R&D: Research Study Amendment Approval

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| Author: | Heather Charles |
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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 in the R&D or ACCORD generic mailboxes (loth.rdoffice@nhs.scot or loth.accord@nhs.scot), 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 is 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 processing amendments for R&D approval.

Instructions for Issue of Amendment Approval

## **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*).

### Amendments will be processed following GS007-WI02 (R&D: Processing of Research Study Amendments).

## **R&D Management Approval Letter**

### Create the R&D management approval letter for the amendment by completing the following steps on SReDA;

* Go to Documents tab > Letters sub-tab,
* Select the ‘Amendment Letter KS’ if the study is a non-commercial study, and ‘Amendment Letter MT’ if the study is a commercial study. The R&D number for commercial studies will have a ‘C’ at the end (e.g., XXXX/1234C).,
* Select the PI’s name from recipient list and click on ‘Generate Letter’ and ‘Open’,
* Input your initials on the top left,
* Change date format (i.e. 27/09/2023 to 27 September 2023),
* Change ‘##PRINCIPAL\_INVESTIGATOR##’ to the PI’s name - copy and paste from line below,
* Delete ‘Substantial’ or ‘Non-Substantial’ as applicable,
* Add the amendment number if there is one,
* Add the date of the amendment – for substantial amendments use the date from the REC FO letter (if applicable). For non-substantial amendments use the date on the Amendment Tool,
* List all updated documents – include dates and version number (e.g. Protocol – Version 2 dated 22 October 2023). Only updated documents need to be listed – you do not need to list any covering letter, notice of amendments forms, e-mails etc
* If the amendment has no updated documents (i.e. change of PI or CI, addition or removal of sites), delete “and the subsequent updated documents” and list the changes as detailed in the Amendment Tool,
* List anyone who needs to be copied into the approval letter e.g. CI, data manager (oncology studies) or person who sent the amendment if different from PI and CI, and any Support Departments.
* Check the completed Governance Review Checklist (GS001-F02 or GS015-F01), R&D management approval letter or any previous amendment letters to see which Support Departments (e.g. Labs, Pharmacy, Radiology, CRF, Edinburgh Imaging) are involved.
* Go to the R&D shared drive (*Research & Development/Admin/Researcher Sign Offs*) to get the most up to date contact details for Support Departments.

### Check on SReDA if there is more than one location for the study with more than one PI. If so, additional approval letters need to be drafted for each PI. Add all the PIs to the R&D Amendment Checklist (GS007-F01).

## **R&D Governance Review of Amendments**

### The R&D Governance Reviewer will send an e-mail to loth.accord@nhs.scot advising the amendment can be approved or that Support Departments need to be contacted e.g. for notification or seeking sign off from the amendment e.g. Labs, Pharmacy etc.

### The R&D Governance Reviewer or a member of the R&D senior management team may also request that the priority of an amendment is changed and provide the justification for this.

### If Support Departments need to be contacted, send e-mail to departments as advised by the R&D Governance Reviewer, including the Amendment Tool and updated protocol (tracked copy if available). Use Amendment E-Mail Template (Appendix 1, section 4.1 or 4.2).

### On the Amendment Tracker, move the amendment details from ‘Commercial All docs received’ or ‘Non-commercial All docs received’ tab to the ‘Non- commercial Amendments’ or ’Commercial Amendments’ tab and add comment to the ‘process status’ column to note who sign off is awaited from.

### Chase any outstanding Support Department approvals weekly. If there is no response after two chases, escalate to the designated R&D Governance Reviewer for action.

### Once all Support Department sign offs are received, save the approval e-mails the study specific amendment folder in the R&D shared drive.

### If a Support Department has a query related to the amendment, refer back to the R&D Governance Reviewer.

## **R&D Governance Approval of Amendments**

### Once the R&D Governance Reviewer has confirmed the amendment can be approved, and all support department sign offs are in place, the amendment approval letter will be issued for review and signature.

### Check the date on the draft saved letter has been changed to today's date, and that the correct signatory is named on the letter.

### Send the amendment approval letter to the NRS Generic Review Manager or R&D Commercial Lead, or designee, for review/signing via Adobe sign.

### Create an e-mail, using Amendment E-Mail Template (Appendix 1, section 4.3), and title the e-mail ‘R&D number – Substantial/Non-Substantial Amendment – amendment number Approval’ e.g. ‘2014/0020 – substantial amendment 1 approval’. Attach the approval letter and send to all relevant parties.

### Copy in the R&D Governance Reviewer in the e-mail. If it is a ‘TMF’ study, copy resgov@accord.scot and monitors@accord.scot.

