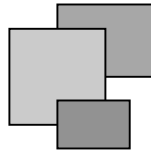


Fax or Mail this form to:



Ethical Review Committee, Inc.

14400 E. 42nd St., Suite 240

Independence, MO 64055

Phone: 816.421.0008 ♦ Fax: 816.356.2227

PRINCIPAL INVESTIGATOR CONTINUING REVIEW INFORMATION REPORTING FORM

This form is to be completed by the Principal Investigator (PI) when the study is ongoing to request an extension of your Institutional Review Board approval and to provide reporting information necessary to conduct Continuing Review. If any items are left blank on this form, your site may not be included in the Continuing Review, which could result in the termination of your approval to conduct the trial.

If your site has completed the study, you should complete the Final Report Form in place of this document. A copy of the Final Report Form can be obtained by contacting the Ethical Review Committee (ERC) or by visiting the ERC website; www.ethicalreview.com

ERC #:	Sponsor Name:	Protocol #:
PI Name:	Address:	City, State, Zip:
Coordinator:	Telephone: () -	Fax: () -

If the ERC has any questions regarding the completion of this form who should be contacted?

Name:

Phone: () -

E-Mail:

Section A: Subject Enrollment

Please read this section **CAREFULLY** and complete all questions as instructed. Failure to complete this section correctly will result in additional reporting requirements and may cause your request for Continuing Review to be delayed or even disapproved. *If you have not consented any subjects, complete with zeros.*

A. How many subjects at your site are currently active? (<i>Active is defined as taking study drug / participating in study procedures or in follow-up but not withdrawn.</i>) Place total answer in box A and then also identify each reason below:	Answer to A
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*Of those active subjects in answer A how many are **actively** on study drug / in study procedures?*

*Of those active subjects in answer A, how many have **completed** study drug / procedures but are still in follow-up?*

B. How many subjects at your site (to date) have completed the entire study (including all required study visits and any required follow-up visits)?	Answer to B
---	--------------------

C. How many subjects at your site (to date) signed an Informed Consent Form and then discontinued prior to completion of the study (for any reason including withdrawals, SAE, AE, screen failure, etc.)	Answer to C
---	--------------------

Of those subjects in answer C, were any consented but discontinued before treatment and/or study procedures began (i.e.: screen failures)?

No Yes

If yes, how many?

Of those subjects in answer C, were any discontinued due to an SAE or AE?

No Yes

*If yes, you are **required** to identify the subject number and provide a description of the event for each:*

Of those subjects in answer C, did any discontinue for any other reason(s) or were any lost to follow-up? No Yes

If yes, you are **required** to identify the subject number and provide a description of the event for each:

D. How many subjects at your site (to date) are in the screening stage?	Answer to D
--	--------------------

E. How many <u>total</u> subjects at your site (to date) have signed an Informed Consent Form?	Answer to E
---	--------------------

Was informed consent obtained from all enrolled subjects prior to performing any study procedures? No Yes
 N/A-no subjects

If no, an explanation is **required**.*:

***Note: No investigator may involve a subject without legally effective informed consent of the subject or the subject's legally authorized representative. If this has taken place, you will need to complete the ERC's Violation Reporting form.**

THE FOLLOWING FORMULA MUST WORK-OUT OR YOUR REPORT WILL NOT BE ACCEPTED:

Answer to A:	+	Answer to B:	+	Answer to C:	+	Answer to D:	=	Answer to E:
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Section B: PI and Site Information

Questions 1 - 14 refer to the period since the initial approval or last continuing review approval, whichever is most recent.

PI SITE SPECIFIC

1	**Have you filed any problem reports (SAE, deviation/violation) since the last ERC review?	<input type="checkbox"/> No <input type="checkbox"/> Yes
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If yes, SAE, ____ (#) occurrences; Deviation, ____ (#) occurrences; Other, ____ (#) occurrences

All SAEs, Unexpected Occurrences, Protocol Deviations/Violations should have been reported as they occurred. Please attach any reports **not previously submitted to the ERC with an explanation of why they were not submitted at the time of occurrence.

