From: OC GCP Questions
To: [redacted]
Subject: 2018-1342: Subject Identification Code List - required details?
Date: Thursday, May 24, 2018 11:35:00 AM
Attachments: [redacted]

Good morning –

FDA's regulations do not use or define the term, "subject identification log," nor does that term appear in FDA's official guidance. The ICH E-6, "Good Clinical Practice: Consolidated Guidance" https://www.fda.gov/downloads/Drugs/Guidances/UCM464506.pdf ICH E6 does, however, include the following definitions and terms:

Section 1.58: "Subject Identification Code" is defined as "A unique identifier assigned by the investigator to each trial subject to protect the subject's identity and used in lieu of the subject's name when the investigator reports adverse events and/or other trial-related data."

Section 8.3.20, Subject screening log: To document identification of subjects who entered pretrial screening

Section 8.3.21, Subject identification code list: To document that investigator/institution keeps a confidential list of names of all subjects allocated to trial numbers on enrolling in the trial. Allows investigator/institution to reveal identity of any subject

Section 8.3.22, Subject enrollment log: To document chronological enrollment of subjects by trial number

You will have to decide how you interpret what you think is needed in your log. When the regulations are silent, sites and institutions can develop their own standard operating procedures to address and issue or situation.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

U.S. FOOD & DRUG ADMINISTRATION

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: Wednesday, May 23, 2018 4:55 PM
To: Industry.Biologics <Industry.Biologics@fda.hhs.gov>
Cc: [redacted]
Subject: RE: 2018-1342: Subject Identification Code List - required details?

Good day,

Thank you, I will wait for a response.
I have just tried calling as well, but realize this is outside your working hours.
I am in [redacted]

[redacted]

From: Industry.Biologics [mailto:Industry.Biologics@fda.hhs.gov]
Sent: Wednesday, 23 May 2018 17:33
To: [redacted]
Cc: [redacted]
Subject: FW: 2018-1342: Subject Identification Code List - required details?

Dear [redacted]

Thank you for your inquiry. The Center for Biologics Evaluation and Research (CBER) is one of seven centers within the Food and Drug Administration (FDA). CBER is responsible for the regulation of biologically-derived products, including blood intended for transfusion, blood components and derivatives, vaccines and allergenic extracts, human cells, tissues, and cellular and tissue-based products (HCT/Ps), gene therapy and xenotransplantation products.

Your inquiry was forwarded to CBER's Manufacturers Assistance and Technical Training Branch (MATTB) for response. We/MATTB respond to inquiries on general regulatory topics from industry. In the future, you may contact us directly at Industry.Biologics@fda.hhs.gov, 800-835-4709, or 240-402-8010.

The FDA's Office of Good Clinical Practice (OGCP) addresses general questions relating to good clinical practice regulations and policy, https://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm134476.htm. You may contact **OGCP** at 301-796-8340 or gcp.questions@fda.hhs.gov.

For your information, OGCP lists replies to common inquiries on their website. You may find this site useful: http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm.

If your inquiry pertains to an Investigational New Drug Application (IND) study that is in effect, please consult the study sponsor, or the Regulatory Project Manager assigned to the IND.

Additional information:

Clinical Trials Guidance Documents, https://www.fda.gov/RegulatoryInformation/Guidances/ucm122046.htm.

Clinical Trials and Human Subject Protection, http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm.

I hope this is helpful.

Sincerely,
Loni

Loni Warren Henderson
Public Affairs Specialist

U.S. Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Communication, Outreach and Development
Division of Manufacturers Assistance and Training

240-402—8020

This communication is consistent with 21 CFR 10.85 (k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, 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: Tuesday, May 22, 2018 8:06 AM
To: CDER DRUG INFO <DRUGINFO@fda.hhs.gov>; ORA OP Feedback <op.feedback@fda.hhs.gov>; CBER OCOD Consumer Account
[redacted]
Subject: Subject Identification Code List - required details?

Good day,

(Please forward my e-mail to the relevant parties, if I am submitting to the incorrect recipients)

I have a question with regard to the Subject Identification Log. What is the purpose of this log? What should be the minimum documentation on this log? I believe its purposes are:

a. it is used to record subject confidential details. This includes name and a hospital registration / personal ID number.
b. the purpose is to link the subject ID no. (or birth date), to the full names and unique study identifier.
c. at the end of the study, this is retained with the investigator while the rest of the documents are archived so that during inspections these can be made available.

We have sites pushing back that the requirement does not specifically ask for the ID no., Birth date, address or gender.
If we understand clearly the purpose of the log, I would say these details are also required? Is there any other reference to further support this? Will the log be considered sufficient (in and audit / inspection/ for its purpose) without the ID no. or Birth Date? Thank you.

Kind regards,

[redacted]