



CAPA Report Template

11 May 2023 / Jeremy Timbers / Proper Data
Correction for Case Report Forms

Complete

Score	0%	Flagged items	0	Actions	0
Site conducted					Sydney
Conducted on					11.05.2023 18:30 PST
Prepared by					Jeremy Timbers
Protocol Title					Proper Data Correction for Case Report Forms
Location					8217 Sounds Ave, Sea Isle City, NJ, 08243

Inspection

CAPA Report Form

Principal Investigator

Jeremy Timbers

Deficiency identified

White out was used on case report forms.

Add photo evidence of deficiency if applicable



Photo 1

Response to deficiency

None. White out was used to obscure incorrect study data entry.

Corrective Action Plan (Action taken to correct specific deficiency identified)

The study team will no longer allow the use of white out on study documents. Data entry will be made using only black ink. Corrections to data entry will be lined through once, initialed and dated, with an explanation as to why the changes were made.

Preventative Action Plan: (Action taken to prevent the recurrence of this problem in the future)

All study team members will be re-trained on FDA and GCP regulations regarding proper data entry technique. The trainings sessions will be documented in a training log form.

Signature of responsible personnel

Jessie Malloy
11.05.2023 18:59 PST

Media summary



Photo 1