2	Are you aware of any problems at your site that are unexpected and related to the study that have not yet been reported to the ERC?	<input type="checkbox"/> No <input type="checkbox"/> Yes
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If yes, explain:

3	Have there been any complaints from subjects or others involved in the research at your site that may be study-related risks?	<input type="checkbox"/> No <input type="checkbox"/> Yes
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If yes, explain:

4	Are you aware of any new findings, publications or other information that has become available that relate to the study?	<input type="checkbox"/> No <input type="checkbox"/> Yes
----------	---	--

If yes, explain:

5	Have any new risks to the subjects or others been identified at your site since the last ERC review?	<input type="checkbox"/> No <input type="checkbox"/> Yes
----------	---	--

If yes, explain:

6	Have any new benefits to subjects been identified at your site since the last ERC review?	<input type="checkbox"/> No <input type="checkbox"/> Yes
----------	--	--

If yes, explain:

7	Have there been any changes in privacy protections or measures to ensure confidentiality at your site?	<input type="checkbox"/> No <input type="checkbox"/> Yes
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If yes, explain:

8	Have you been involved in any publication of data from this study?	<input type="checkbox"/> No <input type="checkbox"/> Yes
---	--	--

If yes, list publications:

PI SPECIFIC		
9	Has the relationship of the PI or any other team member changed in such a way as to now create a potential conflict of interest?	<input type="checkbox"/> No <input type="checkbox"/> Yes

If yes, provide details:

10	Have your hospital privileges been suspended, revoked, restricted, placed on probation, or subject to disciplinary action within the last year?	<input type="checkbox"/> No <input type="checkbox"/> Yes
----	---	--

If yes, provide details:

11	Has your medical license(s) been suspended, revoked, denied, or interrupted within the last year?	<input type="checkbox"/> No <input type="checkbox"/> Yes
----	---	--

If yes, provide details:

12	Have you had any board action(s) filed with the licensing agency within the last year?	<input type="checkbox"/> No <input type="checkbox"/> Yes
----	--	--

If yes, provide details:

13	Has any medical legal action(s) been filed against you or resolved within the last year?	<input type="checkbox"/> No <input type="checkbox"/> Yes
----	--	--

If yes, provide details:

14	Have you been audited by the FDA within the last year?	<input type="checkbox"/> No <input type="checkbox"/> Yes
----	--	--

A. *If yes, what date did the audit occur?*

Was a FDA Form 483 issued? No Yes N/A

B. Was it a "For Cause" Inspection?

No Yes N/A

If issued, attach all copies of EIR Forms (Established Inspection Reports).

Also, attach copies of ALL communications you have received from/forwarded to the FDA.

Section C: Sub Investigator Information

Please indicate the Sub Investigators approved for conduct of the study under your responsibility:

N/A, No Sub Investigators (*Please proceed to Section D*)

Sub Investigators:

Provide the following information that has occurred since their original approval or last re-approval as it applies to the Sub Investigators identified above:

1	Have any had their medical license(s) suspended, revoked, denied, or interrupted within the last year?	<input type="checkbox"/> No <input type="checkbox"/> Yes
---	--	--

If yes, explain:

2	Have any of their hospital privileges been suspended, revoked, restricted, placed on probation, or subject to disciplinary action within the last year?	<input type="checkbox"/> No <input type="checkbox"/> Yes
---	---	--

If yes, explain:

3	Do any have board action(s) on file with the licensing agency within the last year?	<input type="checkbox"/> No <input type="checkbox"/> Yes
----------	--	--

If yes, explain:

4	Has any medical legal action(s) been filed against them or resolved within the last year?	<input type="checkbox"/> No <input type="checkbox"/> Yes
----------	--	--

If yes, explain:

Section D: Signature and Licensing

By signing this form, I hereby declare that my medical license in the state in which I practice, and the state where the research site is located, is current and I will notify the Ethical Review Committee if such situation(s) changes. I further state that I am in good standing with the Medical Board governing my licensure, except as noted above (if applicable).

I also agree that when my license is renewed, I will FAX or MAIL a copy of the renewed license to the Ethical Review Committee and that I will continue to do so as long as the study I am conducting is ongoing and until the Final Report is submitted to the ERC.

*** REMINDER - PLEASE PROVIDE A COPY OF PAGE ONE (1) OF THE CURRENT CONSENT FORM***

Medical License #: _____ State: _____ Expiration Date: _____

Other License(s): _____ State: _____ Expiration Date: _____

PI CHECKLIST

Before submitting your application for continuing review, please review the following:

- | | |
|---|---|
| <input type="checkbox"/> Copy of page 1 of the current Consent Form is included | <input type="checkbox"/> All questions are answered |
| <input type="checkbox"/> Copies of requested explanations are included | <input type="checkbox"/> Section 1 Formula is correct |
| <input type="checkbox"/> Copy of Current Medical License(s) for Sub Investigator(s) is included | <input type="checkbox"/> Original PI signature |

Principal Investigator's Signature (*Original Signature Only*)

_____/_____/_____
Date

Type or Print Name

Upon receipt by the ERC, an acknowledgment of receipt will be faxed to your site.
File a copy of this completed form, and all documents you receive from the ERC, in your study file.

<i>For Office Use Only</i>
Report Audited _____
License Verified _____
Date: ____/____/____