Standard Operating Procedures (SOP) for:			
Process for JRMO - Amendments for Sponsored Studies (including halting studies and early termination)			
SOP Number:	**17a**	Version Number:	**7.0**
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Signature	
Date	**4/7/16**

Purpose and Objective:
To outline the JRMO procedure for processing amendments to projects sponsored by Barts Health NHS Trust (BH) and Queen Mary University of London (QMUL). To ensure that the JRMO (as Sponsor) are aware of all QMUL/BHT sponsored studies and give sponsor authorisation prior to the amendment being submitted to REC/MHRA/HRA. To ensure that the most up to date document versions are contained in the Sponsor file and Sponsor's database (ReDA). To ensure that JRMO are aware of the relevant requirements for gaining Medicine & Healthcare Products Regulatory Agency (MHRA) and/or NHS REC (Research Ethics Committee) approval(s) and HRA when processing amendments to health related research projects.
Scope:
This SOP applies to all projects sponsored by Barts Health NHS Trust (BH) and Queen Mary University London (QMUL), including CTIMPs and non-CTIMPs. This SOP applies to all amendments including temporary halting and early termination of research. For BH/QMUL as a site – refer to SOP 17b: Amendments for Hosted Studies. For researchers processes – refer to SOP 17c: Researcher process - Amendments for Sponsored Studies.

SOP Text		
	Responsibility	**Activity**
1.	Research Governance Officer (RGO)	**Receive amendments and check that all documents have been received to review.** Check the generic research amendments email inbox on a regular basis. Valid submission of an amendment includes all of the attachments below in an email: • IRAS Amendments Form • Cover Letter to REC • Cover Letter to the MHRA (if applicable) • All amended documents with tracked changes • Completed and signed Cost Declaration Form

		• Written Confirmation from the CI that they approve all amended documents • Revised protocols must be signed by the CI (and Statistician for CTIMPs) Send an email to the CI or person submitting the amendment, confirming that the amendment is a valid submission. If the amendment submission is invalid, request missing documents and/or information but save received documents in indemnity under the CI's name and study. Request that missing documents and information is sent in one email to the research amendments inbox informing CI that the amendment will not be reviewed until a valid submission is received. Following the HRA and MHRA guidance of the Amendment type, highlight the amendment classification (e.g. Non substantial or substantial).
2.	Research Governance Officer (RGO)	**Save the amendment documents and update ReDA. Coordinate the review with research team and internal JRMO staff.** Once a valid submission has been received, save the amendment email and all attachments in Indemnity folder, under the CI's name and study number. Save the amendment in a folder according to the amendment number, Substantial/Non substantial, and the date of the amendment. Update the Post Approval tab on ReDA with all relevant information: • Type: Substantial or non-substantial • Reference: Sub Am number i.e. Sub Am 05 • Title: Include version and date of document • Summary of Amendment: Add brief summary of amendment (e.g. PI change Site or IMP dose change) • General Notes: Used this section to note status e.g. 'waiting for updated information', 'items are outstanding', if there are issues with the amendment and for general information. For all sponsored CTIMPs and high risk sponsored Non CTIMPs (defined as the first four IRAS filter categories or vulnerable patient group or deemed so by Research Governance Officer) send an email to the allocated GCP Manager to review, classify and approve the amendment (see appendix A for template wording). When studies are reviewed by GCP Manager, track amendments progress within ReDA events tab: • Sent to GCP manager for Review • GCP sent amendment comments to Researcher • Amendment approved by GCP manager Send an email to the study team explaining that the amendment is with the GCP managers and/or other areas for their review and that they will be informed as soon as they have given their approval.
3.	Research Governance Officer (RGO)	**Liaise with Costing and Contracts Manager.** If there are any cost implications to the amendment as per the JRMO costs form, forward the email and cost form to the Costing and Contracts manager. The costing and the GCP managers review process and approval will be run in parallel.

