**INVESTIGATOR COMPLIANCE SEARCH FORM**

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| **ICON Project Number:** | $$ICON | **Sponsor Protocol No.:** |  |
| **Principal Investigator Name / ML# (If Applicable):** | $$PrincipalInvName | **Address:** |  |
| **Sub-Investigator Names / ML # (If Applicable)** | $$SubInvName |  |  |

**Please list all relevant sources of Investigator information, against which the checks have been performed for the Investigator(s).**

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| **SOURCE #** | **SOURCE NAME** | **SOURCE DATE** | **WEB LINK** | **ISSUES IDENTIFIED** |

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| 1. | FDA Debarment List | *$$Date* | <http://www.fda.gov/ora/compliance_ref/debar/default.htm> | No | Yes |
| 2. | Clinical Investigator Inspection List (CLIIL) (CDER) | *$$Date* | <http://www.accessdata.fda.gov/scripts/cder/cliil/index.cfm> | No | Yes |
| 3. | FDA Warning Letters And Responses | *$$Date* | <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm> | No | Yes |
| 4. | Notice Of Opportunity For Hearing (NOOH) – Proposal To Debar | *$$Date* | <http://www.fda.gov/RegulatoryInformation/FOI/ElectronicReadingRoom/ucm143240.htm> | No | Yes |
| 5. | Adequate Assurances List For Clinical Investigators | *$$Date* | <http://www.fda.gov/ora/compliance_ref/bimo/asurlist.htm> | No | Yes |
| 6. | Clinical Investigators – Disqualification Proceedings (FDA Disqualified/Restricted) | *$$Date* | <http://www.accessdata.fda.gov/scripts/SDA/sdNavigation.cfm?sd=clinicalinvestigatorsdisqualificationproceedings&previewMode=true&displayAll=true> | No | Yes |
| 7. | PHS Administrative Actions Listing | *$$Date* | [http://ori.hhs.gov/misconduct/AdminBulletinBoard.shtml](http://ori.hhs.gov/misconduct/AdminBulletinBoard.shtml" \o "http://ori.hhs.gov/misconduct/AdminBulletinBoard.shtml) | No | Yes |
| 8. | Clinical Investigator Inspection List (CBER) | *$$Date* | [http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ComplianceActivities/ucm195364.htm](http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ComplianceActivities/ucm195364.htm" \o "http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ComplianceActivities/ucm195364.htm) | No | Yes |
| 9. | HHS/OIG/ Exclusions Database Search/ Fraud | *$$Date* | <http://exclusions.oig.hhs.gov/> | No | Yes |
| 10. | HHS/OIG Corporate Integrity Agreements/Watch List | *$$Date* | <http://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp> | No | Yes |
| 11. | SAM/System For Award Management | *$$Date* | [https://www.sam.gov/portal/public/SAM](https://www.sam.gov/portal/public/SAM" \o "https://www.sam.gov/portal/public/SAM) | No | Yes |
| 12. | List Of Specially Designated Nationals | *$$Date* | <http://www.treasury.gov/resource-center/sanctions/SDN-List/Pages/default.aspx> | No | Yes |
| 13. | World Check (Only for PI & Institute) | *$$Date* | <https://sentinel.truthtechnologies.com> | No | Yes |
| 14. | ICON Internal Flag Check | *$$Date* | ISprint Database | No | Yes |

**Please list all Sponsor / Country Specific checks, against which the review has been completed for the Investigator(s).**

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| **Source #** | **Source Name** | **Source Date** | **Web Link** | **Issues Identified** |

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| 15. | Country Specific Search (If any) |  |  | No | Yes |
| 16. |  |  |  | No | Yes |

**If issues are identified (Yes checked above), please provide additional details. Details may be printed and attached.**

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| **SOURCE #** | **DATE OF INSPECTION/ ACTION** | **DESCRIPTION OF FINDINGS** |

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**Search Performed By:**

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| --- | --- | --- | --- |
| **SEARCH PERFORMED BY:** | **SIGNATURE:** |  | **NAME / DATE (DDMMMYYYY):** |
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