REMAP-CAP WI: Informed Consent - Appendix IV

Appendix IV: Informed consent monitoring

Purpose

This work instruction (WI) appendix is intended to be used by REMAP-CAP staff involved in monitoring of informed consent for trial participation. The aim is to provide users with a instruction on informed consent monitoring.

On site monitoring

During an on-site visit the monitor must verify the informed consent process and ICF in accordance with the current version of the monitoring plan. (Potential) high impact findings, including potential serious breaches, need to be documented, discussed and escalated to the Sponsor as per the monitoring plan and applicable Standard Operating Procedures.

Consent (form) monitoring:

- Was the correct version / type used
- Are all fields completed on the form and in a GCP complaint way
- Was consent provided for all randomized domains (if relevant)
- Was form dated and signed by delegated and trained staff member
- Are all pages of form filed (not only signature page)
- PATIENT consent: Was form signed and dated by patient? If not, was there confirmation in source/on form that subject was (in)capacitated?
- LAR consent: Does LAR relation to patient meet country regulatory requirements?
- For professional LAR consent: Was the professional LAR independent from the trial? (i.e. did not perform trial-related tasks including eligibility assessment, and is not on the delegation log)
- For professional LAR consent: Was it appropriate to defer to professional LAR?
- For NO CONSENT: documented attempts to reach the subject or personal LAR.
- For No Patient/personal LAR consent: reason for no consent is documented in source and eCRF.
- For verbal consent: Did impartial witness, if applicable, sign the form? Was the reason for verbal consent documented in source?

Remote monitoring

Monitors should remotely keep track of timely and complete eCRF data entry of consent information and if patient consent is obtained / entered for all subjects. They should follow-up with sites as needed.
In the UK, consent logs are collected and ICFs can be checked remotely; process is described in the UK appendix to the European Region Monitoring Plan.

Consent status reports will be generated by the Data Coordination Centre (DCC) at least quarterly and used to monitor consent type details and progress of consent entry in the eCRF. Follow-up requests will be sent to monitors for potentially non-compliant sites.