**R&D: PROCESSING 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 in 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 (IB), 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.

# INSTRUCTIONS FOR PROCESSING & APPROVING AMENDMENTS

## **R&D Amendments 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 receipted following GS007-WI01 (R&D: Receipt of Research Study Amendments).

### If a research team gets in touch with the R&D office requesting an update on their priority ‘3’ amendment, and the implementation date has passed, change this to priority ‘2’ in the tracker. Respond to the research team using Amendment E-Mail Template (Appendix 1 (section 4.1)), copying the following R&D staff;

* Commercial Amendments: R&D Commercial Lead and R&D Coordinators in the R&D Commercial Team.
* Non-Commercial Amendments: NRS Generic Review Manager and R&D Coordinators in the R&D Non-Commercial Team.

### If a research team gets in touch with the R&D office requesting an update on their amendment and it is justified as urgent, change this to priority ‘1’ and respond to the research team using Amendment E-Mail Template (Appendix 1 (section 4.1)), copying the following R&D staff;

* Commercial Amendments: R&D Commercial Lead and R&D Coordinators in the R&D Commercial Team.
* Non-Commercial Amendments: NRS Generic Review Manager and R&D Coordinators in the R&D Non-Commercial Team.

### Use the ‘Most Recent Chase’ column in the Amendments Tracker (R&D shared drive) to record the date the priority was changed., and add the correct number of ‘chases’ i.e. when and how many times the Sponsor, Contract Research Organisation (CRO) or researcher has been in contact with R&D to request an update on amendment review.

## **Category A, B (Substantial and relevant to Lothian) and Category C (Substantial) Amendments**

### Check the Amendment Tool to see what the amendment relates to. Look for ‘End of Study Date’ extensions and for a change in Principal Investigator (PI) in Lothian. Also check that the Amendment Tool has been signed by an appropriate person i.e. someone from the sponsoring organisation and not the CI.

### For an amendment, we should have receipt of;

|  |  |
| --- | --- |
| **Substantial Amendment** | **Non-Substantial/Minor Amendment** |
| * Amendment Tool * Research Ethics Committee (REC) Favourable Opinion (FO) letter * MHRA authorisation letter – only CTIMPs (check Amendment Tool to see if amendment has been submitted to MHRA). * Updated documents e.g. Participant Information Sheet (PIS), Consent Form (CF) etc * Copies of documents with tracked changes (TC) are needed if this is not the first version of the document | * Amendment Tool * Updated documents and TC copies. |
| * For both - CV (and GCP certificate if CTIMP) if new researcher is added for NHSL. Check if they have an Honorary Contract with NHSL, clinical/non-clinical. If not, they will need to submit a Research Passport application – see ACCORD SOP GS006 Research Passports. | |

### If documents are missing, or the documents do not match those detailed on the REC FO letter, contact the person who submitted the REC cover letter or the Chief Investigator (CI), and request the missing documents by e-mail.  Do not contact the PI (unless they are also the CI).

### Study amendments can be implemented within 35 days without R&D approval. Check the implementation date. Where the implementation date is within 14 days of amendment receipt and/or where we have not received the REC FO and/or MHRA approval, e-mail the PI (Amendment E-Mail Template (Appendix 1, section 4.2, 4.7 or 4.8) asking for additional time to review the amendment. Verify this with the R&D Commercial Lead or NRS Generic Review Manager before e-mailing the Sponsor/CI.

### For non-substantial amendments, check if there is an update to the study end date and /or recruitment end date only (i.e. no new documents). If so, then send an acknowledgement e-mail to the PI (using Amendment E-Mail Template (Appendix 1, section 4.3 or 4.4) and copy the relevant personnel;

### If the study has a ‘Portfolio ID (confirm on SReDA), then copy R&Drecruitmentuploads@nhslothian.scot.nhs.uk

### Copy resgov@accord.scot if UoE/NHSL co-sponsored,

### Copy monitors@accord.scot if a ‘TMF’ study (i.e. R&D number format 2021/XXXX/TMF).

### 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 (GS012), copy the appropriate Committee secretary (the CRF QA Manager or [loth.atgmcommittee@nhslothian.scot.nhs.uk](mailto:loth.atgmcommittee@nhslothian.scot.nhs.uk), respectively).

