



930 Calle Negocio, Suite B, San Clemente, CA 92673
T: 949-542-3882 F: 949-940-0134

www.alphaairb.com

ADVERSE/SERIOUS ADVERSE /UNEXPECTED/UNANTICIPATED REPORT FORM

- DRUG OR BIOLOGIC DEVICE
- ADVERSE EVENT SERIOUS ADVERSE EVENT UNEXPECTED EVENT UNANTICIPATED EVENT

PROTOCOL NUMBER: _____ SPONSOR: _____

INVESTIGATOR _____ PHONE: _____

SITE NAME: _____

SUBJECT ID: _____ BIRTH DATE: ____/____/____ SEX F M AGE: ____
(Subject Number or Initials only – NO NAMES)

REPORT TYPE: INITIAL FOLLOW-UP # _____ FINAL OTHER:

ONSET DATE ____/____/____ DATE SITE BECAME AWARE OF EVENT: ____/____/____

EVENT RESULTED IN:

- DEATH: DATE ____/____/____, CAUSE OF DEATH:
- THREAT TO LIFE
- INPATIENT OR PROLONGED HOSPITALIZATION:
DATE OF ADMISSION ____/____/____
- SEVERE OR PERMANENT DISABILITY
- NONE OF THE ABOVE

DESCRIPTION OF THE ADVERSE/ SERIOUS ADVERSE/UNEXPEDTED/UNANTICIPATED EVENT :

TREATMENT OF EVENT:



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WAS THE EVENT RELATED TO THE STUDY DRUG OR DEVICE?

PROBABLY POSSIBLY REMOTELY NOT RELATED

WAS THE SUBJECT REMOVED FROM THE STUDY DUE TO THIS EVENT? No Yes If yes, STOP DATE: ____/____/____

DID THE STUDY DRUG/DEVISE RESUME? No Yes If yes, START DATE: ____/____/____

ARE CHANGES REQUIRED TO THE IRB APPROVED INFORMED CONSENT FORM No Yes

If yes, attach revised consent form or indicated when these changes will be submitted:

WILL YOU BE SENDING FOLLOW-UP INFORMATION ABOUT THIS EVENT? No Yes

SIGNATURE Person Reporting Serious Adverse Event

_____/_____/_____
Date of Report