:**

**REC No:**

**R&D No:**

**IRAS No:**

**Amendment No:**

**Amendment Date:**

Thank you for email dated xxxxxx together with attached documentation relating to an Amendment (Category X) to the above study.

The papers you have submitted will receive an initial review and we will revert to you regarding this as soon as possible.

**PLEASE BE AWARE THAT CHANGES TO YOUR EXISTING STUDY CANNOT BE IMPLEMENTED UNTIL SUCH TIME AS YOU HAVE RECEIVED R&D MANAGEMENT APPROVAL FOR THIS AMENDMENT.**

Kind regards

## **E-Mail Template: Acknowledgement of a Non-Substantial Amendment (e-mail the PI)**

Dear

**Study Title:**

**REC No:**

**R&D No:**

**IRAS No:**

**Amendment No:**

**Amendment Date:**

Thank you for email dated xxxxxx together with attached documentation relating to an Amendment to the above study.

The papers you have submitted will receive an initial review and we will revert to you regarding this as soon as possible.

Kind regards

## **E-Mail Template: Advising Researcher to Re-Send Amendment to NRS PCC**

Dear

Thank you for your email. We need to receive the amendment from NRSPCC before we can process it.

Kind Regards