**INVESTIGATOR COMPLIANCE SEARCH (ICSF)**

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| **ICON Project Number:** | 2102/0103 | **Sponsor Protocol No.:** | IgPro10\_2001 |
| **Institute Name:** | Complejo Hospitalario Universitario A Coruña | **Address:** | c/ Xubias de Arriba, 84 A Coruña 15006 Spain |

**Investigators:**

|  |  |  |  |
| --- | --- | --- | --- |
| **ROLE** | **INVESTIGATOR NAME**  **(As per 1572/Info received)** | **Medical License Number** | **INVESTIGATOR NAME**  **(All Combination Searched)** |
| PI | Mark-L - Brody MD | 151509475 | Mark Lawrence Brody |

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **SOURCE #** | **SOURCE NAME** | **SOURCE DATE** | **WEBLINK** | **ISSUES IDENTIFIED** |
| 1 | FDA Debarment List | 30 May 2020 | http://www.fda.gov/ora/compliance\_ref/debar/default.htm | Yes |
| 2 | Clinical Investigator Inspection List (CLIL)(CDER) | 30 May 2020 | http://www.accessdata.fda.gov/scripts/cder/cliil/index.cfm | Yes |
| 3 | FDA Warning Letters and Responses | 30 May 2020 | http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm | No |
| 4 | Notice of Opportunity for Hearing (NOOH) – Proposal to Debar | 30 May 2020 | http://www.fda.gov/RegulatoryInformation/FOI/ElectronicReadingRoom/ucm143240.htm | No |
| 5 | Clinical Investigators – Disqualification Proceedings (FDA Disqualified/Restricted) | 30 May 2020 | http://www.accessdata.fda.gov/scripts/SDA/sdNavigation.cfm?sd=clinicalinvestigatorsdisqualificationproceedings&previewMode=true&displayAll=true | No |
| 6 | PHS Administrative Actions Listing | 30 May 2020 | https://ori.hhs.gov/ORI\_PHS\_alert.html?d=update | No |
| 7 | Clinical Investigator Inspection List (CBER) | 30 May 2020 | http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ComplianceActivities/ucm195364.htm | No |
| 8 | HHS/OIG/ Exclusions Database Search/Fraud | 30 May 2020 | https://oig.hhs.gov/exclusions/exclusions\_list.asp | No |
| 9 | HHS/OIG Corporate Integrity Agreements/Watch List | 11 Jul 2019 | http://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp | No |
| 10 | System for Award Management (SAM) | 29 May 2020 | https://www.sam.gov/SAM/pages/public/searchRecords/search.jsf | No |
| 11 | List of Specially Designated Nationals (SDN) | 30 May 2020 | http://www.treasury.gov/resource-center/sanctions/SDN-List/Pages/default.aspx | No |
| 12 | World Check (PI) |  | http://www.truthtechnologies.com/ | No |
| 13 | World Check (Institute) |  | http://www.truthtechnologies.com/ | No |
| 14 | ICON Internal Flag Check (ICON Investigator Database - ISprint) |  |  | No |

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **SOURCE #** | **SOURCE NAME** | **SOURCE DATE** | **WEBLINK** | **ISSUES IDENTIFIED** |
| 15 | Spain - ORGANIZACION MEDICA COLEGIAL DE ESPANA |  | http://www.cgcom.es/consultapublicacolegiados | No |

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

|  |  |  |  |
| --- | --- | --- | --- |
| **SOURCE #** | **INVESTIGATOR/**  **INSTITUTE NAME** | **DATE OF INSPECTION** | **DESCRIPTION OF FINDINGS** |
| 1 | Mark-L - Brody MD | 10 Mar 2011 |  |
| 2 | Mark-L - Brody MD | 02 May 2012 |  |

**Search Performed By:**

|  |  |
| --- | --- |
| **Printed Name:**chavhan | **Date:**30 May 2020 |
| **Signature:** | |