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| Form IDE: INVESTIGATIONAL DEVICES IN RESEARCHVA Ann Arbor Healthcare System (FWA-00000348)Subcommittee on Human Studies (IRB-00000264)2215 Fuller Rd. Phone: 734-761-7950Ann Arbor, MI 48105 FAX: 734-761-7693 FDA Policy on IDE at this link -> <http://www.access.gpo.gov/nara/cfr/waisidx_98/21cfr812_98.html> |
| PRINCIPAL INVESTIGATOR:  |
| TITLE OF STUDY:  |
| Section 1. Identification of Investigational Devices *(use separate form for each device)**(Complete this form if the research activity involves the use of a device, other than the use of an approved medical device in the course of medical practice.*a. What is the name of the device? ->b. Describe the type of device: ->c. Manufacturer of the device: ->d. Purpose/ Function of the device (generally and for this study) ->======================================================================================Section 2. Determination of Investigational Device Exemption Status [21 CFR 812.2(c)][ ] (1) A device, other than a transitional device, in commercial distribution immediately before May 28, 1976, when used or investigated in accordance with the indications in labeling in effect at that time.[ ] (2) A device, other than a transitional device, introduced into commercial distribution on or after May 28, 1976, that FDA has determined to be substantially equivalent 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.[ ] (3) A diagnostic device, if the sponsor complies with applicable requirements in 809.10(c) and if the testing:(i) Is noninvasive,(ii) Does not require an invasive sampling procedure that presents significant risk,(iii) Does not by design or intention introduce energy into a subject, and(iv) Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.[ ] (4) A device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, if the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk.[ ] (5) A device intended solely for veterinary use.[ ] (6) A device shipped solely for research on or with laboratory animals and labeled in accordance with 812.5(c).[ ] (7) A custom device as defined in 812.3(b), unless the device is being used to determine safety or effectiveness for commercial distribution.* IF YOU CAN CHECK ONE ITEM IN SECTION 2, THEN THIS STUDY IS REGULATED BY THE FDA, BUT IS EXEMPT FROM THE REQUIREMENTS FOR AN IDE --> GOTO SECTION 6 (With the exception of 812.119, disqualification of a clinical investigator).
* IF YOU CANNOT CHECK AT LEAST ONE ITEM IN SECTION 2, THEN CONTINUE TO SECTION 3

======================================================================================Section 3. Determination if the device represents a Significant Risk [21 CFR 812.3(m)] [ ] (1) A device intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject? [ ] (2) A device purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject? [ ] (3) A device 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? [ ] (4) The device otherwise presents a potential for serious risk to the health, safety, or welfare of a subject?* IF YOU DO NOT CHECK ANY QUESTION IN SECTION 3, GO TO SECTION 4
* IF YOU CHECK ANY QUESTION IN SECTION 3, FDA APPROVAL IS REQUIRED -->GO TO SECTION 5

\*\*You must provide an IDE number or produce documentation from FDA that no IDE is required\*\*Section 4: Abbreviated Requirements For Non-Significant Risk Devices The following categories of investigations are considered to have approved applications for IDE's, unless FDA has notified a sponsor under 812.20(a) that approval of an application is required: [21 CFR 812.2(b)][ ] (1) An investigation of a device other than a significant risk device, if the device is not a banned device and the sponsor:(i) Labels the device in accordance with 812.5;(ii) Obtains IRB approval of the investigation after presenting the reviewing IRB with a brief explanation of why the device is not a significant risk device, and maintains such approval;(iii) Ensures that each investigator participating in an investigation of the device obtains from each subject  under the investigator's care, informed consent under part 50 and documents it, unless documentation is  waived by an IRB under 56.109(c).(iv) Complies with the requirements of 812.46 with respect to monitoring investigations;(v) Maintains the records required under 812.140(b) (4) and (5) and makes the reports required under  812.150(b) (1) through (3) and (5) through (10);(vi) Ensures that participating investigators maintain the records required by 812.140(a)(3)(i) and make the reports required under 812.150(a) (1), (2), (5), and (7); and(vii) Complies with the prohibitions in 812.7 against promotion and other practices.[ ] (2) An investigation of a device other than one subject to paragraph (e) [Investigations subject to INDs] of this section, if the investigation was begun on or before July 16, 1980, and to be completed, and is completed, on or before January 19, 1981.======================================================================================Section 5. The investigator must submit the VA IRB "Device Management Application Form"  <http://www.annarbor.research.va.gov/>\*\*You must provide an IDE number or produce documentation from FDA that no IDE is required\*\*Section 6. Investigator Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature of Principal Investigator Date |

* The VA IRB will determine if the device meets one of the exemption categories for an IDE
* The VA IRB will determine if the device meets the abbreviated IDE requirements
* The VA IRB will determine if the device presents non-significant risk
* The VA IRB Coordinator will contact FDA to validate an existing IDE approval number