



CAPA Report Template

conducted for

Proper Data Correction for Case Report Forms

Conducted on

11 Mar 2019 04:26 PM

Prepared by

Jeremy Timbers

Location

8217 Sounds Ave, Sea Isle City, NJ, 08243



Completed on

11 Mar 2019 04:30 PM

Score

0/0.0 - 0.00%

Inspection

Question	Response	Details
CAPA Report Form		
Principal Investigator	Jeremy Timbers	
Deficiency identified	White out was used on case report forms.	
Add photo evidence of deficiency if applicable		
 <p style="text-align: center;">Appendix 1</p>		
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	

Media



Appendix 1