Standard Operating Procedure (SOP) for:			
QM Ethics of Research Committee application and approval procedure			
SOP Number:	**15**	Version Number:	**4.0**
Effective Date:	**20th March 2018**	Review Date:	**20th March 2020**

Author:	**Hazel Covill, QM Research Ethics Committee Facilitator**		
Signature:		**Date**	6.3.18
Reviewer:	**Katherine Ouseley, Research Support Unit Manager**		
Signature:		**Date:**	06/03/18
Reviewer:	**Mays Jawad, Research and Development Governance Operations Manager**		
Signature:		**Date:**	06/03/18

Authorisation:	
Name/Position:	**Coleen Colechin, Acting Director of Research Services & Business Development**
Signature:	
Date:	06/03/18

Purpose:
To outline the general administration and management of applications and amendments to the QM Ethics of Research Committee (QMERC) for research ethics approval.
Scope:
All research involving human participants and materials derived from human participants carried out within or by Queen Mary University of London, and its staff and students, wherever located, that does not fall within the remit of an NHS Research Ethics Committee, the HRA or any other specialised Research Ethics Committee.

Abbreviations:	
BH	Barts Health NHS Trust
GAfREC	Governance Arrangements for NHS Research Ethics Committees: A Harmonised Edition
HRA	Health Research Authority
JRMO	Joint Research Management Office
NHS	National Health Service

PI	Principal Investigator
QMERC	QM Ethics of Research Committee
QMUL	Queen Mary University of London
RSU	Research Support Unit

Relevant SOPs:

This SOP is closely linked with:
SOPs 11,12,13 regarding BH/QMUL Sponsorship

SOP Text:

	Responsibility	Activity
1.	Principal Investigator	**To read Governance Arrangements for NHS Research Ethics Committees (GAfREC): A Harmonised Edition.** **To familiarise themselves with GAfREC and the remit of the NHS REC. To make a decision about ethical review requirements relating to their study.** **To, if planning research in an NHS or social care context, read the Health Research Authority's advice and guidance and complete the HRA toolkit on the necessity of NHS REC review on www.hra.nhs.uk** If the study does not fall within the remit of NHS REC or HRA then: Complete the relevant QMERC application form and provide supporting documentation to the QMERC Facilitator as described on the website: http://connected.qmul.ac.uk/governance/research/ethics-of-research-committee/ Minimum requirements of paperwork include a fully signed and dated application form, relevant draft materials to participants and a Risk Assessment if appropriate (only required if the research involves travelling abroad or interviewing in participant's homes).
2.	QMERC Facilitator (or delegated other)	**Ensure that all applications that fall within the QMERC remit are reviewed as per the SOP and that standard applications, and amendments thereof, to QMERC do not fall within GAfREC2: A Harmonised Edition (NHS Research Ethics Committee remit).** If it falls within NHS REC or HRA remits, then inform the PI of the appropriate approval route to take and from whom advice can be sought. To work closely with the Research Governance team/other JRMO colleagues to confirm appropriate definition of project and provide effective and timely handover of researcher and application if needed. If study is not deemed as research (e.g. audit, service evaluation) then advice investigator to contact the Clinical Effectiveness Unit (clinical.effectiveness@bartshealth.nhs.uk ; http://ceu/)

3.	QMERC Facilitator (or delegated other)	**Acknowledge, record and check application** Acknowledge receipt of the application, record on the appropriate spreadsheet, and screen for compliance with QM Policy on Research with Human Participants, and any other applicable policies. Submissions should be either emailed directly to the Facilitator, or sent to the generic email of research-ethics@qmul.ac.uk N.B. All submissions made by filling in the online questionnaire version of the fast track application are submitted automatically to research-ethics@qmul.ac.uk
4.	QMERC Facilitator (or delegated other)	**Assess risk and triage accordingly** Triage application with regard to risk - liaising as appropriate with QMERC Chair and Review Panel Chairs - advising researcher of review method (fast track, standard panel or full QMERC review). Fast track review is applicable if screening questions on the Fast Track Form are either answered, or would be answered, in the negative: otherwise standard panel review is assumed. Full QMERC Review to occur either as a decision taken by the Chair of QMERC at the outset or as a result of referral to QMERC by members of a Review Panel. To bring to the particular attention of members of QMERC Review Panels any factors that the Facilitator feels may constitute a reputational risk to the organisation. N.B. Special arrangements are in place whereby any research into the subject of, or related to, radicalisation will always require review by full QMERC.
5.	QMERC Facilitator (or delegated other)	**Establish whether 'dual review' (sponsorship by the JRMO) is applicable** Dual review is applicable if the research, while GAfREC exempt, involves heightened risk to the institution and/or participant, a novel or invasive research intervention, additional indemnity and full sponsorship, or if JRMO liaison is required to ensure regulatory compliance. Decision to be taken in liaison with colleagues in the JRMO. Inform researcher if JRMO sponsorship is applicable.
6.	QMERC Facilitator (or delegated other)	**Prepare application for the QMERC Review** To collate the documentation ready for QMERC review and circulate to members in a timely fashion and in agreed format in advance of the meeting.
7.	QMERC Facilitator (or delegated other)	**Facilitate QMERC Review** To attend review meetings. To write minutes and get approval from the Chair prior to circulating to members. To advise members of compliance with any relevant legislation. To assist with the administration of any further review that is required.

