

**APPLICATION FOR FEDERAL ASSISTANCE  
SF 424 (R&R)**

		3. DATE RECEIVED BY STATE	State Application Identifier
<b>1. TYPE OF SUBMISSION*</b>		<b>4.a. Federal Identifier</b>	
<input type="radio"/> Pre-application <input checked="" type="radio"/> Application <input type="radio"/> Changed/Corrected Application		<b>b. Agency Routing Number</b>	
<b>2. DATE SUBMITTED</b>	<b>Application Identifier</b>	<b>c. Previous Grants.gov Tracking Number</b>	
<b>5. APPLICANT INFORMATION</b> <div style="text-align: right;"><b>UEI*</b>: KED8PDBTFTL3</div> <p>Legal Name*: CERVU, INC          Department:          Division:          Street1*: 113 DORCHESTER PINES CT          Street2:          City*: CARY          County:          State*: NC: North Carolina          Province:          Country*: USA: UNITED STATES          ZIP / Postal Code*: 275115788</p>			
<p>Person to be contacted on matters involving this application</p> <p>Prefix: First Name*: Alan      Middle Name:      Last Name*: Rosenbaum      Suffix:          Position/Title: Co-Founder and CEO          Street1*: 113 DORCHESTER PINES CT          Street2:          City*: CARY          County:          State*: NC: North Carolina          Province:          Country*: USA: UNITED STATES          ZIP / Postal Code*: 27511-5788</p>			
Phone Number*: 7654124512		Fax Number:	Email: alan@cervuhealth.com
<b>6. EMPLOYER IDENTIFICATION NUMBER (EIN) or (TIN)*</b> 86-2013813			
<b>7. TYPE OF APPLICANT*</b> R: Small Business			
Other (Specify): <div style="display: flex; justify-content: space-around;"> <span>Small Business Organization Type</span> <span><input type="radio"/> Women Owned</span> <span><input type="radio"/> Socially and Economically Disadvantaged</span> </div>			
<b>8. TYPE OF APPLICATION*</b>		If Revision, mark appropriate box(es). <div style="display: flex; justify-content: space-around;"> <span><input checked="" type="radio"/> New</span> <span><input type="radio"/> Resubmission</span> <span><input type="radio"/> A. Increase Award</span> <span><input type="radio"/> B. Decrease Award</span> <span><input type="radio"/> C. Increase Duration</span> </div> <div style="display: flex; justify-content: space-around;"> <span><input type="radio"/> Renewal</span> <span><input type="radio"/> Continuation</span> <span><input type="radio"/> Revision</span> <span><input type="radio"/> D. Decrease Duration</span> <span><input type="radio"/> E. Other (specify):</span> </div>	
<b>Is this application being submitted to other agencies?*</b>		<input type="radio"/> Yes	<input checked="" type="radio"/> No      What other Agencies?
<b>9. NAME OF FEDERAL AGENCY*</b> National Institutes of Health		<b>10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER</b> TITLE:	
<b>11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT*</b> Mobile application for remote therapy monitoring of pelvic pain and dyspareunia in female cancer survivors			
<b>12. PROPOSED PROJECT</b> Start Date* 12/01/2024		<b>13. CONGRESSIONAL DISTRICTS OF APPLICANT</b> Ending Date* 12/31/2025 NC-013	

**SF 424 (R&R)** APPLICATION FOR FEDERAL ASSISTANCE

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**14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION**

Prefix: First Name\*: Caitlyn Middle Name: Last Name\*: Tivy Suffix:  
 Position/Title: Chief Clinical Officer  
 Organization Name\*: CERVU, INC  
 Department:  
 Division:  
 Street1\*: 310 Harrington Street  
 Street2:  
 City\*: Raleigh  
 County:  
 State\*: CO: Colorado  
 Province:  
 Country\*: USA: UNITED STATES  
 ZIP / Postal Code\*: 276030000  
 Phone Number\*: na Fax Number: Email\*: ctivy.consulting@gmail.com

**15. ESTIMATED PROJECT FUNDING**

a. Total Federal Funds Requested*	\$390,778.00
b. Total Non-Federal Funds*	\$0.00
c. Total Federal & Non-Federal Funds*	\$390,778.00
d. Estimated Program Income*	\$0.00

**16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?\***

- a. YES  THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:  
 DATE:
- b. NO  PROGRAM IS NOT COVERED BY E.O. 12372; OR  
 PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

**17. By signing this application, I certify (1) to the statements contained in the list of certifications\* and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances \* and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 18, Section 1001)**

I agree\*

\* The list of certifications and assurances, or an Internet site where you may obtain this list, is contained in the announcement or agency specific instructions.

**18. SFLLL or OTHER EXPLANATORY DOCUMENTATION**

File Name:

**19. AUTHORIZED REPRESENTATIVE**

Prefix: First Name\*: Alan Middle Name: Last Name\*: Rosenbaum Suffix:  
 Position/Title\*: Co-Founder and CEO  
 Organization Name\*: Cervu Inc.  
 Department:  
 Division:  
 Street1\*: 113 DORCHESTER PINES CT  
 Street2:  
 City\*: Cary  
 County:  
 State\*: NC: North Carolina  
 Province:  
 Country\*: USA: UNITED STATES  
 ZIP / Postal Code\*: 275115788  
 Phone Number\*: 7654124512 Fax Number: Email\*: alan@cervuhealth.com

**Signature of Authorized Representative\***

Completed on submission to Grants.gov

**Date Signed\***

03/23/2024

**20. PRE-APPLICATION** File Name:**21. COVER LETTER ATTACHMENT** File Name:

## 424 R&R and PHS-398 Specific

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## Project/Performance Site Location(s)

**Project/Performance Site Primary Location**

I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: CERVU, INC  
UEI: KED8PDBTFTL3  
Street1\*: 113 DORCHESTER PINES CT  
Street2:  
City\*: CARY  
County:  
State\*: NC: North Carolina  
Province:  
Country\*: USA: UNITED STATES  
Zip / Postal Code\*: 275115788  
Project/Performance Site Congressional District\*: NC-013

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**Project/Performance Site Location 1**

I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: CERVU, INC  
UEI: KED8PDBTFTL3  
Street1\*: 107 Cheney Ct  
Street2:  
City\*: Garner  
County:  
State\*: NC: North Carolina  
Province:  
Country\*: USA: UNITED STATES  
Zip / Postal Code\*: 275290000  
Project/Performance Site Congressional District\*: NC-013

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## Project/Performance Site Location 2

I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: CERVU, INC  
UEI: KED8PDBTFTL3  
Street1\*: 310 Harrington Street  
Street2:  
City\*: Raleigh  
County:  
State\*: NC: North Carolina  
Province:  
Country\*: USA: UNITED STATES  
Zip / Postal Code\*: 276030000  
Project/Performance Site Congressional District\*: NC-002

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**Additional Location(s)**

File Name:

**RESEARCH & RELATED Other Project Information****1. Are Human Subjects Involved?\***  Yes  No

## 1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations?  Yes  NoIf YES, check appropriate exemption number:  1  2  3  4  5  6  7  8If NO, is the IRB review Pending?  Yes  No

IRB Approval Date:

Human Subject Assurance Number

**2. Are Vertebrate Animals Used?\***  Yes  No

## 2.a. If YES to Vertebrate Animals

Is the IACUC review Pending?  Yes  No

IACUC Approval Date:

Animal Welfare Assurance Number

**3. Is proprietary/privileged information included in the application?\***  Yes  No**4.a. Does this project have an actual or potential impact - positive or negative - on the environment?\***  Yes  No

## 4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed?

## 4.d. If yes, please explain:

**5. Is the research performance site designated, or eligible to be designated, as a historic place?\***  Yes  No

## 5.a. If yes, please explain:

**6. Does this project involve activities outside the United States or partnership with international collaborators?\***  Yes  No

## 6.a. If yes, identify countries:

## 6.b. Optional Explanation:

Filename

**7. Project Summary/Abstract\*** Summary-Cervu.pdf**8. Project Narrative\*** Narrative-Cervu.pdf**9. Bibliography & References Cited** LitCited-Cervu.pdf**10. Facilities & Other Resources** Facilities-Cervu-2024.03.15.pdf**11. Equipment** Equipment-Cervu-2024.03.15.pdf

**Summary:** More than half of female cancer survivors will experience chronic pelvic pain and dyspareunia (painful intercourse) due to their cancer treatments. As the number of cancer survivors continues to grow, so too will the number of women in need of effective treatments for this life-altering condition. Pelvic floor physical therapists currently recommend and demonstrate several different devices for at-home therapy (vaginal dilators, pelvic wands, vibration devices), where the majority of therapy is performed. Regular clinic visits to assess progress, identify problems, and update the care plan require frequent in-clinic visits which pose time, financial, and transportation challenges to women already burdened with cancer-related care. Further complicating the ability to provide the optimal care, outcomes are hampered by low therapy adherence, at-home therapy recall bias, and lack of progress tracking. Currently, there are no comprehensive RTM solutions specifically tailored to the sexual health of female cancer survivors. This population has unique needs due to their cancer diagnosis and treatments, including typically older age and other comorbidities (e.g., arthritis) which alter their ability to interact with treatment technologies. There is a significant unmet need for a solution that provides the knowledge, skills, and confidence to advocate for their own sexual health. Cervu, Inc. is developing a mobile application (app) for the highly individualized needs of female cancer survivors this is uniquely designed to track baseline chronic pain, sexual function, and the performance and progress of multiple therapies including dilation, vibration, myofascial release, and trigger point massage, which is then shared with the treatment team. Such an app has the potential to improve patient outcomes, experience, and adherence by providing progress tracking. Increased access to care and reduced healthcare costs will result from reduced time, economic, and transportation barriers. The improved quality of patient-reported therapy data will enable the clinician to create improved individualized exercise plans and provide remote supervision. The objectives of this Phase I SBIR are to progress to a functional and intuitive UI/UX and to acquire comprehensive user feedback. **Aim 1. Design and develop mockup and prototype-level UI/UX.** To establish feasibility of producing functional 'works like, looks like' app prototypes with a user-validated interface, we will validate use cases, feature sets, user tasks and flows (navigation & interactions), visual design, and usability, and complete iterative cycles of design reviews and implementation of modifications. **Aim 2. Demonstrate ability to meet patient and provider usability needs.** We will validate usability through pre-formative user testing in female cancer survivors with dyspareunia/chronic pelvic pain and providers who manage this condition to ensure the value needed for adherence. **Impact and Future Directions.** The mobile app has the potential to transform care for cancer survivors suffering from chronic pelvic pain and dyspareunia, minimizing cancer treatment's debilitating side effects and improving the lives of cancer survivors. Future work includes front and back-end development and validation followed by clinical testing.

**Narrative:** Female patients surviving cancer consistently report that pelvic pain and dyspareunia (pain with sexual intercourse) are among their biggest quality of life concerns. Current solutions are largely unregulated, provide only a single form of therapy, and do not provide comprehensive progress tracking for the patient and provider. This study is designed to develop and evaluate an innovative mobile application that will deliver at-home pelvic floor physical therapy diary logging, progress tracking, and provider communication to improve patient compliance, quality of life (QoL), and treatment recommendations.

## FACILITIES AND OTHER RESOURCES

### Cervu, Inc.

**Office:** We currently have access to the Raleigh Founded shared office space located at 310 Harrington Street in Raleigh, North Carolina. This space is made available courtesy of North Carolina State University to participants in the Andrews Launch Accelerator, including Cervu, Inc. The entrepreneurial space houses 30 private turn-key office suites, co-working space, three large conference rooms, six smaller huddle rooms, café space with a full service kitchen, and multipurpose rooms for classes, workshops, and events. The facility has a secure internal network with high-speed internet access throughout.

**Laboratory/Workshop:** While not directly relevant for our software development project, our ~600 sq.ft. workshop space located at 107 Cheney Court in Garner, North Carolina is well equipped for prototype validation. The facility includes test benches and power supplies together with an assortment of prototyping tools.

**Clinical:** Not Applicable

**Animal:** Not applicable

**Computer:** Cervu will use cloud-based secure services for recruiting, screening, and consent as well as conduct of interviews and storage of data. This provides the necessary resources to securely maintain the research participant data collected during this effort. This cloud server capacity will provide redundant data backups and support. We additionally have a variety of desktop and laptop computers in both PC and Macintosh formats for design and data analysis.

**Environment:** Cervu is located in the Research Triangle Park area of North Carolina, a hub for entrepreneurship with world-class business infrastructure, talented resource pool with access to top universities (Duke University, University of North Carolina – Chapel Hill, and North Carolina State University), and a flourishing angel investment and venture capital environment.

**Biohazards:** There are no areas of concern with respect to biosafety.

**Intellectual Property:** Specific innovative design features as well as protectable aspects of the mobile app will be covered by a combination of a provisional patent and trade secrets, as appropriate. Additional IP will be filed for developments arising from this project. We plan to initially approach the domestic market, having filed therapy device-related patents with the USPTO.

### Theresa Neil Interface Designs LLC, DBA: Guidea, ("Guidea")

Guidea is a product design agency specializing in human centered design for femtech, medtech, healthtech, and digital health. They have led the product research and digital design for more than 40 applications used by +660M people worldwide, including 14 FDA cleared solutions. In 2022, they launched a UX sponsorship program for early stage femtech founders and have supported forty early stage teams with \$1.3M in research and design services. They have conducted over 1000 hours of user research with women and people AFAB, and hundreds of hours of research with healthcare providers.

They have mentored and provided the research and design work for 100 start-ups since Guidea was founded in 2005. They have also worked with health giants: Cigna (9 years), Johnson & Johnson (4 years), the top biopharma companies, and prestigious institutions including Yale Medical School, Oxford Medical, and Jhpiego by Johns Hopkins.

Guidea work on behalf of Cervu, Inc. includes but is not limited to:

- Journey mapping
- Concept design
- Methodology development
- Remote research

- Research documentation
- Synthesis
- Detailed flow and screen design for workflows
- Design updates & recommendations from research

**Office:** Theresa Neil Interface Designs is a Texas LLC, having an address of 10924 Gerald Allen Loop, Austin, TX 78748. Guidea team members include Lead Researcher, UX Designer, and Detail Designer. Guidea has 12 full time employees with the following titles: COO/Partner, CEO/Founder, Dir. of Design & Strategy, UX Researcher, Business Manager, Associate Dir of Design & Strategy, Principal UX Designer (2), Associate Director, Assistant UX Designer, and Associate Dir of Research & Strategy. Guidea has 12 Contracted employees with the following titles: Principal UX Designer (4), Visual Designer, UX Designer (2), Director of Research & Strategy, Content & Marketing, and Dir. of Product Strategy & Innovation.

Guidea has U.S. employees based in the following locations: Atlanta, GA; Austin, TX; Aurora, CO; Brooklyn, NY; Denver, CO; Hanover, VA; Hilton Head, SC; Huntsville, AL; Los Angeles, CA; New Orleans, LA; Portland, OR; San Diego, CA; Santa Cruz, CA.

**Laboratory/Workshop:** Not applicable

**Clinical:** Not applicable

**Animal:** Not applicable

**Computer:** Guidea will use cloud-based secure services for recruiting, screening, and consent as well as conduct of interviews and storage of data. This provides the necessary resources to securely maintain the research participant data collected during this effort. This cloud server capacity will provide redundant data backups and support. They additionally have a variety of desktop and laptop computers in both PC and Macintosh formats for design and data analysis. All work from Guidea for Cervu, Inc., including but not limited to design workflows and research outcomes, will only be shared or accessed outside of Guidea with Cervu and will comply with all aspects of the NDA between Guidea and Cervu, Inc.

**Software:** Figma will primarily be used for wireframing, LoopPanel for UX research analysis, Notion for project tracking and document management, Zoom for meetings and interviews, Fathom to generate transcripts and annotations to interviews and sessions, and Miro as the whiteboarding tool.

**Biohazards:** There are no areas of concern with respect to biosafety.

## **EQUIPMENT**

### **Cervu, Inc.**

No specialized equipment is necessary for the conduct of this software development project. Computing resources necessary for software design and the virtual interviews and associated data analysis are described within the **Facilities and Other Resources** document.

### **Theresa Neil Interface Designs LLC, DBA: Guidea, (“Guidea”)**

Computing resources necessary for the virtual interviews, concept design, workflow design and work related to design and research are described within the **Facilities and Other Resources** document.

**RESEARCH & RELATED Senior/Key Person Profile (Expanded)**

<b>PROFILE - Project Director/Principal Investigator</b>				
Prefix:	First Name*: Caitlyn	Middle Name	Last Name*: Tivy	Suffix:
Position/Title*:	Chief Clinical Officer			
Organization Name*:	CERVU, INC			
Department:				
Division:				
Street1*:	310 Harrington Street			
Street2:				
City*:	Raleigh			
County:				
State*:	CO: Colorado			
Province:				
Country*:	USA: UNITED STATES			
Zip / Postal Code*:	276030000			
Phone Number*:	na	Fax Number:		
E-Mail*: ctivy.consulting@gmail.com				
Credential, e.g., agency login: CAITLYNTIVY				
Project Role*:	PD/PI	Other Project Role Category:		
Degree Type:	DPT, BS	Degree Year: 2016, 2010		
<b>Attach Biographical Sketch*:</b>	File Name:	Bio-Tivy-2024.03.20.pdf		
<b>Attach Current &amp; Pending Support:</b>	File Name:			

PROFILE - Senior/Key Person						
Prefix:	First Name*:	Alan	Middle Name	Last Name*:	Rosenbaum	Suffix:
Position/Title*:	Co-Founder and CEO					
Organization Name*:	Cervu Inc.					
Department:						
Division:						
Street1*:	113 DORCHESTER PINES CT					
Street2:						
City*:	Cary					
County:						
State*:	NC: North Carolina					
Province:						
Country*:	USA: UNITED STATES					
Zip / Postal Code*:	27511-5788					
Phone Number*:	7654124512		Fax Number:			
E-Mail*:	alan@cervuhealth.com					
Credential, e.g., agency login: a_rosenbaum						
Project Role*:	Other (Specify)		Other Project Role Category: Other significant contributor			
Degree Type:	MS, MS, MD, BS, BA		Degree Year: 2022,2020,2014,2008,2008			
Attach Biographical Sketch*:	File Name:		Bio-Rosenbaum-2024.03.15.pdf			
Attach Current & Pending Support:	File Name:					

PROFILE - Senior/Key Person						
Prefix:	First Name*:	Abigail	Middle Name	Last Name*:	Scheer	Suffix:
Position/Title*:	Co-Founder and Chief Design Officer					
Organization Name*:	Cervu Inc.					
Department:						
Division:						
Street1*:	113 DORCHESTER PINES CT					
Street2:						
City*:	Cary					
County:						
State*:	NC: North Carolina					
Province:						
Country*:	USA: UNITED STATES					
Zip / Postal Code*:	27511-5788					
Phone Number*:	None		Fax Number:			
E-Mail*:	abby@cervuhealth.com					
Credential, e.g., agency login: ABBY.SHEER						
Project Role*:	Other (Specify)		Other Project Role Category: Other significant contributor			
Degree Type:	MID, BFA		Degree Year: 2022, 2012			
Attach Biographical Sketch*:	File Name:		Bio-Scheer-2024.03.15.pdf			
Attach Current & Pending Support:	File Name:					

## BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.  
Follow this format for each person. DO NOT EXCEED FIVE PAGES.

