Study approval reference table

This guidance document clarifies the approval requirements for Barts Health NHS Trust (Barts Health) or Queen Mary University of London (Queen Mary) sponsored studies involving tissues, data and staff only as well as student projects and primary care studies.

Please use the HRA decision tool (http://www.hra-decisiontools.org.uk/research/) to determine whether your study is research. Clinical Audits, Service Improvement Projects and Service Evaluations are not research. To set up these non- research studies, contact the relevant Institute Manager for Queen Mary Studies or the Clinical Effectiveness Unit for Barts Health studies (c.effectiveness@nhs.net).

The table below confirms JRMO sponsorship, MHRA, HRA, REC and Confidentiality Advisory Group (CAG/Section 251 exemption) approval requirements for the various research studies. Other approvals (e.g. Administration of Radioactive Substances Advisory Committee (ARSAC), Gene Therapy Advisory Committee (GTAC), Her Majesty's Prison and Probation Service (HMPPS), Social care research ethics committee, Queen Mary Ethics of Research Committee (QMERC)) may also be required depending on the study. Please liaise with the Governance Team for further advice (research.governance@qmul.ac.uk).

Tissue Studies **NHS definition of a tissue is *'a group of similar cells which unite to perform a specific function'***					
	JRMO/Sponsorship requirement	**MHRA**	**HRA**	**REC**	**CAG**
Tissue Bank – Defined as 'A collection of human tissue or other biological material, which is stored for potential research use beyond the life of a specific project with ethical approval or for which ethical approval is pending'	Follow SOP 13a research studies, relevant protocol template and relevant checklist Select *'Research Tissue Bank'* on the IRAS filter. Extras needed for sponsorship: NHS REC Research Tissue Bank (RTB) Form, CV for RTB Manager, Advertisements and electronic copy of the HTA Licence Assess the arrangements in place for sample transfer across sites within Barts Health/Queen Mary. Assess tissue access committee requirements for approving individual studies requiring access to these samples. JRMO require sponsorship and renewal every 5 years.	N/A	N/A	Optional but highly recommended	Yes – if relevant

Specific research studies including use of tissue/biological samples for the purpose of research	Follow SOP 13a research studies, relevant protocol template and relevant checklist Where the study involves taking samples but no other physical intervention or procedure, select either '*Basic science study involving procedures with human participants*' or *'Research limited to use of tissue, other human biological samples and/or data'*. The set of questions generated in the application form(s) in IRAS will be the same in either case. Sponsorship review will include lab to be used and lab approvals. Check consent for future research and storage arrangements Assess the arrangements in place for sample transfer across sites within Barts Health/Queen Mary and handling of samples at the end of the study (destroyed or stored). Approval from RTB Manager is required if samples will be stored.	N/A	Yes	Yes	N/A

Data Study

Studies that are designed to collect data from participants, either prospectively or retrospectively. Data studies have little (or no) interaction with the patient other than to gain consent to access the relevant information on the patient or to gain further information not found in the medical records.

	JRMO/Sponsorship requirement	MHRA	HRA	REC	CAG
Retrospective Anonymised data accessed by Barts Health or Queen Mary staff.	Yes - SOP 13a and checklist Specific Guidance on Retrospective Data agreed with HRA available – SOP 13b AD14	N/A	N/A (agreed with HRA)	N/A	N/A
Data accessed by clinical care team at single or multiple trusts, sent to sponsor in anonymised format	Yes - SOP 13a and checklist	N/A	Yes	N/A	N/A
Data accessed by the clinical care team with patient consent	Yes - SOP 13a and checklist	N/A	Yes	Yes	N/A
Data access by clinical care team at multiple trusts but sent to sponsor in identifiable format without consent	Yes - SOP 13a and checklist	N/A	Yes	Yes	Yes

Data accessed by people outside the clinical care team without consent from the patients	Yes - SOP 13a and checklist	N/A	Yes	Yes	Yes
Data accessed by people outside the clinical care team with consent from patients	Yes - SOP 13a and checklist	N/A	Yes	Yes	N/A
Research database Defined as 'A collection of data, which is stored for potential research use beyond the life of a specific project with ethical approval or for which ethical approval is pending'	Not mandatory but recommended - SOP 13a, relevant protocol template and checklist The researcher must notify the JRMO. HRA guidance: There is no formal requirement for databases to apply for ethical review under NHS research governance systems, and ethical approval would only be required by legislation if processing identifiable data without consent. Applications for ethical review will therefore normally be made on a voluntary basis. However, ethical approval for a database may have benefits by facilitating programmes of research without a need for individual project-based ethical approval. The database application form has an option for the applicant to seek generic ethical approval prospectively for a range of research to be carried out by the establishment responsible for the database and/or by other researchers to whom data is released within the conditions of the ethical approval. Such approval may be given for a period of up to 5 years and will be renewable.	N/A	N/A	Voluntary basis can apply for ethical review but no general requirement to apply for ethical review	N/A
Staff Study ***Research involving NHS staff as participants (not Queen Mary staff)***					
	JRMO/Sponsorship requirement	**MHRA**	**HRA**	**REC**	**CAG**
Research involving NHS staff with no ethical concerns	Yes - SOP 12a or 13a and Interventional checklist/Research checklist. *if staff have consented to being contacted for research from a previous study they have worked on, HRA approval may not be required. Please	N/A	Yes*	N/A*	N/A

	liaise with Research Governance team or email the HRA Queries Line at queries@hra.nhs.uk.				
Research involving NHS staff with ethical concerns e.g. identifiable data, vulnerable cohort, sensitive topics	Yes - SOP 12a or 13a and Interventional checklist/Research checklist	N/A	Yes	Yes	N/A (unless no consent is being sought)
Research involving NHS staff in a MHRA regulated study? CTIMP/Device	Yes - SOP 11a and checklist	Yes	Yes	Yes	N/A
Student Project **Studies which are primarily for the purpose of obtaining an educational qualification**					
	JRMO/Sponsorship requirement	**MHRA**	**HRA**	**REC**	**CAG**
Student project Studies where the main purpose is to undertake specific research – and the educational qualification is secondary – do not fall into this category.	Yes - SOP 11a, 12a, 13a and corresponding checklist (MHRA-Regulated/Interventional/Research checklist) The JRMO does not recommend conducting MHRA-regulated studies as student studies. Sponsor can only be the educational Institution of the student. CI must be supervisors (exception PhD/Post-doctorate) and if MHRA-regulated trial then the CI must be an Authorised Health Professionals.	YES if applicable	YES (Exception: Undergraduate and Masters)	YES	YES if applicable
Primary Care Studies ***Recruiting patients from community settings e.g. GP Surgeries, Dental Practises, Pharmacies and more***					
	JRMO/Sponsorship requirement	**MHRA**	**HRA**	**REC**	**CAG**
Primary care study (MHRA Regulated, Interventional or Research study)	Yes - SOP 11a, 12a, 13a and corresponding checklist (MHRA-Regulated/Interventional/Research checklist) In addition, NOCLOR coordinates local approvals between sponsors and primary care sites within a geographical area.	Yes	Yes	Yes	if applicable