

APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)

		3. DATE RECEIVED BY STATE	State Application Identifier
1. TYPE OF SUBMISSION*		4.a. Federal Identifier	
<input type="radio"/> Pre-application	<input checked="" type="radio"/> Application	<input type="radio"/> Changed/Corrected Application	b. Agency Routing Number
2. DATE SUBMITTED	Application Identifier	c. Previous Grants.gov Tracking Number	
5. APPLICANT INFORMATION		Organizational DUNS* : 0303159800000	
Legal Name*: COLLEGE OF NEW JERSEY			
Department:			
Division:			
Street1*:	PO BOX 7718		
Street2:	2000 Pennington Road		
City*:	EWING		
County:	Mercer		
State*:	NJ: New Jersey		
Province:			
Country*:	USA: UNITED STATES		
ZIP / Postal Code*:	086280718		
Person to be contacted on matters involving this application			
Prefix: Ms.	First Name*: Kortnay	Middle Name:	Last Name*: Woods
Position>Title:	Suffix: Ph.D		
Executive Director			
Street1*:	PO BOX 7718		
Street2:	2000 Pennington Road		
City*:	Ewing		
County:	Mercer		
State*:	NJ: New Jersey		
Province:			
Country*:	USA: UNITED STATES		
ZIP / Postal Code*:	086280718		
Phone Number*:	6097713120	Fax Number:	6096375171
		Email: woodsk@tcnj.edu	
6. EMPLOYER IDENTIFICATION NUMBER (EIN) or (TIN)*		222797398	
7. TYPE OF APPLICANT*		H: Public/State Controlled Institution of Higher Education	
Other (Specify):			
Small Business Organization Type		<input type="radio"/> Women Owned	<input type="radio"/> Socially and Economically Disadvantaged
8. TYPE OF APPLICATION*		If Revision, mark appropriate box(es).	
<input checked="" type="radio"/> New	<input type="radio"/> Resubmission	<input type="radio"/> A. Increase Award	<input type="radio"/> B. Decrease Award
<input type="radio"/> Renewal	<input type="radio"/> Continuation	<input type="radio"/> C. Increase Duration	<input type="radio"/> D. Decrease Duration
	<input type="radio"/> Revision	<input type="radio"/> E. Other (specify):	
Is this application being submitted to other agencies?*		<input type="radio"/> Yes	<input checked="" type="radio"/> No
What other Agencies?			
9. NAME OF FEDERAL AGENCY* National Institutes of Health		10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER TITLE:	
11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT* An Innovative mHealth Intervention for Dependence on Smoked Tobacco Using a Connected, Enhanced CO Monitor with Motivational Messaging and Gamification Features			
12. PROPOSED PROJECT Start Date* 07/01/2019		13. CONGRESSIONAL DISTRICTS OF APPLICANT Ending Date* 06/30/2021 NJ-012	

SF 424 (R&R) APPLICATION FOR FEDERAL ASSISTANCE**14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION**

Prefix: Dr. First Name*: Larry Middle Name: Last Name*: Pearlstein Suffix: Ph.D
 Position>Title: Associate Professor
 Organization Name*: COLLEGE OF NEW JERSEY
 Department: Electrical & Comp Engineering
 Division:
 Street1*: PO BOX 7718
 Street2: 2000 Pennington Road
 City*: Ewing
 County: Mercer
 State*: NJ: New Jersey
 Province:
 Country*: USA: UNITED STATES
 ZIP / Postal Code*: 086280718
 Phone Number*: 6097712529 Fax Number: 6096375135 Email*: pearlstl@tcnj.edu