### If the study has a ‘Portfolio ID’ in SReDA and the amendment involves any change to study end date, copy loth.rdrecruitmentuploads@nhs.scot.

### For studies where the R&D number is suffixed by ‘MM’ (Musketeer Memorandum studies), copy Yanick Crow (yanick.crow@ed.ac.uk) if he is not the PI) and Nicola Onyeador, Genetic Counsellor (Nicola.Onyeador@nhs.scot).

### If the study has approval from the Clinical Research Facility (CRF) Phase I Committee and/or the NHS Lothian Advanced Therapy and Gene Modification Safety Committee (SOP GS012), copy the appropriate Committee secretary (e.g. James.Gibson@nhs.scot or loth.atgmcommittee@nhs.scot, respectively).

### Save the signed amendment letter and the e-mail from your sent box into the appropriate study specific amendment folder on the R&D shared drive and re-name the amendment specific folder to show ‘Approved’ e.g. ‘SA01 – Cat A – 01.05.19 – Approved’.

### For studies co-sponsored by UoE/NHSL with an R&D number ending ‘TMF’, print the amendment approval letter or e-mail acknowledgement and file in the appropriate Trial Master File (TMF) or Sponsor File in the Quality Assurance/Monitors office.

### For all studies sponsored by NHSL or co-sponsored by UoE/NHSL, save an electronic copy of the amendment approval letter or e-mail acknowledgement to the relevant folder on the ACCORD SharePoint (Studies/CI Name/Study Name/Approvals/Amendments). Name the file using the NRS naming convention guidance (NRS-GUI-009) e.g. SA01, NSA01

### On the Amendment Tracker in the R&D shared drive, move the amendment details from ‘Commercial All docs received’ or ‘Non-commercial All docs received’ tab to ‘Approved amendments’ tab on spreadsheet. Copy and paste the R&D number, study title, date received, and date of 1st chase then add date e-mail received from the R&D Governance team or date last sign off received and date of approval.

### For multi-centre studies;

* Go to the SReDA ‘Documents’ tab,
* In the green ‘Local Documents’ folder, click on the ‘Amendments’ folder,
* Click ‘Open ‘Add new documents’,
* There is no need to upload the updated documents as they are already saved on SReDA.

### For single centre studies;

* Go to the SReDA ‘Documents’ tab,
* Create a new folder in the amendment folder by clicking on ‘amendments’, right click and select new folder,
* Right click again and select re-name and name it the same as on the F: Drive. Make sure you are on the amendment folder when you do the first right click, and not the main folder.
* Upload all documents relating to the amendment from the R&D shared drive into this folder.

## **Update SReDA**

### Make the following updates to SReDA;

* Click on the ‘Post Approval’ tab,
* Click ‘Add amendment’,
* Type: Use drop down box to select ‘Substantial, Modified or Minor’,
* Reference: Amendment number or date,
* Title: ‘NHS Lothian’,
* Enter Date of Amendment,
* Enter Date of R&D approval,
* Enter Date of MHRA approval (if applicable),
* Enter Date of Ethics approval (if applicable),
* Summary of amendment – copy list of documents/amendment details from approval letter,
* Press ‘Save’,
* Change of CI, PI or Research Team Members (Study Details > Stakeholders Tab). For NRS studies – if the new researcher is the CI this will be changed by NRS PCC,
* Addition or Removal of a Site (Study Details > Location Tab).

References

* SOP GS001 R&D Governance Review of Non-Commercial Studies
* SOP GS006 Research Passports
* SOP GS007 R&D Review of Amendments
* SOP GS011 Sponsor Approval Amendments
* SOP GS012 Advanced Therapy and Gene Modification Safety Committee Approval for Research
* SOP GS015 R&D Governance Review of Commercial Studies

Appendix 1

## **E-Mail Template: Notification of Amendment to Support Departments (for information)**

Dear All

**Study Title:**

**REC No:**

**R&D No:**

**IRAS No:**

**Amendment No:**

**Amendment Date:**

Research and Development have been advised of an amendment to the above study.

Please find attached the amendment tool and updated protocol for your information only.

Kind regards

## **E-Mail Template: Support Department Sign-Off for Amendments**

Dear All

**Study Title:**

**REC No:**

**R&D No:**

**IRAS No:**

**Amendment No:**

**Amendment Date:**

Research and Development have been advised of an amendment to the above study. Could you please confirm your departments are happy with this amendment?

Kind regards

## **E-Mail Template: Approvals for Amendments**

Dear

**Study Title:**

**REC No:**

**R&D No:**

**IRAS No:**

**Amendment No:**

**Amendment Date:**

Please find attached an approval letter for the amendment to the above study.

Kind regards