

### INVESTIGATOR COMPLIANCE SEARCH FORM

<b>ICON Project Number:</b>	0078-0609	<b>Sponsor Protocol No.:</b>	IM103116
<b>Principal Investigator Name:</b>	Donald Hricik, MD	<b>Address:</b>	University Hospitals Cleveland Medical Center 11100 Euclid Avenue Cleveland , OH 44106 / USA
<b>Medical License Number (if applicable)</b>	35.047761		

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	<a href="http://www.fda.gov/ora/compliance_ref/debar/default.htm">http://www.fda.gov/ora/compliance_ref/debar/default.htm</a>	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes
2.	CLINICAL INVESTIGATOR INSPECTION LIST (CLIL) (CDER)	22 Sep 2016	<a href="http://www.accessdata.fda.gov/scripts/cder/clil/index.cfm">http://www.accessdata.fda.gov/scripts/cder/clil/index.cfm</a>	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes
3.	FDA WARNING LETTERS and RESPONSES	06 Dec 2016	<a href="http://www.fda.gov/ICEV/EnforcementActions/WarningLetters/default.htm">http://www.fda.gov/ICEV/EnforcementActions/WarningLetters/default.htm</a>	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes
4.	NOTICE OF OPPORTUNITY FOR HEARING (NOOH) – PROPOSAL TO DEBAR	29 Nov 2016	<a href="http://www.fda.gov/RegulatoryInformation/FOI/ElectronicReadingRoom/ucm143240.htm">http://www.fda.gov/RegulatoryInformation/FOI/ElectronicReadingRoom/ucm143240.htm</a>	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes
5.	ADEQUATE ASSURANCES LIST FOR CLINICAL INVESTIGATORS	24 Apr 2014	<a href="http://www.fda.gov/ora/compliance_ref/bimo/asurlist.htm">http://www.fda.gov/ora/compliance_ref/bimo/asurlist.htm</a>	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes
6.	CLINICAL INVESTIGATORS – DISQUALIFICATION PROCEEDINGS (FDA DISQUALIFIED/RESTRICTED)	05 Dec 2016	<a href="http://www.accessdata.fda.gov/scripts/SDA/sdNavigation.cfm?sd=clinicalinvestigatorsdisqualificationproceedings&amp;previewMode=true&amp;displayAll=true">http://www.accessdata.fda.gov/scripts/SDA/sdNavigation.cfm?sd=clinicalinvestigatorsdisqualificationproceedings&amp;previewMode=true&amp;displayAll=true</a>	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes
7.	PHS Administrative Actions Listing	06 Dec 2016	<a href="http://ori.hhs.gov/misconduct/AdminBulletinBoard.shtml">http://ori.hhs.gov/misconduct/AdminBulletinBoard.shtml</a>	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes
8.	Clinical Investigator Inspection List (CBER)	27 Oct 2016	<a href="http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ComplianceActivities/ucm195364.htm">http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ComplianceActivities/ucm195364.htm</a>	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes
9.	HHS/OIG/ EXCLUSIONS DATABASE SEARCH/ FRAUD	07 Nov 2016	<a href="http://exclusions.oig.hhs.gov/">http://exclusions.oig.hhs.gov/</a>	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes
10.	HHS/OIG Corporate Integrity Agreements/Watch List	18 Nov 2016	<a href="http://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp">http://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp</a>	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes

11.	SAM/SYSTEM FOR AWARD MANAGEMENT	11 Nov 2016	<a href="https://www.sam.gov/portal/public/SAM">https://www.sam.gov/portal/public/SAM</a>	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes
12.	LIST OF SPECIALLY DESIGNATED NATIONALS	02 Dec 2016	<a href="http://www.treasury.gov/resource-center/sanctions/SDN-List/Pages/default.aspx">http://www.treasury.gov/resource-center/sanctions/SDN-List/Pages/default.aspx</a>	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes
13.	World Check (Only for PI)	07 Dec 2016	<a href="http://www.truthtechnologies.com/">http://www.truthtechnologies.com/</a>	<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	12 October 2001 Donald Hricik, MD ID # 388802 DA / VAI / 03 / 04	<b>DA - Data Audit:</b> An inspection in which the focus is on verification of study data <b>VAI - Voluntary Action Indicated.</b> Objectionable conditions were found but the problems do not justify further regulatory action. Any corrective action is left to the investigator to take voluntarily. <b>03</b> Inadequate informed consent form 21 CFR 50.25 <b>04</b> Inadequate drug accountability 21 CFR 312.60, 312.62

