

INVESTIGATOR COMPLIANCE SEARCH FORM

ICON Project Number:	0456-0083	Sponsor Protocol No.:	R2810-ONC-1624
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Medical License Number (if applicable)	NA		

Please list all relevant sources of Investigator information, against which this Investigator has been checked.

SOURCE #	SOURCE NAME	SOURCE DATE	WEBLINK	ISSUES IDENTIFIED	
1.	FDA DEBARMENT LIST	04 Apr 2016	http://www.fda.gov/ora/c/ompliance_ref/debar/default.htm	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes
2.	CLINICAL INVESTIGATOR INSPECTION LIST (CLIIL) (CDER)	22 Sep 2016	http://www.accessdata.fda.gov/scripts/cder/cliil/index.cfm	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes
3.	FDA WARNING LETTERS and RESPONSES	16 Nov 2016	http://www.fda.gov/ICEC/EnforcementActions/WarningLetters/default.htm	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes
4.	NOTICE OF OPPORTUNITY FOR HEARING (NOOH) – PROPOSAL TO DEBAR	22 Sep 2016	http://www.fda.gov/RegulatoryInformation/FOI/ElectronicReadingRoom/ucm143240.htm	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes
5.	ADEQUATE ASSURANCES LIST FOR CLINICAL INVESTIGATORS	24 Apr 2014	http://www.fda.gov/ora/c/ompliance_ref/bimo/asurlist.htm	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes
6.	CLINICAL INVESTIGATORS – DISQUALIFICATION PROCEEDINGS (FDA DISQUALIFIED/RESTRICTED)	25 Oct 2016	http://www.accessdata.fda.gov/scripts/SDA/sdNavigation.cfm?sd=clinicalinvestigatorsdisqualificationproceedings&previewMode=true&displayAll=true	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes
7.	PHS Administrative Actions Listing	17 Nov 2016	http://ori.hhs.gov/misconduct/AdminBulletinBoard.shtml	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes

8.	Clinical Investigator Inspection List (CBER)	27 Oct 2016	http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ComplianceActivities/ucm195364.htm	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes
9.	HHS/OIG/ EXCLUSIONS DATABASE SEARCH/ FRAUD	07 Nov 2016	http://exclusions.oig.hhs.gov/	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes
10.	HHS/OIG Corporate Integrity Agreements/Watch List	03 Nov 2016	http://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes
11.	SAM/SYSTEM FOR AWARD MANAGEMENT	11 Nov 2016	https://www.sam.gov/portal/public/SAM	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes
12.	LIST OF SPECIALLY DESIGNATED NATIONALS	14 Nov 2016	http://www.treasury.gov/resource-center/sanctions/SDN-List/Pages/default.aspx	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes
13.	World Check (Only for PI)	17 Nov 2016	http://www.truthtechnologies.com/	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes

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

SOURCE #	DATE OF INSPECTION/ ACTION	DESCRIPTION OF FINDINGS
2	10 May 2010 Mustafa Ozguroglu ID # 488567 DA / VAI / 06	DA - Data Audit: An inspection in which the focus is on verification of study data. VAI - Voluntary Action Indicated. Objectionable conditions were found but the problems do not justify further regulatory action. Any corrective action is left to the investigator to take voluntarily. 06 Inadequate and inaccurate records, 21 CFR 312.62

Search Performed By:

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Vinithaa Raguram

Vinithaa Raguram 18 Nov 2016 10:04:001+0000

I approve this document as author.


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Clinical Investigator Inspection Search

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