From: OC GCP Questions
To: [redacted]

Subject: RE: Generic Pre-Screen ICF
Date: Friday, July 17, 2015 4:02:00 PM
Attachments:

[redacted]

Thank you for your inquiry.

1. With regard to your question about record retention for generic ICF for screening testing for those subjects that **did not qualify for a specific protocol**, whether the study in question is for a drug or device, it appears that these documents would not be part of the case histories because the person would not have received the investigational drug/device/biologic or control, and therefore would not be subject to FDA record retention requirement. However, I recommend that you check with your sponsor as well as the appropriate individuals at your institution to see what their expectations are with respect to record retention for the purpose of documenting recruitment/screening efforts.

   Relevant FDA regulations (http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title21/21tab_02.tpl):

   - Drugs/Biologics - 21 CFR 312.62(b) *Case histories.* An investigator is required to prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation **on each individual administered the investigational drug or employed as a control** in the investigation. Case histories include the case report forms and supporting data including, for example, signed and dated consent forms and medical records including, for example, progress notes of the physician, the individual's hospital chart(s), and the nurses' notes. The case history for each individual shall document that informed consent was obtained prior to participation in the study.

   - Devices - 21 CFR 812.140(a)(3) **Records of each subject's case history and exposure to the device**. Case histories include the case report forms and supporting data including, for example, signed and dated consent forms and medical records including, for example, progress notes of the physician, the individual's hospital chart(s), and the nurses' notes. Such records shall include…

2. With regard to your question about scanning the generic ICF used for screening testing and destroying the original paper version, *in particular for those subjects that did qualify for a specific protocol,* **you should keep the paper sources or a certified copy** as they may need to be reviewed by FDA. I believe what you are describing is to have a certified copy substitute for the original. For more information, see below and refer to the guidance for Electronic Source Data in Clinical Investigations http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm328691.pdf .

   - **C. Retention of Records by Clinical Investigator(s)**

     The clinical investigator(s) should retain control of the records (i.e., completed and signed eCRF or certified copy of the eCRF). The clinical investigator(s) should provide FDA inspectors with access to the records that serve as the electronic source data.

     When data elements are transcribed from paper sources into an eCRF, the clinical investigator(s) must also retain the paper sources, or certified copies, for FDA review.[18] Other records (electronic and paper) required to corroborate data in the eCRF (see section III.A.2.a) may also be requested by FDA during an inspection.[19]
   - **Certified Copy** means a copy of original information that has been verified, as indicated by dated signature, as an exact copy having all of the same attributes and information as the original.
     The use of certified copies as described above generally applies to situations where original

records are copied to a different media for archiving purposes and the originals are destroyed. However, if it is decided to have a certified copy substitute for the original, it would be desirable to have a "standard operating procedure" (SOP) describing how such copies would be made, verified, and documented. The person who certifies the copy as an accurate and complete representation of the original, having all of the same attributes and information should be the same person who actually made the copy from the original. Certification should be accomplished by having the person who makes the copy, sign or initial and date the copy to indicate it meets the requirements of a certified copy as described above. This should be described in the SOP and can be accomplished by initialing and dating each copy or by initialing and dating a document certifying copies in bulk. Whichever method is used the SOP should describe the procedure. (There are many ways to accomplish this, and the procedures described above are only suggested examples.)

If you wish to use the scanned copies in lieu of the paper source date (i.e., destroy the paper source data), then the scanned copies would have to meet the definition of the certified copy.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

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From: [redacted]
Sent: Thursday, July 16, 2015 11:24 AM
To: OC GCP Questions
Subject: Generic Pre-Screen ICF

Hello,

Our site utilizes a non-study-specific (generic) ICF for pre-screening purposes. This form is IRB approved. Prior to signing a protocol-specific ICF, we use the generic ICF to test a potential subject's HbA1c value, cholesterol level, etc. to determine if the person pre-qualifies for a protocol-specific screening visit. Of course, the subject will sign a protocol-specific ICF prior to performing actual protocol procedures.

Currently at our site, if the subject pre-qualifies for a particular study, we maintain the generic ICF with the applicable study records to tell the full story of how we screened the subject. If the subject does not pre-qualify for a protocol-specific screening visit, then we simply file the generic ICF separate from study records.

I have a couple of questions:

1. For subjects that do not pre-qualify for a protocol-specific screening visit, do we have to maintain the signed generic ICF indefinitely, or can we destroy these after a given timeframe, such as 6 months to 1 year?

2. Is it appropriate to scan the generic ICFs and file electronically while destroying the original paper version?

I look forward to your response.

Thank you,

[redacted]