---

NAME: Tivy, Caitlyn

---

eRA COMMONS USER NAME (credential, e.g., agency login): CAITLYNTIVY

---

POSITION TITLE: Chief Clinical Officer

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EDUCATION/TRAINING (*Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.*)

INSTITUTION AND LOCATION	DEGREE (if applicable)	END DATE MM/YYYY	FIELD OF STUDY
University of Denver, Denver, CO	BS	06/2010	Molecular Biology; Chemistry; Spanish
National Institutes of Health, Bethesda, Maryland	NIH training grant	06/2012	Postbaccalaureate Intramural Research Training Fellowship
University of Colorado Denver, Aurora, CO	DPT	12/2016	Physical Therapy
Evidence in Motion, Austin, TX	Resident	12/2017	Residency in Orthopedic Manual Physical Therapy

### A. Personal Statement

As the Principal Investigator of this grant, I will be tasked with overseeing the completion of this phase of product development. I will be coordinating and leading interviews with study participants who will be testing Cervu Health's mobile application (app) for dyspareunia and pelvic pain in female cancer survivors. As PI, I will collect, organize, and interpret data from our participant interviews and surveys, and I will liaise with other members of the Cervu team to generate actionable insights from this data that will inform the subsequent phases of our research and development.

During my early years of clinical work as a physical therapist, I undertook subspecialty training in pelvic health rehabilitation with the Herman & Wallace Pelvic Rehabilitation Institute. This training allowed me to found and grow a pelvic health program for people of all genders in the rural community where I live. I've continued to practice as a pelvic health and orthopedic specialist since that time; as a result, I've gained a deep understanding of the nuances of pelvic health rehabilitation.

From 2021 – 2023, I was employed by a health tech startup, Sword Health, which focused on musculoskeletal health and pain management. The company was growing rapidly, and I was soon recruited to assist in the development of their women's health vertical, Bloom.

Since 2020, I have been researching and writing for health tech and women's health companies. I specialize in translating the latest clinical research findings into plain language educational content for patients and providers. I also create provider-facing materials to increase awareness of new women's health products among healthcare professionals, and I provide clinical consulting services to emerging women's health, LGBTQ+ health, and femtech startups. I'm currently undergoing certification as a Femtech Medical Consultant to advance my skills as a clinical advisor to women's health tech companies.

As the Founder and President of my consulting and medical communications business, C Tivy Consulting, LLC, I routinely rely on my skills in project and resource management, client success, and strategic development. These skills will be invaluable in my role as Chief Clinical Officer at Cervu Health.

I'm a passionate advocate for women's health research and advancements. I serve on the Healthcare Professionals Advisory Board of a novel hormonal health application, and I volunteer my time as an ambassador for an organization promoting education, outreach, and support for young women with breast cancer. I look forward to continuing to contribute to advancements in women's health with this project.

1. Pisitkun P, Ha HL, Wang H, Claudio E, **Tivy CC**, Zhou H, Mayadas TN, Illei GG, Siebenlist U. Interleukin-17 cytokines are critical in development of fatal lupus glomerulonephritis. *Immunity*. 2012 Dec 14;37(6):1104-15. PubMed Central PMCID: PMC3594848.

## B. Positions, Scientific Appointments and Honors

### Positions and Scientific Appointments

- 2024 - Chief Clinical Officer, Cervu Health, Cary, NC  
2023 - Founder and President, C Tivy Consulting, LLC, Carbondale, CO  
2022 - 2023 Program Developer and Beta Testing Lead, Sword Health, LLC, Draper, UT  
2021 - 2023 Pelvic Health Specialist, Sword Health, Inc, Draper, UT  
2010 - 2012 Postbaccalaureate Intramural Research Fellow, National Institutes of Health, Bethesda, MD

### Honors

- 2018 - 2024 Physical Therapist Licensure, Colorado, Colorado Dept of Regulatory Agencies  
2017 - 2019 Physical Therapist Licensure, Texas, Executive Council of Physical Therapy & Occupational Therapy  
2014 - 2016 Inaugural Recipient of NWSS Scholarship for Rural Healthcare Providers, National Western Stock Show  
2024 Femtech Medical Consultant Certification, FemInnovation  
2021 Pelvic Health Capstone, Herman & Wallace Pelvic Rehabilitation Institute  
2018 Orthopedic Certified Specialist, American Board of Physical Therapy Specialties  
2016 Doctor of Physical Therapy (DPT), University of Colorado Denver, Anschutz Medical Campus  
2010 Summa Cum Laude Honors Graduate, University of Denver Honors College  
2010 Phi Beta Kappa Society Inductee, Phi Beta Kappa Honor Society

## C. Contribution to Science

1. I began my career in the basic biomedical sciences with undergraduate research in neuroendocrinology. I received an award for postbaccalaureate research at the NIH in Bethesda, MD. While at the NIAID, I worked on several projects in a basic immunology laboratory, investigating the mechanisms behind cytokine signaling pathways. One project resulted in a publication in *Cell: Immunity*, cited below.
  - a. Pisitkun P, Ha HL, Wang H, Claudio E, **Tivy CC**, Zhou H, Mayadas TN, Illei GG, Siebenlist U. Interleukin-17 cytokines are critical in development of fatal lupus glomerulonephritis. *Immunity*. 2012 Dec 14;37(6):1104-15. PubMed Central PMCID: PMC3594848.
2. After several years of clinical work as a physical therapist, I joined a health tech startup, Sword Health, in 2021. As a member of the founding team, I collaborated with clinical and non-clinical colleagues to design exercise protocols for Bloom's pelvic floor rehabilitation program. I collated background research on pelvic health conditions and health economics to support our telehealth platform. I also wrote more than 170 evidence-based educational articles for integration into Bloom's patient-facing application.

During my time at Bloom, I lead the beta testing program to validate the intra-vaginal device and the protocols we had developed to address more than 40 pelvic health conditions in people with vaginal anatomy. I onboarded and educated our beta testers, directed clinical adjustments to their protocols, and collected data on symptom improvement, pain reduction, quality of life change, and satisfaction with the platform. I used a subset of these data to write a white paper on menopause in the workplace and Bloom's solution.

**BIOGRAPHICAL SKETCH**

Provide the following information for the Senior/key personnel and other significant contributors.  
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: Rosenbaum, Alan

ERA COMMONS USER NAME (credential, e.g., agency login): a\_rosenbaum

POSITION TITLE: Co-Founder and CEO

EDUCATION/TRAINING (*Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.*)

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
Indiana University, Bloomington, Indiana	BA	05/2008	Chemistry, Spanish
Indiana University, Bloomington, Indiana	BS	05/2008	Biology
University of Pittsburgh, Pittsburgh, Pennsylvania	MD	06/2014	Global Health Area of Concentration
The Ohio State University, Columbus, Ohio	Resident	06/2018	Obstetrics and Gynecology
University of North Carolina, Chapel Hill, NC	Fellow	06/2020	Global Women's Health
University of North Carolina, Chapel Hill, NC	MS	06/2020	Clinical Research, Technology Commercialization and Entrepreneurship, Global Health
University of North Carolina, Chapel Hill, NC	Fellow	09/2021	Women's Reproductive Health Fellowship
North Carolina State University and University of North Carolina, Raleigh, NC	MS	06/2022	Biomedical Engineering
American Board of Obstetrics and Gynecology, Dallas, TX	Other training	present	Board certification

**A. Personal Statement**

As an obstetrician-gynecologist with interest in global health and biomedical engineering, I have pursued several ongoing projects with engineering teams at multiple institutions. My primary research projects aim to improve access to technology in low-resource locations. Past and current projects include the development of a low-cost novel obstetric ultrasound for global health use in collaboration with Google and the Bill and Melinda Gates Foundation, a containment system for tissue extraction during minimally invasive gynecologic surgery, a treatment tool for Bartholin's cysts and abscesses, and a therapy device to improve access to care for female cancer survivors with dyspareunia and chronic pain. I've filed provisional patents, founded start-up companies, and pursued and won funding awards that support diverse academic and private industry activities such as epidemiological analyses, stakeholder group meetings, device engineering, and business development.

As part of three years of post-medical training research fellowships, I have completed two Master of Science degrees: one in Clinical Research and one in Biomedical Engineering. I've had the opportunity to collaborate with engineers in projects that span across the research spectrum, from bench top and translational research to user testing and clinical studies. These experiences help build upon the knowledge that I gain from daily clinical practice to understand unmet needs and the systems into which potential solutions will be deployed and operate. A significant proportion of referrals to gynecologists are for chronic pain and dyspareunia. In my 10 years of

experience providing gynecologic care, I've seen first-hand the toll that that these conditions takes on cancer survivors; a group poorly served by current treatments.

My underlying mission is to use new technologies to improve access to care for women and children, combining the varying benefits and interests of academia, philanthropy, and private industry across the specialties of medicine and engineering to create novel technologies that will enhance the quality and delivery of care for women locally, nationally, and internationally. I seek to collaborate with others who are committed to tackling difficult challenges and aim to do so by bringing together teams of innovators who share a similar vision.

1. Cai Q, Hu J, Chen M, Prieto J, **Rosenbaum AJ**, Stringer JSA, Jiang X. Inertial Measurement Unit Assisted Ultrasonic Tracking System for Ultrasound Probe Localization. *IEEE Trans Ultrason Ferroelectr Freq Control*. 2022 Sep 23;PP PubMed PMID: 36150002.
2. Sizer C, Scheer A, **Rosenbaum AJ**, inventors. North Carolina State University and University of North Carolina - Chapel Hill, assignee. A Treatment Device for Dyspareunia and Pelvic Pain. USA 63317353. 2022 March 07.
3. **Rosenbaum AJ**, Smith RM, Hade EM, Gupta A, Yilmaz A, Cackovic M. Use and experiences with external fetal monitoring devices among obstetrical providers. *J Matern Fetal Neonatal Med*. 2020 Jul;33(14):2348-2353. PubMed Central PMCID: PMC6561831.
4. **Rosenbaum AJ**, Maine RG. Improving Access to Laparoscopy in Low-Resource Settings. *Ann Glob Health*. 2019 Aug 19;85(1) PubMed Central PMCID: PMC6707090.

## **B. Positions, Scientific Appointments, and Honors**

### **Positions and Scientific Appointments**

- 2022 - OBGYN Hospitalist, UNC Rex Healthcare, Raleigh, NC  
2022 - Subspecialty Exploration Task Force Member, Society of OBGYN Hospitalists  
2022 - CEO and Cofounder, Cervu, Cary, NC  
2021 - Strategic Advisor, Kalia Health  
2021 - Strategic Advisor, Levi Diagnostics  
2012 - 2013 Grantee to El Salvador, Fulbright U.S. Student Program, U.S. Department of State, San Salvador

### **Honors**

- 2022 First and Third Place Entrepreneurship-Games - \$14,000 award, North Carolina State University  
2022 Flash Grant - \$20,000 award, North Carolina Biotechnology Center  
2022 Andrews Launch Accelerator - \$12,000 award, North Carolina State University  
2021 TraCS \$2k Stakeholder Grant - \$2,000 award, University of North Carolina  
2019 Bowes-Cefalo Young Research Award - \$1,950 award, University of North Carolina  
2018 UNC Zambia Hub Travel Award - \$2,000 award, University of North Carolina  
2017 REDCap Award - \$1,100 award, The Ohio State University  
2017 First Gear Program - \$3,000 award, University of Pittsburgh  
2015 Resident Award in Student Teaching, Ohio State University  
2014 Center for Medical Innovation - \$10,000 award, University of Pittsburgh

## **C. Contributions to Science**

1. Co-founder and CEO of women's health cancer care solution company Cervu, which seeks to improve at-home pelvic floor physical therapy treatment for female cancer survivors suffering from dyspareunia and chronic pelvic pain. Based upon technology developed through my biomedical engineering master's program, Cervu technology was created through the development of dozens of prototypes refined via feedback from female cancer patients and pelvic floor physical therapists. We have been awarded a half-dozen non-dilutional grants totaling approximately \$40,000. The company is incorporated and is licensing the technology from NCSU/UNC, who hold the provisional patent for the technology. The company is building a minimum viable product with the collaboration of a mechanical engineer to allow for subsequent user device testing and fundraising.

- a. Sizer C, Scheer A, **Rosenbaum AJ**, inventors. North Carolina State University and University of North Carolina - Chapel Hill, assignee. A Treatment Device for Dyspareunia and Pelvic Pain. USA 63317353. 2022 March 07.
  - b. Scheer A, **Rosenbaum A**, Sizer C. Cancer + Dyspareunia: Decreasing pain with intercourse for women. North Carolina State University Industry Advisory Board Meeting; 2021 November 19; Durham, NC.
2. The Fetal Age and Machine Learning Initiative (FAMLI) is a Bill and Melinda Gates Foundation-funded initiative containing four components: (1) curation of historical obstetric ultrasound images with attached clinical metadata, (2) collection of prospective obstetric ultrasound images (2D, cineloop, 3D) according to a defined protocol, (3) development and integration of a probe position sensor system, and (4) training deep learning algorithms to recognize and measure structures and make certain diagnoses. We have accessed and curated tens of thousands of historical ultrasound images from the United States and Zambia are in the initial stages of using machine learning to classify fetal anatomic still-frame ultrasound images and segment the structures to allow for measurement and calculation of the fetal gestational age.
  - a. Cai Q, Hu J, Chen M, Prieto J, **Rosenbaum AJ**, Stringer JSA, Jiang X. Inertial Measurement Unit Assisted Ultrasonic Tracking System for Ultrasound Probe Localization. *IEEE Trans Ultrason Ferroelectr Freq Control*. 2022 Sep 23;PP PubMed PMID: 36150002.
  - b. Cai Q, Peng C, Lu JY, Prieto JC, **Rosenbaum AJ**, Stringer JSA, Jiang X. Performance Enhanced Ultrasound Probe Tracking With a Hemispherical Marker Rigid Body. *IEEE Trans Ultrason Ferroelectr Freq Control*. 2021 Jun;68(6):2155-2163. PubMed PMID: 33560983.
  - c. Prieto J, **Rosenbaum AJ**, Jiang X, Skandarajah A, Price JT, Stamilio D, Stringer JSA. Fully Automated Gestational Age Prediction with Fetal Biometry Images and Deep Neural Networks: The Fetal Age and Machine Learning Initiative (FAMLI). American Institute of Ultrasound in Medicine; 2019; Orlando, FL, USA.
  - d. **Rosenbaum AJ**, Prieto J, Jiang X, Skandarajah A, Price JT, Stamilio D, Stringer JSA. Developing an Improved Obstetric Ultrasound for Use in Low-Resource Settings: the Fetal Age and Machine Learning Initiative (FAMLI). American Institute of Ultrasound in Medicine; 2019; Orlando, FL, USA.
3. As part of the Fulbright Award, I investigated a low-cost HPV self-test to prevent cervical cancer in rural El Salvador as part of Dr. Miriam Cremer's team. Focuses of the project in which I participated included patient acceptability, adherence to screening during the trial, as well as patient perception of cervical cancer risk. Our group demonstrated that a low-cost HPV self-test cervical cancer screening programs is an acceptable option for low-resource settings. In this project, I led a team of Research Assistants who administered questionnaire survey, provided cervical cancer education programs, and collected research data. I had a primary role in data management, statistical evaluation of the study results and drafting manuscripts.
  - a. **Rosenbaum AJ**, Figueroa R, Rowland M, Maza M, Alfaro K, Chang J, Cremer M. Cervical cancer risk perceptions and justifications among women in rural El Salvador. American Congress of Obstetricians and Gynecologists, Annual Clinical and Scientific Meeting; 2017; San Diego, California, USA.
  - b. Alfaro KM, Gage JC, **Rosenbaum AJ**, Ditzian LR, Maza M, Scarinci IC, Miranda E, Villalta S, Felix JC, Castle PE, Cremer ML. Factors affecting attendance to cervical cancer screening among women in the Paracentral Region of El Salvador: a nested study within the CAPE HPV screening program. *BMC Public Health*. 2015 Oct 16;15:1058. PubMed Central PMCID: PMC4609068.
  - c. **Rosenbaum AJ**, Gage JC, Alfaro KM, Ditzian LR, Maza M, Scarinci IC, Felix JC, Castle PE, Villalta S, Miranda E, Cremer ML. Acceptability of self-collected versus provider-collected sampling for HPV DNA testing among women in rural El Salvador. *Int J Gynaecol Obstet*. 2014 Aug;126(2):156-60. PubMed PMID: 24880188.
4. Within my interest in device development, I have submitted several invention disclosures to the universities where I have worked or studied. Most projects have won varying amounts of funding awards for development of prototypes from university-based funding sources. However, as my research interest grew, I realized that pursuing non-university funding awards would require a dedication to publishing in peer-reviewed journals. Recently, for a project involving an analysis of shortcomings of current external fetal monitoring systems and the clinical need for an improved device, an abstract was submitted and accepted for an upcoming

international conference with a manuscript submitted for publication. We plan to pursue DOE or NIH funding to continue working to develop an improved external fetal monitoring device.

- a. **Rosenbaum AJ**, Smith RM, Hade EM, Gupta A, Yilmaz A, Cackovic M. Use and experiences with external fetal monitoring devices among obstetrical providers. *J Matern Fetal Neonatal Med.* 2020 Jul;33(14):2348-2353. PubMed Central PMCID: PMC6561831.
- b. **Rosenbaum AJ**, Smith R, Hade E, Gupta A, Yilmaz A, Cackovic M. Use and experiences with external fetal monitoring devices among obstetrical providers. International Federation of Gynecologists and Obstetricians, World Congress; 2018; Rio de Janeiro, Brazil.

**BIOGRAPHICAL SKETCH**

Provide the following information for the Senior/key personnel and other significant contributors.  
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: Abigail Scheer

ERA COMMONS USER NAME (credential, e.g., agency login): abby.sheer

POSITION TITLE: Co-Founder and Chief Design Officer

EDUCATION/TRAINING (*Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.*)

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
Rhode Island School of Design, Providence, RI	Bachelor of Fine Arts Certificate	06/2012	Textile Design
Parsons School of Design, New York City, NY		12/2018	Design Leadership and Business
North Carolina State University, Raleigh, NC	Master of Industrial Design	05/2022	Industrial Design

**A. Personal Statement**

As a multidisciplinary designer, I am equipped and well versed in communicating across many disciplines, stakeholders, and partners. I am a passionate user advocate in every phase of the design and manufacturing process. I have spent my career designing products that serve a wide range of needs. As a textile designer, I worked in vertically integrated mills. I developed skills and experience in creative direction, planning, implementing pilot production, and working across sales, marketing, operations, and manufacturing to maintain production and quality. My interest in materials, manufacturing, and marketing developed by leading the expansion of a contract textile division. My technical skills in yarn/color development and weave programming were utilized in leading R&D projects that pushed the limits of material and manufacturing.

