Joint Research Management Office Standard Operating Procedure for:			
Annual Progress Reports			
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Background:

Annual Progress Reports (APR) are required by sponsors and regulatory bodies to maintain oversight of studies that have been approved. It is a condition of favourable opinion to provide these progress reports to the NHS Research Ethics Committee (REC) and the Confidentiality Advisory Group (CAG) that has issued a favourable opinion and in their absence to the Health Research Authority (HRA) (if HRA approval was sought at the start of the study). In addition, for Clinical Trial of an Investigational Medicinal Products (CTIMP) and Advanced Therapy Investigational Medicinal Products (ATIMP), there is a legal regulatory requirement for sponsors to submit the Development Safety Update Reports (DSUR) annually. DSURs are not required for clinical investigations.

Purpose and scope:

This Standard Operating Procedure (SOP) describes the procedure for the preparation and submission of sponsor oversight questionnaire and the regulatory body progress report for all Barts Health NHS Trust (Barts Health) and Queen Mary University of London (Queen Mary) sponsored studies.

The submission of an APR is now only a condition of the REC favourable opinion for studies with an expected duration of over two years and for studies which were reviewed at a full REC meeting (studies submitted through proportionate review no longer need to submit an APR). For further details please see https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/progress-reports/

Where studies intend on completing within 2 years however extend beyond this period, it is the Chief Investigator's (CI) responsibility to ensure that an APR is submitted on the 2nd anniversary of the initial favourable opinion.

The SOP does not cover those studies covered by Queen Mary Ethics of Research Committee approval or externally sponsored studies hosted by Barts Health or Queen Mary.

This SOP applies to all CIs, investigators, study teams and Joint Research Management Office (JRMO) staff involved in the set up and conduct of studies sponsored by Queen Mary and Barts Health.

This SOP does not cover safety reporting-refer to *SOP 26a Site level Pharmacovigilance for MHRA regulated studies*, *SOP 26b Site level Pharmacovigilance for Interventional and Research studies*, *SOP 26c Pharmacovigilance (Process for the Sponsor and CI)*, *SOP 26d Site level Pharmacovigilance for Clinical Investigations of Medical Devices*.

Abbreviations:	
APR	Annual Progress Report
ATIMP	Advanced Therapy Investigational Medicinal Products
Barts Health	Barts Health NHS Trust
CAG	Confidentiality Advisory Group
CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
DSUR	Development Safety Update Report
GCP	Good Clinical Practice
HRA	Health Research Authority
JRMO	Joint Research Management Office
MHRA	Medicines and Healthcare products Regulatory Agency
PI	Principal Investigator
Queen Mary	Queen Mary University of London
REC	Research Ethics Committee
SOG	Sponsor Oversight Group
SOP	Standard Operating Procedure

SOP Text:

REC/Ethics APRs & Sponsor Oversight Annual Questionnaire

	Responsibility	Activity
1.	JRMO staff	**Set up reminders for APR due dates** The Good Clinical Practice (GCP) & Governance team will set up reminders for all sponsored Medicines and Healthcare products Regulatory Agency (MHRA) regulated studies at the time of set up as *SOP 26c AD2 ReDA instructions to log safety events* and *Associated Document 1 APR and DSUR Template Emails*. APRs are created once the notification period is over and is subsequently due with the REC within 30 days of the end of the reporting period. For all other sponsored studies, the Research Governance and Performance team (or delegate) will be sending out email reminders to the CI and study team 2 months prior to the annual favourable opinion date. For all Interventional and Research studies of all risk levels, a *Sponsor oversight questionnaire (See Associate document 2)* should also be sent to the CI with the reminder.

2.	CI	**A draft progress report should be submitted to the JRMO for review prior to submission to REC** Please submit the draft APR to the JRMO (research.governance@qmul.ac.uk) at the 12-month anniversary of the initial favourable opinion to give the JRMO time to review and approve the draft within the 30-day deadline. The CI is advised to visit the HRA website (https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/progress-reports/) to complete the correct study type form for submission. Study extensions will need to be submitted via the normal amendment process *(SOP 17a, b and c Amendment Series).* Failure to submit or late submission of the APR or/and annual sponsor questionnaire to the JRMO will be classified as a non-compliance. Note this includes direct submission to REC and HRA without prior JRMO approval.
3.	Governance section staff or delegate	**For all Interventional and Research studies of all risk levels, once the draft progress report and annual oversight questionnaire (as appropriate) has been received by the JRMO, the JRMO will then verify the data against JRMO records** Review APR and sponsor oversight questionnaire (*Associated Document 3 Progress Report Guidance for JRMO reviewers*). Update any records i.e., EDGE to reflect the data provided and seek clarifications wherever needed. If previous APRs are not available, then request these from the CI. Once the JRMO has completed their checks and received clarifications, to include updating EDGE (Associated *Document 2 Sponsor Oversight Annual Questionnaire and Associated Document 3 Progress Report Guidance for JRMO reviewers*) the CI will be notified to submit the report to the regulatory body. The appropriate EDGE Form will be completed. EDGE Form "JRMO APR" and both the dates of APR requested and received will need to be logged – this will be updated with any required information and the APR submission logged. Failure to submit the APR to the JRMO will be classified as a non-compliance and should be reported to the Quality Assurance Manager following *SOP 31 Non-Compliance.*
4.	GCP and Governance team	**For regulated sponsored studies, review and log information on per EDGE workflows.** Once reviewed and any actions are completed inform the CI and study team they may proceed to submit.
5.	CI	**Submit to the appropriate REC office once the JRMO confirmation is received.** The CI should visit the HRA website to ensure approving REC contact details of original approving committee are current.