15. ESTIMATED PROJECT FUNDING

a. Total Federal Funds Requested*	\$393,516.89
b. Total Non-Federal Funds*	\$0.00
c. Total Federal & Non-Federal Funds*	\$393,516.89
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: Mr. First Name*: David Middle Name: Last Name*: Blake Suffix: Ph.D
 Position>Title: Vice Provost
 Organization Name*: The College of New Jersey
 Department:
 Division:
 Street1*: PO BOX 7718
 Street2: 2000 Pennington Road
 City*: Ewing
 County: Mercer
 State*: NJ: New Jersey
 Province:
 Country*: USA: UNITED STATES
 ZIP / Postal Code*: 086280718
 Phone Number*: 6097713048 Fax Number: 6096375161 Email*: srcompliance@tcnj.edu

Signature of Authorized Representative*

David Blake

Date Signed*

10/16/2018

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

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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: COLLEGE OF NEW JERSEY

Duns Number: 0303159800000

Street1*: PO BOX 7718

Street2: 2000 Pennington Road

City*: EWING

County: Mercer

State*: NJ: New Jersey

Province:

Country*: USA: UNITED STATES

Zip / Postal Code*: 086280718

Project/Performance Site Congressional District*: NJ-012

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: Henry J. Austin Health Center

DUNS Number:

Street1*: 321 North Warren Street

Street2:

City*: Trenton

County: Mercer

State*: NJ: New Jersey

Province:

Country*: USA: UNITED STATES

Zip / Postal Code*: 08618-4741

Project/Performance Site Congressional District*: NJ-012

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 Yes No 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_Abstract.pdf**8. Project Narrative*** Project_Narrative.pdf**9. Bibliography & References Cited** References.pdf**10. Facilities & Other Resources** Facilities_and_Other_Resources.pdf**11. Equipment** Equipment.pdf

Project Summary/Abstract

Smoking, the leading cause of preventable death in the United States, affects 15.5% of the population and 25.3% of persons living below the poverty level. The conventional treatment for tobacco dependence consists of monthly provider office visits with counseling, nicotine replacement therapy, and prescription medication. Significant barriers to utilizing such treatment exist for low-socioeconomic status (SES) individuals due to infrequent provider appointments, transportation difficulties, inability to take time off from work, and language barriers. Thus there is a critical need to provide a tobacco dependence program that can reach low-income individuals remotely and on their schedules, which would strengthen patient adherence to treatment, reduce barriers to communication with providers, and improve provider monitoring of patient progress. The long term goal of this study is to reduce smoking among vulnerable low-SES populations. The objective of this R21 application is to develop, implement, and evaluate a novel telehealth intervention at a Federally Qualified Health Center (FQHC), which serves socioeconomically disadvantaged individuals. The proposed study will pursue three specific aims: (1) Develop technology that incorporates an affordable bilingual mHealth device and telemetry, allowing for remote access in the acquisition, visualization, and monitoring of biomedical CO data, and contemporaneous patient self-reporting; (2) Compare smoking outcomes, retention rates, and patient-provider communication between the treatment group and the control group; and (3) Analyze the potential effectiveness of engagement with the device, including measuring CO levels, reading/listening to motivational messages, and interacting with gamification components, on improving smoking outcomes within the treatment group. The research design involves a 3-month individually randomized group-treatment trial (IRGT). The “control” group will receive the standard smoking cessation regimen. The “treatment” group will be given our device, and instructed to measure their daily CO levels and provide status updates. Collected data will be automatically transmitted via a secure link to a cloud database that will be readily accessible to authorized providers. Patients will receive motivational messages, collect virtual rewards, and engage remotely on a frequent basis with their providers using their devices. The methods will include means comparisons between the control group and treatment group regarding the program effectiveness, and correlations between device engagement and program effectiveness within the treatment group. The proposed research aligns with both the NIH and NIBIB missions of developing scalable biomedical technologies and utilizing multidisciplinary approaches to improve health, lengthen life, and reduce illness and disability.

Project Narrative

The proposed research project is relevant to public health as it seeks to address smoking, the nation's leading cause of preventable death, as well as to reduce health disparities by focusing on low-income individuals, which would improve health, lengthen life, and reduce illness and disability, and lower the nation's health care bill. The proposed intervention utilizes a multidisciplinary approach to develop novel biomedical technology, which enables an interactive tobacco dependence treatment combined with motivational messages and gamification components tailored to low-income individuals. If this study proves successful with low-income individuals, it could be easily scalable to treat millions of patients enrolled at hundreds of FQHCs nationwide, complement or even radically transform standard tobacco dependence treatment for any income group, and be readily applicable to a wide variety of other health conditions.