My expansion into industrial design – specifically medical device development – has further honed my skills at creating innovative and visionary products that serve the needs of many types of stakeholders. Working at both the front-end innovation phase as well as design for manufacturing has equipped me to leverage my previous experiences in new ways. My training in human factors psychology and research test methods have complemented my user centered design practice. The understanding of human cognition including mental workload, mental models, and attention has informed the way I approach research, design ideation, and user testing. I am confident in my ability to design user feedback research, execute and disseminate qualitative feedback into design requirements, and execute these requirements within a creative product development process. My passion for women's health has propelled me to focus my design career on the research and development of devices and mobile apps that holistically address a woman's life. As a co-founder of a women's health company, Cervu, and member of the Cambridge Design Partnership Femtech Team, I continue to support, innovate, and propel forward the needs of women and products and services that will continue to positively contribute to their health and wellbeing.

## B. Positions, Scientific Appointments, and Honors

### Positions

2022 – current	Co-Founder and Chief Design Officer, Cervu, Cary, NC
2022 – current	Industrial Design Associate, Cambridge Design Partnership, Raleigh, NC
2019 – 2022	Industrial Design Master's Student, Raleigh, NC
2021 – 2021	Industrial Design Intern, Cambridge Design Partnership, Raleigh, NC
2021 – 2021	Industrial Design Intern, Trig – Industrial Design Firm, Raleigh, NC
2019 – 2022	Graduate Teaching Assistant, North Carolina State University, Raleigh, NC
2019 – 2019	Senior Textile Designer, Decorative Fabrics of America, Burlington, NC
2012 – 2018	Textile Designer, Valdese Weavers, Valdese, NC
2012 – 2012	Technical Textile Designer, West Elm, Brooklyn, NY

### Honors

2022	Gold Award, International Design Excellence Awards, Industrial Designers Society of America
2022	1 <sup>st</sup> Place NC State Graduate Research Symposium, NC State Graduate School Student Association
2022	Graduate Faculty Award for Academic Excellence, Industrial Design, North Carolina State University
2022	\$3,000 Award, 3 <sup>rd</sup> Place Think Category, NCSU eGames, North Carolina State University
2022	\$20,000 Award, NC Biotech Flash Grant, NC Biotechnology Center, Durham, NC
2022	\$1,500 Award, VentureWell Innovator Stipend, VentureWell E-Team Program, Hadley, MA
2021	\$2,000 Award, TraCS Stakeholder Grant, NC TraCS Institute, Chapel Hill, NC
2021	\$450 Award, Industrial Design Academic Enhancement Grant, North Carolina State University
2020	\$400 Award, Industrial Design Academic Enhancement Grant, North Carolina State University
2018	Fresh Exhibition 1st place (juried), CAM Museum
2018	Hand Weaving Accessories Category-2nd Place, Blue Ridge Fiber Show
2016	Museum of New Mexico Design Winner, Museum of New Mexico Advisory Board
2015	Extreme Fibers Exhibitor (juried), Muskegon Museum of Art
2014	Exhibitor (juried), Fine Contemporary Craft of the Southeastern US
2012	Outstanding Senior Award, Rhode Island School of Design

## C. Contributions to Science

1. Co-founder and Chief Design Officer of Cervu, a women's health cancer care solution company seeking to provide better treatment options for female cancer survivors suffering from dyspareunia and chronic pelvic pain. Following design of the technology during my biomedical engineering master's program, Cervu was founded to further develop and commercialize the technology. We have been awarded non-dilutional grants totaling approximately \$40,000, some of which has been used to engage stakeholders (cancer survivors and providers) to provide critical feedback on 'looks-like' prototypes during the design refinement phase. For the proposed SBIR project, Cervu intends to build a prototype mobile application to allow for subsequent pre-formative user testing. Development progress achieved will be used for additional fundraising necessary for commercialization.
  - a. Sizer C, **Scheer A**, Rosenbaum AJ., Inventors. North Carolina State University and University of North Carolina - Chapel Hill, assignee. A Treatment Device for Dyspareunia and Pelvic Pain. USA 63317353. 2022 March 07.
  - b. **Scheer A**, Rosenbaum A, Sizer C. Cancer + Dyspareunia: Decreasing pain with intercourse for women. North Carolina State University Industry Advisory Board Meeting; 2021 November 19; Durham, NC.
2. The North Carolina State University Graduate School and Graduate Student Association host an annual, Research Symposium each spring. The poster presentations include more than 200 graduate students

– across all colleges - from North Carolina State University and students are nominated by Directors of Graduate Programs to participate in the symposium. Posters are judged by faculty. The goal is to showcase the outstanding quality and diversity of graduate-level research at NC State.

- a. **Scheer A**, 1<sup>st</sup> Place – Design Category: Cancer and Dyspareunia: Decreasing Pain with Intercourse for Women.

## RESEARCH &amp; RELATED BUDGET - SECTION A &amp; B, Budget Period 1

UEI\*: KED8PDBTFTL3

Budget Type\*:  Project  Subaward/Consortium

Enter name of Organization: CERVU, INC

Start Date\*: 12-01-2024

End Date\*: 12-31-2025

Budget Period: 1

A. Senior/Key Person												
Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base	Calendar	Academic	Summer	Requested	Fringe	Funds Requested (\$)*
						Salary (\$)	Months	Months	Months	Salary (\$)*	Benefits (\$)*	
1.	Caitlyn		Tivy		PD/PI	194,133.00	4.2			72,800.00	13,104.00	85,904.00
<b>Total Funds Requested for all Senior Key Persons in the attached file</b>												
Additional Senior Key Persons: File Name:										<b>Total Senior/Key Person</b>		<b>85,904.00</b>

## B. Other Personnel

Number of Personnel*	Project Role*	Calendar	Months	Academic	Months	Summer	Months	Requested Salary (\$)*	Fringe	Benefits*	Funds Requested (\$)*
Post Doctoral Associates											
	Graduate Students										
	Undergraduate Students										
	Secretarial/Clerical										
1	UX Engineer		3.0					22,100.00	3,978.00		26,078.00
1	<b>Total Number Other Personnel</b>								<b>Total Other Personnel</b>		<b>26,078.00</b>
<b>Total Salary, Wages and Fringe Benefits (A+B)</b>											<b>111,982.00</b>

RESEARCH &amp; RELATED Budget {A-B} (Funds Requested)

**RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 1**

UEI\*: KED8PDBTFTL3

Budget Type\*:  Project  Subaward/Consortium

Organization: CERVU, INC

Start Date\*: 12-01-2024

End Date\*: 12-31-2025

Budget Period: 1

**C. Equipment Description**

List items and dollar amount for each item exceeding \$5,000

Equipment Item

Funds Requested (\$)\*

Total funds requested for all equipment listed in the attached file

Total Equipment

0.00

Additional Equipment: File Name:

**D. Travel**

Funds Requested (\$)\*

1. Domestic Travel Costs ( Incl. Canada, Mexico, and U.S. Possessions)

2. Foreign Travel Costs

Total Travel Cost

0.00

**E. Participant/Trainee Support Costs**

Funds Requested (\$)\*

1. Tuition/Fees/Health Insurance

2. Stipends

3. Travel

4. Subsistence

5. Other:

Number of Participants/Trainees

Total Participant Trainee Support Costs

0.00

RESEARCH &amp; RELATED Budget {C-E} (Funds Requested)

## RESEARCH &amp; RELATED BUDGET - SECTIONS F-K, Budget Period 1

UEI\*: KED8PDBTFTL3

Budget Type\*:  Project  Subaward/Consortium

Organization: CERVU, INC

Start Date\*: 12-01-2024

End Date\*: 12-31-2025

Budget Period: 1

F. Other Direct Costs		Funds Requested (\$)*
1. Materials and Supplies		
2. Publication Costs		
3. Consultant Services		
4. ADP/Computer Services		2,592.00
5. Subawards/Consortium/Contractual Costs		
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. CRO - Guidea		141,933.00
9. Technical assistance		6,500.00
	<b>Total Other Direct Costs</b>	<b>151,025.00</b>

G. Direct Costs		Funds Requested (\$)*
	<b>Total Direct Costs (A thru F)</b>	<b>263,007.00</b>

H. Indirect Costs		Indirect Cost Rate (%)	Indirect Cost Base (\$)	Funds Requested (\$)*
Indirect Cost Type				
1 . Modified Total Direct Costs		40.0	256,567.00	102,627.00
	<b>Total Indirect Costs</b>			<b>102,627.00</b>
<b>Cognizant Federal Agency</b>				
(Agency Name, POC Name, and POC Phone Number)				

I. Total Direct and Indirect Costs		Funds Requested (\$)*
	<b>Total Direct and Indirect Institutional Costs (G + H)</b>	<b>365,634.00</b>

J. Fee		Funds Requested (\$)*
		<b>25,144.00</b>

K. Total Costs and Fee		Funds Requested (\$)*
		<b>390,778.00</b>

L. Budget Justification*	File Name: BJ_w_q_Cervu_3.23.24.pdf
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RESEARCH &amp; RELATED Budget {F-K} (Funds Requested)

## **BUDGET JUSTIFICATION**

Upon careful review of the budget required to complete the Aims as outlined, and review of the eligible waiver topics, we respectfully request the following budget outlined that is in excess of the hard cap. This document justifies the budget and provides a basis for inclusion of the waiver topics. As stipulated in the NIH published guidance titled, "Health and Human Services (HHS) Approved SBIR/STTR Topics for Awards over Statutory Budget Limitations", Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) Gynecologic Health and Disease Branch will consider "P. Development of marketable novel or improved methods, devices, and technologies for the diagnosis, monitoring, and therapy of uterine fibroids, endometriosis, adenomyosis, benign ovarian cysts, abnormal uterine bleeding (including amenorrhea and heavy menstrual bleeding/menorrhagia), reproductive tract abnormalities (including congenital structural abnormalities and complications from female genital cutting), female pelvic floor disorders (including drugs and devices used for treatment of pelvic organ prolapse, urinary incontinence, fecal incontinence, and other female pelvic floor disorders), and gynecologic pain disorders (including chronic pelvic pain, vulvodynia, and dysmenorrhea)." Because we are developing a mobile application for progress tracking of pelvic pain and dyspareunia in female cancer survivors, we request a hard-cap budget waiver for this proposal

### **PERSONNEL \$111,982**

#### **Senior/Key Personnel**

##### **Caitlyn Tivy, DPT, PD/PI (4.2 months)**

Dr. Tivy is Chief Clinical Officer and will serve as Principal Investigator. She has several years of clinical experience as a physical therapist followed by private industry experience in a health tech startup focused on pelvic floor rehabilitation programs. She has ample experience in women's health and digital health product development to lead this project. Dr. Tivy will work closely with the CEO/OBGYN, Chief Design Officer, software prototyping partner, UX Designer, and regulatory and reimbursement experts to guide commercialization efforts with the objective of gaining patient and provider feedback for the prototype software app developed in this SBIR Phase I project.

#### **Other Personnel**

##### **Maggie Jarrett, BS, UX Designer (3.0 months)**

Ms. Jarrett is the lead UI/UX Designer for Cervu and will be responsible for the creation of the visual language and interactive components of the mobile application project plan, feature set translation, user tasks and flows, and developing a usable interface based upon user feedback. She will work under the direct supervision of Dr. Tivy.

## **OTHER SIGNIFICANT CONTRIBUTORS**

### **Abigail Scheer, MFA, MID**

Ms. Scheer is a Cervu Co-founder and its Chief Design Officer. She is skilled in front-end innovation concept exploration, user research, ideation and prototyping, human centered product development, and design for manufacturing. Ms. Scheer will guide product development, QMS management, and design history file documentation. She will not be paid a salary for participation in the project.

### **Alan Rosenbaum, MD, MSCR, MSMBE**

Dr. Rosenbaum is a Cervu Co-founder and its Chief Executive Officer. He is a practicing board-certified obstetrician-gynecologist with expertise in gynecology, patient interviewing, and clinical trial design. Dr. Rosenbaum manages the patient and clinician stakeholder group. He will provide an OBGYN clinical perspective and guidance and will not be paid a salary for participation in the project.

### **AUTOMATIC DATA PROCESSING AND COMPUTER SERVICES \$2,592**

Funding is requested to purchase three seats for Figma for one year for wireframe development (\$432), and 2 seats for Adobe Creative Cloud for one year for their suite of design and development software (\$2160).

## **FEE FOR SERVICE CONTRACTS \$141,993**

### **Guidea, LLC \$141,993**

Guidea will provide software design consulting and software prototype development services as well as assist in garnering patient and provider feedback. (See **SOW**)

### **INDIRECT COSTS**

An indirect cost rate of 40% has been applied to all direct costs (there are no sub-award or equipment costs).

### **FEE**

A fee of 7% is requested which we believe demonstrates a reasonable profit margin for for-profit organizations performing research and development work.

## **DISCRETIONARY TECHNICAL ASSISTANCE \$6,500**

We request \$6,500 in discretionary technical assistance for technical regulatory guidance from our regulatory advisors at Proxima Clinical Research, Inc. (See **Quote**). We will consult with regulatory experts at Proxima to assist with FDA 513(g) packet preparation and submission and QMS support. Pursuant to 84 FR 12794 published by the Small Business Administration, these funds are requested above and beyond the hard cap budget limits prescribed. Cervu anticipates significant benefits will arise from this support, as it will position the product for a more strategic and protected commercialization pathway.



## Statement of work for services

This Statement of Work (“SOW #1”) is executed in connection with and subject to the Services Agreement, dated as of March 11, 2024, as amended from time to time (the “Agreement”), by and between Theresa Neil Interface Designs LLC, DBA: Guidea, (“Guidea”) and Cervu, Inc, (“Company”).

### Project Dates

#### Guidea Project Team

- Lead Researcher
- UX Designer
- Detail Designer

#### Scope of Services

Guidea to provide services on the Patient UX iPhone App project as follows:

Phase	Approach	Corresponding Deliverables
<b>Alignment</b> (2 weeks)	<ul style="list-style-type: none"> <li>- Journey mapping workshop</li> <li>- Concept collaboration</li> </ul>	<ul style="list-style-type: none"> <li>- Draft journey map</li> <li>- List of prioritized concepts</li> </ul>
<b>Concept Design &amp; Validation</b> (7 weeks)	<ul style="list-style-type: none"> <li>- Concept Design</li> <li>- Methodology Design</li> <li>- Research: 12, 1:1 remote sessions</li> <li>- Synthesis</li> <li>- Readout &amp; prioritization workshop with team</li> <li>- <i>Note: Style tiles will be developed by Cervu designer and incorporated into testing by the Guidea team</i></li> </ul>	<ul style="list-style-type: none"> <li>- Testing plan</li> <li>- Testable concepts for research sessions</li> <li>- Raw videos and transcripts (from research)</li> <li>- Updated concepts based on research insights</li> <li>- Final summary report of insights and recommendations</li> <li>- List of prioritized workflows for detailed design phase</li> </ul>
<b>Detailed Design</b> (4 weeks)	<ul style="list-style-type: none"> <li>- Detailed design phase focusing on the prioritized flows in a single modality, designed for iOS</li> <li>- <i>Note: Additional screen designs for other modalities and/or formats will be done by Cervu</i></li> </ul>	<ul style="list-style-type: none"> <li>- Detailed design for 4-5 workflows (max 60 iOS screens/screen states)</li> </ul>



<b>Usability Study &amp; Design Updates (4 weeks)</b>	<ul style="list-style-type: none"> <li>- Methodology Development</li> <li>- Recruiting</li> <li>- Testing 12 users, 1:1 remote 60 minute sessions</li> <li>- Synthesis</li> <li>- Design Updates</li> </ul>	<ul style="list-style-type: none"> <li>- Raw testing data (videos and transcripts)</li> <li>- Final research report</li> <li>- Updated designs</li> </ul>
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See attached project plan for detailed timeline.

#### Assumptions

- Designs will be delivered in Figma in 1 Form Factor (iOS)
- Maximum number of 2 rounds of revision are included. Additional rounds of revisions may impact cost and timeline.
- No Code, CSS or HTML will be delivered as part of Design Deliverables.
- Recordings of research sessions will be provided except in the case of blind or double blind studies where participant identity must be anonymous, in which case redacted transcripts will be provided.

#### Company Responsibilities

- Providing a single point of contact to act as the Project Manager to coordinate activities and assignments of the collective teams.
- Ensuring that all necessary Company stakeholders will be available for applicable meetings, including before, during and after design reviews to answer questions and provide supporting material and feedback within mutually agreed upon project schedule

#### Fees and Payment

The services outlined in this SOW will be provided to Company on a time and materials basis, billed twice monthly in arrears, using the following rate schedule. Partial weeks will be billed on a prorated basis.

Resource	Est. Time	Weekly Rate	Cost	Cost with Femtech Discount (15%)
Lead Researcher	11.4 wks	\$8,000/wk	\$91,200	\$77,520
UX Designer	4.75 wks	\$7,400/wk	\$35,150	\$29,878
Detail Designer	5.5wks	\$7,400/wk	\$40,700	\$34,595
<b>Cost:</b>			<b>\$167,050</b>	<b>\$141,993</b>

Expense costs for participant incentives and recruiting, should they be required, are not included in the above estimate. All expenses will be approved in advance, and will be directly passed through with no markup, with supporting invoices/receipts. Expenses are invoiced monthly in arrears.

Billing Contact: Alan Rosenbaum (Alternate to main Point of Contact)

Email: alan@cervuhealth.com Phone: 765-412-4512



### Additional Terms and Conditions

In the event that additional scope is requested, a change order identifying changes to timelines or additional cost would be mutually agreed upon in advance and executed.

In the case of a pause or termination of work, or reduction in scope, Company will give a minimum of 30 days' notice, and will be charged for resources at the allocations and rates described in this SOW, throughout that notice period.

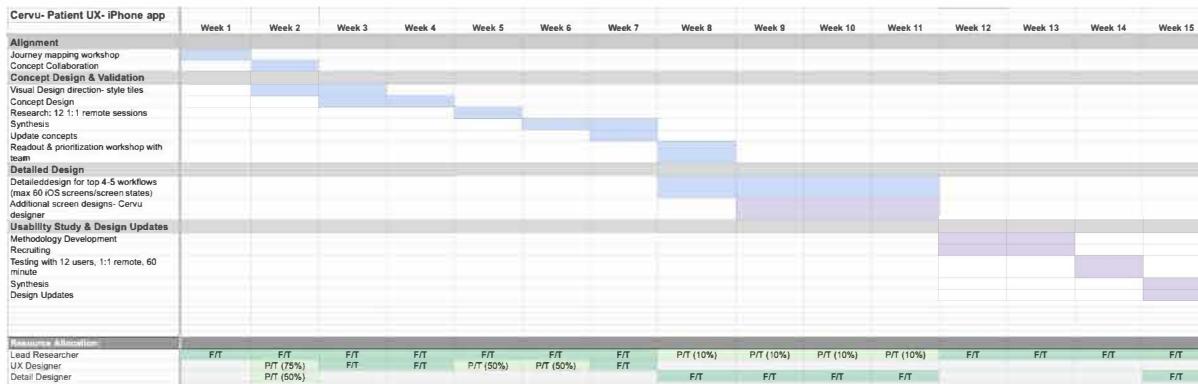
In the case of a stop, pause or reduction in scope with less than 30 days remaining in the project timeline, Company will be charged the remaining balance of budget.

