

Goodwyn Institutional Review Board, Ltd.

Adverse Event / Medical Device Effect Report

*Use this form to report unanticipated adverse events related to the research.
 Submit one adverse event report for each reportable event within 10 working days of its occurrence.
 Goodwyn IRB Reporting Guidelines are available at <http://www.GoodwynIRB.com>*

Sponsor:		Protocol #:	
Principal Investigator:			
Contact for additional information about this report:			
Phone:		Fax:	
Date Event Reported:	Date Sponsor Notified:	Date of Event Onset:	
Report Type:	<input type="checkbox"/> Initial Report	Report #	Initial Report Date
	<input type="checkbox"/> Follow-up Report		
Outcome:	<input type="checkbox"/> Resolved	<input type="checkbox"/> Stabilized	<input type="checkbox"/> Ongoing

PATIENT DATA:

Subject Number: _____	Age: _____	Sex: _____
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ADVERSE EVENT INFORMATION

<p>A. Was the event serious? Check all that apply below:</p> <table style="width:100%;"> <tr> <td><input type="checkbox"/> Death</td> <td><input type="checkbox"/> Life Threatening Event</td> </tr> <tr> <td><input type="checkbox"/> Severe or Permanent Disability</td> <td><input type="checkbox"/> Hospitalization / Extended Hospitalization</td> </tr> <tr> <td><input type="checkbox"/> Congenital Abnormality</td> <td><input type="checkbox"/> Required intervention to prevent any of the outcomes listed above</td> </tr> <tr> <td><input type="checkbox"/> Other (specify: _____)</td> <td></td> </tr> </table> <p><i>If you did not check any of the criteria above, then the event is not considered "serious."</i></p> <p>Was the event serious? (Did you check any of the criteria above) <input type="checkbox"/>Yes <input type="checkbox"/>No</p>	<input type="checkbox"/> Death	<input type="checkbox"/> Life Threatening Event	<input type="checkbox"/> Severe or Permanent Disability	<input type="checkbox"/> Hospitalization / Extended Hospitalization	<input type="checkbox"/> Congenital Abnormality	<input type="checkbox"/> Required intervention to prevent any of the outcomes listed above	<input type="checkbox"/> Other (specify: _____)	
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<input type="checkbox"/> Severe or Permanent Disability	<input type="checkbox"/> Hospitalization / Extended Hospitalization							
<input type="checkbox"/> Congenital Abnormality	<input type="checkbox"/> Required intervention to prevent any of the outcomes listed above							
<input type="checkbox"/> Other (specify: _____)								
<p>B. Was the event unanticipated? Check all that apply below:</p> <p><input type="checkbox"/> The event is not identified in nature or severity in relevant study product documentation (e.g., investigators brochure, device manual).</p> <p><input type="checkbox"/> The event is not identified in specificity or severity as a risk in the informed consent document.</p> <p><input type="checkbox"/> There is another reason that the event was unanticipated (e.g. unexpected frequency of occurrence). Explain:</p> <p><i>If you did not check any of the criteria above, then the event is not considered "unanticipated."</i></p> <p>Was the event unanticipated? (Did you check any of the criteria above) <input type="checkbox"/>Yes <input type="checkbox"/>No</p>								
<p>C. Was the event related to the study product/intervention?</p> <p>This question is about the extent of relationship between a drug/device or study intervention and a suspected adverse reaction. Naranjo's Algorithm (<i>Naranjo et al., Clin Pharmacol Ther 30: 239-45 (1981)</i>) is a commonly used scale for determining the likelihood an adverse event being due to a drug/device rather than the result of other factors.</p> <p>Step 1: Complete the following questionnaire.</p>								

Modified Naranjo Scale (Modified to include study intervention as well as drugs/devices as a potential source of adverse reaction.)

To assess relatedness of the adverse reaction to a drug/device/study procedure (intervention), answer the following questionnaire to determine the pertinent score(s). [In the score column, indicate the value associated with your answer of “yes” or “no” to each question. At the end of the questionnaire, add the scores for the total.]

	Yes	No	Do Not Know	Score
1. Are there any previous reports from any source on this reaction indicating possible, probably or definite relationship to drug/device/procedure (intervention) required by the protocol?	+1	0	0	
2. Did the adverse event appear after the suspected drug/device/intervention was administered?	+2	-1	0	
3. Did the adverse reaction improve when the drug/device/intervention was discontinued, or a specific antagonist was administered?	+1	0	0	
4. Did the adverse reaction reappear when the drug/device/intervention was re-administered?	+2	-1	0	
5. Are there alternative causes (other than the drug/device/intervention) that could on their own have caused the reaction?	-1	+2	0	
6. Did the reaction reappear when a placebo was given?	-1	+1	0	
7. Was the drug/device detected in the blood (or other fluids) in concentrations known to be toxic?	+1	0	0	
8. Was the reaction more severe when the dose was increased, or less severe when the dose was decreased?	+1	0	0	
9. Did the patient have a similar reaction to the same or similar drug/device/intervention in <u>any</u> previous exposure?	+1	0	0	
10. Was the adverse event confirmed by objective evidence?	+1	0	0	
11. Total Score:				

Step 2: Assign the probability of relatedness. Based on the value of the total score, check the appropriate box below:

- Definitely Related (Score ≥ 9)
- Possibly Related (Score 1-4)
- Probably Related (Score 5-8)
- Doubtful/Unknown Relationship (Score ≤ 0)

If you did not check any of the criteria above – or checked either “Possibly Related” or “Doubtful/Unknown Relationship” – then the event is not considered “related” to study product / intervention.

Was the event related to study product/intervention? (Did you check either “Definitely Related” or “Probably Related” above) Yes No

D. Criteria for IRB Review

Goodwyn IRB reviews events that are considered both **unanticipated** and **related** to the research. If you have checked "NO" above in section **B** (you determined that the event or its frequency was anticipated) or **C** (you determined that the event was unrelated), then this event report will simply be placed in your file. Use this printed report as your acknowledgement.

Have you checked "NO" to either question B or C above: Yes No

E. Event Description

In the description below, include current findings, hospitalization dates (if necessary), duration of treatment with study drug, relevant past history, treatment for the event and treatment plans for the follow-up (if necessary).

Note: If this report did not meet the Goodwyn IRB criteria for review, enter only a brief description.

Describe the Adverse Event/Effect:

Did the subject discontinue taking / use of the test article due to this event? Yes No
If yes, did the subject resume taking / use of the test article later? Yes No

F. Assessment

In the Principal Investigator's opinion:

- Does this event alter the current risk/benefit profile of this trial?** Yes No
- Do you recommend any change to the protocol?** Yes No
(If **yes**, attach recommended changes (marked in the protocol or a detailed summary.)
- Do you recommend a change to the consent document/template?** Yes No
(If **yes**, attach the consent changes, marking the changes in the document.)
- Has the sponsor reviewed these recommended changes?** Yes No

Principal Investigator's Signature

Date: _____

Principal Investigator

Printed Name of Reporter