

From: OC GCP Questions
To: [REDACTED]
Subject: 1572 expiration
Date: Friday, July 07, 2017 2:34:00 PM
Attachments: [REDACTED]

Good afternoon --

You do not have to submit a new 1572 form. FDA's 1572 guidance <https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf> states --

7. When must a 1572 be updated or a new 1572 completed and signed by an investigator to reflect new or changed information?

There are two instances when it is necessary for an investigator to complete and sign a new 1572: when an investigator is participating in a new protocol that has been added to the IND and when a new investigator is added to the study (21 CFR 312.53(c)).

If there are other changes to information contained on a signed and dated 1572 (e.g., an IRB address change, the addition of new subinvestigators, the addition of a clinical research lab), the investigator should document the changes in the clinical study records and inform the sponsor of these changes, so that the sponsor can appropriately update the IND. The 1572 itself does not need to be revised and a new 1572 need not be completed and signed by the investigator. The sponsor can accumulate certain changes and submit this information to the IND in, for example, an information amendment or a protocol amendment.

Kind regards,

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



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: Thursday, July 06, 2017 3:39 PM
To: OC GCP Questions
Subject: 1572 expiration

Is it required by FDA regulations that an updated 1572 be submitted if an expired version was inadvertently used? And does it make a difference if the study has been closed?

Thank you,

[REDACTED]