Services provided are considered work for hire, the product of which shall be considered accepted upon completion. There will be no acceptance period for the fees incurred. Project Activities are anticipated to be carried out remotely.

This section must be signed by both parties in order for the project to commence. Guidea agrees to provide the services described in this Statement of Work on behalf of Company for the consideration set forth herein.

Cervu		Guidea	
By:		By:	
Name:	Alan Rosenbaum	Name:	Jessica Gentry
Title:	CEO, Co-Founder	Title:	COO
Date:	March 11, 2024	Date:	March 11, 2024

### Project Plan:





**Inventing Tomorrow Together**

Cervu

December 16, 2023

# Project Strategy and Cost Estimate

Prepared for:

**Cervu**

**Cervu**

Alan Rosenbaum  
Co-Founder & CEO  
113 Dorchester Pines Ct  
Cary, NC 27511  
alan@cervuhealth.com

## Proxima Clinical Research, Inc.

Chelsea Isaac  
Business Development Strategist  
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## PROPOSAL SUMMARY

Proxima Clinical Research, Inc. (Proxima) appreciates the opportunity to submit this proposal and budget estimate to Cervu for management of the regulatory and quality development for their pelvic floor physical therapy tool.

Cervu has requested the following services:

- 513(g) Packet & Submission
- QMS “SOP Starting Pack” Support
- General Regulatory and Quality Consulting

The estimated costs for this project are as follows:

BUDGET SUMMARY (USD)	
513(g) Packet and Submission	\$5,750 - \$8,000
QMS “SOP Starter Pack” Support	\$8,250
General RA/QA Consulting	\$4,000

We would be happy to discuss the above cost estimate with Cervu. As with any proposal, this is based on our understanding of your requirements and our assumptions regarding the proposed scope of work.

### 1. TASKS

#### 1.1 513(g) Packet and Submission

A 513(g) Request for information is a submission to FDA to obtain information about device classification and regulatory requirements that are applicable to your device. Proxima will draft a 513(g) with Cervu and submit on their behalf. The FDA has 60 days post-receipt of this submission to provide written feedback.

This submission will include information provided by Cervu about the device. Proxima requests that Cervu share the following information about the device:

- Device description and specifications,
- Proposed intended use statement,
- Intended clinical applications and labeling claims,
- Available test data, and
- Literature references and articles

If Cervu is eligible for the small business designation and has not already received this, we recommend initiating the process as soon as possible. FDA can take up to 60 days to review this status, and it is required before submission of the 513(g) to be eligible for the reduced small business fee.



## 1.2 QMS “SOP Starter Pack” Support

The Proxima Project Manager will be the primary point of contact for Cervu and will manage the project team that assists with the requested development of the SOP “Starter Pack.” This starter pack will consist of primary SOP templates that Proxima will provide to Cervu. Proxima will work with Cervu to customize these SOPs to Cervu’s infrastructure and product.

SOPs Templated & Supported:

1. Document Control and Change Management SOP
2. Record Control SOP
3. Design Controls SOP
4. Risk Management SOP
5. Software Lifecycle SOP
6. Supplier Qualification SOP

These SOPs also have dedicated work forms, which Cervu can complete for Proxima review or Proxima can create for Cervu’s review. This workflow could affect timelines and budget.

The templates provided and personalized by Proxima on behalf of Cervu are for Cervu use only, cannot be used to provide services competitive to Proxima for contract research or consulting services, and are not for resale. If Cervu wishes to purchase SOP templates for resale or to provide services outside of Cervu, a separate agreement and scope must be discussed by Cervu and Proxima.

## 1.3 General Regulatory and Quality Consulting

Proxima will assist Cervu with any additional regulatory or quality questions or issues as they work to develop their pelvic floor physical therapy device. This budget can be used to have bi-weekly meetings, answer email inquiries, provide review of regulatory documentation, or other hourly consulting tasks as requested by Cervu. Proxima will only perform work as requested by Cervu. The work requested will be performed on an hourly basis and invoiced monthly. Proxima will keep client apprised on the status of this budget as projects progress or as Cervu moves towards a specific milestone or deliverable.

# 2. PROXIMA TEAM

## 2.1 Relevant Experience

Proxima has worked with over 200+ medtech and biotech companies. Our team has extensive experience in the women’s health and physical therapy spaces, with staff backgrounds in both regulatory affairs and clinical trial management. Within these spaces, our team members have worked on over 40 projects including developing regulatory strategies, FDA submissions such as Pre-Submissions, QMS support, and various clinical activities.

The Proxima team has set up and managed QMS systems per 21 CFR 820 and ISO 13485:2016 for both large and small companies. Within this space, our team has worked to help provide SOP templates, write or review SOPs at any stage of development, develop eQMS & paper-based systems, performed Gap Analyses to ensure both 21 CFR 820 and ISO 13485 compliance, and managed post-market Quality Tasks.



We have identified a team that will bring the relevant knowledge, experience, and skills to successfully implement this project. Their specific experience and strengths are summarized below.

### **2.1.1 Director of Regulatory Affairs, Isabella Schmitt, MBA, RAC**

Proxima has assigned Isabella Schmitt, MBA, RAC to provide directorial leadership and support to the project team. She will serve as an escalation and communication point for Cervu as well as primary oversight and may provide final review. Isabella is the Director of Regulatory Affairs at Proxima Clinical Research where she has worked on over 100 medical device and drug product consulting projects, strategies, FDA interactions, breakthrough device designations, and pre-market applications across all stages of development for both large global companies and small local companies. Isabella has over a decade in the life sciences and medical industry. Prior to joining the Proxima team, Isabella served as the Senior Regulatory and Quality Manager at two medical device companies, where she was charged with outlining the regulatory strategy and putting together design controls and design history documentation. Additionally, as the Director of CMC and Quality at a biopharmaceutical company, she oversaw all manufacturing and analytical processes and timelines and ensured CMC regulatory strategy was sufficient for filings in Europe and the US. She has also served in additional regulatory affairs and clinical research roles in which she contributed to multiple regulatory submissions and clinical affairs projects across a wide range of indications. Isabella serves as an advisor, mentor, and speaker at multiple medical device accelerators.

### **2.1.2 Senior Manager of Regulatory Affairs, Ellie Reynolds, MBE**

Proxima has assigned Ellie Reynolds, MBE as the Senior Manager for this project. At Proxima, Ellie has been critical in managing QMS integration projects for large and small companies and has contributed to and authored several regulatory strategies, pre-submission packets, and pre-market submissions and has led 10 projects in the women's health and physical therapy spaces. Prior to joining Proxima, Ellie worked for a small life sciences consulting firm, where she performed market landscape assessments and provided strategic insights to major pharmaceutical companies. Ellie has a Master of Bioengineering, with a focus in Global Medical Innovation, from Rice University and has worked on multiple medical devices from need identification through the entire development process. She has also served in additional regulatory affairs and quality assurance roles in which she developed regulatory and technical transfer strategies for both medical device and pharmaceutical companies across a range of therapeutic areas.

### **2.1.3 Quality and Regulatory Affairs Manager, Michelle Lewis**

Proxima has chosen Michelle Lewis to support the regulatory and quality efforts and serve as the primary point of contact for Cervu. She has led several QMS projects in the women's health space. Michelle has 20+ years of experience in the life sciences industry and has served in many senior level regulatory and quality positions and contributed to multiple regulatory submissions and clinical affairs projects across a wide variety of indications. Immediately prior to joining the Proxima team, Michelle served as the Director of Accreditation at the premier standard setting body, non-profit, scientific, and educational organization, where she managed the accreditation program.



Michelle is ASQ CMDA and RAC certified, is passionate about engaging with startups, and is eager to assist with the advancement of innovative technologies in health care.

#### **2.1.4 Quality and Regulatory Affairs Manager, Rob MacCuspie, PhD**

Proxima has assigned Rob MacCuspie, PhD as the Project Manager and primary point of contact for Cervu. At Proxima, Rob works on various medical device and drug product consulting projects and submissions across all stages of development. He has led nearly 10 projects in the women's health and physical therapy spaces including developing regulatory strategies and FDA submissions. Prior to joining the Proxima team, Rob served as the VP of Science at a materials science startup. He led their entrance to the medical device space by identifying regulatory strategies and building their first quality management systems. He also served as Director of Science at a leading dietary supplement company. He contributed to the company's first medical device product development, regulatory and testing strategies, and developed and delivered product education for practitioners and consumers. He has previously been the First Faculty and Director of Nanotechnology and Multifunctional Materials programs on the startup team at Florida Polytechnic University and founded a consulting company to help scientific startups accelerate their path to market. Rob previously worked in the national lab system including the National Institutes of Standards and Technology - contributing with the Nanotechnology Characterization Lab collaboration between NIST, NCI, and FDA to develop standards and methods to accelerate cancer nanomedicines from bench to bedside. Rob earned a PhD in nanotechnology and materials chemistry from The Graduate Center of the City University of New York and completed a two-year postdoc at Air Force Research Lab on structure-property relationships of nanomaterials. Rob has published 45 peer-reviewed publications which have been cited over 3,700 times and holds a US Patent.

#### **2.1.5 Quality Affairs Associate II, Travia Belton**

Travia Belton currently serves as Quality Affairs Associate II at Proxima Clinical Research supporting many QMS clients and projects and has contributed to several QMS projects in the women's health space. Ms. Belton has worked in GCP, GCLP and CLIA regulated laboratories where she was charged with quality management and QA Oversight in lab operations. She also served as a QC Data Reviewer for another contract research organization where she reviewed data from pharmacokinetic and antidiug antibody studies. She is completing a Master of Science in biotechnology with a specialization in regulatory affairs. She also holds her Bachelor of Science in biology from the University of Maryland and is a certified Quality Improvement Associate.

#### **2.1.6 Regulatory Affairs Associate II, Syd Wiggins, MS**

Proxima has chosen Syd Wiggins as the Regulatory Affairs Associate for this project. At Proxima, she has worked on various medical device and drug product consulting projects and submissions across all stages of development, including 510(k), BDD, EUA, and IND submissions. She has contributed to over 10 projects in the women's health and physical therapy spaces including developing regulatory strategies and FDA submissions. Syd has experience in biomaterials, polymer chemistry, immunology, drug development and delivery, regenerative medicine, and tissue engineering. Prior to joining the Proxima team, Syd received her Master of Science in biomedical engineering from the University of Florida, where her research aimed



to improve the efficacy of islet transplantation for the treatment of type 1 diabetes by developing polymer scaffolds for localized drug/cytokine delivery and immuno-protective polymer cell coatings. She has experience planning, developing, and executing experiments for not only multiple independent projects, but also and collaborative research endeavors.

### 2.1.7 Regulatory Affairs Associate, Caroline Jennings

Proxima has chosen Caroline Jennings as a Regulatory Affairs Associate for this project. Prior to joining the Proxima team, she worked for a startup in Northwest Arkansas, where she completed customer and market research as well as the curation of an extensive marketing project portfolio, including pitch decks, blogs, social media content, and website content. She began her journey in the field of healthcare as an abstractor for Baptist Health Fort Smith, a role that required the interpretation and transport of patient data between two software platforms. Caroline graduated Summa Cum Laude from the University of Arkansas with degrees in both English and Mathematics, complemented by the addition of a Spanish minor. During her undergraduate career, she completed several semesters of mathematical research which involved original proof and MATLAB code writing in the process of determining a more efficient and precise Gram Schmidt algorithm. Caroline loves interacting within the startup environment and is excited to have the opportunity to contribute to the advancement of medical technologies.

## 3. DELIVERABLES

- A 513(g) Packet will be submitted to FDA to receive classification determination. We estimate this will be completed in about 4-6 weeks after all documents have been received.
- Proxima will provide Cervu with SOP templates and assist in customizing the templates to Cervu's product and infrastructure. Timeline is dependent on receipt of all required materials and input from Cervu.
- General regulatory and quality consulting will be provided by Proxima to fulfill regulatory, quality, and clinical support, as requested by Cervu.



#### 4. BUDGET ESTIMATE

The budget is based on the expected number of hours to complete this scope of work. If the scope of work changes, the budget may need to be revised.

BUDGET SUMMARY (USD)	
513(g) Packet and Submission	\$5,750 - \$8,000
QMS "SOP Starter Pack" Support	\$8,250
General RA/QA Consulting	\$4,000

Additional tasks requested by Cervu may be billed at an hourly rate. The hourly rates for various positions are found below.

HOURLY RATES (USD)	
RA/QA Director	\$315
Senior Manager of RA/QA	\$230
RA/QA Manager	\$205
RA/QA Specialist	\$185
RA/QA Associate II	\$165
RA/QA Associate	\$155

#### 5. GENERAL ASSUMPTIONS

1. This proposal is based on information provided by Cervu.
2. This proposal is valid for 30 days from the cover date. If no decisions on the awarding of this project are made within this time frame, the proposal may require amendment.
3. Proxima may begin work on this project upon execution of a contract.
4. Cost estimates are based on rates for year 2023.
5. Actual costs will be billed monthly.
6. This proposal is governed by an executed Master Services Agreement, other project-specific agreement, or a Time & Materials based contract.
7. The budget covers only the services specified in this proposal. Additional work will be outlined and agreed upon by Cervu and Proxima.
8. This proposal is confidential and shall not be discussed with any third party, excepting those as permitted by the Master Services Agreement or other contract.

**RESEARCH & RELATED BUDGET - Cumulative Budget**

	Totals (\$)
Section A, Senior/Key Person	85,904.00
Section B, Other Personnel	26,078.00
Total Number Other Personnel	1
Total Salary, Wages and Fringe Benefits (A+B)	111,982.00
Section C, Equipment	0.00
Section D, Travel	0.00
1. Domestic	0.00
2. Foreign	0.00
Section E, Participant/Trainee Support Costs	0.00
1. Tuition/Fees/Health Insurance	0.00
2. Stipends	0.00
3. Travel	0.00
4. Subsistence	0.00
5. Other	0.00
6. Number of Participants/Trainees	0
Section F, Other Direct Costs	151,025.00
1. Materials and Supplies	0.00
2. Publication Costs	0.00
3. Consultant Services	0.00
4. ADP/Computer Services	2,592.00
5. Subawards/Consortium/Contractual Costs	0.00
6. Equipment or Facility Rental/User Fees	0.00
7. Alterations and Renovations	0.00
8. Other 1	141,933.00
9. Other 2	6,500.00
10. Other 3	0.00
11. Other 4	0.00
12. Other 5	0.00
13. Other 6	0.00
14. Other 7	0.00
15. Other 8	0.00
16. Other 9	0.00
17. Other 10	0.00
Section G, Direct Costs (A thru F)	263,007.00
Section H, Indirect Costs	102,627.00

Section I, Total Direct and Indirect Costs (G + H)	365,634.00
Section J, Fee	25,144.00
Section K, Total Costs and Fee (I + J)	390,778.00

**SBIR/STTR Information**

Agency to which you are applying (select only one)\*

 DOE       HHS       USDA       Other:

SBC Control ID:\*

883061454

Program Type (select only one)\*

 SBIR       STTR Both (See agency-specific instructions to determine whether a particular agency allows a single submission for both SBIR and STTR)

Application Type (select only one)\*

 Phase I       Phase II       Fast-Track       Direct Phase II       Phase IIA       Phase IIB       Phase IIC Commercialization Readiness Program (See agency-specific instructions to determine application type participation.)

Phase I Letter of Intent Number:

\* Agency Topic/Subtopic:

Questions 1-8 must be completed by all SBIR and STTR Applicants:

1a. Do you certify that at the time of award your organization will meet the eligibility criteria for a small business as defined in the funding opportunity announcement?\*       Yes       No

1b. Anticipated Number of personnel to be employed at your organization at the time of award.\*      3

1c. Is your small business majority owned by venture capital operating companies, hedge funds, or private equity firms?\*       Yes       No1d. Is your small business a Faculty or Student-Owned entity?\*       Yes       No2. Does this application include subcontracts with Federal laboratories or any other Federal Government agencies?\*       Yes       No

If yes, insert the names of the Federal laboratories/agencies:\*

3. Are you located in a HUBZone? To find out if your business is in a HUBZone, use the mapping utility provided by the Small Business Administration at its web site: <http://www.sba.gov> \*       Yes       No4. Will all research and development on the project be performed in its entirety in the United States?\*       Yes       No

If no, provide an explanation in an attached file.      Explanation:\*

5. Has the applicant and/or Program Director/Principal Investigator submitted proposals for essentially equivalent work under other Federal program solicitations or received other Federal awards for essentially equivalent work?\*       Yes       No

If yes, insert the names of the other Federal agencies:\*

6. Disclosure Permission Statement: If this application does not result in an award, is the Government permitted to disclose the title of your proposed project, and the name, address, telephone number and email address of the official signing for the applicant organization to state-level economic development organizations that may be interested in contacting you for further information (e.g., possible collaborations, investment)?\*       Yes       No7. Does the application include a request of SBIR or STTR funds for Technical and Business Assistance (TABA)? If yes, please follow the agency specific instructions to provide the budget request and justification. (Please answer no if you plan to use the agency TABA vendor, which does not require you to include a request for TABA funds in your application.)\*       Yes       No

8. Commercialization Plan: The following applications require a Commercialization Plan: Phase I (DOE only), Phase II (all agencies), Phase I/II Fast-Track (all agencies). Include a Commercialization Plan in accordance with the agency announcement and/or agency-specific instructions.\*

Attach File:\*

## SBIR/STTR Information

### SBIR-Specific Questions:

Questions 9 and 10 apply only to SBIR applications. If you are submitting ONLY an STTR application, leave questions 9 and 10 blank and proceed to question 11.

9. Have you received SBIR Phase II awards from the Federal Government? If yes, provide a company commercialization history in accordance with agency-specific instructions using this attachment.\*

Yes  No

Attach File:\*

10. Will the Project Director/Principal Investigator have his/her primary employment with the small business at the time of award?\*

Yes  No

### STTR-Specific Questions:

Questions 11 - 13 apply only to STTR applications. If you are submitting ONLY an SBIR application, leave questions 11 - 13 blank.

11. Please indicate whether the answer to BOTH of the following questions is TRUE:\*

Yes  No

(1) Does the Project Director/Principal Investigator have a formal appointment or commitment either with the small business directly (as an employee or a contractor) OR as an employee of the Research Institution, which in turn has made a commitment to the small business through the STTR application process; AND

(2) Will the Project Director/Principal Investigator devote at least 10% effort to the proposed project?

