Sponsorship of Retrospective Anonymised Data studies: guidance for JRMO staff

This guidance is to be used when the below criteria are met for retrospective fully anonymised data studies only.

- Barts Health NHS Trust (Barts Health)/Queen Mary University of London (Queen Mary) sponsored study and only site is Barts Health.
- Access to data is by the direct care team only and anonymised before use for research purposes. If research team is not part of the direct care team, then the data must be anonymised before sending to research team.
- Set-up/sponsorship review will be as per normal sponsorship with conditions process but will also incorporate the confirmation of capacity and capability review. The submission checklist should not be completed and instead only the following documents will be required:
- The following documents are required for sponsorship review:
    - Protocol (research studies template)
    - Chief Investigator Agreement
    - Scientific peer review
    - Departmental authorisation
    - Clinical director sign off (C&C review)
    - Declaration of No Cost form (if applicable)
    - CV's of CI and lead study team
    - Evidence of Good Clinical Practice (GCP) training for study team
- Approval route:
    - Barts Health authorisation will need to be gained
    - Final Confirmation of Sponsorship to be issued with email template (SOP 12a AD3).

Adding to EDGE:

- Add study to EDGE.
- Complete sponsorship workflow and appropriate attribute set on green level as per normal process.
- Add site.
    - Date site invited: when we first received correspondence about the study
    - Date site selected: received valid submission date
    - Date site confirmed by sponsor/Date site confirmed: date of sponsorship/Capacity and capability confirmation.
    - Add note on EDGE confirming that capacity and capability workflow will not be completed as this is a retrospective fully anonymised study and no Health Research Authority (HRA) submission has been made.
    - Complete appropriate attribute set.

Amendments:

- Any significant amendment (adding a site, transfer of date to another organisation etc.) will need to be submitted to HRA so the study can come under the HRA.
- Any other amendments are to be processed by Joint Research Management Office (JRMO) only. Email template approval as per amendment process.