Site Initiation and minimum requirements guidance

The Principal Investigator (PI), lead research staff (i.e., site research nurses), and site pharmacist must be present during the Site Initiation Visit (SIV) (separate SIVs can be conducted if they all cannot attend on the same date/time). It is best practice to include the CI where possible in SIVs (if they are different to the PI).

Associated Document 3: Site activation checklist, *Associated Document 4: SIV presentation template and Associated Document 5: Site initiation report*, or alternatives that have been agreed by the Joint Research Management Office (JRMO) Good Clinical Practice (GCP) & Governance Manager, should be used to conduct the meeting, and document the visit in a report format.

The person delegated by the CI to conduct the SIV should be thoroughly trained in the study and protocol, including having a good understanding of all study procedures, consent forms, Case Report Forms (CRF), expected adverse events (AEs), unblinding procedures (for Investigational Medicinal Product (IMP), investigational devices and / or imaging as appropriate) and Standard Operating Procedures (SOP)s. This should be documented and reflected on the coordination delegation log (*SOP 45: Essential documentation including TMFs and files for all external sites and facilities*).

During the visit, the following should occur as a minimum:

- A meeting with the PI, pharmacy, and key staff (i.e., monitor, site research nurse(s), trial coordinator), to discuss and review the protocol and all trial procedures. Pharmacy representatives can be met with separately.
- A study initiation presentation should be given to the PI and their research team (for topics that should be included in the presentation *see associated document 4: SIV Presentation template*). This should include the PI and site team's responsibilities.
- The study team should be provided with the opportunity to ask questions. Any issues highlighted at the SIV which are not resolved during the visit need to be documented and followed-up before the site is activated.
- A visit and review of any sample processing or storage areas.
- An agreement of which documents and systems constitute "source data" and their location. This should be documented in the ISF (*SOP 45: Essential documentation including TMFs and files for all external sites and facilities*).
- An assessment of local computerised systems (*SOP 38a: Use of computerised equipment, software, and systems in clinical research*).
- Training the team of study specific software, equipment, or devices, including the requirements for calibration and verification before the study starts, and maintenance once the study is open.
- Completion of the trial delegation log.

Clinical Trial of an Investigational Medicinal Product (CTIMP) SIVs should also include:

- A visit to (and meeting with) the pharmacy and / or any out of pharmacy storage areas. This visit must ensure that they are familiar with the IMP documentation and satisfied with

the IMP management plan (and any other IMP related documents). Request details of the IMP storage arrangements and, where necessary, review IMP storage facility at the site.

Clinical Investigation SIVs should also include:

- Training on the use of the investigational device and the associated investigator brochure, instructions for use and any clinical investigation agreements.
- Confirmation that the site has an adequate number of investigational devices and can store them appropriately.