

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

You are reviewing the informed consent document and notice that something is missing. Maybe one of the signatures is missing a date or 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 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. That's it!

This is not a situation that requires re-consenting, but rather updating the existing record. Please *do not* re-consent the patient.