**Joint Research Management Office (JRMO)**

**Early engagement meeting: Clarification Tool**

*This tool can be used by either the Assigned governance officer or assigned Good Clinical Practice (GCP) manager and Costing & Contract Manager at the initial planning stages of a Medicines and Healthcare products Regulatory Agency (MHRA) Regulated study.*

*Text in Italics are items to be considered and not an exhaustive list; these can be removed. A summary should be inserted into each section.*

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| **Sponsor**  Who is the Chief Investigator’s (CI) substantive employer?  UK or International |
| **CI Experience**  As CI on:  Non-Commercial MHRA Regulated study  Commercial MHRA Regulated study  Or as Principal Investigator on:  Non-Commercial MHRA Regulated study  Commercial MHRA Regulated study  Or as co-investigator  (N.B Locum & Emeritus Professor cannot be Investigators - see SOP 11a for guidance) |
| **Sites**  In the UK  How many Countries  Total  (See SOP 21a for Sponsorship, management and oversight of international-only research: Competent Authority Regulated studies and interventional research for guidance on National Coordinating Centres (NCC)) |
| **Service Providers**   * *Site agreements (are we providing any consumables? E.g. tissue kits, equipment, device / funding for collaborators / Investigational Medicinal Product(IMP) to the sites)?* * *Are you planning to recruit from any other sites? (Site or Participant Identification Centres (PIC))* * *Which areas in Barts Health/Queen Mary will you be using for clinical and non-clinical interventions?* * *Contract Research Organisation (CRO)?* * *Will they be using Clinical Research Coordinator (CRC) or another unit if a lone investigator?* * *IMP technical agreement* * *IMP supply agreement* * *IMP - Bart’s manufacturing* * *Lab Service Level Agreement(s)* * *Material Transfer Agreement(s) – Any data or tissue being sent any location other research sites?* * *Database Provider ?* * *Statistician* * *Unblinding service* * *Randomisation service* * *International Agreements* * *Translators* * *Importers/ Exporters* * *Device/Equipment* * *Is there any equipment or device on loan or being gifted by from manufacturer? Is it on the Master Indemnity Agreement (MIA) (indemnifying the kit)?* |
| **Risk Assessment (See SOP 23 Risk Assessments)** |
| **Funding**   * *Funding award agreement(s)* * *Funding letters for Portfolio Adoption process (stating amount and duration to cover project)* |
| **Protocol Peer review (See SOP 14 Peer Review)** |
| **Data Management (See SOPs 38d Data Management)** |
| **IMP Management**  Oncology / Non-oncology - Give Pharmacy contact |
| **Pharmacovigilance (see SOP 26c Pharmacovigilance)** |
| **Monitoring (see SOP 28 Monitoring)** |
| **Quality Assurance/Compliance/Study Specific SOPs?**  See JRMO SOPs |
| **Integrated Research Application System (IRAS) application - progress and JRMO submission** |