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| Deviation Reporting Spot Check | |
| **Short Study Title:** |  |
| **Chief Investigator (CI):** |  |
| **Study Identifier:**  **(IRAS Ref)** |  |
| **Date of Spot Check:** |  |

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| Compliance Summary | | |
| **Number of Locations Spot Checked:** |  | |
| **Location Compliance Level:** | **Red (add no. of locations):** |  |
| **Amber (add no. of locations):** |  |
| **Green (add no. of locations):** |  |
| **\*Overall Compliance Level (Red/Amber/Green):** |  | |
| **Recommendations for Action:** | **[Delete as appropriate as agreed with QA Coordinator/Manager]**   * Please remind all PIs / locations of the importance of protocol compliance in terms of deviation reporting in accordance with the trial protocol. * Please contact the following PIs / locations regarding the importance of protocol compliance in terms of deviation reporting in accordance with the trial protocol.   **[insert trial locations(s)]**   * Please advise on any further action instigated and deemed appropriate by the Trial Manager and/or CI. * Sponsor QA/Monitoring team to determine if a monitoring visit is required for **[insert location(s)]**. | |
| **Sign On Completion** | | |
| **Quality Assurance Administrator:** |  | |
| **QA Manager or QA Coordinator:** |  | |

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| **[ADD LOCATION NAME/NUMBER and SATO date]** | | | | |
| **Is the location compliant with Protocol Deviation Reporting Requirements?** | [ADD QUARTER]  [ADD YEAR] | [ADD QUARTER]  [ADD YEAR] | [ADD QUARTER]  [ADD YEAR] | [ADD QUARTER]  [ADD YEAR] |
| No  Yes  N/A | No  Yes    N/A | No  Yes  N/A | No  Yes  N/A |
| **If ‘NO’, is there email confirmation that no Deviations were reported in this Quarter?** | No  Yes  N/A | No  Yes  N/A | No  Yes  N/A | No  Yes  N/A |
| **Location Compliance Level:** | 100% (Green)75% (Green) 50% (Amber)  25% (Amber) 0% (Red) | | | |

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| **[ADD LOCATION NAME/NUMBER and SATO date]** | | | | |
| **Is the location compliant with Deviation Reporting Requirements?** | [ADD QUARTER]  [ADD YEAR] | [ADD QUARTER]  [ADD YEAR] | [ADD QUARTER]  [ADD YEAR] | [ADD QUARTER]  [ADD YEAR] |
| No  Yes  N/A | No  Yes  N/A | No  Yes  N/A | No  Yes  N/A |
| **If ‘NO’, is there email confirmation that no Deviations were reported in this Quarter?** | No  Yes  N/A | No  Yes  N/A | No  Yes  N/A | No  Yes  N/A |
| **Location Compliance Level:** | 100% (Green)75% (Green) 50% (Amber)  25% (Amber) 0% (Red) | | | |

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| **[ADD LOCATION NAME/NUMBER and SATO date]** | | | | |
| **Is the location compliant with Protocol Deviation Reporting Requirements?** | [ADD QUARTER]  [ADD YEAR] | [ADD QUARTER]  [ADD YEAR] | [ADD QUARTER]  [ADD YEAR] | [ADD QUARTER]  [ADD YEAR] |
| No  Yes  N/A | No  Yes    N/A | No  Yes  N/A | No  Yes  N/A |
| **If ‘NO’, is there email confirmation that no Deviations were reported in this Quarter?** | No  Yes  N/A | No  Yes  N/A | No  Yes  N/A | No  Yes  N/A |
| **Location Compliance Level:** | 100% (Green)75% (Green) 50% (Amber)  25% (Amber) 0% (Red) | | | |

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| **[ADD LOCATION NAME/NUMBER and SATO date]** | | | | |
| **Is the location compliant with Protocol Deviation Reporting Requirements?** | [ADD QUARTER]  [ADD YEAR] | [ADD QUARTER]  [ADD YEAR] | [ADD QUARTER]  [ADD YEAR] | [ADD QUARTER]  [ADD YEAR] |
| No  Yes  N/A | No  Yes    N/A | No  Yes  N/A | No  Yes  N/A |
| **If ‘NO’, is there email confirmation that no Deviations were reported in this Quarter?** | No  Yes  N/A | No  Yes  N/A | No  Yes  N/A | No  Yes  N/A |
| **Location Compliance Level:** | 100% (Green)75% (Green) 50% (Amber)  25% (Amber) 0% (Red) | | | |

**[ADD/DELETE ADDITIONAL TABLES BASED ON THE NUMBER OF LOCATIONS TO CHECK.]**