From: Woollen, Stan - OC on behalf of OC GCP Questions
Sent: Wednesday, June 11, 2003 10:01 AM
To: [Redacted]; Woollen, Stan - OC
Cc: Lepay, David; Lee, Bonnie; El Hage, Antoine N
Subject: RE: Who keeps the original of the informed consent?

[Redacted],
Sorry for the delay in responding to your question below regarding copying and retention of consent forms, I'm just catching up from being out last week when your question arrived.

First, under 312.62(b) the signed consent form is considered to be part of the case history just as medical records and other supporting data are. Therefore, the requirements for retention of the consent form are not different than for any other element of the case history. Many hospitals reduce their medical records to microfiche copies and we have accepted this practice for many years. Our practice of recognizing microfiche records as equivalent to the original was most recently articulated in our ICH E6 Consolidated Guideline on GCPs which defines source documents and source data to include certified copies as follows:

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).

Given the above regulations and guidance it would be acceptable to retain the consent form as a microfiche copy provided the copying process includes a procedure for ensuring that copies or transcriptions are certified after verification as being accurate and complete.

Ideally, the original signed paper copy of the consent form is the gold standard for record retention and verification purposes, however a certified copy is also acceptable. As to the question of where the consent form should be retained, I would refer people to section 8.3.12 of the ICH E6 Consolidated Guideline which deals with Essential Documents. This section only states the signed consent form should be retained in the files of the investigator/institution. This would suggest that either location is acceptable. I would emphasize this is guidance and FDA regulations are generally even less explicit in identifying a storage site for Essential Documents.

I hope this information is helpful in addressing your question.

Sincerely,
Stan W. Woollen
Associate Director for Bioresearch Monitoring
Good Clinical Practice Programs
OSHC, Office of the Commissioner

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: [Redacted]
Sent: Tuesday, June 03, 2003 12:46 PM
To: Woollen, Stan - OC
Cc: Lepay, David; Lee, Bonnie; elhagea@cder.fda.gov
Subject: Who keeps the original of the informed consent?

Hello Stan, David, Bonnie and Tony:

Here is another question that was sparked by the talks given by FDA at the ACRP meeting in Philadelphia. If the Medical Records people insist on keeping the original of the signed informed consent and then convert it to microfiche, what happens during an FDA inspection? Will FDA accept the copy that is kept with the study records? Will FDA accept the microfiche? Tony ElHage said FDA would accept only the original signed document. I am not sure this is true in all circumstances, but I would like to be able to accurately advise the person who sent the message quoted below.

Here is a copy of a message I received:
"We need a clarification from the FDA concerning original informed consent forms issues raised at the ARCP conference.
I am running into a serious problem. Medical Records people insist on keeping the original informed consent form as part of the medical records. Medical Records then converts the paper medical record to microfilm. The original paper consent form is destroyed. Medical records state that the microfilmed version is the original. This procedure has already affected many research studies. Putting the consent form and the medical records on microfilm also presents problems to reviewers. Hospitals usually only have one microfilm machine."

Best personal regards to all

[Redacted]