12. In the joint research and development proposed in this project, does the small business perform at least 40% of the work and the research institution named in the application perform at least 30% of the work?\*

Yes  No

13. Provide UEI of non-profit research partner for STTR.\*

## PHS 398 Cover Page Supplement

### 1. Vertebrate Animals Section

Are vertebrate animals euthanized?  Yes  No

If "Yes" to euthanasia

Is the method consistent with American Veterinary Medical Association (AVMA) guidelines?

Yes  No

If "No" to AVMA guidelines, describe method and provide scientific justification

.....

### 2. \*Program Income Section

\*Is program income anticipated during the periods for which the grant support is requested?

Yes  No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

\*Budget Period \*Anticipated Amount (\$) \*Source(s)

### 3. Human Embryonic Stem Cells Section

\*Does the proposed project involve human embryonic stem cells?  Yes  No

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: [http://grants.nih.gov/stem\\_cells/registry/current.htm](http://grants.nih.gov/stem_cells/registry/current.htm). Or, if a specific stem cell line cannot be referenced at this time, check the box indicating that one from the registry will be used:

Specific stem cell line cannot be referenced at this time. One from the registry will be used.

Cell Line(s) (Example: 0004):

### 4. Human Fetal Tissue Section

\*Does the proposed project involve human fetal tissue obtained from elective abortions?  Yes  No

If "yes" then provide the HFT Compliance Assurance

If "yes" then provide the HFT Sample IRB Consent Form

### 5. Inventions and Patents Section (Renewal applications)

\*Inventions and Patents:  Yes  No

If the answer is "Yes" then please answer the following:

\*Previously Reported:  Yes  No

### 6. Change of Investigator/Change of Institution Section

Change of Project Director/Principal Investigator

Name of former Project Director/Principal Investigator

Prefix:

\*First Name:

Middle Name:

\*Last Name:

Suffix:

Change of Grantee Institution

\*Name of former institution:

## PHS 398 Research Plan

<b>Introduction</b>	
1. Introduction to Application (for Resubmission and Revision applications)	
<b>Research Plan Section</b>	
2. Specific Aims	SA-Cervu.pdf
3. Research Strategy*	RS-Cervu.pdf
4. Progress Report Publication List	
<b>Other Research Plan Section</b>	
5. Vertebrate Animals	
6. Select Agent Research	
7. Multiple PD/PI Leadership Plan	
8. Consortium/Contractual Arrangements	
9. Letters of Support	LOS_merged_Cervu_3.23.24.pdf
10. Resource Sharing Plan(s)	Resource_Sharing_Plan-Cervu.pdf
11. Other Plan(s)	DMSP-Cervu.pdf
12. Authentication of Key Biological and/or Chemical Resources	Authentication-Cervu.pdf
<b>Appendix</b>	
13. Appendix	

## SPECIFIC AIMS

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The widespread prevalence of pelvic pain and dyspareunia (pain with sexual intercourse) amongst female cancer survivors combined with low therapy adherence,<sup>1-3</sup> a lack of effective treatment progress tracking,<sup>4</sup> and therapy recall deficiencies<sup>5</sup> represent a large untapped opportunity. Cervu, Inc. is developing an innovative mobile application that will deliver at-home pelvic floor physical therapy diary logging, progress tracking, and provider communication to improve patient compliance, quality of life (QoL), and treatment recommendations.

Between 10-20% of women suffer from dyspareunia,<sup>6</sup> with a much higher incidence amongst female cancer survivors.<sup>7</sup> Even with non-gynecologic malignancies, surgery, radiation, and chemotherapy can cause dyspareunia and chronic pelvic pain by altering vaginal anatomy, causing tissue dryness and atrophy, reducing elasticity, and producing musculoskeletal dysfunction.<sup>8-10</sup> By 2025, advances in cancer treatment will enable 15 million female cancer survivors in the U.S. and E.U. to expect survival beyond 5 years, and over half of them will experience chronic pelvic pain and dyspareunia due to their cancer treatments.<sup>11</sup> Associated long-term negative mental and physical health consequences remain one of the most common issues affecting QoL.<sup>12,13</sup>

After an initial in-clinic evaluation and instruction on treatment options by pelvic floor physical therapists, who specialize in treating these conditions, the majority of therapy is subsequently performed at home. Regular clinic visits then assess progress, identify problems, and update the care plan. This paradigm requires frequent in-clinic visits which pose time, financial, and transportation burdens to women already inundated with cancer-related care. Additionally, outcomes are hampered by low therapy adherence, at-home therapy recall bias, and lack of progress tracking.<sup>1-5</sup> While remote therapy monitoring (RTM) was assigned billing codes in 2020, there are no comprehensive RTM solutions specifically tailored to the sexual health of female cancer survivors. This population has unique medical and technical needs due to their cancer diagnosis and treatments, typically older age, and other comorbidities which alter their ability to interact with treatment technologies. Survivors deserve a solution that provides them with the knowledge, skills, and confidence to advocate for their own sexual health.

Cervu, Inc. is developing a mobile application (app) designed for the highly individualized needs of female cancer survivors suffering from dyspareunia and chronic pelvic pain. The app is uniquely designed to track baseline chronic pain, sexual function, and the performance and progress of multiple therapies including dilation, vibration, myofascial release, and trigger point massage, which is then shared with the treatment team. This will be, to our knowledge, the first app designed specifically for sexual function and chronic pelvic pain in female cancer survivors. Such an app has the potential to: (i) improve patient outcomes and experience, (ii) improve adherence by providing progress tracking, (iii) increase access to care by reducing time, economic, and transportation barriers, (iv) reduce healthcare costs by shifting in-clinic visits to remote monitoring, (v) improve the quality of patient-reported therapy data, (vi) enable the clinician to create improved individualized exercise plans and provide remote supervision, and (vii) collect and analyze data from a connected device and the therapy diary to potentially drive future innovations.

Non-animated prototype wireframes have been provided to patients (n=6) and providers (n=11) for the purpose of obtaining initial feedback to refine UX designs. Results have allowed feature prioritization (n=11 high-priority features identified), ascertained the data needed by providers to ensure that patients are performing their therapy safely and effectively, and assessed the data collection burden on patients (every treatment use ideally logged for 3 months minimum). The objectives of this Phase I SBIR are to progress to a functional and intuitive UI/UX and to acquire comprehensive user feedback.

**Aim 1. Design and develop mockup and prototype-level UI/UX.** To establish feasibility of producing functional 'works like, looks like' app prototypes with a user-validated interface, we will: (1) convert "need to have" features into mock-ups (high-fidelity wireframes) then prototypes (interaction and navigation systems used for user testing) to gain user feedback early in the development process. **Goals:** (i) validation of use cases, feature sets, user tasks and flows (navigation & interactions), visual design, and usability, and (ii) complete iterative cycles of design reviews and implementation of modifications.

**Aim 2. Demonstrate ability to meet patient and provider usability needs.** We will validate usability through pre-formative user testing in female cancer survivors with dyspareunia/chronic pelvic pain and providers who manage this condition. Twenty subjects (10 patients and 10 clinicians) will be provided the app (patient) or app output (clinician) and interviewed on features, therapy tracking, ease of use, understandability, and use efficiency using a 5-point Likert scale and free-form responses. **Goal:** More than 80% of users rate each feature  $\geq 3$ .

**Impact and Future Directions.** The mobile app has the potential to transform care for cancer survivors suffering from chronic pelvic pain and dyspareunia, meeting NCI's Cancer Moonshot priority for minimizing cancer treatment's debilitating side effects and improving the lives of cancer survivors. Future work includes front and back-end development and validation of the fully functional mobile app followed by use and testing in clinical cases.

## SIGNIFICANCE

**Addressing Side Effects of Cancer Treatment is an NIH Priority**—In 2022, more than 1.9 million people in the U.S. will be diagnosed with cancer and the majority will undergo surgery, radiation, hormonal therapy, or chemotherapy individually or in combination.<sup>14</sup> Many will experience side effects severe enough to interfere with normal activities of daily living that require additional care. The financial, psychological, and social costs of these side effects amplify the burden of cancer treatment and represent an often-overlooked public health concern. To address this concern, NCI's Cancer Moonshot initiative includes a research priority to *Minimize Cancer Treatment's Debilitating Side Effects*.<sup>15</sup> By focusing research on this topic, NCI hopes to reduce the frequency and severity of treatment-related side effects to improve patient quality of life (QOL), improve adherence, and reduce costs associated with lost productivity and additional care. Thus, research and products that address the debilitating side effects of cancer treatment have the potential to advance a critical NIH priority.

**Pelvic Pain and Dyspareunia are Among the Most Common Issues Affecting Quality of Life for Female Cancer Survivors**—More than 50% of female cancer survivors will experience chronic pelvic pain and dyspareunia as a result of their cancer treatments,<sup>11</sup> far exceeding the 10-20% incidence in the general female population.<sup>6,7</sup> While gynecological malignancies result in the highest reported rates of adverse change in sex life due to pain (50-77%),<sup>16-19</sup> surgery, radiation, or chemotherapy can cause dyspareunia through alterations in vaginal anatomy, tissue dryness or atrophy, and reduced elasticity even with non-gynecologic malignancies.<sup>20,21</sup> Advances in cancer treatment and a corresponding increase in the number of cancer survivors will result in more than 15 million long-term female cancer survivors in the U.S. and E.U. by 2025; this population is projected to grow by more than 24% in the next ten years.<sup>11,22</sup> Dyspareunia, chronic pain, and the associated long-term negative physical and mental health consequences of these conditions will continue to grow as one of the most common issues affecting quality of life for cancer survivors.<sup>12,13</sup>

**Intravaginal Devices are Effective for Addressing Dyspareunia and Chronic Pain**—Pelvic floor physical therapists currently recommend use of several different devices during in-clinic and at-home therapy including vaginal dilators, pelvic wands, and vibration devices. The use of vaginal dilators to expand vaginal tissue has been shown to improve dyspareunia symptoms, though it often suffers from low adherence.<sup>23,24</sup> Pelvic wands and physical therapy techniques used for internal massage and myofascial release have shown efficacy in the reduction of pain,<sup>25</sup> and vibration devices have shown reduction in soreness and pain through relaxation.<sup>26</sup>

**The Majority of Therapy is Performed at Home**—Pelvic floor physical therapists typically provide an initial in-clinic evaluation and instruction on the use of treatment device options. The majority of subsequent therapy following initial evaluation and instruction is performed at home. Regular clinic visits then assess progress, identify problems, and update the care plan. This paradigm requires frequent in-clinic visits which pose time, financial, and transportation burdens to women already inundated with cancer-related care. Additionally, outcomes are hampered by low therapy adherence, at-home therapy recall bias, and lack of progress tracking.<sup>1-5</sup> While remote therapy monitoring (RTM) was assigned billing codes in 2020, there are no comprehensive RTM solutions specifically tailored to the sexual health of female cancer survivors. These survivors have unique needs. The typically older age and other comorbidities (e.g., tissue health, arthritis) can alter their ability to perform treatments and interact with treatment technologies. Survivors seek and deserve an effective multi-functional solution that also provides them with the knowledge, skills, and confidence to advocate for their own sexual health.

**Cervu's Mobile Application is Designed to Improve Treatment Adherence to Improve Sexual Health in Female Cancer Survivors with Dyspareunia**—Cervu, Inc. is developing a multi-functional mobile app for the highly individualized needs of female cancer survivors dealing with dyspareunia (Fig. 1). The app will provide progress tracking of multiple therapies including dilation, vibration, myofascial release, and trigger point massage which along with therapy reminders will improve adherence. Therapy logging data will be collected immediately, reducing recall bias and improving the quality of data received by the provider. The app will also be able to have adjustable safety cutoffs that inform the patient that they should stop therapy and contact their provider – for instance if their pain scores are too high.

Therapy data will be transmitted to the clinician, enabling the healthcare professional to provide remote supervision and adjust individualized treatment plans. This also allows physical therapists to make use of Remote Therapy Monitoring (RTM) CPT billing codes. This is in contrast to other existing sexual health apps that are largely unregulated, are primarily

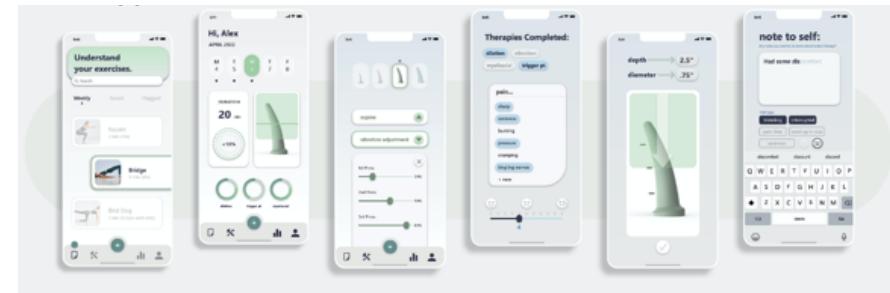


Figure 1. Cervu mobile application high-fidelity wireframes/mockups.

designed for non-cancer populations, and, therefore, are not designed to capture data relevant to the unique symptoms, experiences, and treatments pertinent to cancer survivors. Most available apps for women consist of general intercourse and menstruation/ovulation tracking or urinary incontinence. Cervu's mobile app design is the first comprehensive dyspareunia treatment tracking solution geared toward the female cancer survivor population and connected to their therapy provider.

**Positioning of This Application in the Commercialization Pathway**—Cervu is a women's health cancer solutions start-up which seeks to improve the lives of female cancer survivors through the treatment of chronic pelvic pain and dyspareunia by providing technologies and services to treat and track these conditions while empowering and educating women about their sexual health. Our mission is to improve the quality of, and increase the access to, dyspareunia and chronic pain care. A North Carolina C-Corporation based in the Research Triangle region, Cervu was founded in 2022 by a multidisciplinary team of entrepreneurs at the University of North Carolina – Chapel Hill (UNC-CH) and North Carolina State University (NCSU) with expertise in biomedical engineering, industrial design, and obstetrics and gynecology. The position of this Phase I SBIR in our commercialization pathway is shown in **Fig. 2**. Guidance from our regulatory and reimbursement consultants suggest 510(k) exemption is likely for the mobile app. A 513(g) request will be submitted to the FDA to confirm the exemption. For initial releases, the app will not be considered software as a medical device (SaMD), though addition of features in the future may require it to be treated as such.

**Cervu team:** Cervu benefits from an experienced team that will conduct the proposed project and shepherd the mobile app through commercialization to market introduction. The company is 50% female-founded, management and ownership are greater than 50% female, and females compose 50% of the advisory board. **Caitlyn Tivy, BS, DPT** will serve as Principal Investigator. Dr. Tivy has several years of clinical experience as a physical therapist followed by private industry experience in a health tech startup focused on pelvic floor rehabilitation programs. She has ample experience in women's health and digital health product development to lead this project. **Alan Rosenbaum, MD, MSCR, MSBME**, Co-founder and CEO, is a practicing board-certified obstetrician-gynecologist with expertise in gynecology, patient interviewing, and clinical trial design. Dr. Rosenbaum manages the patient and clinician stakeholder group. **Abigail Scheer, BFA, MID**, Co-founder and Chief Design Officer, is skilled in front-end innovation concept exploration, user research, ideation and prototyping, human centered product development, and design for manufacturing. Ms. Scheer will lead product integration between Cervu hardware and digital products. **Maggie Jarrett** is the lead UI/UX Designer for Cervu. Her experience in the design of digital healthcare products and expertise in graphic design provide the necessary background to drive the visual language and interactive components of the app.

**Scientific Advisory Board:** **David Zaharoff, PhD**, Associate Professor in the Joint BME Dept and Director of the MS-BME program in the Joint BME Dept at UNC/NCSU, whose instruction guided the electromechanical aspects of Cervu's hardware offering. **Devin Hubbard, PhD**, Professor in the Joint BME Dept at UNC/NCSU, whose instruction guided the development of the data, software, and regulatory considerations of Cervu technology. **Matt Penny**, Associate Professor of the Practice and Associate Director of the MS-BME program in the Joint BME Dept at UNC/NCSU, with 15+ years of medical device development and commercialization; **Kelly Umstead**, Associate Professor and Graduate Programs Director of Industrial Design at NCSU, Adjunct Associate Professor in the Joint BME Dept at UNC/NCSU, with 10 years of medical device product development experience; **Larry Copeland, MD**, gynecologic oncologist at The Ohio State University, with 45 years of clinical experience. He is President of the GOG Foundation, Past-President of the Society of Gynecologic Oncology, and past Associate Editor of the American Journal of Obstetrics and Gynecology; **Alaina Newell, DPT**, pelvic floor and oncology physical therapy specialist with a decade of clinical experience and Director of Education at ReVital Cancer Rehabilitation; **Annie Ellis**, ovarian cancer survivor and research advocate with the Ovarian Cancer Research Advocates (Chair), the FDA, the American Society of Clinical Oncology, the American Association for Cancer Research, and the Society of Gynecologic Oncology; **Brittany Barreto, PhD**, serial entrepreneur, Co-founder of Coyote Ventures and FemTech Focus, and a global Femtech Leader.

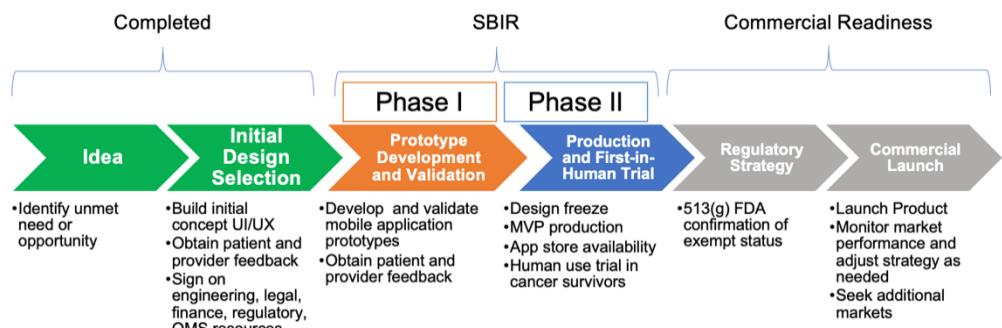


Figure 2. Commercialization pathway.

