**INVESTIGATOR COMPLIANCE SEARCH FORM**

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| **ICON Project Number:** |  | **Sponsor Protocol No.:** |  |
| **Institute Name:** |  | **Address:** |  |

**Investigators:**

|  |  |  |  |
| --- | --- | --- | --- |
| **ROLE** | **INVESTIGATOR NAME**  **(As per 1572/Info received)** | **MEDICAL LICENSE NUMBER** | **INVESTIGATOR NAME**  **(All Combination Searched)** |
| Principal | Jeffrey Welch | 7890 |  |

**Relevant sources of Investigator information, against which this Investigator has been checked.**

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| --- | --- | --- | --- | --- |
| **SOURCE #** | **SOURCE NAME** | **SOURCE DATE** | **WEBLINK** | **ISSUES IDENTIFIED** |
| 1 | FDA Debarment List |  | http://www.fda.gov/ora/compliance\_ref/debar/default.htm | No |
| 2 | Clinical Investigator Inspection List (CLIL)(CDER |  | http://www.accessdata.fda.gov/scripts/cder/cliil/index.cfm | No |
| 3 | FDA Warning Letters and Responses |  | http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm | No |
| 4 | Notice of Opportunity for Hearing (NOOH) – Proposal to Debar |  | http://www.fda.gov/RegulatoryInformation/FOI/ElectronicReadingRoom/ucm143240.htm | No |
| 5 | Adequate Assurances List for Clinical Investigators |  | http://www.fda.gov/ora/compliance\_ref/bimo/asurlist.htm | No |
| 6 | Clinical Investigators – Disqualification Proceedings (FDA Disqualified/Restricted) |  | http://www.accessdata.fda.gov/scripts/SDA/sdNavigation.cfm?sd=clinicalinvestigatorsdisqualificationproceedings&previewMode=true&displayAll=true | No |
| 7 | PHS Administrative Actions Listing |  | https://ori.hhs.gov/ORI\_PHS\_alert.html?d=update | No |
| 8 | Clinical Investigator Inspection List (CBER) |  | http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ComplianceActivities/ucm195364.htm | No |
| 9 | HHS/OIG/ EXCLUSIONS DATABASE SEARCH/ FRAUD |  | https://oig.hhs.gov/exclusions/exclusions\_list.asp | Yes |
| 10 | HHS/OIG Corporate Integrity Agreements/Watch List |  | http://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp | No |
| 11 | SAM/SYSTEM FOR AWARD MANAGEMENT |  | https://www.sam.gov/portal/public/SAM | No |
| 12 | LIST OF SPECIALLY DESIGNATED NATIONALS |  | http://www.treasury.gov/resource-center/sanctions/SDN-List/Pages/default.aspx | No |
| 13 | World Check (Only for PI) |  | http://www.truthtechnologies.com/ | No |
| 14 | World Check (Institute) |  | http://www.truthtechnologies.com/ | No |
| 15 | ICON Internal Flag Check |  | ISprint Database | No |

**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** | **WEBLINK** | **ISSUES IDENTIFIED** |
| 16. |  |  |  | No |
| 17. |  |  |  | No |

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

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| --- | --- | --- | --- |
| **SOURCE #** | **INVESTIGATOR / INSTITUTE NAME** | **DATE OF INSPECTION/ ACTION** | **DESCRIPTION OF FINDINGS** |
| 11 | Jeffrey Welch | 20 September 2001 | **Exclusion Type:** Prohibition/Restriction  **Excluding** **Agency** : HEALTH AND HUMAN SERVICES, DEPARTMENT OF  **Status**: Active  **Comments**: Excluded by the Department of Health and Human Services from participation in all Federal health care programs pursuant to 42 U.S.C. § 1320a-7 or other sections of the Social Security Act, as amended and codified in Chapter 7 of Title 42 of the United States Code (the scope and effect of Federal health care program exclusions is described in 42 C.F.R. § 1001.1901). |

**Search Performed By:**

|  |  |
| --- | --- |
| **Printed Name:** | **Signature:** |
| **Date: 17 Apr 2017** |