From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Tuesday, October 21, 2003 10:07 AM
To: [redacted]
Subject: RE: storing essential documents

Dear [redacted],

Your question was forwarded to me for direct reply. I apologize for the delay in my reply to your question. For drug studies, study records must be retained for a period of 2 years following the date a marketing application is approved; or if no application is to be filed or if the application is not approved for an indication, until 2 years after the investigation is discontinued AND FDA is notified (21 CFR 312.62). A reserve sample for each test article used in bioequivalence or bioavailability studies must be retained for a period of at least 5 years following the date on which the application or supplemental application is approved; or if such application or supplemental application is not approved, at least 5 years following the date of completion of the bioavailability or bioequivalence study in which the sample from which the reserved sample was obtained was used (21 CFR 320.38).

I hope you find this information helpful. Please contact us again should you have any additional questions.

Sincerely,

Pat Beers Block
Good Clinical Practice Programs
Office of Science and Health Coordination
Office of the Commissioner/FDA
301-827-3340

-----Original Message-----
From: [redacted]
Sent: Tuesday, October 07, 2003 2:42 PM
To: gcpquestions@oc.fda.gov
Subject: storing essential documents

For how long does study material need to be kept and stored after a trial is officially closed?

Thanks,
[redacted]