		For tissue banks, the final agreed APR should be forwarded to the current Human Tissue Authority licence holder or designated individual (k.ersapah@nhs.net) prior to or at REC submission stage for information only. The JRMO (research.governance@qmul.ac.uk) should be copied in when submitting or forwarded the appropriate correspondence to REC.
6.	CI	**Copies of the APR must be sent to the sponsor, the Principal Investigator at all sites and the Research & Development offices of all active sites.** Please forward any acknowledgement from the REC to the JRMO. For multicentre studies, please forward a copy of the REC acknowledged APR to the host site study teams for filing.
HRA only Progress Reports		
7.	CI and JRMO staff	**Draft and submit APR to HRA** Progress reports for research studies with HRA Approval but which did not require REC review, should be sent to approvals@hra.nhs.uk. Follow sections 1 to 6 to submit.
CAG Annual review		
8.	CI and JRMO staff	**Draft and Submit CAG report to CAG team** An annual review report should be submitted to the Confidentiality Advice Team by email (cag@hra.nhs.uk) four weeks before the approval expires (i.e., no later than 11 months following the final approval date) using the report template. At this stage, the CI should consider if it would be possible to reduce the amount of confidential patient information that they are processing. Please refer to HRA guidance (https://www.hra.nhs.uk/about-us/committees-and-services/confidentiality-advisory-group/guidance-confidentiality-advisory-group-applicants/) on reducing the disclosure of confidential patient information prior to submitting your annual review report. Follow steps 1 to 6. Any queries or substantial changes to the original CAG form should be escalated to the Caldicott Guardian to confirm information is in line with current practice.
DSUR Reporting		
9.	Assigned Clinical Trial Monitor	**Set up reminders for DSUR due dates** Automated reminders should be set up in REDA that will be emailed to the CI and study team prior to report due date as per *SOP 26c AD2 ReDA instructions to log safety events* and *Associated Document 1 APR and DSUR Template Emails.*
10.	CI or delegate	**A draft progress report should be submitted to the JRMO for review prior to submission to the MHRA**

		The CI on behalf of the sponsor is required to submit a DSUR within one year of the Development International Birth Date – the date of first authorisation of a clinical trial in any country worldwide and provide annual DSUR submissions until all open clinical trials have ended (the final clinical trial is completed, and its study report has been submitted). Please submit the draft DSUR to the JRMO (research.governance@qmul.ac.uk) with an aim of 1 week prior to submission deadline month (anniversary of the initial favourable opinion plus 60 days) to give the JRMO time to review and approve the draft. The CI should use the *DSUR template* and *DSUR cover letter template (Associated document 4 and 5).** *A shortened DSUR is permitted for CTIMPS and ATIMPS approved through the Notification scheme using the Health Research Authority Annual Progress Report. Failure to submit or late submission of the DSUR to the JRMO will be classified as a non-compliance. Note this includes direct submission to MHRA without prior JRMO approval. *If there are delays in DSUR submission it may be necessary to escalate to the Sponsor Oversight Group (SOG) for assessment of delay.*
11.	GCP & Governance manager or delegate	**Once the draft report has been received by the JRMO, the JRMO will then verify the data against JRMO records** Update any records i.e., EDGE to reflect the data provided and seek clarifications wherever needed. Review DSUR as per EDGE workflow, liaising with the CI and the study team as necessary. This review should include ensuring that current templates are used, that all sections are complete, and that all information is correct (to the sponsor's knowledge) e.g., all SUSARs are listed. Once review is complete, notify CI to submit the report to the regulatory body. The appropriate points of the DSUR EDGE workflow must be completed prior to issuing approval to submit.
12.	CI	**Submit to the MHRA once the JRMO confirmation is received.** A DSUR report should be submitted to the MHRA which gave the favourable opinion, within 60 days of the MHRA favourable opinion was given. DSUR and appropriate safety report or cover letter should also be submitted to the approving REC for information. The JRMO (research.governance@qmul.ac.uk) should be copied in when submitting and in all correspondence with REC and MHRA including and acknowledgements or submission receipts.

13.	Assigned Clinical Trial Monitor	**Ensure reminders are set up and actioned (this includes appropriate escalation) within ReDA** Individual event reminders must not be switched off until final version and submission evidence is received. Ensure draft copies of annual reports, GCP & Governance Manager's approval, final version and evidence of submission are saved as per *SOP 27 JRMO Internal Filing* Ensure SOG papers accurately reflect DSUR report status.

Change control

Background	Removal of background section
Purpose and Scope	Streamlining of this section
Throughout	Hyperlinks for relevant SOPs and websites
Throughout	General administrative changes

List of associated documents

Associated Document 1	APR and DSUR Template Emails
Associated Document 2	Sponsor Oversight Annual Questionnaire
Associated Document 3	Progress Report Guidance for JRMO reviewers
Associated Document 4	DSUR Template
Associated Document 5	DSUR cover letter template