

# AURA

## SBIR / Technical Proposal Coherence Review - Excerpt

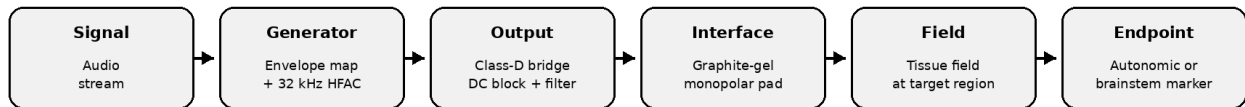
Prepared by InTelluric | Pre-Submission Technical Review | May 2026

### Executive Decision Summary

AURA is strongest as a Phase I feasibility project for a music-modulated HFAC cranial-nerve stimulation platform. It should not be submitted as a completed therapeutic claim. The electronics chain is comparatively well specified; the biological delivery chain is the critical coherence gap. The proposal must prove field geometry, safety, target engagement, and biomarker response before asserting clinical value. This matches the SBIR Phase I mandate to establish technical merit, feasibility, and commercial potential [1,2].

### Critical Coherence Gap

The unresolved chain is: graphite-gel pad -> tissue field distribution -> cranial-nerve engagement -> physiological signal -> development path. Literature supports auricular stimulation as a serious neuromodulation field, but it does not validate AURA's specific single-pad, music-envelope HFAC approach [8-13]. That gap becomes the Phase I work plan.



Coherence rule: each arrow must be supported by a measurement, model, control, or go/no-go threshold.

### Claim Matrix Excerpt

#### Claim 1 - AURA can deliver a bounded field to superficial cranial-nerve target regions.

**Evidence required:** Measured field distribution in tissue phantom; computational model; pad impedance map.

**Present support:** Engineering premise and first-pass geometry model.

**Missing evidence:** No measured 3D field map, no model validation, no anatomical selectivity analysis.

**Risk / repair action:** High. Make Aim 2 a field-validation aim with pass/fail depth and hotspot thresholds.

#### Claim 2 - Music-envelope HFAC is a meaningful neuromodulation waveform.

**Evidence required:** Comparator study against sham, unmodulated HFAC, and standard taVNS pulse train.

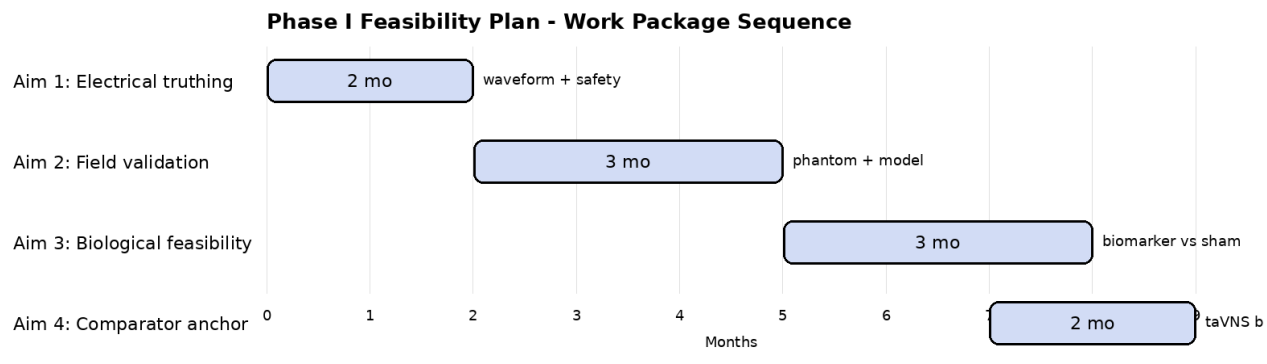
**Present support:** Coherent signal-generation logic; literature supports electrical auricular access to vagal projections [9].

**Missing evidence:** No demonstration that music-derived envelopes outperform or differ physiologically from simpler envelopes.

**Risk / repair action:** High. Phrase as hypothesis; test envelope variants rather than claiming superiority.

## Phase I Aim Structure

Aim 1: electrical truthing and safety envelope. Aim 2: field geometry and tissue-interface validation. Aim 3: biological feasibility with sham and non-envelope controls. Aim 4: comparator anchor against standard taVNS or a validated research stimulator. The work packages retire one uncertainty class at a time rather than mixing prototype construction with unsupported efficacy language.



## Reviewer Objection Map Excerpt

### Objection 1 - The proposal overclaims therapeutic effect.

Evidence needed: feasibility endpoint only; no efficacy claims. Rewrite action: use investigational language and define Phase I as mechanism validation.

### Objection 2 - The mechanism is underspecified.

Evidence needed: causal diagram, waveform table, tissue-field model, and controls. Rewrite action: state each causal link and map it to a test.

### Objection 3 - The auricular target is anatomically ambiguous.

Evidence needed: target-site justification and current-flow model. Rewrite action: do not imply broad ear placement is automatically vagal; test placement sensitivity [8,10].

## Selected References

- [1] SBIR.gov. Policies: SBIR/STTR Phase I objective and review considerations. <https://www.sbir.gov/about/policies>
- [2] NIMH. SBIR/STTR Program Structure. <https://www.nimh.nih.gov/funding/sbir/sbir-sttr-program-structure.shtml>
- [8] Peuker ET, Filler TJ. The nerve supply of the human auricle. *Clinical Anatomy*. 2002;15:35-37. <https://doi.org/10.1002/ca.1089>
- [9] Frangos E, Ellrich J, Komisaruk BR. Non-invasive access to vagus nerve central projections via electrical stimulation of the external ear. *Brain Stimulation*. 2015;8(3):624-636. <https://pubmed.ncbi.nlm.nih.gov/25573069/>
- [10] Adair D, Truong D, Esmailpour Z, et al. High-resolution computational modeling of current flow in the outer ear during taVNS. *Brain Stimulation*. 2020/2021. <https://pmc.ncbi.nlm.nih.gov/articles/PMC8608747/>
- [11] Farmer AD, Strzelczyk A, Finisguerra A, et al. Minimum reporting standards in research on transcutaneous vagus nerve stimulation. *Frontiers in Human Neuroscience*. 2021. <https://pubmed.ncbi.nlm.nih.gov/33854421/>

- [13] Kim AY, Marduy A, de Melo PS, et al. Safety of transcutaneous auricular vagus nerve stimulation: systematic review and meta-analysis. *Scientific Reports*. 2022;12:22055. <https://www.nature.com/articles/s41598-022-25864-1>
- [15] Gabriel C, Gabriel S, Corthout E. The dielectric properties of biological tissues: I. Literature survey. *Physics in Medicine & Biology*. 1996;41(11):2231-2249. <https://pubmed.ncbi.nlm.nih.gov/8938024/>