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|  | **VCOM IRB****Protocol Deviation Form** |

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| PI Name:       |
| Protocol #:      |
| Project Title:       |
| Date Form Completed:       |

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| **Question 1: Describe the protocol deviation/violation.** |
| **Answer 1:**       |
| **Question 2: When did the deviation/violation occur?** |
| **Answer 2:**       |
| **Question 3: What occurred to result in the protocol deviation/violation?** |
| **Answer 3:**       |
| **Question 4: Why was the IRB not notified regarding changes to the protocol? (if applicable)** |
| **Answer 4:**       |
| **Question 5: Describe the steps taken to avoid recurrence of the deviation/violation.** |
| **Answer 5:**       |

**PI Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**