

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Query regarding 21 CFR 312.68 and 21 CFR 812.145
Date: Monday, October 05, 2015 2:00:05 PM

Good morning –

FDA regulations do not prohibit patient (subject) identifiers or names on study documents. 21 CFR 312.68 Inspection of investigator's records and reports states –

*An investigator shall upon request from any properly authorized officer or employee of FDA, at reasonable times, permit such officer or employee to have access to, and copy and verify any records or reports made by the investigator pursuant to 312.62. **The investigator is not required to divulge subject names unless the records of particular individuals require a more detailed study of the cases, or unless there is reason to believe that the records do not represent actual case studies, or do not represent actual results obtained.** [emphasis added]*

Below is a link to our new draft guidance on informed consent.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.

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.

The Privacy Rule also indicates the following: "...the Privacy Rule provides that, unless the use or disclosure is otherwise permitted or required by the rule, the use or disclosure of the protected health information of an individual, such as a research subject, is permitted only if the individual signs an authorization for the use or disclosure (45 CFR 164.508)."

One of the required elements of an Informed Consent Form is a statement describing the extent to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the FDA may inspect the records. By signing the ICF the study subject is, in part, authorizing the disclosure of study info to FDA.

You might be interested in FDA's guidance document on Protecting the Rights, Safety, and Welfare of Study Subjects. Link below.

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf>

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
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [REDACTED]
Sent: Monday, October 05, 2015 9:47 AM
To: OC GCP Questions
Subject: Query regarding 21 CFR 312.68 and 21 CFR 812.145

Good morning,

A Canadian IRB has provided us with a query regarding the following statement:

(c) *Records identifying subjects.* An investigator shall permit authorized FDA employees to inspect and **copy records** that identify subjects, upon notice that FDA has reason to suspect that adequate informed consent was not obtained, or that reports required to be submitted by the investigator to the sponsor or IRB have not been submitted or are incomplete, inaccurate, false, or misleading.

Specifically, they have asked whether the records containing identifying information that are copied are taken off site. If so, are these records de-identified prior to being removed from the site or might they still contain identifying information?

Thank you in advance,

[REDACTED]