

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

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**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: