

PEDS-C

Protocol Deviation Report

PDC 08
Rev 0
02/15/2005
Page 1 of 1



55563

Please Use Black Pen To Fill Out Form.

Form Completion Date

fdate / /
mm dd yyyy

Sequence #

seqno

Patient ID

idn - -

Patient Letter Code

letcode

correct
Correction

Instructions

Use this form to report protocol deviations. If you are reporting the first deviation, sequence # = 01. If you are reporting subsequent deviations, use a separate form for each deviation and give each form a separate consecutive sequence number, starting with 01.

Nature of the Deviation

CRA Use Only

1. Date of Protocol deviation:

protdevdt / /
mm dd yyyy

2. What was the nature of the deviation?

3. Why did the deviation occur?

Prevention Plan of Action

4. Detail your plan of action to prevent this Protocol deviation in the future:

Impact

5. Outline the impact this deviation will/may have on the individual as well as on the study:

Signature: _____

Certif. #: _____

staffid1 -