



Monday Morning Practice Pearls #22

How to handle Personally Identifiable Information (PII) in a report submitted to the IRB or IND/IDE sponsor)?

What is Personally Identifiable Information (PII)?

The Office of Management and Budget (OMB) defines Personally Identifiable Information (PII) as information that can be used to distinguish or trace an individual's identity, either alone or when combined with other personal or identifying information that is linked or linkable to a specific individual. The recent HIPPA training course talked about this also. PII includes:

Name	Medical record number
Personal/home postal address	Bank account information
Social Security number (SSN)	Health information
Date of birth (DOB)	Passport number
Birthplace	Credit card information
Home or cell telephone number	Genetic information
Mother's maiden name	Personal characteristics
Relatives' name	Criminal History
Personal e-mail address	Driver's license number

So, what does this mean for the various reports documents submitted to the IRB or IND/IDE sponsor?

1. When providing a description of a reportable event, **DO NOT** include the subject's name (e.g., Mr. Smith presented to the ER with severe pain and fever). Instead, use terms such as: patient, subject or research participant (e.g., The subject presented to the ER with severe pain and fever).
2. When including supporting documents (e.g., discharge summary, autopsy report), remove **ALL** the PII. This can easily be done with a black marker. REMEMBER to add the subject's study number.

LabCorp
Laboratory Corporation of America

Specimen Number	Patient ID	Control Number	Account Number	Account Phone Number	Rate												
Patient Last Name			Account Address														
Patient First Name		Patient Middle Name		Private MD Labs 93 MATHIS DRIVE DICKSON, TN 37055													
Patient SSN	Patient Phone	Total Volume															
Age (Y/M/D)	Date of Birth	Subject ID: 1001001															
ACCOUNT BILLING NEW HAVEN, CT 06511			Additional Information														
Date and Time Collected 04/16/12	Date Entered 04/16/12	Date and Time Reported 04/17/12	Physician Name	NPI	Physician ID												
Growth Hormone, Serum			Tests Ordered														
General Comments																	
<table border="1"> <thead> <tr> <th>TESTS</th> <th>RESULT</th> <th>FLAG</th> <th>UNITS</th> <th>REFERENCE INTERVAL</th> <th>LAB</th> </tr> </thead> <tbody> <tr> <td>Growth Hormone, Serum</td> <td>34.3</td> <td>High</td> <td>ng/mL</td> <td>0.0-2.9</td> <td>01</td> </tr> </tbody> </table>						TESTS	RESULT	FLAG	UNITS	REFERENCE INTERVAL	LAB	Growth Hormone, Serum	34.3	High	ng/mL	0.0-2.9	01
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