**INNOVATION**—Cervu has designed a mobile app that is expected to allow patient and clinician tracking of multimodal therapy with improved therapy adherence and quality of care. Although over the counter consumer apps exist (Rosy, Eve, Perifit, Leva), there currently does not exist an FDA-registered and clinical trial-proven comprehensive treatment tracking tool designed for female cancer survivors that provides a multimodal approach with progress tracking and provider communication capabilities (**Table 1**). This will be, to our knowledge, the first app designed specifically for sexual function and chronic pelvic pain in female cancer survivors. Mobile app capabilities enable a team approach to manage chronic pelvic pain and dyspareunia that includes physicians, physical therapists, counselors, and patients, improving quality of sexual dysfunction care in this neglected area of cancer treatment.<sup>27</sup> Remote therapy monitoring enables the clinician to assess treatment performance and progress, confirm patient safety, and modify individualized exercise plans. A mobile app will provide the patient with treatment tracking, patient reminders, and personal care support. Both patient and provider will benefit from app-provided educational resources, an important barrier in effective treatment.<sup>23</sup>

**Table 1. Competitive comparison.**

Feature	Cervu	Rosy	Eve	Perifit	Leva
Designed for cancer survivors	✓	X	X	X	X
Designed for chronic pelvic pain	✓	X	X	X	X
Designed for sexual health	✓	✓	✓	X	X
Remote clinican monitoring	✓	X	X	X	✓
Pain scoring	✓	X	X	X	X

**Intellectual Property (IP) and Commercial Vision:** Specific innovative design features as well as protectable aspects of the mobile app will be covered by a combination of a provisional patent and trade secrets, as appropriate. Additional IP will be filed for developments arising from this project. We plan to initially approach the domestic market, having filed therapy device-related patents with the USPTO. We intend the mobile app to primarily be utilized alongside the Cervu intravaginal treatment device that is covered by insurance as a DME product. However, for individuals whose care does not require the treatment device, we anticipate licensing the mobile application for a monthly fee. This business model would be anticipated to have the greatest impact on access to care, as well as result in the greatest market share for our product as most patients select their therapy devices based upon the recommendation of their physical therapist.

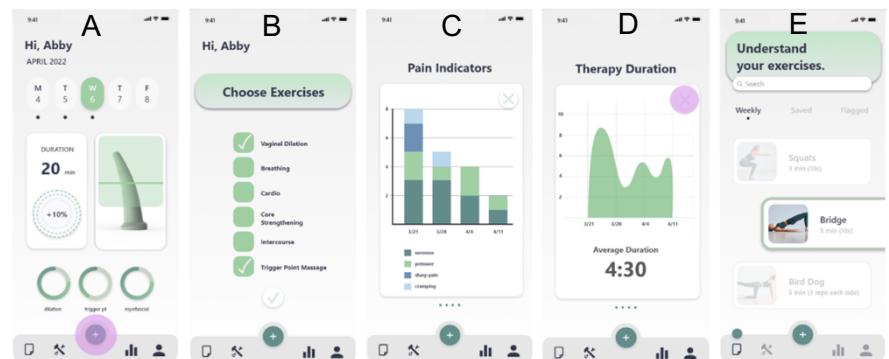
### APPROACH: Preliminary Studies

Establishment of Stakeholder Group. To date, Cervu has been awarded a total of \$108,500 in equity-free seed capital from numerous funding sources including university-based, local and state innovation and research grants, as well as \$391,500 in NIH funding for the development of our hardware product (R43 HD113449-01). An award from the UNC North Carolina Translational and Clinical Sciences Institute (NC TraCS) funded the establishment of a stakeholder group tasked initially with providing feedback on device design. The stakeholder group remains in place will be used for the proposed Aims and in the future beyond the Phase I work plan.

High Fidelity Wireframes / Mockups: Initial non-animated wireframes were created by Cervu to gather initial feedback from patients and providers and gain a better understanding of user needs and priorities. A sampling of the screens used in the interviews is provided in **Fig. 3**.

Patient and Provider Feedback: The participant was first asked to watch an approximately 5½ minute narrated video providing a walk-through of screens and features and provided with a survey to complete regarding their perception of usefulness, indication of frequency of use, and any free-form responses they chose to add. The initial survey consisted of a series of questions to be answered on a 5-point Likert scale (**Table 2**) to rate various aspects of the UI/UX design and potential usage of the app. The initial groups consisted of n=6 patients and n=3 providers. Several insights were gained including: (i) overall encouraging responses from patients and providers with 10 out of 12 questions resulting in a response between 4 and 5 (best), and (ii) some issues remain with aesthetic appeal of the app – this is to be expected given the early stage of the non-animated wireframes and will be addressed in this proposal.

A more detailed survey of another group of providers (n=8) asked the participants to rate features as “need to have”, “nice to have”, or “not needed”. Results are provided in **Table 3**. Features were prioritized based on these results and an initial target of highest priority features was determined for inclusion in the development



**Figure 3. Sample mockups for initial user feedback.** (A) Home screen showing calendar, duration of use summary, and visual tracking aids; (B) Exercise selection; (C) Summary of pain indicators; (D) Therapy duration history; (E) Educational aids.

efforts described in the proposed **Approach** (highlighted in light green in **Table 3**). The initial target list was determined by including features where at least half of the providers rated the feature as “need to have”.

Providers were also polled regarding recommended frequency of app-based data collection by patients. Several participants indicated that use should be at least weekly with the majority saying use should be every time treatment for dyspareunia is undertaken. Most providers also indicated that the treatment data collection should last at least 8-12 weeks and that, depending on patient specifics, may be phased out for some patients. They indicated that there may be cases where indefinite tracking would be recommended. Most providers indicated a desire for visual and aggregated data with the ability to review the data in greater granularity when needed. They also requested automatic notification of data outliers to ensure patient safety.

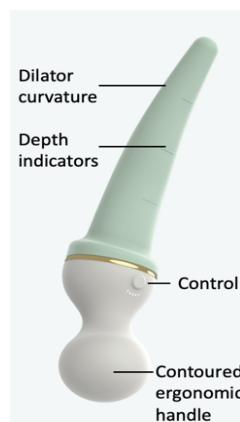
**Table 2. Patient/provider feedback - non-animated wireframes.**

App Subjective Quality	Patient	Provider
Would you recommend this app to people who might benefit from it? (5=definitely)	4.83	NA
How many times do you think you would use this app in the next 12 months if it was relevant to you? (4=10-50, 5=>50)	4.67	NA
What is your overall star rating for the app in its current state?	4.00	NA
<b>Perceived impact</b>		
<b>Awareness:</b> App is likely to increase awareness of the importance of addressing pelvic floor physical therapy for dyspareunia.	4.50	4
<b>Knowledge:</b> App is likely to increase knowledge and understanding pelvic floor physical therapy for dyspareunia.	4.67	4.33
<b>Attitudes:</b> App is likely to change attitudes toward improving pelvic floor physical therapy for dyspareunia.	4.33	3.67
<b>Intention to change:</b> App is likely to increase intentions/motivation to address pelvic floor physical therapy for dyspareunia.	4.67	4.67
<b>Help seeking:</b> App use is likely to encourage further help seeking for pelvic floor physical therapy for dyspareunia.	4.17	4.33
<b>Behavior Change:</b> App use is likely to increase pelvic floor physical therapy adherence.	4.83	4.67
<b>Aesthetics</b>		
<b>Graphics:</b> How high is the quality/resolution of graphics used for buttons/icons/menus/content?	4.17	4.33
<b>Visual appeal:</b> How good does the app look?	3.67	4.33

**Table 3. Clinician feedback/prioritization - functionality.**

Functionality	Need	Nice	Not
<b>Features</b>			
Therapy goals and treatment plans	5	1	2
Reminders to log data	6	2	0
Educational materials uploaded by provider	2	5	1
Educational materials provided by Cervu	2	6	0
App makes AI suggestions	0	5	3
App makes AI recommendations	0	2	6
Note taking	1	7	0
Encouraging and motivational messages	3	5	0
<b>Therapy Adherence Tracking</b>			
Track therapy adherence frequency/duration	5	2	1
Vaginal dilation progress	6	1	1
Patient positioning	4	3	1
Track vibration use	1	6	1
<b>Pain and Symptom Tracking</b>			
Pre-therapy pain score	6	1	1
In between therapies pain score	4	4	0
Post-therapy pain score	8	0	0
Pain quality descriptor	5	3	0
<b>Other Tracking</b>			
Stress, functional, life changes	6	1	1
Medication, lubrication changes	5	3	0

Cervu’s Intravaginal Device. Cervu has developed a patent-pending multi-functional and connected intravaginal prototype designed for female cancer survivors dealing with chronic pain and dyspareunia (**Fig. 4**). The intravaginal device provides multiple therapies including dilation, vibration, myofascial release, and trigger point massage. Female cancer survivors are likely to have medical comorbidities and joint limitations that necessitate particular attention to appropriate ergonomics and comprehensive functionality that adapts to the patients’ highly variable body position (e.g., supine, hands and knees, and lateral recumbent), individual differences in grip, and other physical challenges that are common to cancer survivors. Cervu’s hardware design is an intravaginal system that represents the first comprehensive dyspareunia treatment solution geared toward this population. The Cervu device design won the 2022 International Designers Society of America Gold International Design Excellence Award (IDEA, Seattle, WA, September 12, 2022), a prestigious international design award selected from more than 2200 entries from 30 countries. While a connectivity capability provides remote therapy monitoring (RTM) to enable the clinician to provide remote supervision and create individualized exercise plans, the mobile app being proposed herein will not require use of the Cervu hardware. The app will be amenable to tracking chronic pain, sexual function, and therapy diary logging independent of the device or treatment being used by the patient. While some additional app features may be available for those using the Cervu device, our primary focus is on development of a standalone app for improving sexual health in female cancer survivors.



**Figure 4.** Cervu intravaginal treatment device with handle and dilator attached.

## APPROACH: Research Plan

### Specific Aim 1. Design and develop mockup and prototype-level UI/UX.

**Rationale:** Initial rounds of user feedback to identify user needs based on non-animated wireframes have enabled the selection of a key functionality to include in the proposed SBIR Phase I project. In this **Aim**, we will collaborate with our digital product partner at **Guidea LLC** (Austin, TX) to create and validate prototypes. Guidea is a women-led specialized digital health product design firm with significant experience working with women's health technologies and teams and bringing regulated digital health products to market. Throughout this design process, we will also engage regulatory and quality expertise, ensure that design choices are compatible with the planned regulatory pathway, and that design history file documentation supports regulatory submission. To establish feasibility of producing functional 'works like, looks like' app prototypes with a user-validated interface, we will convert "need to have" features into high fidelity wireframes/mockups then functional prototypes of the user interface frames and design elements to gain user feedback early in the development process. We will engage user feedback early in the design process, regularly validate design direction, and seek to understand key interactions and value for the user.

**Sub-Aim 1.1 Alignment:** Following knowledge transfer, Cervu and Guidea will meet with the core team to develop an end-to-end journey map representing the vision for the patient experience. As part of this exercise, key research questions will be captured, alignment set on the highest priority user flows, and mapping out of the target population for research completed with alignment established on value propositions and success criteria. **Deliverables:** (1) Conduct two 90-minute journey mapping workshops with the team; (2) Deliver a topline summary with target user, key research questions, prioritized flows, and concepts.

**Sub-Aim 1.2 Concept Design and Validation:** We will work closely with Guidea to develop targeted concept explorations that can be used to detail design feedback from target users (n=12) with the objective of designing a system that can optimize adherence by meeting a threshold of value and desirability. These sessions will be one on one, conducted remotely, and will use a digital canvas to understand the patient journey and common barriers before moving into a co-creation exercise using the concept designs as stimuli. Our findings will be used to update the concepts and journey map, as well as provide a foundation for detailed design. Activities will include (i) concept exploration for prioritized flows and concepts, (ii) build style tiles to showcase and evaluate 2-3 divergent visual design directions, (iii) build kit for concept testing, (iv) recruit and schedule target users, (v) evaluate concepts with target users, (vi) synthesize findings to report back to the team, (vii) update concepts, and (viii) share findings with the team in a collaborative prioritization workshop. **Deliverables:** (1) research report with key insights and findings; (2) updates to the journey map; and (3) updated concepts with detailed design feedback.

**Sub-Aim 1.3 Detailed Design:** Using the foundation from research in Sub-Aims 1.1 and 1.2, we will begin detailed design for up to 60 screens in a single form factor, covering the 4-5 highest priority workflows. During this time, regularly meetings between the Guidea and Cervu teams will review design progress and provide feedback. **Deliverable:** Figma files with "lightweight" interaction documentation (i.e., not technical).

### Specific Aim 2. Demonstrate ability of the app to meet patient and provider usability needs.

**Rationale:** We will validate that the app meets user needs through pre-formative user testing in female cancer survivors with dyspareunia/chronic pelvic pain and providers who manage this condition.

**Study Design.** At least 20 subjects (10 patients and 10 providers) will be provided the app prototype (patient) or app output (provider) and subsequently interviewed by our staff on the specific features of the app and anticipated ability to track therapy. Feedback from the semi-structured interviews will be in the form of a 5-point Likert scale as well as free-form responses, as appropriate for the feature/function for which feedback is sought. In addition to the interview questions outlined in the Preliminary Data, specific factors to be surveyed include: (i) potential to improve patient outcomes and the patient experience, (ii) potential to improve adherence, (iii) perceived benefit of potential increase in access to care, (iv) perceived benefit of reduced in-clinic visits with remote monitoring, and (v) perceived benefit to the provider to create individualized exercise plans and provide remote supervision.

**Recruitment of Patients.** Participants will include members of our existing stakeholder group to which we will add new participants who are unfamiliar with the app. We continually seek more stakeholders who can diversify our stakeholder group based upon a variety of factors such as their type of cancer, past treatments, race/ethnicity, and age. We will ask providers who have already participated in prior feedback to recommend patients they think might be eligible/interested in participating, including Origin Physical Therapy, which operates 20 brick-and-mortar pelvic floor physical therapy clinics around the country as well as offering online care options. Participating providers will be asked to hang flyers in their offices containing QR code, email contact, and website methods of contacting us. We will also send email notices through cancer advocacy networks with which we have already

engaged. Stakeholders receive compensation for continued participation in the group. Non-stakeholders will also receive an incentive for participation. The ratio of patient to provider in the study is expected to be ~1:1. Biological female cancer survivors who have experienced and been treated for chronic pelvic pain and/or dyspareunia would be eligible candidates.

**Recruitment of Providers.** For non-stakeholder providers, we will reach out by identifying their office online. They may also be referred by other providers participating in this study, or by patients who received care from them. We will contact their offices to set up a provider screening interview. Providers who actively provide clinical care for biological female cancer survivors who are eligible to participate in this study are eligible to participate.

**Collection of Feedback.** Following WCG IRB approval, screening and consent will be sought online via Qualtrics at a time and place of participants choosing. Participants will access the consent form through a link in the recruitment material. After confirming eligibility and consenting the participants, we will schedule a time for the semi-structured interview and provide the mobile app prototype on a mobile device for use during the interview.

**Deliverables:** (1) IRB approval; (2) Completed research report with findings of more than 80% of users rating each feature  $\geq 3$  on 5-point Likert scale; (3) Updated app designs produced based on patient and provider feedback; (4) Updated documentation completed.

**Risks.** There is no physical risk to providing feedback on the mobile app. The primary risk is associated with privacy due to the sensitive nature of the information. Therefore, data security is of great importance, and we will maintain data sets and audio- and video-recorded interviews only on a password-protected secure Google Drive, as described in the **Protection of Human Subjects** documentation. All research staff involved in this project have completed Collaborative Institutional Training Initiative (CITI) Training. Drs. Rosenbaum and Tivy have years of experience discussing sensitive health topics with patients as part of their professions.

**Potential Pitfalls and Alternative Solutions:** If less than 80% of users find any metric to be at least adequate, their feedback will be incorporated in subsequent app development to achieve 80% approval. There is risk that we are unable to produce an app in a way that fulfills the proposed clinical, business, and regulatory plan while also achieving this rating on every feature/question, although it is mitigated by our approach of having multiple phases of design with repeated target user validation. Recognizing that user assessment does not equate to efficacy, as we create a higher-fidelity app and begin to test the use in a clinical setting, we may uncover additional adjustments necessary to improve adherence which would require further iteration of the app design. The usability sessions can also be used to answer any remaining questions about user preferences or explore any remaining detailed design questions. This study will not be packaged for human factors engineering (HFE) but it will help us be better prepared for formative and summative testing that will be packaged. Early identification of potential strategic changes will allow our project to pivot successfully toward an appropriate response that meets the needs of both patient and provider.

**Analysis and Statistical Considerations:** Following *Guidance for Industry and FDA Staff: Applying Human Factors and Usability Engineering to Medical Devices (Issued 2/3/2016)*, *Guidance for Industry and FDA Staff: Design Considerations for Devices Intended for Home Use (Issued 11/24/2014)*, and *IEC62366-1: Medical Devices – Application of Usability Engineering to Medical Devices*, we will conduct usability analysis of all tasks to identify any opportunities for improving app design prior to live use cases with cancer survivors. **Sample Size Justification.** We intend to recruit until thematic saturation is achieved, as is commonly done in usability studies.

Based upon published literature,<sup>28-30</sup> we can anticipate this to occur with 10 patient and 10 provider participants. Research has found that the first 5 to 6 interviews produce the majority of new information and >80% of all concepts are identified within the first 10 interviews.<sup>30</sup> We intend to focus recruitment on ensuring diversity (e.g., age, race/ethnicity, cancer and treatment history) and this may necessitate increasing sample size to a maximum of 20 patient and 20 provider interviews to achieve saturation in this case. **Sex as a Biological Variable:** The app is specifically designed for female cancer survivors and therefore no sex based differences can be observed.

**Impact and Future Directions.** **Table 4** provides the proposed Phase I timeline. The mobile app has the potential to transform care for cancer survivors suffering from chronic pelvic pain and dyspareunia. The proposed work is expected to show that the app can be implemented with the functionality and usability required for improving the survivor experience while ensuring user acceptance. Future work includes front- and back-end development and validation of the fully functional mobile app followed by testing in clinical cases where longer term adherence/compliance as well as improvements in sexual health can be assessed. Clinical studies will also assess whether the app would be more beneficial to certain segments of the population (e.g., cancer type, age).

Sub-Aims	Month											
	1	2	3	4	5	6	7	8	9	10	11	12
1.1 Alignment		■										
1.2 Concept Design/Validation			■	■								
1.3 Detailed Design					■	■						
2.1 Usability Testing							■	■	■	■	■	■

## PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001

Expiration Date: 01/31/2026

### Use of Human Specimens and/or Data

Does any of the proposed research in the application involve human specimens and/or data \*

Yes

No

Provide an explanation for any use of human specimens and/or data not considered to be human subjects research.

Are Human Subjects Involved

Yes

No

Is the Project Exempt from Federal regulations?