### Update end dates on SReDA as per SOP AD005 (End of Study Date).

## **Amendment Processing: Category B & C (not relevant to Lothian and Non-Substantial)**

### Category B & C amendments that are not applicable to NHSL and that are classified as non-substantial, do not require R&D approval.

### Check the Amendment Tool to see if an end of study extension in included in the amendment. If ONLY an extension, follow SOP AD005 (End of Study Date). If there is a study extension and updated documents, follow the instructions below, but update the end date on SReDA.

### Check there are no previous amendments for the study awaiting approval on the R&D shared drive. If there are, check if the documents in the Cat C amendment are updated versions of documents in the amendment which are not yet approved. If they are, the acknowledgement cannot be sent at this time and will be sent at the same time as the Cat A/B approval letter. If the documents are different to those related to the amendment which is not yet approved, the acknowledgement e-mail can be sent.

### Send the acknowledgement e-mail, using Amendment E-Mail Template (Appendix 1, section 4.5), to the PI and data manager/research nurse where appropriate. If the R&D number has ‘TMF’ at the end, the monitors should be copied in ([monitors@accord.scot](mailto:monitors@accord.scot)) and [resgov@accord.scot](mailto:resgov@accord.scot), and print and file the e-mail in the Trial Master (TMF) or Sponsor file in the QA/Monitors office.

### Check if there is an updated protocol; if there is, check R&D management approval letter to see if there are any Support Departments involved (e.g. Labs, Pharmacy, Radiology, CRF, Edinburgh Imaging). If Support Departments are involved, send the updated protocol to the relevant parties using Amendment E-Mail Template (Appendix 1, section 4.6). Save the e-mail in the study specific amendments folder in the R&D shared drive.

## **Amendment Processing: Category C (Non-Substantial)**

### Acknowledge receipt of Category C (Non-substantial) amendments using Amendment E-Mail Template (Appendix 1, section 4.5) if no other amendments for the study are outstanding.

## **Amendment Checklist**

### An R&D Amendment Checklist (GS007-F01) will be generated for all amendments that required R&D review/approval.

### Open the R&D Amendment Checklist (GS007-F01) via SReDA Documents tab > Letters > Amendment Checklist and select the PI, then click ‘Generate Letter. Complete the study information section. To put an ‘X’ in the box, right click ‘Properties’, under ‘Default Values’ click the button for ‘Checked’ then press ‘ok’.

### List all the updated documents with versions and dates under ‘Documents’ on the R&D Amendments Checklist (GS007-F01).

### Complete the question regarding notification from NRS PCC, as appropriate.

### Complete the ‘Full Document Set (FDS) Date’: This means the date that all amendment documents have been received.

### If the REC FO (and MHRA authorisation, if applicable) letter were in the file when NRS PCC notified us of the amendment then enter the date that NRS PCC notified us of the amendment. If NRS PCC notified us of the REC FO and/or the MHRA authorisation after the original email, enter this date. If REC and/or MHRA letter are still outstanding, leave the date blank until all documents received.

### ‘Date Amendment approved’: Leave this box blank, the R&D Governance Reviewer will complete this.

### Check on SReDA that if there is more than one location for the study with another PI. If so, add both PIs to the R&D Amendment Checklist (GS007-F01).

### The amendment checklist should then be saved in the appropriate study specific amendment folder (R&D shared drive) as Amendment Checklist (SAXX) i.e. follow the same naming convention on SReDA or in the Amendment Tool.

### If we have not received the REC FO letter (and MHRA authorisation if applicable), send an e‑mail to the Sponsor or CRO (commercial amendments) or study manager/co-ordinator or CI (non-commercial amendments) to request the REC FO letter (and MHRA authorisation if applicable) – use Amendment E-Mail Template (Appendix 1, section 4.7 or 4.8).

