

**Goodwyn Institutional Review Board, Ltd.**

Please check the type of status report you are submitting:

PERIODIC     RENEWAL     FINAL (completion or termination)

Sponsor:

Protocol Title:

Principal Investigator: \_\_\_\_\_

You must submit the following items with this completed form:

- a) **A copy of the study monitor sign-in sheet (visitor log).** This is the visit log signed by your monitor upon each monitoring visit. Please indicate on the report form if your site was never initiated into the study.
- b) **A copy of any subject materials.** Attach any site-specific advertisements, recruitment materials or other written information provided to potential subjects / enrolled subjects. The IRB needs to be aware of all advertising and recruitment materials that you have used for recruiting subjects. Any materials produced by the study sponsor need not be submitted as part of this application.

Status of your study, check one:

Recruitment still ongoing

Study closed to enrollment

Check one:

Subjects still being followed in protocol visits

No subjects on follow-up but sponsor's data monitoring is ongoing

**Study closed (final report)** Close-out date: \_\_\_\_\_  
(No subjects on follow-up AND sponsor's monitoring close-out visit completed)

**Study terminated (final report)** Reason: \_\_\_\_\_

**Other** Specify: \_\_\_\_\_

You must complete all of the following questions:

1. Date first subject signed a consent form: \_\_\_\_\_
2. Date most recent subject initially signed a consent form: \_\_\_\_\_
3. Last ICF used for consenting / re-consenting subjects: Version Number \_\_\_\_\_ Template Date \_\_\_\_\_

If your site has additional consent forms available for use in the above referenced study, please indicate the type of ICF(s), version number(s), and template date(s) below:

Sub-Study	_____	Version Number	_____	Template Date	_____
Translation	_____	Version Number	_____	Template Date	_____
Other	_____	Version Number	_____	Template Date	_____

If the last ICF used for consenting/re-consenting subjects is not the most current version available for use, please explain: \_\_\_\_\_

4. Are you reporting any site or investigator changes (e.g. changes in office location, phone number, investigators) with this form? If yes, please attach.  
 Yes       No
  
5. Are you reporting any serious and unexpected adverse events and/or protocol deviations with this form? If yes, please complete Goodwyn IRB's Serious Adverse Event Form and/or Protocol Deviation Report Form supplied with your approval and attach.  
 Yes       No
  
6. Have there been any unanticipated problems involving risks to subjects?  
 Yes       No  
 If yes, please explain:
  
7. Has your opinion of the study's risk and benefits changed since this study was last reviewed?  
 Yes       No  
 If yes, please explain:
  
8. Did you or are you currently advertising for this study?     Yes     No  
**If yes**, submit your site-specific advertisements (flyers, posters, newspaper ads)  
**Or**, only used sponsor provided advertisements:     Yes  No

9. Since your initial IRB approval, indicate the number of subjects who: **# of subjects**

a. Have signed the informed consent form(s)	
b. Are currently active	
c. Were screen failures <small>(Subjects who signed the informed consent form(s) but did not meet inclusion/exclusion criteria)</small>	
d. Prematurely terminated from the study after meeting enrollment criteria <small>(Reasons for premature termination must be provided in question #10)</small>	
e. Have completed the study	

**NOTE: 9b + 9c + 9d + 9e should equal 9a (Total # of subjects who signed the consent form(s))**

10. Premature Termination Causes  
 Indicate the number of subjects who: **# of subjects**

a. Withdrew consent	
b. Lost to follow-up	
c. Protocol violation	
d. Adverse event	
e. Serious adverse event	
f. Non-compliance	
g. Did not continue to meet the inclusion / exclusion criteria	
h. Disease progression	
i. Lack of efficacy	
j. Sponsor decision (reason):	
k. Other (reason):	
<b>Total:*</b>	

**\*The total number of premature terminations noted in question #10 should equal the number in #9d.**

11. Do you expect to enroll subjects in the coming year?     Yes     No
  
12. Have you received any complaints from subjects about the research?     Yes     No  
 If yes, please describe:
  
13. Has your site been audited by the FDA, OHRP, sponsor or CRO and/or any other regulatory agencies since your last review/approval? If yes, please attach.     Yes     No

14. Has your site received a Form FDA 483, Warning Letter, and/or any other notification of regulatory deviations since your last review/approval? If yes, please attach. Yes No
15. Have there been any professional disciplinary or legal actions involving study staff and/or your site(s) since your last review/approval? If yes, please attach. Yes No
16. Has any subject in this study sought compensation for injury? Yes No  
If yes, please describe:
17. Has your site experienced any problems protecting subject confidentiality? Yes No  
If yes, please describe:
18. Does the principal investigator or any co-investigator (or any member of their immediate family) currently:
- a. Own or control an equity interest in any drug, device or technology involved in this research study? Yes No
  - b. Have a financial interest in any listed source of external support? Yes No
  - c. Function as an advisor, employee, officer, director, or consultant for any listed commercial source of external support? Yes No

If yes, please provide detailed information to permit the IRB to determine if such involvement should be disclosed to potential research subjects:

**Who should the IRB contact for questions regarding this form?**

\_\_\_\_\_  
Print Name

\_\_\_\_\_  
Telephone Number

**My signature verifies that the above information is complete and accurate.**

\_\_\_\_\_  
**Principal Investigator Signature**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Principal Investigator Printed Name**

Completed application forms should be sent to:  
**Goodwyn Institutional Review Board, Ltd.**  
**9380 Main Street, Cincinnati, OH 45242**  
**Submission Fax: 513-793-2800 or 513-793-4800**