Yes

No

Exemption Number

1  2  3  4  5  6  7  8

Other Requested Information

**Human Subject Studies**

<b>Study#</b>	<b>Study Title</b>	<b>Clinical Trial?</b>
<u>1</u>	Mobile application for remote therapy monitoring of pelvic pain and dyspareunia in female cancer survivors	No

## Section 1 - Basic Information (Study 1)

### 1.1. Study Title \*

Mobile application for remote therapy monitoring of pelvic pain and dyspareunia in female cancer survivors

### 1.2. Is this study exempt from Federal Regulations \*

Yes  No

### 1.3. Exemption Number

1  2  3  4  5  6  7  8

### 1.4. Clinical Trial Questionnaire \*

#### 1.4.a. Does the study involve human participants?

Yes  No

#### 1.4.b. Are the participants prospectively assigned to an intervention?

Yes  No

#### 1.4.c. Is the study designed to evaluate the effect of the intervention on the participants?

Yes  No

#### 1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?

Yes  No

### 1.5. Provide the ClinicalTrials.gov Identifier (e.g.

NCT87654321) for this trial, if applicable

## Section 2 - Study Population Characteristics (Study 1)

### 2.1. Conditions or Focus of Study

- Pelvic pain and dyspareunia

### 2.2. Eligibility Criteria

#### Inclusion Criteria - Patient:

1. Biological female cancer survivors with dyspareunia, including those who have attempted intravaginal therapies in the past for dyspareunia such as dilation, vibration, biofeedback, or myofascial release / trigger point massage and providers who help manage pelvic pain and dyspareunia care.
3. Subjects must be age 18 and older.
4. Subjects must be able to understand and willingly give informed written consent to participate.

#### Inclusion Criteria - Provider:

1. Actively practicing physical therapist with current patients undergoing treatment for dyspareunia or pelvic floor pain.
2. Subjects must be age 18 and older.
3. Subjects must be able to understand and willingly give informed written consent to participate.

#### Exclusion Criteria - Patient:

1. Pregnant biological females or biological females who become pregnant during this study.

#### Exclusion Criteria - Provider:

1. None

2.3. Age Limits	Min Age: 18 Years	Max Age: N/A (No limit)
2.3.a. Inclusion of Individuals Across the Lifespan	INCLUSION_LIFESPAN-Cervu-2024.03.15.pdf	
2.4. Inclusion of Women and Minorities	INCLUSION-WOMEN-Cervu-2024.03.15.pdf	
2.5. Recruitment and Retention Plan	RECRUITMENT-Cervu-2024.03.15.pdf	
2.6. Recruitment Status	Not yet recruiting	
2.7. Study Timeline	STUDY_TIMELINE-Cervu-2024.03.15.pdf	
2.8. Enrollment of First Participant	06/01/2025	Anticipated

## **INCLUSION OF INDIVIDUALS ACROSS LIFESPAN**

**Age Range Patients:** This study includes biological female patients 18 years of age and older, with no upper limit.

**Age Range Providers:** This study includes male and female providers 18 years of age and older, with no upper limit, who are engaged in the treatment of dyspareunia and/or pelvic floor pain.

**Ages Excluded:** This study excludes children under the age of 18.

**Rationale for Inclusion/Exclusion:** The Cervu mobile application is designed for the treatment of pelvic pain and dyspareunia in adult female cancer survivors. Given the low incidence in children, no persons under the age of 18 will be included in this study. Additionally, we are not pursuing regulatory approval for use in children at this time. To ensure diversity of perspectives in the formative user study, recruitment and enrollment will seek to involve participants across the widest adult age range practicable.

## **INCLUSION OF WOMEN AND MINORITIES**

**Distribution of Subjects:** This human subjects study includes remote interviews that draw from diverse populations, potentially across the U.S. The racial/ethnic distribution in the U.S. is approximately 78% White, 14% African American or Black, 6% Asian descent, <2% American Indian/Alaskan Native or Native Hawaiian/Other Pacific Islander. Within these groups, approximately 18-20% will also identify as Hispanic or Latino. We intend to recruit adult female patients and adult male or female providers who meet our inclusion/exclusion criteria.

**Rationale for Selection of Inclusion Parameters:** **Sex**—no male patients will be recruited as our treatment mobile application is designed to be used by biological female cancer survivors. **Race/Ethnicity**—While ethnic differences have been found in arousal, pain, desire, and frequency of sexual intercourse, only arousal was statistically significant. Given that the intent is to conduct a formative user study, it is important to gain perspective from a diverse range of subjects. We will therefore gear recruitment and enrollment toward accessing as many racial and ethnic backgrounds as reasonably achievable. For that reason, actual enrollment may differ somewhat from the demographic distribution provided above. Differences in feedback by race/ethnicity will be examined in our planned analysis. Recruitment occurs in the context of subjects who are (1) cancer survivors with experience with other treatments for pelvic pain and dyspareunia, and (2) those providing care for these conditions. Coordinating staff will review enrollment against targets on a regular basis and adjust if inclusion appears to be skewed relative to targets.

**Inclusion and Excluded Groups:** We do not intend to exclude any groups by race/ethnicity.

## **RECRUITMENT AND RETENTION PLAN**

A minimum of 10 patients and 10 providers will be enrolled in this study. Participants will include biological female cancer survivors who have experienced pelvic pain and dyspareunia and have used an intravaginal device in the past, as well as male or female providers who treat the condition.

Participants will be recruited from of our existing stakeholder group of patients and providers to which we will add new participants unfamiliar with the device. Providers currently participating in our stakeholder group will be asked to recommend patients they think might be eligible/interested in participating. Participating providers will be asked to hang flyers in their offices containing QR code, email contact, and website methods of contacting us. We will also send email notices through the cancer advocacy networks with which we have already engaged. For new provider participants, we will reach out by identifying potential offices online. They may also be referred by other providers participating in this study, or by patients who received care from them. We will contact their offices to set up a screening interview. Given our existing stakeholder group and network of potential new participants, recruitment and enrollment is expected to be completed over a four month period.

We seek to identify new stakeholders who can diversify our stakeholder group based upon a variety of factors such as their type of cancer, age, experience with past treatments, and race/ethnicity. Recruitment of Black or African American participants with pelvic pain and dyspareunia and a history of use of other treatment approaches has been challenging in the past and a concerted effort will be undertaken, if necessary, to ensure this group is represented in the proposed study through specific outreach to care facilities serving this population.

A participant incentive of \$50 will be offered per interview. No more than two interviews will be held with any participant for a total maximum incentive of \$100.

**STUDY TIMELINE**

ACTIVITY	2024		2025										
	M11	M12	M1	M2	M3	M4	M5	M6	M7	M8	M9	M10	Post
Completion of protocol, site contract, clinicaltrial.gov registration, IRB approval													
Aim 1. Develop and validate app prototypes													
Earliest possible enrollment date													
Recruitment, Enrollment, Assessment 25%													
Recruitment, Enrollment, Assessment 50%													
Recruitment, Enrollment, Assessment 75%													
Recruitment, Enrollment, Assessment 100%													
Completion of study data collection													
Completion of all endpoint data analyses													
Complete Final Study Report													
Report results on clinicaltrials.gov													
Submission for publication of primary study results (at our discretion)													

PHASE I start anticipated Nov 1, 2024. IRB approval estimated no later than April 2025. Human subjects estimated to begin May 2025.

2.9. Inclusion Enrollment Reports

IER ID#	Enrollment Location Type	Enrollment Location
<u>Study 1, IER 1</u>	Domestic	Remote - anywhere in the U.S.

**Inclusion Enrollment Report 1**

1. Inclusion Enrollment Report Title\* : Mobile application prototype usability study
2. Using an Existing Dataset or Resource\* :  Yes  No
3. Enrollment Location Type\* :  Domestic  Foreign
4. Enrollment Country(ies): USA: UNITED STATES
5. Enrollment Location(s): Remote - anywhere in the U.S.
6. Comments: Planned recruited for ethnic and racial categories will be designed to gain a cross section of diverse user perspectives.

**Planned**

Racial Categories	Ethnic Categories					Total	
	Not Hispanic or Latino		Hispanic or Latino				
	Female	Male	Female	Male			
American Indian/ Alaska Native	0	0	0	0	0	0	
Asian	1	0	0	0	0	1	
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	
Black or African American	3	1	2	0	6		
White	6	2	3	1	12		
More than One Race	1	0	0	0	1		
<b>Total</b>	11	3	5	1	20		

**Cumulative (Actual)**

Racial Categories	Ethnic Categories									Total	
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity				
	Female	Male	Unknown/Not Reported	Female	Male	Unknown/Not Reported	Female	Male	Unknown/Not Reported		
American Indian/ Alaska Native	0	0	0	0	0	0	0	0	0	0	
Asian	0	0	0	0	0	0	0	0	0	0	
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0	
Black or African American	0	0	0	0	0	0	0	0	0	0	
White	0	0	0	0	0	0	0	0	0	0	
More than One Race	0	0	0	0	0	0	0	0	0	0	
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0	
<b>Total</b>	0	0	0	0	0	0	0	0	0	0	

### Section 3 - Protection and Monitoring Plans (Study 1)

- 3.1. Protection of Human Subjects PROTECTIONS-Cervu-2024.03.15.pdf
- 3.2. Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?  Yes  No  N/A  
Single IRB plan attachment
- 3.3. Data and Safety Monitoring Plan DATA\_SAFETY\_MONITORING-Cervu-2024.03.15.pdf
- 3.4. Will a Data and Safety Monitoring Board be appointed for this study?  Yes  No
- 3.5. Overall structure of the study team STUDY\_TEAM-Cervu-2024.04.15.pdf

## **PROTECTION OF HUMAN SUBJECTS**

### **1. Risks to Human Subjects**

#### **a. Human Subjects Involvement, Characteristics, and Design**

**Design and Study Population:** The work proposed in this Phase I includes a pre-formative user study conducted remotely in 10 subjects who are female cancer survivors who have experienced pelvic pain and dyspareunia and 10 providers who treat such a condition. Assessments will include a series of interview questions regarding their perceptions of the Cervu mobile application. Subjects targeted to enroll in the study may reflect the demographic makeup of the United States, though attempts will be made to ensure diversity in user feedback. Subjects must meet all inclusion criteria and none for the exclusion criteria, for participation. **Randomization:** None.

**Collaborating Site:** None. Recruitment, screening, enrollment, and interviews will be conducted by Cervu staff. Interviews will be conducted remotely.

#### **b. Study Procedures, Materials and Potential Risks**

**Implementation:** Decisions for session continuation will be based on a real-time review of observed tolerance for each individual during the interview.

#### **Measures and Data Collection:**

**Endpoints:** For all subjects, endpoints include perception of usability based on a 5-point Likert scale as well as free-form input.

All subjects will receive:

#### **Screening and Consent**

- All study procedures necessary for subject selection, determination of eligibility and participation initiation should be performed within 30 days of interviews, unless otherwise indicated.
- Informed Consent must be obtained prior to interview initiation.
- Past cancer history, history of use of treatments for pelvic pain and dyspareunia, and demographic information including age and race/ethnicity will be collected from patients.

#### **During Study**

- Usability assessments will be conducted in a single interview estimated to last approximately 1 hour.

#### **Private Identifiable Information:**

**Subject privacy:** All interviews with the subjects, including the informed consent interview, will be conducted privately.

**Data security and confidentiality:** All source documents, results and case report forms are held in secure, double-locked study site locations. Access to this information is strictly limited to the principal investigator, sub-investigators, and authorized study personnel as identified in the HIPAA authorization. Coding keys, such as screening and subject identification logs for any de-personalized information will be held in a double-locked secure research location at the site, with strictly limited access to study personnel.

**HIPAA Authorization:** The Privacy Rule of the federal Health Insurance Portability & Accountability Act (HIPAA) is a law that protects the confidentiality of the subjects' personal health information. Information to this effect will be provided to all subjects.

#### **Potential Risks:**

There is no physical risk to providing feedback on the Cervu mobile application. The primary risk is associated with privacy due to the sensitive nature of the information; the interviews may also have some social or emotional risks. We are interested in discussing health information related to cancer treatments, sexual health, and dyspareunia treatments. Public disclosure of this information would be expected to result in significant distress, embarrassment, anger, and mistrust. Therefore, the security of the data is of great importance, and we will maintain data sets and audio- and video-recorded interviews only on a password-protected secure Google Drive. All participants will be informed of the nature of the questions and given

clear guidance on their ability to excuse themselves from participating in any component of the interview, survey, or guided walk-through. All research staff involved in this project have completed appropriate Collaborative Institutional Training Initiative (CITI) Training. Drs. Rosenbaum and Tivy also have years of experience interacting and discussing sensitive health topics with patients as part of their professions.

## **2. Adequacy of Protection Against Risks**

### **a. Informed Consent**

Informed consent will be obtained prior to any protocol-related activities. The principal investigator or designated research personnel must explain orally or in writing the nature, duration, and purpose of the study in such a manner that the subject is aware of the potential risks, inconveniences, or adverse effects that may occur. They should be informed that the subject may withdraw from the study at any time. They will receive all information that is required by federal regulations. After a potential study subject is identified, the principal investigator or the research staff designated as persons who will obtain consent will be responsible for instituting the informed consent process. Before starting any study procedures, the investigator or research staff will discuss the proposed research study in detail with the potential subject. The subject will be allowed ample time to read, review and ask questions. The informed consent document will be reviewed with the subject in depth by the participating investigator and/or delegated research staff to ensure the potential participant has a good understanding of the study, what is required from them, risks, benefits and their rights as a participant. The investigators will be available by phone or in the office to answer any questions the participant may have.

After the subject has read and reviewed the informed consent document and has agreed to participate, he/she will be asked to sign and date the document via a secure online site. A copy of the consent form will be provided to the subject. The subject is informed during the consent process and ICF contains the following information regarding confidentiality: your study records will receive a unique code in place of information that can be used to identify you (such as your name or address). The sponsor and the people and companies that it works with on the study will have access to and use these coded records and accompanying data to conduct the research described in this form. However, they will not be able to see the key that links the code to you. Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The local institutional review board may review your study records. If this study is regulated by the Food and Drug Administration (FDA), there is a possibility that the FDA might inspect your records. In addition, for treatment studies, the study sponsor and possibly foreign regulatory agencies may also review your records.

### **b. Protections Against Risk**

Participant names will not be on interviews or records. They will be identified by a number. While the subject will be video-recorded, no personal identifiers are distributed or are allowed outside the confines of the protocol-specified server. Once data from the videos has been coded and summarized, data analysis will be performed on the de-identified data. Videos will be securely archived thereafter for a period not to exceed 10 years. Therefore, there is minimal risk. Participant confidentiality will be protected by limiting access to identifying data to the study investigators and requiring personal identification codes to access computerized data. Published results from the proposed study will be in the form of group data and will not permit identification of individuals. Staff will respect and maintain confidentiality procedures. Participants will be given the phone number and may contact the PI for questions or problems. Information obtained in interviews is personal and sensitive. The team is experienced with conducting studies which involve sensitive topics. Interviews will take place privately. Records are maintained in a locked facility.

### **c. Vulnerable Subjects**

Cervu recognizes that there are categories of vulnerable persons who should be carefully considered as research subjects. This includes subjects under 18 years of age, fetuses, prisoners, military persons, and students in hierarchical organizations, comatose, physically and intellectually challenged individuals, elderly individuals, visual or hearing impaired, refugees, economically and educationally disabled persons. However, by design, the Cervu system may benefit older and disabled persons. If successful, Cervu's system could improve their quality of life. Our inclusion criteria therefore include the ability of a

subject to understand and willingly give informed written consent and excludes subjects with any diagnosis that affects mental state.

**3. Potential Benefits of the Proposed Research to Research Participants and Others**

We promise no direct benefit to trial subjects from participation in the study.

**4. Importance of the Knowledge to be Gained**

Knowledge gained from this study will be used to refine the Cervu mobile application in preparation for formative usability studies and app publication.

## **DATA AND SAFETY MONITORING PLAN**

Cervu, Inc. and designee(s) will evaluate the progress of the study to review procedures for maintaining confidentiality of data, the quality of data collection and management, analysis, recruitment, and screening. The Cervu mobile application is low risk and will be studied in female cancer survivors who have experienced pelvic pain and dyspareunia and who have tried other products. Healthcare providers who have treated the condition will also be recruited. A detailed monitoring plan will be included as part of the study protocol submitted to the IRB (WCG-IRB).

### **Data Monitoring Plan**

All Study documentation will be collected and compiled in a central electronic data capture ("EDC") database. Appropriate quality control measures will be established to ensure accurate and complete transfer of information from the Study documentation to the EDC database. Case report forms ("CRFs") will be used to capture Study data. Data will be reviewed manually and electronically for accuracy and completeness by Cervu. Standard checks will be incorporated into the EDC database. Interviews will be conducted remotely. There is no clinical site and therefore no site visits. The PI will review study progress, data quality, and participant's safety at least monthly.

### **Data Safety and Monitoring Board (DSMB)**

A Data Safety Monitoring Board (DSMB) is not necessary and will not be established.

### **Protection of Confidentiality**

The completion of the study involves the collection and processing of personal data. All processing of personal data at Cervu must be carried out in accordance with national legislation concerning the protection of personal data. The Investigator must ensure that the subject's privacy is maintained. On the CRF or other documents, subjects will be identified by a subject identification number only.

As part of the required content of the Informed Consent Form, subjects will be informed that their records may be reviewed by Cervu or its designee and by regulatory agencies. Should access to medical records require a separate waiver or authorization, it will be the Investigator's responsibility to obtain such permission from the subject in writing before the subject is entered into the study.

## **OVERALL STRUCTURE OF THE STUDY TEAM**

### **Cervu, Inc.**

Cervu, Inc. will oversee all work performed. Cervu will manage study design and execution, regulatory findings, product development, fundraising, manufacturing, and business development related to the scope of work described in this proposal aimed at the development of the Cervu mobile application for treatment progress track and remote treatment monitoring of pelvic pain and dyspareunia in female cancer survivors. Cervu is responsible for protocol development, trial design, screening and enrolling subjects per an IRB-approved trial protocol (WCG IRB), conduct of subject interviews, and analysis/reporting of results.

- Caitlyn Tivy, Principal Investigator
- Alan Rosenbaum (Other Significant Contributor), CEO
- Abigail Scheer (Other Significant Contributor), Chief Design Officer
- Maggie Jarrett (Support Staff), UI/UX Software Engineer

### **Design Partner Site (Nova Design, LLC)**

Guidea, LLC is responsible for production of up to 5 workflows with a maximum of 60 iOS screens to be used in the pre-formative user study.

- Jessica Gentry, COO

### **Data Safety Monitoring Board (DSMB)**

A DSMB is not required nor necessary for this non-significant risk project and will not be established for the study.

## Section 4 - Protocol Synopsis (Study 1)

### 4.1. Study Design

#### 4.1.a. Detailed Description

#### 4.1.b. Primary Purpose

#### 4.1.c. Interventions

Type	Name	Description

#### 4.1.d. Study Phase

Is this an NIH-defined Phase III Clinical Trial?  Yes  No

#### 4.1.e. Intervention Model

4.1.f. Masking  Yes  No

Participant  Care Provider  Investigator  Outcomes Assessor

#### 4.1.g. Allocation

### 4.2. Outcome Measures

Type	Name	Time Frame	Brief Description

### 4.3. Statistical Design and Power

### 4.4. Subject Participation Duration

4.5. Will the study use an FDA-regulated intervention?  Yes  No

4.5.a. If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) status

4.6. Is this an applicable clinical trial under FDAAA?  Yes  No

### 4.7. Dissemination Plan

**Delayed Onset Studies**

Delayed Onset Study#	Study Title	Anticipated Clinical Trial?	Justification
The form does not have any delayed onset studies			

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January 27, 2024

Alan Rosenbaum, MD, MSCR, MSBME  
Chief Executive Officer, Cervu  
113 Dorchester Pines Ct  
Cary, NC 27511  
Phone (765) 412-4512

Dear Dr. Rosenbaum,

I am writing to support Cervu's Phase I SBIR grant application. I support your strategy of pursuing federal funding to develop your novel technology. I'm excited to see your team seek to acquire and manage non-dilutive funding and make the transition from user feedback to the design and development of a digital product to help female cancer survivors regain and maintain quality of life and sexual function.

