SOP 17a Associated Document 1
Sponsored amendments guidance for the JRMO

Sponsored Amendments Guide

Queen Mary University of London or Barts Health NHS Trust is sponsor for the study.

1. Research Management and Governance Officer (RMGO) or delegate, review of sponsored amendments

RMGO review should include, but is not limited to:

- Is the application valid (this includes the following as a minimum; completed amendment tool, confirmation of cost form, clean and tracked versions of all relevant documents)
- Create EDGE amendment workflow on sponsor green level (this should be done as you work through the amendment as per EDGE manual)
- Save all documents and correspondence into study folder under CI's name (name folder after amendment number and date e.g. SA1, NON-SA1)
- Ensure the number of the amendment is correct by checking historical amendments.
- Check previous amendments and workflows have been completed.
- Review amendment and ensure the amendment tool has generated the appropriate classification (substantial or non-substantial, Category A, B, C). Examples of amendment types here https://www.hra.nhs.uk/approvals-amendments/amending-approval/examples-of-substantial-and-non-substantial-amendments/
- Change section of tool: each change should be listed separately in tool, ensure each change has explanation & justification and assess if any changes need any documents updated (protocol, PIS, ICF etc)
- Ensure consistency between documents and versions are updated correctly
- If change is regarding the number of patients, ensure statistical section is updated within the protocol.
- Does the change require existing patients to be reconsented?
- Is there a change of primary and secondary objectives/end point – if it is a total change, advise this should be a new study submission.
- Do any changes have a cost implication? (Assess impact of cost for each change). If the cost form has implications, forward to costings. If the form states no cost but they are increasing recruitment target, adding additional samples/tests etc, check with costings to see if they have the budget for this.
- Is cost form accurate? (ie extension is never no cost)
- Is there a new vendor? (Let preaward team know)
- Does change move away for protocol mandated text or our SOPs?
- If the change is of CI/PI - CV and GCP provided (and checked) and new sponsor-CI agreement signed
- Does the amendment require approval from any other stakeholders? E.g., support department, GCP manager
- Is change a result of audit or non-compliance? if so, check with auditor or QA manager (respectively)
- If the amendment is a substantial change confirmation TSC aware and agrees (email or minutes)
- Once amendment is finalised and support department/GCP approval (if required) has been obtained, sign the amendment tool off as: Dr Mays Jawad, research.amendments@qmul.ac.uk. The amendment date will be the date you lock the tool. Locking the tool generates a pdf version, send this to the research team with the relevant email template.

- For non-substantial, non-notifiable amendments, issue email template appendix E with the locked tool attached. This is also approval to implement the amendment
- For all other amendments, issue email template appendix B with the locked tool attached. This approval submits the amendment but not to implement the amendment
- Once REC and HRA approvals have been issued, cross-check the documents to ensure we have the final documents as listed in the REC approval letter (if REC approval is issued)
- Finally issue final sponsor confirmation to implement the amendment using template email appendix C/D depending on amendment type

1.1. MHRA regulated non substantial Amendments needing GCP Manager review:

The GCP managers do not need to review minor administrative changes to the study but should be informed of every amendment. If you are unsure – please ask your GCP manager.

2. GCP managers review

GCP managers review is additional to the GO review (like the support departments) and should cover (as a minimum):

- GCP and regulatory compliance
- Monitoring changes
- Imp change (pharmacy) Inc RSI
- Risk assessment update, if required
- Change of sponsor CI or statistician– are they suitable (assess CV and GCP)
- Increase in site number – can monitoring be covered?
- New vendor assessment
- Advise team to update CRF if applicable

3. Halted

SOP Point 11 described process when a study is 'halted'. For the purpose of this SOP halted means:
A temporary halt is defined as a stoppage of either the trial or one or more research sites not foreseen in the protocol, but with the intent to resume the trial in the future
For CI/PIs on long term leave (3+ months), an amendment to temporarily replace the CI/PI should be submitted.

4. USM

"The sponsor and investigator may implement urgent safety measures to protect clinical trial participants from immediate hazards to their health and safety. "

5. Submission of documents to MHRA

Studies submitted to REC and MHRA via Combined review IRAS should submit amendment via CR IRAS portal, however those set up prior to the introduction of CR should submit via the MHRA Submission Portal. Further guidance can be found at https://www.myresearchproject.org.uk/help/hlpamendments.aspx#Amendment-Tool