4.	Costing and Contracts Manager	**Review cost implications of the amendment.** Review documentation by assessing any implications on original costing, funding available and need for additional contracts or Amendments to contracts. Send response or respond to RGO with approval or actions required.
5.	Research Governance and GCP Manager or Research Governance Officer (RGO)	**Review amendment.** For all amendments referred to the GCP Manager, the GCP manager will conduct the below checks, for all others these will be conducted by the RGO. Review documentation by assessing any implications for continuation of sponsorship. Communicate with research team to make any changes as required. Consider: • Financial implications (see Associated Document 4) • Impact on service departments (radiology, pharmacy etc.) • Statistical impact (seek trial's statistician's review and approval where necessary) • Patient safety, burden and risks • Institutional reputational risks • Compliance with applicable regulatory guidelines • If required, re-risk project in accordance with risk assessment SOP 23 • If required, amend the monitoring plan • Classify the amendment as per HRA and MHRA guidance (e.g. substantial /non substantial). GCP manager/RGO must not give their approval until the financing of the study has been agreed. If comments/suggestions are required, email these to the Research Approval Coordinator, and only once satisfied approve the amendment. If no changes are necessary or changes have been made as requested, email authorisation to the Amendment Team. Identify clearly in Sponsor's approval email the amendment's classification as per HRA and MHRA guidance (e.g. substantial/non substantial). Special attention should be paid to number of sites, addition of countries and/or vendors, extensions to study period and whether the amendment impacts the primary end points. Any amendment can be escalated to GCP manager if needed. Any concerns should be escalated appropriately.
6.	Research Governance Officer (RGO)	**Coordinate with study team.** Communicate with the study team any comments, actions requested by the GCP manager in order to approve the amendment. Check that the study team have submitted changed/updated documents as requested via the generic amendments inbox and notify the GCP managers if they have undertaken a review. Evidence of GCP and Costing approval if applicable must be in place via email or authorising the IRAS form before sponsor authorisation can be given.
7.	Research Governance Officer (RGO)	**Arrange for signatures on the IRAS forms.** Email the study team with the outcome of the amendment and inform them to submit the IRAS Amendment form for sponsor authorisation via IRAS to sponsorsrep@bartshealth.nhs.uk Check IRAS form and provide authorisation and inform the study team once executed. Issue approval via email, for amendment to be submitted to REC/HRA and/or MHRA to the CI and Study Team.

		Inform study team sponsor signature has been done, adding into the same instructions email for team to copy in Research.Amendments@bartshealth.nhs.uk in the email submission to REC/MHRA/HRA.
8.	Research Governance Officer (RGO)	**Ensure that the Chief Investigator approves of the CTIMP amendment.** **CTIMPs only**: JRMO will request email confirmation from the CI that they authorise for the amendment to be submitted to both MHRA and REC (as the CI will not be authorising the IRAS amendment form). Save the email confirming the approval of the amendment from the GCP Manager and CI in the Indemnity folder. Add new email alert on ReDA under the Monitoring tab, to be sent out in 4-5 weeks of the date of giving sponsor authorisation. This email should be to the CI and contact person/PI requesting copies of REC/MHRA approvals be sent to the JRMO. Ensure research amendments generic inbox is copied into email correspondence. Wait for regulatory approvals (REC/MHRA) for amendment but chase CI and study team amendment if notification of approvals exceeds 5-weeks. Issue follow-up email to chase outcome of Amendment. Repeat monthly for a maximum of 2 months for CTIMPs. If no response received for CTIMPs notify GCP Manager after 5-weeks.
9.	GCP manager	**Raise any issues in line with the JRMO Escalation Policy.** If alerted to a problem with an amendment follow escalation policy to resolution.
10.	Research Governance Officer (RGO)	**Check that the JRMO have received all final versions of approved documents.** Upon receipt of REC/MHRA approval ensure that the JRMO are in receipt of all documents including: • Notice of Amendment form • REC approval letter and all correspondence • MHRA approval letter (where applicable) and all correspondence • All updated documents as listed on REC approval letter • Updated Clinical Trial Authorisation application form (where applicable) • **CTIMPS only:** Evidence of payment of MHRA fee, if applicable • **Final Protocol signed by the CI (and Statistician)** • **HRA Minor amendment form (where applicable – available on the HRA website)** Ensure all documents are saved in Indemnity shared folder, ReDA Study documents. Save all amendment information including all emails and attachments electronically in ReDA, under Study Docs Tab and section 04- Amendments. Make an appropriate folder to match information as it is in Indemnity, save all documents and emails. For all sponsored Substantial Amendments an Amendment Acknowledgment letter (associated document 1) needs to be sent to the CI. For CTIMPs-Ensure allocated monitor is copied into the Amendment acknowledgement.
11.	Research Governance Officer (RGO)	**If the amendment is to extend the study alert JRMO Finance Officer.**

