FRIENDS RESEARCH INSTITUTE, INC.
INSTITUTIONAL REVIEW BOARD
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Deviation Form

Name of Investigator: IRB Study #:

Title of Protocol: Date of Submission:

Please submit this completed form to report deviations from the written protocol, regulations, IRB policy or IRB procedures.

1. Date of occurrence:	
2. This deviation involved:	
☐	a. Written Protocol ☐ Eligibility criteria ☐ Dose, dosage schedule, or use of device ☐ Visit schedule ☐ Use of medications not allowed by protocol ☐ Lab Values ☐ Recruitment ☐ Standard Operation Standard ☐ Other (specify):
☐	b. IRB Policy (specify):
☐	c. IRB Procedure (specify):
☐	d. FDA/DHHS Regulations (specify):
☐	e. Other (specify):
3. Describe the deviation and the net effect on risk:	
4. Was the deviation: ☐ Staff error ☐ Subject/Participant error ☐ Circumstance	
5. Explain why the deviation occurred:	
6. Explain what is being done to prevent future occurrences:	
7. Were subjects/participants adversely affected by the deviation? ☐ No ☐ Yes (if yes, explain):	
8. Was the subject/participant informed of the deviation? ☐ No ☐ Yes (if yes, explain):	
9. Will the subject/participant remain in the study? ☐ No ☐ Yes (if yes, explain):	

_____ _____

Principal Investigator's Signature Date