



Monday Morning Practice Pearls #31

What should you do if you notice that there is something missing on the signed informed consent document – paper version?

You are reviewing the informed consent document (obtained via paper version) and notice that something is missing. Maybe one of the signatures is missing the printed name. Maybe the patient forgot to initial all the correct places in the optional studies section of the document. What should you do?

Step 1: Obtain the original signed consent document from the medical record department.

Step 2: Have the individual who needs to complete the missing information add the information and then date (using current date) and initial the new entry.

Note: for patients this should be the next time they are at NIH.

Step 3: Take the updated original signed consent document to medical records with a cover memo requesting that this version be re-scanned into CRIS.

Step 4: Amend the original Documentation of Research Consent note in CRIS to indicate the change made to the IC document.

Note: If a signature is missing a date and research related activities were performed, this is noncompliance with NIH HRPP Policy 301 and reportable to the IRB via REF within 7 days. The IRB will let you know if the patient needs to be reconsented.

If iMED consent process was used, the informed consent document will not save as complete if a required signature/initial field is not completed. See M2P2 #69 *What is iMedConsent™?* for more information.