Using this form – To check the checkboxes, double click on the box. To enter text in the text boxes, click once on the gray box and then type your response*.*

**Medical Devices**

**(Investigational Devices)**

(COMPLETE ONE FORM FOR EACH DEVICE BEING TESTED IN RESEARCH WITHOUT A CURRENT IDE)

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| **Section 1: Device Information:** | | |
| **1.a. Generic Name of the Device** | | **Brand Name / Manufacturer(s)** |
| insert generic name of device | | insert trade name of device /  insert name of device manufacturer |
| Provide a brief narrative description of the device: | insert description of device | |
| Provide a brief description of the device indications. | insert approved device indications | |

Check if [combination drug/device product](http://www.fda.gov/CombinationProducts/AboutCombinationProducts/ucm118332.htm)

***\*\*NOTE\*\**** *include a copy of the following materials with your IRB application:*

* *FDA cleared labeling information (Form S, IRB application checklist), device brochure, instruction manual, or information from the manufacturer describing the device (Form CC, IRB application checklist).*
* *As appropriate, include supporting documents reporting prior investigations with the device.*

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| **1.b. Current FDA Marketing Status**  **For information on how to Classify your medical device, click** [**here**](http://www.fda.gov/%20MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm) | | |
|  | **N/A – Investigational Device that has not been approved or cleared for marketing.**  This includes devices used in an early feasibility study to allow for early clinical investigation of devices to prove proof of principle and initial clinical safety data. |
|  | **This is a Class I or II device that is exempt from the premarket notification [510(k)]**  Devices exempt from 510(k) are either: pre-amendment devices not significantly changed or modified; or Class I/II devices specifically exempted by regulation.  This device can be found on the FDA’s [listing of medical devices exempt from 510(k) webpage](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/315.cfm). |
|  | **This is a Class III device that is being evaluated under an Approved Premarket Approval (PMA)**  All devices categorized as class III are subject to PMA requirements. An approved PMA is a license to market a particular medical device. (**Note:** A Product Development Protocol (PDP) is an alternative procedure for obtaining FDA approval of certain Class III devices. |

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| **Section 2 – Applicability of Investigational Device Exemption (IDE) Regulatory Requirements** *Research testing the safety or effectiveness of a medical device must fit in* ***one*** *of the following three categories*:  **CATEGORY 1 - Studies Exempt From IDE Requirements:** To be exempt from IDE requirements the study would need to meet one of the exemptions in the device regulations [[21 CFR 812.2](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=812.2)].  **CATEGORY 2 -** **Nonsignificant Risk (NSR) Device Study:** Conducted only under the purview of the IRB as an Abbreviated IDE. A formal IDE submission to FDA is NOT required [[see *Abbreviated Requirements* at 21 CFR 812.2](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=812.2)].  **CATEGORY 3 -** **Significant Risk (SR) Device Study:** Conducted under a formal IDE submitted to and approved by FDA [[21 CFR 812](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=812)].  NOTE: If the device study does not meet one of the Category 1 exemptions, the convened IRB must review the sponsor or sponsor-investigator’s SR or NSR determination and modify the determination if the IRB disagrees with the sponsor. Consultation with the FDA may be required at the discretion of the IRB.  If FDA has already made an Exempt, SR, or NSR determination for the study, the agency's determination is final.  FDA contact information *is available at the end of this form.* | | | |
| **1. STUDIES EXEMPT FROM IDE REQUIREMENTS** | | | |
| *Indicate if the device meets any of the following IDE Exemption categories and attach any supporting documentation from the FDA or the Sponsor. Specific criteria or conditions within each category must be met to qualify for exemption from IND requirements. Before checking an exemption, ensure the device meets all required criteria or conditions of the exemption.*  *If unsure, consult FDA regulations (*[21 CFR 812.2](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=812.2)*), links to additional guidance, or consult the FDA.* | | | |
| 1. **Approved/cleared devices (all of the following must be Yes)** | | | |
|  | The device was not regulated as a drug before enactment of the Medical Device Amendments (Transitional Device). | |
|  | The device is FDA-approved/cleared. [[1]](#endnote-1) | |
|  | The device is being used or investigated in accordance with the indications in the FDA approved/cleared labeling | |
|  | Yes to all – **C:\Users\oilepo\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\NVSY3N9F\6503264653_40dc082989_z[1].jpg** – qualifies for IDE Exemption – *Do not complete the rest of this form* | |
|  | No to any – *Go to Category II* | |
| **II. Diagnostic Device: (all of the following must be Yes)** | | | |
|  | The device is a diagnostic device. | |
|  | The sponsor will comply with applicable requirements in [21 CFR 809.10(c).](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=809.10) | |
|  | The testing is noninvasive.[[2]](#endnote-2) | |
|  | The testing does not require an invasive sampling procedure that presents significant risk. | |
|  | The testing does not by design or intention introduce energy into a subject | |
|  | The testing is not used as a diagnostic procedure without confirmation by another, medically established product or procedure. | |
|  | Yes to all – **C:\Users\oilepo\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\NVSY3N9F\6503264653_40dc082989_z[1].jpg** – qualifies for IDE Exemption – *Do not complete the rest of this form* | |
|  | No to any – *Go to Category III* | |
| **III. Modifications, Consumer Preference testing, and combination devices: (all of the following must be Yes)** | | | |
|  | The device is undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution | |
|  | Testing is not for the purpose of determining safety or effectiveness | |
|  | The use does not put subjects at risk. | |
|  | Yes to all – **C:\Users\oilepo\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\NVSY3N9F\6503264653_40dc082989_z[1].jpg** – qualifies for IDE Exemption – *Do not complete the rest of this form* | |
|  | No to any – *Go to Category IV* | |
| **IV. Custom Device: (all of the following must be Yes)** | | | |
|  | The device is a custom device as defined in [21 CFR 812.3(b)](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=812.3) | |
|  | Device is NOT being used to determine safety or effectiveness for commercial distribution. | |
|  | Yes to all – **C:\Users\oilepo\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\NVSY3N9F\6503264653_40dc082989_z[1].jpg** – qualifies for IDE Exemption – *Do not complete the rest of this form* | |
|  | No to any – IDE is required, *Go to Section 3* | |

