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| **Section I: Instructions** | | | | |
| **1.** Use this form to help determine whether FDA Investigational Device Exemption (IDE) regulations at [21 CFR 812](https://www.ecfr.gov/cgi-bin/text-idx?SID=a21c0d1d1486ca875939925ce3447681&mc=true&node=pt21.8.812&rgn=div5) apply to the research project. It is recommended to complete this checklist during protocol development. | | | | |
| **2.** Complete this form electronically and include it with your OSF Research Application for device studies where an IDE application to FDA has not been completed. | | | | |
| **3.** IDE regulations describe 3 types of device studies: | | | | |
| **a.** device studies that are exempt from IDE regulations; | | | | |
| **b.** significant risk (SR) device studies that must comply with the IDE regulations; and | | | | |
| **c.** nonsignificant risk (NSR) device studies that must comply with abbreviated IDE regulations. | | | | |
| **4.** For device studies that are not exempt, the sponsors/PIs are responsible for making the initial SR/NSR determination. Unless the FDA has already made a SR/NSR determination, the IRB is required to review the sponsor’s/PI’s determination. Consult the [FDA guidance on SR/NSR device studies](https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126418.pdf) for further details. | | | | |
| **Section II: General Information** | | | | |
| **1. Principal Investigator Name:** | | | | |
| **2. Project/Protocol Title:** | | | | |
| **Section III: IDE Applicability** | | | | |
| **1. Is the device to be used in the research a legally marketed device used in accordance with its labeling?** | | | | |
| No | | | | |
| Yes **>** The device study is exempt from IDE regulations.  STOP completing Section III here and proceed to Section IV. | | | | |
| **2. Is the device to be used in the research a diagnostic device?** | | | | |
| No | | | | |
| Yes **>** Complete **a.**: | | | | |
| **a. Does the testing of the diagnostic device meet the all of the following criteria?** | | | | |
| **-** It complies with the labeling requirements of [21 CFR 809.10(c)](https://www.ecfr.gov/cgi-bin/text-idx?SID=de5cdff7475bb7bf1d2e981005245bb5&mc=true&node=pt21.8.809&rgn=div5#se21.8.809_110). | | | | |
| **-** It is non-invasive. | | | | |
| **-** It does not require an invasive sampling procedure that presents significant risk. | | | | |
| **-** It does not by design or intention introduce energy into a subject. | | | | |
| **-** It is not used as a diagnostic procedure without confirmation by another medically established diagnostic product or procedure. | | | | |
| No **>** The device study requires IDE approval from the FDA.  STOP completing Section III here and proceed to Section IV. | | | | |
| Yes **>** The device study is exempt from IDE regulations.  STOP completing Section III here and proceed to Section IV. | | | | |
| **3. Is the device to be used in the research undergoing consumer preference testing, testing of a modification, or testing of a combination of marketed devices** **(that is, the devices have an approved PMA, cleared Premarket Notification 510(k), or are exempt from 510(k)), and the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk?** | | | | |
| No | | | | |
| Yes **>** The device study is exempt from IDE regulations.  STOP completing Section III here and proceed to Section IV. | | | | |
| **4. Is the device to be used in the research intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject?** | | | | |
| No **>** Provide protocol specific rationale: | | | | |
| Yes **>** This is a significant risk device study requiring IDE approval from the FDA.  STOP completing Section III here and proceed to Section IV. | | | | |
| **5. Is the device to be used in the research 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?** | | | | |
| No **>** Provide protocol specific rationale: | | | | |
| Yes **>** This is a significant risk device study requiring IDE approval from the FDA.  STOP completing Section III here and proceed to Section IV. | | | | |
| **6. Is the device to be used in the research 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?** | | | | |
| No **>** Provide protocol specific rationale: | | | | |
| Yes **>** This is a significant risk device study requiring IDE approval from the FDA.  STOP completing Section III here and proceed to Section IV. | | | | |
| **7. Does the device to be used in the research otherwise present a potential for serious risk to the health, safety, or welfare of a subject?** | | | | |
| No **>** Provide protocol specific rationale: | | | | |
| Yes **>** This is a significant risk device study requiring IDE approval from the FDA.  STOP completing Section III here and proceed to Section IV. | | | | |
| **Section IV: Final Determination** | | | | |
| **1. If the responses to questions III.3 through III.6 are all “No”, you are conducting a nonsignificant risk device study that must comply with the abbreviated IDE requirements under** [**21 CFR 812.2 (b)**](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?FR=812.2)**.** | | | | |
| **a. The final determination for this device research is (choose one):** | | | | |
| A significant risk device study that requires an IDE approval **>** Complete **i.**: | | | | |
| **i. What is the status of the IDE application to the FDA?** | | | | |
| An IDE approval from the FDA is held by the sponsor or investigator **>** Attach copies of documentation | | | | |
| An IDE application has not yet been submitted to FDA **>** Proceed with the [FDA IDE application process](https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm046706.htm) | | | | |
| A nonsignificant risk device study that must comply with the abbreviated IDE requirements **>** Complete **ii.**: | | | | |
| **ii. My signature below confirms I have evaluated the above named study in light of the regulations in** [**21 CFR Part 812**](https://www.ecfr.gov/cgi-bin/text-idx?SID=be09a3cc8d632197deb057da7f395fe9&mc=true&node=pt21.8.812&rgn=div5) **and** [**related guidance**](https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM127067.pdf)**, determined that the research is a nonsignificant risk device study, and will comply with the abbreviated IDE requirements.** | | | | |
|  |  |  |  |  |
|  | Principal Investigator Signature |  | Date |  |
| The research is exempt from IDE regulations **>** Complete **iii.**: | | | | |
| **iii. My signature below confirms I have evaluated the above named study in light of the regulations in** [**21 CFR Part 812**](https://www.ecfr.gov/cgi-bin/text-idx?SID=be09a3cc8d632197deb057da7f395fe9&mc=true&node=pt21.8.812&rgn=div5) **and** [**related guidance**](https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM127067.pdf)**, and determined that the study qualifies for exemption from the IDE regulations in accordance with the cited requirements and guidance.** | | | | |
|  |  |  |  |  |
|  | Principal Investigator Signature |  | Date |  |