

REQUEST FOR REINSTATEMENT OF IRB APPROVAL

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This form must be completed in its entirety and submitted with a Research Status Report Form and all relevant documents in order for the Board to consider reinstating IRB approval.

NOTE: Federal Regulations preclude the Board from providing retroactive approval. The lapse of IRB approval will be clearly noted in the reinstatement letter.

a. Sponsor: _____ b. Protocol #: _____

c. Protocol Title: _____

d. Expiration Date: _____

e. Principal Investigator: _____

f. Site Address: _____

g. Reason for delay in request for Continuing Review (*attach separate sheet if necessary*):

h. Have any study subject visits taken place since the expiration of IRB approval?

No Yes – *list all visits that have occurred since the expiration of IRB approval (attach separated sheet if necessary):*

<u>Subject #</u>	<u>Study Visit(s)</u>	<u>Study Procedures</u>

i. Have any protocol mandated follow-up phone calls been made to subjects since the expiration of IRB approval?

No Yes – *list all follow-up phone calls that occurred since the expiration of IRB approval (attach separated sheet if necessary)*

<u>Subject #</u>	<u>Follow-up Phone Calls(s)</u>

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j. Have any Serious Adverse Events or unexpected and related Adverse Events occurred since the expiration of IRB approval?

No Yes – list below and submit reports with this form (attach separated sheet if necessary)

<u>Subject #</u>	<u>Date of AE</u>	<u>AE Description</u>

k. Have any significant Protocol Deviations / Violations occurred since the expiration of IRB approval?

No Yes – list below and submit reports with this form (attach separated sheet if necessary)

<u>Subject #</u>	<u>Date of Deviation / Violation</u>	<u>Deviation / Violation Description</u>

I acknowledge, as Principal Investigator, that the information provided in response to the questions of the IRB is true and accurate.

Signature of Principal Investigator

Date