# 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?*