# VA Portland Health Care System (VAPORHCS) - Institutional Review Board

**IRQ Appendix E – Medical Devices Being Evaluated**

**VAPORHCS PI Name:       Date:**

**Study/Project ID#:**

**This appendix should be completed as prompted on the IRQ. Please complete a separate appendix for each device. *NOTE:*** *If any fields on this appendix do not allow enough space to provide a thorough answer, state “see attached”, and include the complete answer on a separate page, identifying clearly to which question the answer refers.*

1. Manufacturer and brand name of the device (if applicable, also specify model, version, etc.):
2. Type of device (e.g. hearing aid) and/or description of the device, including its proposed mechanism of action:
3. Attach available manufacturer information about the device (e.g. user’s manual, package insert, investigator’s brochure). [ ]  Documentation attached [ ]  None – explain reason:
4. Who initiated this research project?

[ ]  PI\* *(\*PI is a “sponsor-investigator” and must fulfill sponsor obligations under FDA regulations)*

[ ]  Device Manufacturer

[ ]  Other - specify:

1. Indicate the status of the device with the FDA (e.g. IDE, NSR, IDE exempt, 510(k) determination or exemption, de novo, PMA, exempt from pre-market notification requirements, HDE, any of the preceding in process, other [specify] or none*)*:
2. Attach copies of the FDA correspondence or regulatory citation documenting the status of the device, as indicated above. [ ]  Documentation attached [ ]  N/A – no status with FDA yet
3. If the device does not yet have a status with the FDA, please indicate below whether it may meet criteria for exemption from the IDE requirements or for the abbreviated IDE requirements.

[ ]  N/A – FDA status other than “none” is listed above (skip to Investigator Assurances)

***Exemptions from IDE requirements:*** *Select the applicable category below.*

[ ]  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.

[ ]  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](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=807&showFR=1&subpartNode=21:8.0.1.1.5.5) in determining substantial equivalence.

[ ]  A diagnostic device, if the sponsor complies with applicable requirements in [809.10(c)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=809.10) and if the testing:

[ ]  Is noninvasive,

[ ]  Does not require an invasive sampling procedure that presents significant risk,

[ ]  Does not by design or intention introduce energy into a subject, and

[ ]  Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.

[ ]  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.

[ ]  A device intended solely for veterinary use.

[ ]  A device shipped solely for research on or with laboratory animals and labeled in accordance with [812.5(c)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.5).

[ ]  A custom device as defined in [812.3(b)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.3), unless the device is being used to determine safety or effectiveness for commercial distribution.

***Abbreviated IDE requirements (non-significant risk [NSR] devices):***

***NOTE:*** *ALL criteria below must* *be met.* *These requirements may not be applied if the FDA has notified the sponsor under* [*812.20(a)*](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.20) *that approval of an application is required*.

[ ]  An investigation of a device, other than a significant risk device, if the device is not a banned device and the sponsor:

[ ]  Labels the device in accordance with [812.5](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.5);

[ ]  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;

[ ]  Ensures that each investigator participating in an investigation of the device obtains from each subject under the investigator's care, informed consent under [21 CFR 50](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50) and documents it, unless documentation is waived by an IRB under [21 CFR 56.109(c)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.109).

[ ]  Complies with the requirements of [21 CFR 812.46](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.46) with respect to monitoring investigations;

[ ]  Maintains the records required under [21 CFR 812.140(b)(4) and (5)](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=812.140) and makes the reports required under [21 CFR 812.150(b)(1)-(3) and (5)-(10)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.150);

[ ]  Ensures that participating investigators maintain the records required by [21 CFR 812.140(a)(3)(i)](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=812.140) and make the reports required under [21 CFR 812.150(a)(1), (2), (5) and (7)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.150); and

[ ]  Complies with the prohibitions in [21 CFR 812.7](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.7) against promotion and other practices.

 ***Answer the following questions based on the proposed device use in this research project*:**

1. Is the device intended as an implant?  [ ]  YES [ ]  NO

If **YES to 8**, does the device present a potential for serious risk to the health, safety, or welfare of a subject? [ ]  YES [ ]  NO

1. Is the device purported, or represented to be, for use supporting or sustaining human life?

[ ]  YES [ ]  NO

If **YES to 9**, does the device present a potential for serious risk to the health, safety, or welfare of a subject? [ ]  YES [ ]  NO

1. Is the device for use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health? [ ]  YES [ ]  NO

If **YES to 10**, does the device present a potential for serious risk to the health, safety or welfare of a subject? [ ]  YES [ ]  NO [ ]

1. Does the device in any other way present a potential for serious risk to the health, safety or welfare of a subject? [ ]  YES [ ]  NO
2. Will subjects need to undergo any related procedures and tests procedure as part of the research project? [ ]  YES [ ]  NO
3. Provide any further information, from the manufacturer or otherwise, that may help the IRB in evaluating the risk and benefits of the device in this study *(e.g. further description of the device, reports of prior investigations with the device):*

**Storage, Security, and Dispensing:**

1. Describe how the PI will provide secure storage for the investigational device(s) used in this study (e.g. according to storage requirements as outlined by the sponsor or manufacturer and/or, as appropriate, the Research Pharmacy).

***NOTE: Other points to consider when responding to Q.14 above (as applicable):***

* *How and where will the device(s) be stored at the VAPORHCS?*
* *How will the device(s) be secured at the VAPORHCS?*
* *Who will be accountable for and have access to the device(s)?*
* *How will the dispensing of the device(s) be tracked?*
* *Who will be responsible for maintaining the records at the VAPORHCS?*