Search Performed By:

Printed Name:	Signature:	Date:
---------------	------------	-------

Mahalakshmi Ganesan

*Mahalakshmi Ganesan* 07 Dec 2016 09:47:009+0000

I approve this document as author.

0aad6933-05fd-4062-b028-0e5b7dc728d9

2nd Review/ QC

Paras Doshi

*Paras Doshi* 07 Dec 2016 09:50:057+0000

I approve this document.

314bc0a0-b9c0-492a-841a-f232c3325c64

# Clinical Investigator Inspection Search

**f** [SHARE \(HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/CLIL/INDEX.CFM?FUSEACTION=SEARCH.SEARCH\)](https://www.facebook.com/sharer/sharer.php?u=http://www.accessdata.fda.gov/scripts/cder/clil/index.cfm?fuseaction=search.search)

**t** [TWEET \(HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=CLINICAL INVESTIGATOR INSPECTION SEARCH &URL=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/CLIL/INDEX.CFM?FUSEACTION=SEARCH.SEA RCH\)](https://twitter.com/intent/tweet/?text=CLINICAL%20INVESTIGATOR%20INSPECTION%20SEARCH&url=http://www.accessdata.fda.gov/scripts/cder/clil/index.cfm?fuseaction=search.search)

**in** [LINKEDIN \(HTTPS://WWW.LINKEDIN.COM/SHAREARTICLE?MINI=TRUE&URL=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/CLIL/INDEX.CFM?FUSEACTION=SEARCH.SEARCH&TITLE=CLINICAL INVESTIGATOR INSPECTION SEARCH&SOURCE=FDA\)](https://www.linkedin.com/sharearticle?mini=true&url=http://www.accessdata.fda.gov/scripts/cder/clil/index.cfm?fuseaction=search.search&title=CLINICAL%20INVESTIGATOR%20INSPECTION%20SEARCH&source=fda)

**@** [PIN IT \(HTTPS://WWW.PINTEREST.COM/PIN/CREATE/BUTTON/?URL=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/CLIL/INDEX.CFM?FUSEACTION=SEARCH.SEARCH&DESCRIPTION=CLINICAL INVESTIGATOR INSPECTION SEARCH\)](https://www.pinterest.com/pin/create/button/?url=http://www.accessdata.fda.gov/scripts/cder/clil/index.cfm?fuseaction=search.search&description=CLINICAL%20INVESTIGATOR%20INSPECTION%20SEARCH)



**✉** [EMAIL \(MAILTO:?SUBJECT=CLINICAL INVESTIGATOR INSPECTION SEARCH&BODY=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/CLIL/INDEX.CFM?FUSEACTION=SEARCH.SEARCH\)](mailto:?subject=CLINICAL%20INVESTIGATOR%20INSPECTION%20SEARCH&body=HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/CLIL/INDEX.CFM?FUSEACTION=SEARCH.SEARCH)

**🖨** [PRINT](#)

Search Results for 'Hricik' in all Fields

Show  entries

Filter:

## Investigator Information

## Inspection Information

ID No.	Name	Location	Address	City	State	Cntry	Zip	Insp. Date	Type	Class.	Def. Codes
388802	hricik, donald e MD	Univ Hosps Case Med Ctr	11100 Euclid Ave	Cleveland	OH	USA	44106	10/12/01	DA	VAI	03,04

ID No.	Name	Location	Address	City	State	Cntry	Zip	Insp. Date	Type	Class.	Def. Codes
--------	------	----------	---------	------	-------	-------	-----	------------	------	--------	------------

Showing 1 to 1 of 1 entries

Previous  Next