**Joint Research Management Office (JRMO) Early engagement meeting: Clarification Tool**

*This tool is to be used to document the review undertaken by assigned Good Clinical Practice (GCP) manager and Costing and Contract Manager at the first study meeting*

*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 studies  Commercial MHRA regulated studies  Or as PI on:  Non-Commercial MHRA regulated studies  Commercial MHRA regulated studies  Or as co-investigator  (N.B Locum and Emeritus Professor cannot be Investigators - see SOP 11a and b Sponsorship of regulated studies for guidance) |
| **Sites**  In the UK  How many Countries  Total  (International - see SOP 21a for guidance on National coordinating centres (NCCs)) |
| **Service Providers**   * *Site agreements (are we providing any consumables? E.g. tissue kits, equipment, device / funding for collaborators)?* * *Are you planning to recruit from any other sites? (Site or Participant Identification Centres (PICs))* * *Which areas in the Barts Health NHS Trust (Barts Health) or Queen Mary University of London (Queen Mary) will you be using for clinical and non-clinical interventions?* * *Contract Research Organisation (CRO)?* * *Will they be using a Clinical Research Coordinator (CRC) or another unit if a lone investigator?* * *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 Manufacturing / Importers Authorisation (MIA) (indemnifying the kit)?* |
| **Risk Assessment (See SOP 23 Risk Assessment)** |
| **Funding**   * *Funding award agreement(s)* * *Funding letters for Portfolio Adoption process (stating amount and duration to cover study)* |
| **Protocol Peer review (See SOP 14 Peer Review)** |
| **Data Management (See SOPs 38 a & b)** |
| **Monitoring (see SOP 28 Monitoring)** |
| **Quality Assurance/Compliance/Study Specific Standard Operating Procedures (SOP)s**  See JRMO SOPs and Kick-off Meeting Checklist |
| **Integrated Research Application System (IRAS) application - progress and JRMO submission** |