### Once all amendment documents have been received, including the REC FO letter and MHRA approval if applicable, update the R&D Amendments Tracker in the R&D shared drive i.e. 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.

# REFERENCES

* SOP AD005 End of Study Date
* SOP GS006 Research Passports
* SOP GS007 R&D Review of Amendments
* SOP GS0012 Advanced Therapy and Gene Modification Safety Committee Approval for Research

# APPENDIX 1

## **E-Mail Template: Response to Amendment Review Status Enquiries**

Dear XXXXX

Thank you for your email regarding (Amendment Number/Date) which was received by the R&D office on xx xxxx xxxx.

The Governance Team (copied into this email) are aware of your amendment and will endeavour to get back to you within the next 5-10 working days with an update on the progress of the review.

Kind regards

XXXXX

## **E-Mail Template: Requesting Additional Time to Review Amendment – (to CI/PI/person who submitted amendment)**

Dear

**Study Title:**

**REC No:**

**R&D No:**

**IRAS No:**

**Amendment No:**

**Amendment Date:**

NRSPCC have advised us of the above amendment on xxxxxxx. Due to the assigned implementation date, the governance team need to request more review time. We will issue our approval letter as soon as possible.

Kind regards

## **E-Mail Template: Change of Study End Date (acknowledgement only)**

## 

Dear

**Study Title:**

**REC No:**

**R&D No:**

**IRAS No:**

**Amendment:**

**Change of Study end date to: XX/XX/XX / Active or In-Follow up**

We have been advised that as following an amendment, the end date of the above research project has been extended.

The extension to your study date and/or the change to your study status (i.e. continuing to recruit or in follow up) notification has been noted by our department.

Kind regards

## **E-Mail Template: Change of Study End Date (where R&D approval required)**

## 

Dear

**Study Title:**

**REC No:**

**R&D No:**

**IRAS No:**

**Amendment:**

**Change of Study end date to: XX/XX/XX / Active or In-Follow up**

We have been advised that as part of an amendment, the end date of the above research project has been extended.

The extension to your study date(s) and/or the change to your study status (i.e. continuing to recruit or in follow up) notification has been noted by our department, and an amendment approval letter will follow once our review is complete.

Kind regards

## **E-Mail Template: Acknowledgement of receipt of a Category C Amendment (no R&D approval required)**

Dear

**Study Title:**

**REC No:**

**R&D No:**

**IRAS No:**

**Amendment No:**

**Amendment Date:**

NRSPCC have advised us of the above Category C amendment (delete as appropriate).

As this amendment does not require R&D approval, you may implement the amendment once any other relevant approvals are in place.

Kind regards

## **E-Mail Template: Acknowledgement of receipt of a Category C Amendment (R&D approval required)**

**Study Title:**

**REC No:**

**R&D No:**

**IRAS No:**

**Amendment No:**

**Amendment Date:**

NRSPCC have advised us of the above amendment but we have not been provided with the REC and MHRA approvals. Could you please forward these on when they become available?

Please note that although this is a Category C amendment, NHS Lothian will need to review and approve it before it can be implemented. As REC and MHRA approvals are outstanding, the governance team need to request more review time. We will issue our approval letter as soon as possible.

## **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: Request REC FO for Amendment**

Dear

**Study Title:**

**REC No:**

**R&D No:**

**IRAS No:**

**Amendment No:**

**Amendment Date:**

NRSPCC have advised us of the above amendment but we have not been provided with the REC approval. Could you please forward this on when it becomes available?

Due to the assigned implementation date, and as REC approval is outstanding, the governance team need to request more review time. We will issue our approval letter as soon as possible.

Kind regards

## **E-Mail Template: Request REC FO & MHRA CTA for Amendment**

Dear

**Study Title:**

**REC No:**

**R&D No:**

**IRAS No:**

**Amendment No:**

**Amendment Date:**

NRSPCC have advised us of the above amendment but we have not been provided with the REC and MHRA approvals. Could you please forward these on when they become available?

Due to the assigned implementation date, and as REC and MHRA approvals are outstanding, the governance team need to request more review time. We will issue our approval letter as soon as possible.

Kind regards