**Sponsor Oversight Annual questionnaire**

The sponsor maintains overall responsibility for the conduct and reporting of the study and must demonstrate oversight of activities to ensure patient safety and data integrity. The questions below will help us with sponsor oversight and must be submitted to the Joint Research Management Office (JRMO) on an annual basis until study closure. Please complete and send to research.governance@qmul.ac.uk.

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| --- | --- | --- |
|  | **Study Details:** Study name:IRAS number:Chief Investigator name:  |  |
|  | Is the EDGE record up to date, including study status, planned end date and recruitment? |  |
|  | Has there been a change in sponsorship? Or employment of the CI? ? If so, what amendment was this part of? |  |
|  | Please list if there has been change in funding / study management. |  |
|  | Please provide a list of all external services to Queen Mary University of London and Barts Health NHS Trust if different from the original application. |  |
|  | Have more sites been added since the original sponsorship approval? If so, what amendment was this part of? |  |
|  | Does the Barts Health Principal Investigator (PI) remain the same? If not, please insert details of the new PI ( and submit Good Clinical Practice (GCP) training evidence and CV) |  |
|  | If applicable, has there been any changes to sample processing, ) i.e. If they are now being sent to another location? If so, have agreements been set up? |  |
|  | Have amendments been submitted to the JRMO? If so, how many? |  |
|  | Are all GCP certificates and CVs updated for the CI, coordinating team and site? |  |
|  | Have all non-compliances been flagged to the JRMO?  |  |
|  | If applicable, please list all committee meetings that have occurred. Is this as per Study protocol ? if not why? |  |
|  | Has the study been audited (internally or externally) or subject to an audit? |  |
|  | Has any monitoring been performed? if yes provide summary |  |