



# Patient Advocacy Council

Institutional Review Board

## Serious or Unanticipated Adverse Event Report Form

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Mobile, Alabama 36606  
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Web Site: [www.pacirb.com](http://www.pacirb.com)

This is to be reported to the IRB within 15 calendar days of the event. In the event of death, report immediately!

SITE INFORMATION			
Protocol Number:	IRB Number:	Sponsor:	
Name of Drug or Device:			
Principal Investigator:			
Company Name:			
Address:	City:	State:	Zip:
Phone #: (    )	Fax #: (    )	Contact Name:	
PATIENT INFORMATION			
Patient ID#	Patient Initials	Age	Sex <input type="checkbox"/> Male <input type="checkbox"/> Female
ADVERSE EVENT OR PRODUCT PROBLEM			
<input type="checkbox"/> Adverse Event <input type="checkbox"/> Product Problem (e.g., defects/malfunctions)			
Type of Report: <input type="checkbox"/> Initial <input type="checkbox"/> Follow-up			
Outcome attributed to adverse event (check all that apply)			
<input type="checkbox"/> death (date) <input type="checkbox"/> congenital anomaly <input type="checkbox"/> life-threatening <input type="checkbox"/> required intervention to prevent permanent impairment/damage <input type="checkbox"/> hospitalization – initial or prolonged <input type="checkbox"/> other <input type="checkbox"/> disability			
Date of Event:	Date of this report:	Date AE Resolved:	
Describe Event or Problem:			
Describe the relationship (if any) to the study medication or device and/or the protocol design:			

Prepared By: \_\_\_\_\_ Date: \_\_\_\_\_

Investigator Signature: \_\_\_\_\_ Date: \_\_\_\_\_