

# Protocol Violation

study\_unique\_id

\_\_\_\_\_

violation\_number

\_\_\_\_\_

violation\_date

\_\_\_\_\_

violation\_nature

- ☐ hypothermia never started
  - ☐ hypothermia initiated at < 6 hrs or > 24 hrs
  - ☐ hypothermia discontinued before 96 hrs
  - ☐ wrong treatment group
  - ☐ other
  - ☐ infant ineligible
  - ☐ no consent
  - ☐ neuro exam at eligibility not done
- (violationNature)

violation\_treatment\_assign

- ☐ Yes
- ☐ No

violation\_treatment\_receive

- ☐ Yes
- ☐ No

violation\_other\_text

\_\_\_\_\_

violation\_circumstance

- ☐ equipment not available
  - ☐ equipment malfunctioned
  - ☐ infant transferred out of study site
  - ☐ parents withdrew consent
  - ☐ neonatologist withdrew child from study
  - ☐ other
- (violationCircumstance)

violation\_other\_circumstance\_text

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violation\_comment

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