**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 studiesCommercial MHRA regulated studiesOr as PI on:Non-Commercial MHRA regulated studiesCommercial MHRA regulated studiesOr 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 UKHow many CountriesTotal (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)?*
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| **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)*
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| **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** |