From: OC GCP Questions
To: [redacted]
Subject: Adding Patient Identifying Information to Consent
Date: Monday, September 14, 2015 6:35:19 AM

Good morning –

FDA regulations do not prohibit patient (subject) identifiers on informed consent documents. Below is a link to our new *draft* guidance on informed consent.

http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM405006.pdf It states --

5. Confidentiality
A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records. (21 CFR 50.25(a)(5).) The consent process must describe the extent to which confidentiality of records identifying subjects will be maintained (21 CFR 50.25(a)(5)) and should identify all entities, for example, the study sponsor, who may gain access to the records relating to the clinical investigation. The consent process must also note the possibility that FDA may inspect records (21 CFR 50.25(a)(5)), and should not state or imply that FDA needs permission from the subject for access to the records. Please note that under the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, FDA does not need permission to inspect records containing health information (45 CFR 164.512). FDA may inspect study records, for example, to assess investigator compliance with the study protocol and the validity of the data reported by the sponsor. Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA may inspect and copy all records relating to the clinical investigation. 21 U.S.C. § 374(a)(1). See also 21 CFR 312.58(a), 312.68, and 812.145(b). FDA generally will not copy records that include the subject's name unless there is reason to believe the records do not represent the actual cases studied or results obtained. When FDA requires subject names, FDA will generally treat such information as confidential, but on rare occasions, FDA may be required to disclose this information to third parties, for example, to a court of law. See 21 CFR 20.63(a) and 20.83(a)-(b). Therefore, the consent process should not promise or imply absolute confidentiality by FDA.

Additionally, there should be adequate provisions in place to protect the privacy of subjects and to maintain the confidentiality of data. Note that neither the regulations or even guidance do not specifically address the methods used to maintain the confidentiality of records identifying the subject nor do they prohibit sponsors/CROs from receiving subject information, even with identifiers. Typically, study sponsors, CROs, and sites usually follow their own Standard Operating Procedures (SOPs) that direct document handling and maintaining confidentiality.

The ICH GCP E6 Good Clinical Practice: Consolidated Guidance, (which is recognized as official FDA guidance) mentions in section 6.10 that the sponsor should ensure the protocol or other written agreement specifies who has access to source data/documents (you can access this guidance at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073122.pdf). I've copied below section 6.10 and other relevant sections of the ICH GCP E6 guidance for your consideration

6.10 Direct Access to Source Data/Documents

The sponsor should ensure that it is specified in the protocol or other written agreement that the investigator(s)/institution(s) will permit trial-related monitoring, audits, IRB/IEC review, and regulatory inspection(s) by providing direct access to source data/documents.

Direct access is defined as:

1.21 Direct Access: Permission to examine, analyze, verify, and reproduce any records and reports that are important to evaluation of a clinical trial. Any party (e.g., domestic and foreign regulatory authorities, sponsors, monitors, and auditors) with direct access should take all reasonable precautions within the

constraints of the applicable regulatory requirement(s) to maintain the confidentiality of subjects' identities and sponsor's proprietary information.

It is expected that all parties involved with a study maintain the confidentiality of subject records and the extent that it is feasible is to be discussed as part of the informed consent process and be included in the informed consent document. The IRB is most often included in the informed consent document as one of the parties who may have access to the subject's records.

Additionally below is the Office of Regulatory Affairs (ORA) said regarding subject records during a FDA inspection.

Although sometimes challenging, ideally FDA would like to see and get copies of, original unchanged records. If not possible, the de-identification of records should be done as to not obliterate the required info necessary to identify the subject and the evidence of his/her participation in the study. Usually a combination of subject initials and subject number on study records will suffice this requirement.

It is strongly recommended that you consult the sponsor and the reviewing IRB to make sure they are aware of what the institution is requiring you to do.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

Doreen M. Kezer, MSN
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Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Saturday, September 12, 2015 1:35 PM
To: OC GCP Questions
Subject: Adding Patient Identifying Information to Consent

A client organization (hospital) requires that research consent forms that are relevant to patient care or treatment are scanned and uploaded into the research subject's/patient's electronic health record.

To ensure that consent forms are uploaded to the correct record, the hospital's medical record department requires that either a patient "sticker" be fastened to the front page of the consent or authorization *or* that two of four possible identifiers are hand-written on the front page.

- The Ambulatory patient label contains the following: Patient name, Date of Birth (DOB), Medical Record Number (MRN), Home Address, Home Phone Number, Sex, Age, Provider, Date of Service (DOS) and time.

- The Hospital patient label contains the following: Facility name, MRN, Patient

name, DOB, Age, Sex, Date of Admit, Account ID, Encounter number.

- The hand-written process would include at least 2 of the following 4 pieces of information: Name, MRN, Date of Birth, or Address.

A researcher has questioned whether the addition of the sticker or handwritten identifying information would be considered an unapproved alteration to the IRB-approved consent form and if this could potentially result in an observation during an inspection.

Any guidance you could offer would be most appreciated.

Sincerely,

[redacted]
