



706B West Ben White Blvd. Austin, TX 78704 TEL: 800-688-2132 FAX: 512-747-9382 www.rcrc-irb.com

SPONSOR: _____	PROTOCOL #: _____
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A. PROTOCOL INFORMATION:

1.	Today's Date:	
2.	Current Site Expiration Date:	

B. INVESTIGATOR and SITE INFORMATION:

1.	Name of Principal Investigator:	
2.	Name of Research Site:	
3.	Complete Mailing Address	
4.	Name of Current Site Contact:	
5.	E-mail Address of Site Contact:	
6.	Phone Number of Site Contact:	
7.	Fax Number of Site Contact:	

Since your last IRB review (either your initial review or your previous continuing review):

8.	Has there been a change in the Principal Investigator that has not been reported to and approved by RCRC IRB?	<input type="checkbox"/> No <input type="checkbox"/> Yes (attached)
9.	Has there been a change in the financial disclosure status of the Principal Investigator that has not been reported to RCRC IRB?	<input type="checkbox"/> No <input type="checkbox"/> Yes (attached)
10.	Has there been a change in the status of Board certification, licensure, or an FDA debarment of the Principal Investigator that has not been reported to RCRC IRB?	<input type="checkbox"/> No <input type="checkbox"/> Yes (attached)
11.	Is there any pending disciplinary action against the Investigator from the state licensing Board?	<input type="checkbox"/> No <input type="checkbox"/> Yes (attached)

C. STUDY STATUS INFORMATION and ENROLLMENT INFORMATION:

This study is: <ul style="list-style-type: none"> <input type="checkbox"/> Completely closed: No participants were <i>consented</i> at this site (<i>skip to section G</i>) <input type="checkbox"/> Completely closed: All data is complete and analysis is complete. <input type="checkbox"/> Completely closed: All data has been collected; data analysis is not complete. <input type="checkbox"/> Completely closed: Sponsor closed the study at this site due to (<i>describe</i>): <input type="checkbox"/> Other (<i>describe</i>):

Provide enrollment information (since the start of enrollment):		Number
1.	Total number of screen failures at this site:	
2.	Total number of participants who voluntarily withdrew their consent and why:	
3.	Total number of participants withdrawn (by PI/Sponsor) without their consent and why:	
4.	Total number of participants that completed protocol procedures:	
5.	Total number of participants that were consented (total of rows 1-4):	

D. PARTICIPANT RIGHTS INFORMATION:

Since your last IRB review (either your initial review or your previous continuing review):		
1.	Have you received any concerns, questions or complaints from your study participants?	<input type="checkbox"/> No <input type="checkbox"/> Yes (attached)
2.	Has anything occurred at your site which altered the original risk/benefit assessment?	<input type="checkbox"/> No <input type="checkbox"/> Yes (attached)
3.	Have you enrolled any participant from whom informed consent was not appropriately, and prospectively, obtained documented?	<input type="checkbox"/> No <input type="checkbox"/> Yes (attached)
4.	Have participants experienced any benefits?	<input type="checkbox"/> No <input type="checkbox"/> Yes (attached)

E. UNANTICIPATED PROBLEMS:

Since your last IRB review (either your initial review or your previous continuing review):		
1.	Have there been any unanticipated problems involving risks to participants or others?	<input type="checkbox"/> No <input type="checkbox"/> Yes
2.	Has there been any relevant information about risks associated with the research drug, device, or procedures?	<input type="checkbox"/> No <input type="checkbox"/> Yes (attached)
3.	Have any participants withdrawn consent due to unanticipated problems involving risks to participants or others?	<input type="checkbox"/> No <input type="checkbox"/> Yes (attached)
4.	In the Investigator's opinion, what has been the most <i>frequent</i> unanticipated problem involving risks to participants or others?	
5.	In the Investigator's opinion, what has been the most <i>severe</i> drug/device related unanticipated problems involving risks to participants or others?	
6.	In the Investigator's opinion, is the frequency, severity, or character of events different from those expected at the outset of the research?	

<i>Include all unanticipated problems involving risks to participants or others that have occurred at your site since your previous IRB review. Note: Unanticipated Problems must be reported separately on FORM 300.</i>			
Participant Identifier	Date of Event	Event Description	Outcome or Causality: (Probably Related, or Definitely Related)

F. AUDIT and MONITORING INFORMATION

<i>Since your last IRB review (either your initial review or your previous continuing review):</i>		
1.	Has this <i>site</i> been monitored by an independent monitoring board for safety?	<input type="checkbox"/> No <input type="checkbox"/> Yes (attached)
2.	Has this <i>site</i> been inspected by the FDA?	<input type="checkbox"/> No <input type="checkbox"/> Yes (attached)
3.	Have there been any multi-center trial reports?	<input type="checkbox"/> N/A (single site) <input type="checkbox"/> No <input type="checkbox"/> Yes (attached)
4.	Have there been any publications in literature relevant to this research?	<input type="checkbox"/> No <input type="checkbox"/> Yes (attached)

G. PRINCIPAL INVESTIGATOR CERTIFICATION STATEMENT and SIGNATURE:

I certify that the above information is true and accurate. Study activities are complete; all enrolled study participants have exited the protocol and no further study activities will take place at this site. At the time of this submission all unanticipated problems involving risks to participants or others, and Safety Reports have been reported to RCRC IRB.

 Signature of Principal Investigator Date

H. LIST OF ATTACHMENTS:

- REQUIRED DOCUMENTS:**
- Completed and signed Final Report (this document).
 - A copy of the first page of the current protocol.
 - A copy of the first page of the current Investigator’s Brochure (if applicable)
 - A BLANK copy of the first and last page of the all current RCRC IRB approved informed consent document(s), (main, foreign, addendums).
 - Attached explanation for any questions answered “Yes” that requires an attachment.

I. IRB ASSESSMENT and ACKNOWLEDGMENT (BOARD USE ONLY):

I have reviewed the information reported on this Final Report and acknowledge the closure of the study at this site.

 Signature of Board Chair or Designee Date