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| Principal Investgator Name (Please Print): Click or tap here to enter text. |
| Signature: Click or tap here to enter text. |
| Initials: Click or tap here to enter text. |
| Date: Click or tap here to enter text. |

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| Study Title: | | | | | |
| Note: This form should be completed prior to the initiation of any study-related tasks/procedures. The original form should be maintained at your site in the study regulatory/study binder. This form should be updated during the course of the study as needed. | | | | | |
| A | Obtaining Informed Consent | G | Instruction of Study Drug Administration | M | Collect and/or Process Specimens/Shipping |
| B | Screening Patient(s) | H | IP Accountability/Order/Inventory | N | Regulatory Documents/IRB Communication |
| C | Physical Examination and History | I | Medication History / Concomitant Meds | O | Case Report Form (CRF) Completion |
| D | Affirmation of Inclusion & Exclusion Criteria | J | Source Document Completion | P | Data Correction (DCF)/Query Resolution |
| E | Patient Randomization | K | Assess Adverse Events/Serious Adverse Events | Q |  |
| F | Patient Follow-Up Visit(s) | L | Reporting of AEs/SAEs | R |  |

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| **Personnel Name**  **(Please Print)** | **Initials** | **Signature** | **Role in Study**  **(PI, SC, Sub-I, Pharmacist, etc.)** | **Authorized Functions (List all that apply from the list above)** | **Start Date** | **End Date** | **PI Initials/Date** |
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| **Personnel Name**  **(Please Print)** | **Initials** | **Signature** | **Role in Study**  **(PI, SC, Sub-I, Pharmacist, etc.)** | **Authorized Functions (List all that apply from the list above)** | **Start Date** | **End Date** | **PI Initials/Date** |
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**Principal Investigator End of Study Declaration:**

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| Principal Investigator Signature (at study close-out) Date |

By signing below, I hereby confirm that the above information is accurate and complete, and that I authorized the delegation of study-related tasks to each individual as listed above.