From: OC GCP Questions
To: [redacted]
Cc: CDRH Small Manu. Assistance
Subject: RE: Quality of Life Questionnaires (signing)
Date: Monday, January 09, 2017 3:37:00 PM
Attachments: [redacted]

Dear [redacted],

FDA would expect forms, questionnaires, and diaries completed by study subjects to be attributable to the individual completing them. However, FDA's regulations do not address the completion of Quality of Life (QOL) Questionnaires nor do the regulations speak to how validation of attributability should be accomplished. When the regulations are silent, IRBs, institutions, sponsors, investigators are free to develop their own procedures and practices as long as applicable regulatory requirements are met. If signatures are required as part of the study plan/protocol, a site would be considered to have a deviation from the investigational plan/protocol if they did not comply with those requirements.

QOL Questionnaires may be considered "source documents" for a clinical trial. ICH E6, which is guidance recognized by FDA, defines source data and source documents as
"1.51 Source Data: All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies).
1.52 Source Documents: Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical trial)."

ICH E6 can be found at
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf

The sponsor or IRB may determine whether or not subjects should sign and date the QOL Questionnaires, whether it is permissible for study staff or a legally authorized representative to complete Questionnaires on behalf of a subject, and how completion of the Questionnaires by subjects or another party should be documented. If the QOL Questionnaire itself is not signed by the person completing it, the sponsor or IRB may require documentation in the study record as to who completed the Questionnaire; if not completed by the subject, a rationale as to why someone else completed the Questionnaire for them. There may also be local laws or institutional policies regarding who may complete documents on behalf of study subjects. The IRB should be aware of any local requirements for documentation; you may wish to consult with them.

I hope this information is helpful to you. If you need further assistance, please feel free to contact the GCP mailbox at gcp.questions@fda.hhs.gov .

Best regards,

Sheila

Sheila Brown, RN, MS
Policy Analyst

Office of the Commissioner (OC)
Office of Good Clinical Practice (OGCP)
U.S. Food and Drug Administration
Tel: 301-796-6563
sheila.brown@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

From: [redacted]
Sent: Friday, January 06, 2017 1:32 PM
To: OC GCP Questions; CDRH Small Manu. Assistance
Subject: Quality of Life Questionnaires (signing)

What is FDA's good documentation practices (GDP) expectations regarding the signing and dating of Quality of Life Questionnaires during a clinical study?

Assuming that a Quality of Life Questionnaire's instructions do not require a signature, is it acceptable for study subject to NOT sign and date the questionnaire after they complete it?

Similarly, if the subject needs assistance completing/writing on the questionnaire (e.g., advanced age, physical limitations) and a research coordinator fills out the questionnaire based on verbal answers, does FDA expect the research coordinator to sign and date the questionnaire with a clarification that it was completed orally?

Thank you,

[redacted]