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| **Section 3: If none of the above exemption categories apply, complete the following:** | | | |
| **A. Does the intended use of this device meet the definition of a Significant Risk Device?** | | | |
|  | **Yes – The device**  • Is intended as an implant **AND** presents a potential for serious risk to the health, safety, or  welfare of a subject; **OR**  • Is purported or represented to be for use supporting or sustaining human life **AND** presents a  potential for serious risk to the health, safety, or welfare of a subject; **OR**  • Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease,  or otherwise preventing impairment of human health **AND** presents a potential for serious risk  to the health, safety, or welfare of a subject; **OR**  • Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.  **6503264653_40dc082989_z[1]STOP HERE. You cannot use this form. An IDE issued by the FDA is required. – Submit to the FDA and update Step 2 – Institutional (item 27) accordingly** | |
|  | **No.** - the device does not meet any of the definitions for significant risk device described above **AND** it does not present a potential for serious risk to the health, safety, or welfare of subjects**:**  **The IRB application will fulfill the IDE submission requirements.**  *Provide a brief explanation why this device should be classified as Non-SR in the space below.* | |
|  | Insert NSR description here | |
|  | **Unsure.** - If unsure of the category that best fits the device(s) you propose to use in your research, consult the OIRB, guidance links at the end of this form, or contact the FDA for an Exempt, SR, or NSR determination. | |

***\*FDA CONTACTS:***  Contact the IDE section of the Office of Device Evaluation (ODE) 301-796-5640 or 800-638-2041 [cdrhide@fda.hhs.gov](mailto:cdrhide@fda.hhs.gov) or CDRH Manufacturer’s Assistance800-638-2041, 301-796-7100, [DSMICA@CDRH.FDA.GOV](mailto:DSMICA@CDRH.FDA.GOV).

To obtain a written risk determination from FDA, submit correspondence labeled “Study Determination” in triplicate to USFDA, CDRH, Document Mail Center – IDE Document Mail Center WO66-G609, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002. Content and submission information is available a

[**http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm311176.pdf**](http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm311176.pdf)

**ADDITIONAL GUIDANCE MATERIALS:**

**FDA Regulations – click here:** [**21 CFR 812 (device)**](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=812) **FDA Frequently Asked Questions about Medical Devices (2006) – Click here:** [**FAQs**](http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM127067.pdf)

**Significant Risk and Nonsignificant Risk Medical Device Studies (2006) – Click here:** [**SR/NSR Guidance**](http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126418.pdf)

**IDE Responsibilities for Sponsors and Investigators of Significant Risk and Nonsignificant Risk Device Studies – Click here:** [**IDE Guidance**](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm046702.htm)

**FDA Decisions for Investigational Device Exemption (IDE) Clinical Investigations (draft 2013) – Click here:** [**FDA IDE Decisions**](http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm279107.pdf)

**FDA IDE for Early Feasibility Medical Device Clinical Studies including First in Human (FIH) Guidance (2013) – Click here:** [**FIH Guidance**](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM279103.pdf)

**In Vitro Diagnostic (IVD) Device Studies – Frequently Asked Questions (2010) – Click here:** [**IVD FAQs**](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM071230.pdf)

***\*FDA CONTACTS:***  Contact the IDE section of the Office of Device Evaluation (ODE) 301-796-5640 or 800-638-2041 cdrhide@fda.hhs.gov or CDRH Manufacturer’s Assistance800-638-2041, 301-796-7100, DSMICA@CDRH.FDA.GOV.

To obtain a written risk determination from FDA, submit correspondence labeled “Study Determination” in triplicate to USFDA, CDRH, Document Mail Center – IDE Document Mail Center WO66-G609, 10903 new Hampshire Ave., Silver Spring, MD 20993-0002. Content and submission information is available at [www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm310375.htm](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm310375.htm)

1. In commercial distribution immediately before May 28, 1976, or FDA has determined to be substantially equivalent (i.e., 510k) to a device in commercial distribution immediately before May 28, 1976, and that is used or investigated in accordance with the indications in the labeling FDA reviewed under subpart E of part 807 in determining substantial equivalence. [↑](#endnote-ref-1)
2. Blood sampling that involves venipuncture is considered non-invasive for purposes of this exemption. The use of surplus samples of body fluids or tissues that are left over from samples taken for non-investigational purposes is also considered non-invasive. https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071230.pdf

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