

Goodwyn Institutional Review Board, Ltd.

**Updates and Alerts Report
(IND Safety or Medical Device Effect Reports)**

*Use this form for reporting new or updated information and alerts to the IRB, including events occurring external to your site / IND safety reports.
Please submit one report within 10 days of each reportable item.*

Goodwyn IRB Reporting Guidelines are available at <http://www.GoodwynIRB.com>.

Sponsor:		Protocol #:
Principal Investigator:		
Contact Person for this report:		
Phone:		Fax:
Date of Report:	Date Sponsor Notified:	MFR# / Report Name:

1. Scope of Report:

<input type="checkbox"/> This report is being submitted by the Principal Investigator listed above. <input type="checkbox"/> This report is being submitted by the Sponsor or CRO on behalf of all investigators for the protocol listed above. <input type="checkbox"/> This report is being submitted by the SMO on behalf of one or more investigators for the protocol listed above. List investigators:

2. Type of Information:

Is the type of information being submitted (Check One):

A <input type="checkbox"/> New or Updated Study Product Safety Information (e.g. Investigator Brochure, Package Insert, Device Manual). A detailed summary of changes or marked changes are required for updates.
B <input type="checkbox"/> DSMB Report / Summary
C <input type="checkbox"/> FDA Safety Alert (e.g. FDA Drug Warnings, Dear Healthcare Professional Letters)
D <input type="checkbox"/> Publication in Literature
E <input type="checkbox"/> Evaluation of Medical Device Effects (according to 21 CFR 812.46) or Final Device Report (according to 21 CFR 812.150(b)(7))
F <input type="checkbox"/> Correspondence to Principal Investigator from FDA, other regulatory agency or sponsor communicating early study termination, marketing withdrawal, or clinical hold.
G <input type="checkbox"/> Other Safety Information or unanticipated problem
H <input type="checkbox"/> IND Safety Report (Report external to PI)
Did you check one of the boxes above? <input type="checkbox"/>Yes <input type="checkbox"/>No If yes, you MUST attach the item being reported.

3. Assessment

- This information is indicative of an increased risk to participants in this research study (the protocol referenced above.)
- This information affects the rights, safety or welfare of the participants in this research study.
- This information affects the integrity of this research study.

In the question below, describe the reason(s) you answered as you did above. What information supports your judgment?

Rationale for the above assessments:

This information is being submitted to satisfy IRB, Sponsor or Site reporting requirements: Yes No

4. Recommendations

Do you recommend any change to the protocol? Yes No

(If yes, please attach recommended changes.)

Do you recommend any change to the informed consent document? Yes No

(If yes, please attach the consent changes, marking the changes in the document.)

Has the sponsor reviewed these recommended changes? Yes No

Reporter's / Principal Investigator's Signature

Date: _____

Reporter / Principal Investigator

Printed Name of Reporter