From: OC GCP Questions
To: [redacted]
[redacted]
Subject: Record Retention for Gene therapy Studies.
Date: Friday, August 17, 2018 11:12:00 AM
Attachments: [redacted]

Good morning –

Yes, that is the correct citation for record retention. However, gene therapy studies might have different requirements. Please contact the Center for Biologics (CBER) at ocod@fda.hhs.gov for further guidance.

Kind regards,

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Office of Good Clinical Practice
Office of the Commissioner, FDA

U.S. FOOD & DRUG ADMINISTRATION

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From: [redacted]
Sent: Thursday, August 16, 2018 1:46 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Record Retention for Gene therapy Studies.

Hi!

We are the sponsor of a multi-center gene therapy clinical study under an IND.

What are the sponsor's obligation in terms of study record retention for gene therapy studies? 21CFR 312.57 states that

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A sponsor shall retain the records and reports required by this part for 2
years after a marketing application is approved for the drug; or, if an
application is not approved for the drug, until 2 years after shipment and
delivery of the drug for investigational use is discontinued and FDA has been
so notified.
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Is that true for gene therapy studies as well? Since gene therapy studies typically have long (15 years) follow-up, do we keep record until how long after the study (and IND) is closed?

Your suggestions will be highly appreciated.

Thank you.