**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 studyOr as Principal Investigator on:Non-Commercial MHRA Regulated studyCommercial MHRA Regulated studyOr as co-investigator(N.B Locum & Emeritus Professor cannot be Investigators - see SOP 11a for guidance) |
| **Sites**In the UKHow many CountriesTotal(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)?*
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| **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)*
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| **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** |