JRMO SOP 26d associated document 1

Guidance on safety reporting for Clinical Investigation Plans

The Clinical Investigation Plan (CIP) must clearly describe the safety reporting procedures for the Investigation. The information in the CIP should match JRMO SOP 26d, but if the manufacturer has been delegated responsibility for reporting safety events to the Medicines and Healthcare products Regulatory Agency (MHRA) then the CIP may be adapted with information from the manufacturer's Standard Operating Procedures (SOP).

Consider whether there are any adverse events that are critical to the evaluation of the results of the clinical investigation and, if so, flag them for expedited reporting in the CIP. If the device manufacturer has specified any adverse events of special interest or device deficiencies of special interest then these must be listed in the CIP.

Each experimental device must have a list of anticipated serious adverse device effects (ASADEs).The document containing the anticipated serious adverse device effects must be submitted to the MHRA as part of the Clinical Investigation application. ISO14155 states that the ASADEs should be listed in the risk analysis report but in the UK this list is normally located in the Investigator Brochure (IB) for the device. The CIP should state the location of the ASADE list. In most circumstances the device manufacturer must be responsible for the development of the investigational medical device documentation, including the Investigator Brochure. In exceptional circumstances where the manufacturer is unable to generate study documents, an approved vendor may be contracted to produce the investigational medical device documentation (see *JRMO SOP 40: Vendor Assessment*).

The CIP should include a procedure for reporting all relevant safety information to the Data Monitoring Committee (DMC).

In the case of multi-centre Clinical Investigations, the CIP or another essential document (e.g. a safety reporting procedure) should include a process for periodically notifying all sites of reported SAEs.

The CI should review all reported Adverse Events (AE) and device deficiencies and confirm agreement or disagreement with the site's assessment. The CIP should describe the procedure for periodically reviewing AEs and device deficiencies. All assessments must be documented. In some cases this activity could be delegated to the device manufacturer.

The CI should assess the potential impact of the experimental medical device and other trial procedures on the health and well-being of pregnancies and pregnant participants. If unsure, seek guidance from a suitable expert e.g. a Professor of Women's Health, Consultant Obstetrician or Consultant of Foetal Medicine. Ensure that the CIP describes the procedure for managing a trial participant who becomes pregnant while participating in the Clinical Investigation.

Where the use of the experimental medical device or other trial specific procedures could have an impact on the health of the participant or their pregnancy, pregnancy reporting procedures should be implemented. See SOP 26d for more information.