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| ***1. GENERAL PROTOCOL/STUDY INFORMATION*** | | |
| **Principle Investigator:** | **Name of Person Completing Log:** | |
| **Research Project Title:** | | |
| **Sponsor** *(if an*y*):* | | **Location where the study is conducted:** |

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| ***2. STUDY SITE PERSONNEL INFORMATION*** | | | | | | | | |
| **Name of Study Personnel** | **Title** | **Initials** | **Signature of Study Personnel** | | **\*Study Task(s)** | **Start Date/**  **End Date** | | **Signature of PI** |
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| * *List individual delegated Research study related tasks (ICH GCP 4.1.5)* * *Signature and initials are required of all personal involved in the research* * *Ensure appropriate CV, certifications and training records on file for all personnel involved in the research* * *Update this log in a timely manner when new personnel are added and/or study roles change* | | | | **\*study task categories, as applicable** | | | | |
| 1. Obtain Informed Consent  2. Obtain Medical History  3. Perform Physical Exam  4. Check Vital Signs  5. Assess Eligibility Criteria  6. Dispense Investigational Product | | | 7. Completing CRF  8. Completing Data Collection Tools  9. Query Completion  10. Maintain Regulatory Documents  11. Maintain IRB Documents  12. Other | |