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| **Date:** |  | **IRB Number:** |  |
| **Protocol Title:** |  | **Principal Investigator:** |  |

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| **Deficiency Identified:**  **­­­­­** | White out was used on case report forms. | | |
| **Compliance Review Report Checklist Item Number \*or\* How Deficiency was Identified :** | Item 8.1 | | |
| **Response to Deficiency:**  EXAMPLE | Concur, white out was used to obscure incorrect study data entry. | | |
| **Root Cause of Deficiency:** | Insufficient staff training | | |
| **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 reoccurrence 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 will be documented in a training log form. | | |
| **Plan to Re-evaluate the CAPA:** | Internal audit on source documents completed from this date on for this study. Audit to occur within 6 months of CAPA date. | | |
| **Responsible Personnel:** | Jane Doe, MD | **Signature and Date:** |  |

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| **Date:** |  | **IRB Number:** |  |
| **Protocol Title:** |  | **Principal Investigator:** |  |

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| **Deficiency Identified:**  **­­­­­** |  | | |
| **Compliance Review Report Checklist Item Number:** |  | | |
| **Response to Deficiency:** |  | | |
| **Corrective Action Plan:**  (Action taken to correct specific deficiency identified) |  | | |
| **Preventative Action Plan:**  (Action taken to prevent the reoccurrence of this problem in the future) |  | | |
| **Responsible Personnel:** |  | **Signature and Date:** |  |