

## **ABET Adendum**

### **1. Desired Needs**

- A non-invasive physical barrier to block environmental carcinogens from entering mammary ducts, targeting a prevention pathway absent from all current clinical strategies
- A human subjects research protocol capable of passing IRB review, enabling safe wear trials that generate real biomarker and comfort data
- A reusable, biocompatible device manufacturable within a limited budget that remains accessible across diverse anatomies and skin types

### **2. Major Constraints**

- Safety/Regulatory: All skin-contact materials required biocompatibility under ISO 10993; IRB approval required informed consent documentation, minimal-risk classification, and iterative protocol revisions to satisfy UCSD's human subjects committee
- Risks: Skin irritation, allergic response from adhesive, protection of subject data
- Global Impact: Device must remain low-cost and manufacturable at scale
- Manufacturability: Fabrication constrained to small-scale printing and manual silicone casting within a restricted academic budget
- Quality Control/Marketability: Seal integrity and adhesion performance had to meet a consistent standard across prototypes

### **3. Engineering Standards**

- ISO 10993-1, -5, -10, -23: Biocompatibility (cytotoxicity, irritation, and sensitization testing for skin-contact materials)
- ASTM F2244, ASTM F2256, ASTM F2258: Adhesion Strength Testing
- ISO 13485 / ISO 14971: Quality/risk management for medical devices structured risk assessment embedded in IRB submission materials

### **4. Ethical, Environmental, and Societal Concerns**

- Ethical responsibility to avoid claiming the device prevents breast cancer; all materials were carefully worded as investigation for ductal carcinogen entry in non-lactating tissue
- Recruitment design required multiple IRB revisions to ensure genuine voluntary participation of accepted participants
- Environmental impact minimized through reusable silicone cover design; single-use adhesive waste was acknowledged and reducing it identified as a priority in the future

### **5. Active Teamwork and Leadership**

- Led IRB documentation efforts, coordinating with regulatory advisors and revising protocols in response to committee feedback across multiple review cycles
- Feedback from Dr. Taylor and Dr. Schmid-Schoenbein on consent language and risk framing was incorporated into each protocol revision
- Led discussions relevant to device alterations before and after conducting wear trials
- Innovated new and cheap alternative for force testing on the adhesive piece

### **6. Significant Motivating Factors**

- Learned human subjects regulations, biocompatibility standards, and wear-trial methodology from scratch
- Persisted through multiple full resubmission cycles while the wear trials ran in parallel

### **7. Innovative and Entrepreneurial Ideas**

- First device designed to physically occlude mammary ductal openings
- IRB framework could serve as a reusable protocol template for future non-invasive breast health research