Bench to Bassinet
Pediatric Cardiac Genomics Consortium: CHD GENES
Form 90: Protocol Violation, Unexpected Event, or Procedural Error
Version: B - 07/18/2011

SECTION A: ADMINISTRATIVE INFORMATION

A1. Study Identification Number:

A2. Date Form Completed: *MM/DD/YYYY*

A3. Corresponding Form Number (if any):

SECTION B: EVENT INFORMATION

B1. Is this event a...
- Protocol Violation
- Unexpected Event
- Data or Specimen Procedural Error

a. Is this Unexpected Event an Adverse Event?
- Yes
- No

B2. Please check each type of protocol violation that applies:

a. Violation of Inclusion/Exclusion Criteria
b. Violation of Consent/Assent Procedures
c. Missing required forms
d. Missing proband specimen
e. Late report of an unanticipated event (as defined by OHRP)
f. Missed report of an unanticipated event (as defined by OHRP)
g. Other

i. If Other, please describe:

B3. Please document and explain all details related to the event in B1 below: