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| Principal Investigator |  | IRB # |  |

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| Study Title |  |

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| Site Name | Event date(MM/DD/YYYY) | Subject ID | Event Description | Site IRB(MM/DD/YYYY) | Sponsor(MM/DD/YYYY) | Comments |
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Note: Investigator should forward the ***serious*** and ***unanticipated*** adverse events to the appropriate authorities.