FRIENDS RESEARCH INSTITUTE, INC.
INSTITUTIONAL REVIEW BOARD
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Supplementary Application: Investigational Drug Information Record

Name of Investigator: IRB Study #:
Title of Protocol: Date of Submission:

Please complete this form only if applicable to your project.

Please attach a copy of the *Investigator's Brochure*. Provide the following information on each Investigational Drug that is not approved by the FDA for the use outlined in the study protocol. If you intend to use an Approved Drug in an unapproved way (e.g., different dosages or routes of administration, new age groups, new indications, etc.) in the research and if you are planning to use the results to seek FDA approval, **you must submit an IND application to the FDA.**

Part A:			
1. Participating investigators authorized to prescribe the investigational agent:			
a. Name			
Address:			
Telephone Number		*Fax Number:*	
E-Mail Address			
b. Name			
Address:			
Telephone Number		*Fax Number:*	
E-Mail Address			
c. Name			
Address:			
Telephone Number		*Fax Number:*	
E-Mail Address			
2. Information about the Sponsor:			
a. Name			
b. Address			
c. Phone Number			
3. Will any approved drugs be used for unapproved (new indications) or in unapproved ways (e.g., different dosages, routes of administration, new age groups)?	☐ Yes ☐ No		
4. Study design: check appropriate categories:	☐ Single-blind ☐ Double-blind ☐ Open-trial ☐ Placebo control ☐ Cross-over ☐ Drug Control ☐ Other:		
5. Approximate duration of investigation (study)			
6. Approximate number of subjects/participants needed			

Part B:	
1. Name holder of IND:	
2. IND Number:	
3. Generic Drug Name and Synonyms:	
4. Source of Drug:	
5. Dosage Forms and Strengths:	
6. Special Storage Requirements, if any:	
7. Stability Information, if applicable:	
8. Indications for Use of Drug:	
9. Mechanisms of Action:	
10. Route of Administration:	
11. Usual Dosage:	
12. Dosage Range:	
13. Treatment Regimen:	
14. Possible Side Effects:	
15. Precautions, Warnings, Contraindications:	
16. Restrictions on Who May Administer the Drug:	
17. Dispensing Instructions to Patients (including warnings):	
18. Known Drug-Drug Interactions:	
19. Known Drug-Laboratory Test Interferences:	
20. Special Information for Intravenous Medications (as applicable):	
a. Recommended dilutent for reconstitution:	
b. Recommended IV solutions for administration:	
c. Stability when diluted in IV solutions:	
d. Recommended rate of IV administration:	