

APPENDIX E:

Sample Protocol Deviation/Violation Log

SAMPLE PROTOCOL DEVIATION/VIOLATION LOG

Protocol Title: _____

Protocol Number: _____ Site: _____ Principal Investigator: _____

Protocol Deviation/ Violation Code:	Participant Initials	Participant ID#	Date Deviation / Violation Occurred: mm/dd/yyyy	Date Protocol Deviation / Violation Form Completed: mm/dd/yyyy	Contact Person (if applicable)

SAMPLE PROTOCOL DEVIATION / VIOLATION CODES

Consent Form:

1. Missing or not obtained
2. Not signed and dated by participant
3. Does not contain all required signatures
4. Outdated, current IRB-approved version not used
5. Not protocol specific
6. Does not include updates or information required by the IRB

Randomization:

7. Ineligible participant enrolled and/or randomized
8. Participant is randomized prior to determining whether eligible for study
9. Occurs outside protocol window

IRB:

10. Not reporting a serious complication within 24 hours
11. Approvals not kept up-to-date
12. Enrollment and/or treatment occurs prior to IRB approval or during period when "on hold"
13. Reportable serious adverse events not reported to IRB

Participant

14. Receives wrong treatment
15. Visits occur outside expected follow-up window
16. Entered into another study

Study Data and/or Forms

17. Missing data and/or forms
18. Missing radiology and/or operative reports
19. Forms or data not sent from clinical site to coordinating center