		If the amendment includes an extension to the study timelines, ensure the appropriate Finance Officer and if a JRMO CTIMP monitor is informed in writing.
12.	JRMO Clinical Trial Monitor	**Save CTIMP amendment documents and correspondence in Sponsor File.** Ensure updated versions of study documents are filed electronically and file amendment documentation in (hard copy) R&D governance folder. Mark all documents as superseded and update version control log.
13.	GCP Team	**CTIMPs Only – Halting studies.** **When a CTIMP is 'halted' remind the CI of their delegated responsibilities to report to the regulators.** If the Sponsor (JRMO) or CI decides to halts the trial temporarily, remind the CI of their responsibility to notify the MHRA (and REC) **immediately and at the latest within 15-days from when the trial is temporarily halted.** This should take the form of a substantial amendment. The notification must clearly explain what has been halted (for example, stopping recruitment and/or interrupting treatment of subjects already included) and the reasons for the temporary halt. To restart the trial that has been temporarily halted a second substantial amendment must be made. If the trial is not restarted an early termination should be submitted as below.
14.	GCP team	**CTIMPs Only – Early termination.** **When a CTIMP is terminated early remind the CI of their delegated responsibilities to submit End of Trial form to the regulators.** Where a study is terminated early (i.e. before the end of trial definition has been reached as defined in the protocol), the End of Trial Form must be submitted to the MHRA and REC **within 15 days if the project is terminated early**. See full guidance in **SOP 18a** (Project Closure – Guidance for Research Staff of JRMO Sponsored Projects)

List of Appendices

Document	Document Name
Appendix A	Template email

List of Associated Documents

Document	Document Name
Associated Document 1	Amendments working instructions (not public document)
Associated Document 2	Notification non substantial (minor) amendments
Associated Document 3	Costs form - Amendments

Change Control

Version	Changes
6.0	Addition of written evidence that Chief Investigator has approved the amendment before the submission to REC
	The revised protocols must be signed by the CI and Statistician before provisional approval is issued by the JRMO
7.0	Email address correction.

Appendix A
Email subject: Amendment Review

Sponsor: Barts Health/QMUL
ReDA:
Study Type:
PI/CI:

Copy and paste where all the documents are saved i.e.:
Q:\Research and Development\Public\Indemnity Folder\ blogs J \002222 Banana Study\4. Amendments\Amendment 1

Brief description of what the amendment entails.

If there are any changes to the original study protocol that are a result of the amendment that affect any of the original support departments or expert approvals, seek their review and approval:

- Study Statistician (as named on the protocol/IRAS form – CTIMPs: Statistician must sign the revised protocol)
- Information Governance
- Imaging/Radiation (all scans)
- Medical Physics (all equipment and devices)
- Tissue (changes to storage or lab analysis)
- Pharmacy
- Contract & Costing (additional resources, receipt of additional services/goods/equipment, change or addition of contracts)
- Chief Investigator (sign the protocol and written evidence they approve all study documents).