



**PART I - APPLICANT INFORMATION**

First Name/Corporate Name	Middle Initial	Last Name
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**PART II - GENERAL QUESTIONS**

Please describe the aims and specific objectives of the research to be performed and by whom. \_\_\_\_\_  
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 \_\_\_\_\_  
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Why is it believed that the experimental treatment being tested may be effective? \_\_\_\_\_

Has it been tested before?  Yes  No If yes, what were the results? \_\_\_\_\_

How long will the trial last? \_\_\_\_\_ Is this research clinical or academic in nature?  Clinical  Academic

What are the risks and potential benefits of the research to the subjects? \_\_\_\_\_  
 \_\_\_\_\_

What primary coverage is in place for this exposure? (If other coverage is in place, provide proof of coverage.) \_\_\_\_\_  
 \_\_\_\_\_

What phase of the approval process through the FDA is the clinical trial in? \_\_\_\_\_

Is there a sponsor for the clinical trial program?  Yes  No

Is there coverage through the sponsor?  Yes  No (If other coverage is in place, provide proof of coverage.)

Are you entering into any hold harmless agreements?  Yes  No (If yes, provide a copy of the agreement.)

How do you handle adverse outcome reporting? \_\_\_\_\_  
 \_\_\_\_\_

*PLEASE ATTACH A COPY OF THE FOLLOWING TO THIS APPLICATION:*

- Study Protocols
- Conflict of Interest Policy
- Patient Selection Criteria
- Informed Consent Policy
- Hospital's Institutional Review Board Rules and Regulations

\_\_\_\_\_  
**Signature of Applicant**

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