MessageFrom: Beers Block, Patricia
Sent: Tuesday, April 25, 2006 7:12 AM
To: 'Claudia Rosso Felipe Bonato'
Subject: RE: a question

Dear Ms FelipeBonato,

FDA regulations do not identify specific forms that need to be used during the conduct of a clinical study. Instead under 21 CFR 312.62b), these records are referred to as case history records. These records, for example, can include case report forms, hospital charts, and nurses' notes (the list in the regulations is not intended to be comprehensive). As noted in ICH E6 (see http://www.fda.gov/cder/guidance/959fnl.pdf), source documents are original documents, data and records. Source documents are basically those records where original observations/data are first recorded.

In answer to your first question, any form can serve as a place where original "source" data are recorded. The appearance of, and names for records where data might be recorded are more influenced by sponsor and/or institutional preferences.

In answer to your second question, FDA regulations do not require approval of forms used during a study. Instead, you might want to check with your sponsor, IRB and/or institution to determine if any one of these parties has procedural requirements for the approval of forms used during the conduct of a study.

I hope this information is helpful to you.

Sincerely,
Patricia M. Beers Block
Good Clinical Practice Program (HF-34)
Office of the Commissioner/ FDA
Telephone: 301-827-3340
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.

-----Original Message-----
From: Claudia Rosso Felipe Bonato [mailto:claudia.felipebonato@gmail.com]
Sent: Tuesday, April 18, 2006 12:42 PM
To: OC GCP Questions

Cc: claudia. felipebonato
Subject: a question

Good morning!

I would like to clarify a question regarding source documents.

At our site, we usually use specific forms to complete information necessary for the studies those are not normally use in the routine of the hospital. They are forms for study purpose only.

Can these forms be considered as source documents?
Since these forms are not in the standard procedures of the hospital, should we submit them for the IRB or hospital approval or not?

I appreciate your attention on this.

Kind regards,

Claudia