ClinEssentials

HOW TO MONITOR AN

Informed Consent Form

As a CRA, what are the key items you look for when monitoring an Informed Consent Form (ICF)? Let's take a look at 6 items that are crucial when monitoring an ICF.

1 STAMP OF APPROVAL

Ensure the correct version of the informed consent was used and it has an Institutional Review Board (IRB) approval stamp.

2 PAGINATION

Ensure the pagination is correct. Are all pages present? 1 of 12, 2 of 12 through 12 of 12?

3 INITIALS & SIGNATURES

Ensure all required initials and/or signatures are present. This includes the patient, witness, person explaining the consent and/or Investigator depending on the IRB used.

4 DATES

Ensure the date corresponds with the date of consent otherwise a clarifying note should be documented.

5 CHECKBOXES

Ensure any checkboxes for notifying the patient's Primary Care Physician (PCP) or authorizing any additional sample tests are completed. If the PCP box is checked, ensure the research site has documentation of when the PCP was notified about the patient's participation in the research study.

6 DOCUMENTATION

Ensure the consent process is documented in the source: Was the patient given ample time to review and ask questions? Was the patient allowed to review with their family or physician before signing (if requested)? Was the patient given a copy of the consent for their records?