**SOP 19 APR AD3 Progress report guidance for JRMO reviews**

1. **Annual Progress Reports (APR)**

***(This is the same process for all types of studies)***

The allocated person will review the APR. This review will include but is not limited to:

1. Check that the APR information matches existing information in EDGE regarding
2. Study title, Chief Investigator (CI) and Sponsor
3. Start date, end date, study type
4. Recruitment figures
5. For non MHRA regulated study safety of participants- if any unexpected and related serious adverse reaction documented - inform the Good Clinical Practice (GCP) team (Clinical trial monitors)
6. Amendments – ensure the information provided matches EDGE and documentation in indemnity – if not flag to the allocated Research Management & Governance Officer (RM & GO) for follow-up
7. Other consistency issues- consider these, address with the CI/sender and escalate as needed
8. If applicable (first 4 IRAS categories) review the public database and ensure the study is live/public and ensure registration details on EDGE are correct (If no registration escalate to the Research Governance & Performance Manager or if a MHRA regulated study, then GCP and Governance Manager)
9. If the APR confirms a plan to increase the number of participants or extend the study period, then an amendment must be submitted (please advise researcher in response)
10. Ensure EDGE is updated with new information and complete relevant workflow and forms set
11. Ensure a signed copy of the APR is received
12. Ensure a signed copy of the APR is saved in EDGE and Indemnity Folder
13. **Sponsor Oversight Annual Questionnaire**

Reviewed as per EDGE workflow.

1. **Confidentiality Advisory Group Annual reports**

The study will be allocated to the RM & GO who reviewed the original section 251 application for this study. Allocated person to perform review as above and additionally:

1. Ensure any conditions set out in the initial approval letter have been met.
2. **Development Safety Update Reports (DSUR)**

The allocated person will review submitted documents to include (but is not limited to):

1. Ensure the DSUR and cover letter present and using [SOP 19 AD 4 and AD5](http://www.jrmo.org.uk/performing-research/standard-operating-procedures-sops/sop-19/), and that no template text remains
2. Read whole report, actions specific sections as below.
   1. Check section 3 against EDGE or and REDA (NB safety actions reasons only, not all amendments should be listed)
   2. Check the Reference Safety Information listed matches EDGE.
   3. Check recruitment numbers are as expected.
   4. Review EDGE for other studies with same SOP sponsored by the same organization (NB Barts Health and Queen Mary are not the same organization)
   5. Section 7b-d – it is not necessary to perform a reconciliation between the JRMO Pharmacovigilance system and report as this is performed regularly by monitors. However, Check EDGE to ensure reconciliation has been performed.
   6. Section 8b- review issues flagged to ensure the GCP team aware, and these have been logged as appropriate.
   7. Section 18, 19 & 20 review with care and assess if risk category or assessment need to be updated. Escalate as needed.
   8. Complete EDGE workflow