Protocol Number:

HRRC #

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Reporting period:      /     /      to      /     /

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|  | **Description of Event** | **Date of event** **mm/dd/yy** | **Was deviation previously reported?** | **Why did deviation occur?** | **Was participant put at additional risk?** | **Was sponsor notified of deviation?** | **Identify corrective action taken** |
| 1 |       |       |       |       |       |       |       |
| 2 |       |       |       |       |       |       |       |
| 3 |       |       |       |       |       |       |       |
| 4 |       |       |       |       |       |       |       |
| 5 |       |       |       |       |       |       |       |
| 6 |       |       |       |       |       |       |       |
| 7 |       |       |       |       |       |       |       |
| 8 |       |       |       |       |       |       |       |
| 9 |       |       |       |       |       |       |       |
| 10 |       |       |       |       |       |       |       |
| 11 |       |       |       |       |       |       |       |
| 12 |       |       |       |       |       |       |       |
| 13 |       |       |       |       |       |       |       |
| 14 |       |       |       |       |       |       |       |

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| 15 |       |       |       |       |       |       |       |

Protocol deviation is any departure or exception from the procedures identified in the IRB approved protocol.