WI #:	TITLE	VERSION DATE
WI-PM-3001	Checking Regulatory Status of Investigators and Sub Investigators	21-DEC-2017
		VERSION #
		V2.0

1. PURPOSE

These instructions are to provide guidance when checking the regulatory status of a site investigator and sub-investigator.

2. APPLICABLE ROLES

Clinical Trial Assistant
Site Monitor
Project Manager

3. PROCESS

Responsible Role	Activity	Timing
CTA or designee	Regulatory agency databases must be checked for Staff Members as determined by the Sponsor; At a minimum, this must be the Principal investigator.	Upon receipt of signed CDA
CTA or designee	After checking each of these lists, enter the results of the search into the STAR Database.	Before initiating PSSV
CTA or designee	If applicable, collect copies of FDA 483 letters and file in the site eISF.	Before initiating PSSV
CTA or designee	Provide feedback to the PM or designee of any study staff who has received any infractions from a regulatory agency	Before initiating PSSV

Source of Verification	Link	Related Questions
FDA Debarment List	http://www.fda.gov/ICECI/EnforcementActions/FDADebarmentList/default.htm	To confirm that Study Staff listed is/are not on the FDA debarred list.
Clinical Investigators - Disqualification Proceedings	http://www.accessdata.fda.gov/scripts/SDA/sdNavigation.cfm?sd=clinicalinvestigatorsdisqualificationproceedings&previewMode=true&displayAll=true	To confirm that Study Staff listed is not on the Disqualified/Totally Restricted List for Clinical Investigators

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Source of Verification	Link	Related Questions
Office of Research Integrity- PHS Administrative Action Bulletin Board	https://ori.hhs.gov/phs-admin-action-bulletinboard	To confirm that Study Staff listed is/are not on the Office of Research Integrity (ORI) PHS Administrative Actions List
Office of Inspector General-Exclusion Database	https://exclusions.oig.hhs.gov/	To confirm that Study is/are not on the OIG Excluded Parties List
CDER-Clinical Investigator Inspection List	http://www.accessdata.fda.gov/scripts/cder/cliil/i ndex.cfm	To confirm whether Site has had regulatory inspection by CDER or CBER
Inspections, Compliance, Enforcement, and Criminal Investigations-Warning Letters	http://www.fda.gov/ICECI/EnforcementActions/W arningLetters/	To confirm if the site or staff (as determined by Sponsor) have received a FDA 483
FDA-Vaccines, Blood & Biologics-Clinical- Clinical Investigator Inspection List	http://www.fda.gov/BiologicsBloodVaccines/Guid anceComplianceRegulatoryInformation/Complianc eActivities/ucm195364.htm https://www.accessdata.fda.gov/scripts/cder/cliil/ index.cfm	To confirm if Site has had regulatory inspection by CDER or CBER

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4. ABBREVIATION LIST

ABBREVIATION	DEFINITION
CBER	Center for Biologics Evaluation and Research
CDA	Confidentiality Disclosure Agreement
CDER	Center for Drug Evaluation and Research
CTA	Clinical Trial Assistant
eISF	Electronic Investigator Site Files
FDA	U.S. Food and Drug Administration
OIG	Office of Inspector General
ORI	Office of Research
PHS	U.S. Public Health Services
PM	Project Manager
PSSV	Pre-Study Site Visit
RBM	Risk Base Monitoring
STAR	Site Tracker Analyzing Risk
TPL	Template
URL	Uniform Resource Locator