8.	QMERC Facilitator (or delegated other)	**Inform PI of QMERC decision** To assist applicants with the submission of revised documents in the case of Conditional Approval or additional review.
9.	Principal Investigator	**Comply with the decision of QMERC, and ensure that all conditions set by QMERC are fully met prior to commencing study** A response to a Conditional Approval is requested within 3 months of date of issue. If no response is received within 6 months, QMERC reserve the right to withdraw the Conditional Approval and the study will require a new application. Periodic reporting, notification of project completion and end-of-study reports are not required unless specified as a condition of approval. Where specified detail will be given to the PI regarding format and timings.
10.	QMERC Facilitator (or delegated other)	**Issue Approval Letter to Principal Investigator, via email and hard-copy post**
Amendment Processing		
11.	Principal Investigator	**Submit an Amendment** Supply a letter addressed to the Chair of QMERC, but submitted to the Facilitator by e-mail, outlining the nature of the amendment, and including any revised and tracked-changed documentation as applicable. Updating any version numbers and dates as applicable.
12.	QMERC Facilitator (or delegated other)	**Screen the Amendment application to confirm that the proposed changes do not alter the original application so significantly as to warrant NHS REC review (i.e. the study ceases to be GAfREC exempt).** Acknowledge receipt of the application, record on the relevant spreadsheet, and screen for continued compliance with QM policies. Advise researcher of QMERC policy of capped number of Amendments that may be submitted.
13.	QMERC Facilitator (or delegated other)	**Inform JRMO staff of Amendment outcome if dual review was originally undertaken and provide final version materials if appropriate.**
14.	QMERC Facilitator (or delegated other)	**Liaise with the Chair of QMERC with regard to the assessment of the proposed Amendment - as either a major or a minor amendment** If it is a minor amendment, liaise between the Chair and the researcher with regard to approving the amendment via Chair's Action. If it is a major amendment, facilitate a Panel Review, advising members of compliance with QM Policy.

		Minor Amendments are those that require either none or minimal changes to the Materials to Participants, for example they might include; time extensions, additional researchers, increased/decreased participant recruitment; error corrections in text, and other minor changes in text etc. Major Amendments are those that involve a significant change to methodology and, as such, generally require a significant change to the Materials to Participants, for example they might include; additional methods of data collection; additional types of participant interaction via focus groups or interview, and additional participant groups etc.
15.	QMERC Facilitator (or delegated other)	**Inform PI of QMERC decision** To assist with application of revised documents to the Chair in the case of Conditional Approval.
16.	Principal Investigator	**Comply with the decision, working to ensure any conditions set are fully met before implementing the changes detailed in the Amendment.**
17.	QMERC Facilitator (or delegated other)	**Issue updated Approval Letter if the Amendment is approved, via email and hard-copy post.**

Change control

This section outlines changes from version **3.0** to version **4.0**

Section changed	Summary and description of changes
Throughout	Updated job title from Administrator to Facilitator.
Throughout	Added "(or delegated other)" in the responsibility column to illustrate cover for QMERC Facilitator
Relevant SOPs, 5, 13 (previously 16)	Removed reference to withdrawn JRMO Proportionate Review SOP No.43; further detail given about Dual Review process.
3	Added generic e-mail address for submissions
13/16	Moved 16 to 13 to reflect order of events
2, 5, 13	Where relevant expand on liaison and communication with JRMO colleagues
14	Added definitions of Amendment types
9	Expanded on time limits for meeting Conditional Approval and subsequent withdrawal
1, Appendix 1	Updated webpage links on external and internal websites.

List of appendices

Appendix ref.	Appendix name
Appendix 1	QMERC webpage on JRMO website: http://www.jrmo.org.uk/performing-research/conducting-non-medical-research/ QMUL intranet: http://connected.qmul.ac.uk/governance/research/ethics-of-research-committee/

List of associated documents

There are no associated documents for this SOP.