Having developed UI/UX digital products, including regulated medical and healthcare products, for the past twelve years, I understand the importance of end user feedback in the rapid iteration and evaluation of prototypes. I've been very impressed with your dedication to these processes with the development of your hardware treatment device, and I am confident that your approach will also translate well into the design and development of a digital product. The proof-of-concept derived from the proposed project will lay a strong foundation for a future Phase II clinical trial.

It's important to understand the complex interactions between the patients and the physical therapists, each will have different needs in a digital product. The many key stakeholders in the form and function of your product further justifies a heavy reliance on end user feedback and rapid prototyping to guide its design. This requires greater up-front work but will significantly de-risk your overall project and increase the certainty of successfully bringing a medical device and digital product to market.

Sincerely,



Cliff Lee  
VP of Digital Health Strategy  
Dawn Health

Brittany Barreto, PhD  
1329 Doylin Drive  
Cary, NC 27511  
brittany@femtechfocus.org

Alan Rosenbaum, MD, MSCR, MSBME  
CEO, Cervu  
113 Dorchester Pines Ct  
Cary, NC 27511  
(765)412-4512

November 20, 2023

Dear Dr. Rosenbaum and Cervu team,

I am writing to offer my unequivocal endorsement of your SBIR Phase I submission. As a serial entrepreneur in the FemTech industry – and having known and mentored your team since incorporation – I am excited to see and support teams like yours working to help women maximize their quality of life. Having co-founded several companies, fundraised venture capital, and mentored and advised dozens of entrepreneurs and startups, I can attest that your team has the grit and persistence to bring a product to market. As part of that process, I look forward to assisting your team with strategy as you grow and raise capital in the future.

I'm glad to see that you've benefited from the broad community that I've cultivated at FemTech Focus and that using this network you've built a comprehensive team of internal and external associates who will help make your product a reality. I've also been pleased with your recognition that women's health will advance so much further as an industry if its members engage with and seek to help each other, as evidenced by your willingness to educate, support, and partner with students, academicians, and other entrepreneurs to build mutually beneficial relationships. As your company grows, that spirit will serve to help attract high-quality employees and deepen your network of potential collaborators.

But what I find most important in your team is inflexibility in maintaining your North Star by keeping the needs of the end user in mind as you work to create a therapy tool. Your unflinching ethical and moral compass guides your business as it ensures that you will always work to deliver women the health outcomes that they deserve.

Sincerely,



Brittany Barreto, PhD  
FemHealth Insights, Founder & Chief Innovation Officer  
Co-Founder, Advisor Coyote Ventures  
Global FemTech Leader

Alaina Newell, PT, DPT  
6464 S Routt St  
Littleton, CO 80127

February 26, 2024

Dear Cervu team –

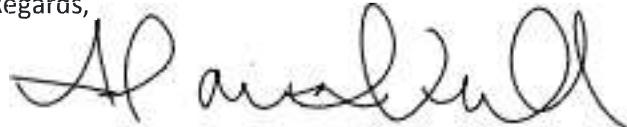
I am very excited to write this letter of support for your *Phase I SBIR* funding application. Together, you have identified an important unmet clinical need where current treatment options have clear shortcomings, and – having participated in usability studies of your hardware and digital prototypes and as a member of your stakeholder group – your proposed treatment system demonstrates great promise. I look forward to participating in future usability studies so that I can continue to impact how your device evolves and hope to one day be able to recommend your products to my patients and colleagues.

I have nearly a decade of experience in pelvic floor and oncology physical therapy clinical practice, and I currently serve as the Director of Education at ReVital Cancer Rehabilitation. We are dedicated to empowering cancer survivors to live their best lives through comprehensive, evidence-based rehabilitation. Our program is designed to support patients where they are at and empower them with tools and resources to improve their quality of life before, during, and after cancer treatment. I have the privilege of educating over 900 physical therapists, occupational therapists, and speech-language pathologists in cancer rehabilitation throughout the Select Medical outpatient rehabilitation network. With ReVital only being five years old we are projected to continue to grow at least 10% per year until we ensure access to care for all cancer survivors throughout the United States.

I have had the pleasure of working closely with each of you for the past three years. However, I have known Dr. Alan Rosenbaum for over a decade: his wife and I were physical therapy students together at the University of Pittsburgh and I was a bridesmaid in their wedding. Alan has a deep and comprehensive understanding of the pelvic floor physical therapy space through his years of clinical practice as an obstetrician-gynecologist, a spouse to a physical therapist, an advocate for women, and an innovator in women's health. He is changing the landscape of care for women throughout the world and is dedicated to improving quality of life for women with sexual and genitourinary dysfunctions.

I am pleased to see that Alan is part of such a promising team who seem equally passionate and hard-working but with complementary expertise. I know that there are many women who stand to benefit greatly from this project, and many physical therapists who will be grateful to have better options to offer their patients.

Regards,



Alaina Newell, PT, DPT  
*Board Certified Clinical Specialist in Women's Health Physical Therapy*  
*Board Certified Clinical Specialist in Oncologic Physical Therapy*  
Director of Education  
ReVital Cancer Rehabilitation, Select Medical

# The James



**THE OHIO STATE UNIVERSITY**  
WEXNER MEDICAL CENTER

The Ohio State University  
College of Medicine  
Department of Obstetrics and Gynecology  
Division of Gynecologic Oncology

**Academic Office:**

Division of Gynecologic Oncology  
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March 7, 2024

Dr. Alan Rosenbaum  
113 Dorchester Pines Ct  
Cary, NC 27511

Division Faculty

Floor J. Backes, MD  
Professor

Kristin Bixel, MD  
Assistant Professor

Laura Chambers, DO  
Assistant Professor

David E. Cohn, MD  
Professor and CMO

Larry J. Copeland, MD  
Professor

Casey Cosgrove, MD  
Assistant Professor

Paul J. Goodfellow, PhD  
Professor

David M. O'Malley, MD  
Professor and Director

Selvendiran Karuppiah, PhD  
Associate Professor

Christa Nagel, MD  
Associate Professor

Dear Dr. Rosenbaum and Cervu team,

I am writing to offer my enthusiastic support for your project to develop a mobile application to improve chronic pelvic pain and dyspareunia treatments for female cancer survivors who are participating in pelvic floor physical therapy. Over the past 45 years of practicing gynecologic oncology, I have had the honor of holding numerous academic, research, and professional society positions including being the past Chair of the Department of Obstetrics and Gynecology at The Ohio State University, past Associate Editor of the American Journal of Obstetrics and Gynecology, past President of the Society of Gynecologic Oncology, and immediate past President of the GOG Foundation. Through these positions, as well as the day-to-day clinical care I have provided to thousands of patients, it is humbling to have witnessed and to have helped create the dramatic improvements in cancer treatments and survival that we have seen over the period of my career.

As a result, female cancer survivors are living longer than ever, oftentimes for many years beyond their original cancer diagnosis. Unsurprisingly, they are seeking out ways to maximize not just the quantity, but also their quality of life. Chronic pelvic pain and dyspareunia are very frequent conditions seen in this population, and successful treatment is limited by both access and management options. A digital tool that improves therapy adherence, permits remote therapy monitoring by providers, and reduces the frequency of visits to the physical therapist's office has an excellent prospect of improving clinical outcomes while improving patient access to care. I would expect nothing less from a project that lists Dr. Alan Rosenbaum among its team members - I have known Alan for nearly a decade and he was most memorable for his creativity and tenacity. Having known him, it is fitting he has obtained a biomedical engineering degree after completing his medical training.

In conclusion, the Cervu team has selected a worthy clinical problem. I wholly support their efforts to help my patients live more fulfilling, complete lives, and believe their team is motivated and capable of achieving these objectives.

Sincerely,

  
Larry J. Copeland, M.D.  
Professor, Division of Gynecologic Oncology  
The Ohio State University, Larry.Copeland@osumc.edu  
President, GOG Foundation, LCopeland@GOG.org

*Joint Department of*  
**BIOMEDICAL  
ENGINEERING**



**NC STATE**  
UNIVERSITY

March 21, 2024

Alan Rosenbaum, MD, MSCR, MSBME  
Chief Executive Officer, Cervu  
113 Dorchester Pines Ct  
Cary, NC 27511  
Phone (765) 412-4512

Dear Dr. Rosenbaum,

I am writing to enthusiastically support Cervu's Phase I SBIR grant application. I agree with your strategy of pursuing federal funding to develop your novel technology. I'm excited to continue advising your team as you seek to acquire and manage non-dilutive funding and make the transition from university classroom to independent company.

As Director of the MS MedTech Program at the Joint Department of Biomedical Engineering at North Carolina State University and the University of North Carolina - Chapel Hill, I have known your team and project since work began over two years ago when you were a student in our master's program. I'm excited to see how your intellectual property and technology has matured and evolved. With this Phase I SBIR work plan, your team is taking the appropriate steps to refine the prototypes created on our campus and demonstrate proof-of-concept. Results from the proposed project will lay a strong foundation for future work to refine the design for optimal manufacturing.

I'm further pleased that your team has proceeded with a sound business approach to do the important and difficult work sooner rather than later, always choosing to pursue the best path for your technology and, ultimately, the patients who will rely upon it. Examples include the heavy reliance on end user feedback and rapid prototyping to guide design criteria and the early decision to create an electronic quality management system. These choices require greater up-front work but will significantly de-risk your overall project and increases the certainty that you will be able to successfully create and bring a medical device to market.

I am proud of the work your team is doing and the way in which you are doing it! Cervu's advances reflect positively on our university and engineering program. It is an honor to play a role in helping guide your work.

Sincerely,

A handwritten signature in blue ink, appearing to read "David A. Zaharoff".

David A. Zaharoff, Ph.D.

Associate Professor & Director, MS MedTech Innovation + Entrepreneurship  
Joint Department of Biomedical Engineering | Pharmacoeengineering Track  
University of North Carolina-Chapel Hill & North Carolina State University

# HATTERAS

VENTURE PARTNERS

Alan Rosenbaum, MD, MSCR, MSBME, FACOG  
Chief Executive Officer, Cervu  
113 Dorchester Pines Ct  
Cary, NC 27511  
alan@cervuhealth.com

28 November 2023

Dear Dr. Rosenbaum and Cervu team,

I am pleased to support your Phase I SBIR proposal to create a digital pelvic floor physical therapy tool to help female cancer survivors. As a Venture Partner at Hatteras Venture Partners, I believe Cervu represents both an important project to help patients and a promising business opportunity. With the success of this SBIR, Cervu will have achieved important de-risking milestones and be in a significantly stronger position for future fundraising efforts with our organization as well as the rest of the investing community. It is clear that their product targets a large and growing population in a sizeable market.

Having first met Dr. Rosenbaum 4 years ago when he was a student in my Fundamentals of Technology Commercialization at the University of North Carolina, I know that he has a deep interest in using his medical and engineering knowledge to bring devices into clinical settings to help his patients. And having taught this technology commercialization course, I know that Cervu has the technology, team, and resources to take a university-based technology, develop it, and bring it to the market. SBIR funding is an important step in that process.

I'm confident that your team will continue to have success in part because you are working to solve an important problem and because your technology represents a viable business and commercialization opportunity. I wish your team the best success as you work to build a better pelvic floor physical therapy treatment option for women.

Sincerely,



Don Rose, PhD  
Venture Partner

Liz Miracle, PT, MSPT, WCS  
1800 Filbert St.  
San Francisco, CA 94123

Alan Rosenbaum, MD, MSCR, MSBME  
CEO, Cervu  
113 Dorchester Pines Ct  
Cary, NC 27511  
765-412-4512

Month Day, 2022

Dear Dr. Rosenbaum,

The Origin team is excited to offer this enthusiastic letter of support for Cervu's SBIR Phase I submission. Origin is a women's health pelvic floor physical therapy startup focused on delivering evidence-based, high-quality in-person and virtual care to tens of thousands of women suffering from common but debilitating pelvic floor conditions. As leaders in the pelvic floor physical therapy space, we seek to improve women's lives by providing excellent care, advancing knowledge through research, and educating patients and communities.

As part of this important work, we believe that Cervu's technology will serve to create a better treatment tool for our patients. Current standard of care treatments suffer from poor adherence as patients get discouraged from slow progress and lack of progress tracking. The ability to bill under the new remote therapy monitoring CPT codes would also be particularly appealing for our business model and for our patient's outcomes. The Cervu mobile application would allow for such progress tracking and remote therapy monitoring, along with the ability to deliver patient education and individualized patient therapy plans. These features would be anticipated to result in improved adherence and patient outcomes.

We are excited to see Cervu's continued progress and view Cervu as a potential partner. Specifically, we would be interested in having our providers and patients review devices and give feedback to help shape future prototype development. When Cervu performs clinical trials for regulatory approval and device reimbursement coverage, we would be interested in possibly serving as a study site. We look forward to this collaboration and we are excited for Cervu to continue working to bring an effective device to market.

Sincerely,



Liz Miracle, PT, MSPT, WCS  
Head of Clinical Quality and Talent, Origin

Liz Miracle, PT, MSPT, WCS  
1800 Filbert St.,  
San Francisco, CA 94123

Alan Rosenbaum, MD, MSCR, MSBME  
CEO, Cervu  
113 Dorchester Pines Ct  
Cary, NC 27511  
765-412-4512

11.10.2023

Dear Dr. Rosenbaum,

The Origin team is excited to offer this enthusiastic letter of support for Cervu's SBIR Phase I submission. Origin is a women's health pelvic floor physical therapy startup focused on delivering evidence-based, high-quality in-person and virtual care to tens of thousands of women suffering from common but debilitating pelvic floor conditions. As leaders in the pelvic floor physical therapy space, we seek to improve women's lives by providing excellent care, advancing knowledge through research, and educating patients and communities. As part of this important work, we have found the current standard of care devices to lack ergonomic design and versatility. As a result, we are always eager to explore and evaluate new treatment options for our patients that make their treatment experiences better.

Cervu's technology will serve to create a better treatment tool for our patients. Your team has designed a device that can effectively perform multiple therapies to treat our most challenging patients – cancer survivors suffering from chronic pain and dyspareunia. The paired mobile application also allows for therapy individualization and monitoring. These features, along with attention to therapy body mechanics and comfort, will improve adherence and outcomes.

We view Cervu as a potential partner in the future. Specifically, we would be interested in having our providers and patients review devices and give feedback to help shape future prototype development. Later, as Cervu performs clinical trials for regulatory approval and device reimbursement coverage, we would be interested in possibly serving as a site for those studies. We look forward to this collaboration and we are excited for Cervu to continue working to bring an effective device to market.

Sincerely,



Liz Miracle, PT, MSPT, WCS  
Head of Clinical Quality and Education, Origin

**Annie Ellis**  
10 Oak Ridge Road, White Plains, NY 10607  
2AnnieEllis@gmail.com / (917) 709-1312

November 30, 2023

Dr. Alan Rosenbaum  
113 Dorchester Pines Ct  
Cary, NC 27511  
765-412-4512

Re: Letter of Support

Dear Cervu team,

I am grateful for your efforts to improve the lives and health of women after cancer treatments. I am gladdened to see the progress your team has made in the past several years during which I have worked with you to build a product that promotes the sexual health and quality of life of cancer survivors. As a woman living with ovarian cancer, I know that there are so many women who could stand to benefit from the commercialization of your technology. Over the past several years I have been fortunate enough to serve as a Research Advocate with the Ovarian Cancer Research Alliance Scientific Advisory Committee, the National Cancer Institute's Council of Research Advocates, the Food and Drug Administration, the American Society of Clinical Oncology, The American Association for Cancer Research, and the Society of Gynecologic Oncology. These experiences have taught me that this is a critical need for the many millions of cancer survivors who are seeking to improve, and not just extend, their lives.

For the past three-years, we have had many interactions through your stakeholder grant. This has been a great experience for me as a patient to give my perspective and input on solutions that I will use, and through repeated meetings I have seen how my opinions have directly shaped your subsequent prototypes. You ask questions about the entire therapy process and have a global perspective on how this important therapy fits into the woman's life. You seek to advocate for the woman and her health beyond the confines of a typical medical device, with an interest in therapy comfort, patient education, and access to effective care. Working to reduce the stigma surrounding sexual health and addressing the barriers to care will allow more women to obtain the help they deserve.

I am excited to watch your team grow over the upcoming years, and I look forward to continuing to help give my perspective and guidance through that process. I sincerely hope your team is successful in your application to the *Phase I SBIR Program* and I am available to offer my unequivocal support in any way possible.

Very best regards,



Annie Ellis  
Ovarian Cancer Survivor / Research Advocate

## **RESOURCE SHARING PLAN**

Cervu will make the results and accomplishments of this research available to the research community and to the public at large by the timely release and sharing of data. As a means of sharing knowledge, the investigators supported by this grant will seek to publish the original research in primary scientific journals. For each publication that results from the grant-supported research, we will include an acknowledgment of NIH grant support and follow guidelines regarding free access to published materials. Information on each publication resulting from work performed under the NIH grant-supported project will be included in the annual and/or final progress report submitted to the NIH awarding office. Cervu will work with other investigators to respond to requests for data for reanalysis or assistance replicating the research, and all reasonable requests will be accommodated given appropriate data and privacy protections, feasibility of complying with the request, and compliance with the policies of all participating institutions and organizations. Cervu is also open to collaboration with outside groups who express interest in this approach. Cervu defines “reasonable request” for data as requiring: (1) at least 30 days to comply, (2) that it is not a significant burden to prepare, (3) that it is not a significant cost to prepare or host, (4) that it is for research purposes only, and (5) has a sound scientific rationale and purpose including one with a testable and plausible hypothesis or reasonable analysis goals.

## ***INTELLECTUAL PROPERTY RIGHTS***

The investigators will assert copyright in scientific and technical articles based on data produced under the grant where necessary, but we will also make every effort to keep technologies developed as a result of this research project widely available and accessible to the research community. If additional patents are filed and the technology licensed, we will only seek exclusivity in cases where this approach is determined to be the best route for successful development of the technology for public use and benefit.

NIH Generated message:

The Other Plan(s) attachment included with the application is not evaluated during the peer review process but will be evaluated prior to a funding decision. Although part of the official submission, the attachment is maintained as a separate document in eRA Commons viewable by authorized users and is not part of this assembled application.

## **AUTHENTICATION OF KEY BIOLOGICAL AND/OR CHEMICAL RESOURCES**

**Overview:** No biological or chemical resources will be used in the proposed work.