

Informed Consent Process – Documentation in Source

The investigator site should document the following key elements (among others) in the participant's source file during the informed consent process:

- Date on which informed consent was discussed
- Version number, date and language of the consent form used
- Name of the individuals who were present during the consent process
- Name of the individuals who discussed the consent and in which language
- Confirmation that participant had time to ask questions
- Questions asked and answers provided (in brief)
- Statement that participant understood the trial and agreed voluntarily
- Date and time consent was signed
- Name of the person who signed the consent form
- Name of the individual who was present as Legally Acceptable Representative/Impartial Witness during the consent process (as applicable) and why
- Statement that Copy of signed consent form was provided to the participant
- Any re-consent details (if applicable) – These details should also include information relevant to the points mentioned above