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| **PROTOCOL TITLE:** | | |
| **PROTOCOL NO.:** | **PRINCIPAL INVESTIGATOR:** | **SITE NAME:** |

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| **Regulatory Document\*** | **Language** | **Version No. and / or Date** | **IRB**  **Submission Date** | **IRB**  **Approval Date** | **HSA**  **Submission Date**  **(if applicable)** | **HSA**  **Approval Date**  **(if applicable)** | **Implementation Date**  **(if applicable)** | **Comments** |
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*\*For e.g.: Protocol and amendments, Informed Consent Form and amendments, Investigator’s Brochure (IB) and updates, Progress Reports to IRB, Trial Status Reports to HSA, Subject Recruitment Materials, Documents provided to Subjects (e.g. diary cards, questionnaires, rating scales) etc.*