Facilities and Other Resources

Facilities

The proposed technology research and development will be organized and carried out by Dr. Larry Pearlstein. This work involves mechanical and electronic design for the T-COM, handoff to manufacturing, design verification and environmental testing, and development of the cloud database and cloud-based applications. Dr. Pearlstein is the director of the Intelligent Media Processing Laboratory (IMPL) at The College of New Jersey (TCNJ), and has at his disposal all of the lab space, computer workstations, design tools and test equipment required to successfully complete the proposed work. After completion of a building extension renovation in December 2019, the IMPL will have approximately 450 ft² of lab space. While the renovation is underway during most of 2019, his lab equipment will be temporarily housed in the recently constructed STEM complex, and the IMPL will be fully operational during the period of renovation. The STEM complex is a modern 89,000 square foot facility that designed to house and showcase TCNJ research labs for science and engineering.

Dr. Hu will create and test motivational messages, design gamification features, and conduct overall and feature specific usability testing through focus groups and one-on-one interviews. The Department of Communication Studies where she works at has a 2500 square foot television studio with cutting-edge video and audio recording and editing equipment. In addition, the department has a newly established computer lab with the most state-of-the-art hardware and software.

Founded in 1855, The College of New Jersey (TCNJ) is a highly selective institution that has earned national recognition for its commitment to excellence. Emphasizing a residential experience for its more than 6,500 undergraduates, TCNJ is one of Barron's 75 "Most Competitive" American colleges. The U.S. News 2019 edition of Best Colleges ranks TCNJ as #4 in Regional Universities North, and #9 in undergraduate teaching. The beneficial student-to-faculty ratio (13:1) and small average class size (21) attracts highly qualified students. TCNJ received a Phi Beta Kappa chapter in 2006, a distinction held by less than 10% of institutions nationally. TCNJ's faculty members are teacher-scholars who share a commitment to undergraduate learning while engaging in active research programs involving undergraduates. Focus on undergraduate research is a key mission of TCNJ, earning it the Council on Undergraduate Research (CUR) 2015 Campus-wide Award for Undergraduate Research Accomplishment, an award that recognizes exemplary programs providing high-quality undergraduate research experiences.

Ivy Pearlstein has an appointment at TCNJ as a Clinical Educator which includes a position as a clinical provider at Henry J. Austin Health Center, the Federally Qualified Health Center (FQHC) where the study will take place. This FQHC employs physicians, nurse practitioners, nurses, medical assistants, behavioral health counselors, clinical pharmacists, and a counselor who specializes in asthma education and tobacco dependence counseling. This health center regularly treats 13,000 patients annually, many of whom identify themselves as smokers, with an interest in quitting. This FQHC uses the Athena electronic medical record for patient records as well as Pacific Interpreters telephone language line service.

Other Resources

a). Student workers

The proposed study will hire student workers to assist the research team at various stages of the study. As noted above, TCNJ employs a *teacher-scholar model* for its faculty. Such a model is immensely valuable to the students, since faculty provide hands-on experience to students in their laboratories conducting research activities and incorporate their research directly into the classroom.

For the proposed study, we will incorporate TCNJ undergraduate students. TCNJ offers a wealth of degree programs through the College's seven schools: Arts and Communication; Business; Education; Engineering; Humanities and Social Sciences; Nursing, Health, and Exercise Science; and Science. TCNJ employs a teacher-scholar model, and one of its five signature experiences is "undergraduate research, mentored internships, and field experiences." Such a model is immensely valuable to the students, since faculty provide

hands-on experience to students in their laboratories conducting research activities and incorporate their research directly into the classroom. Many students are highly skilled in their respective areas of concentration and obtain valuable experience while contributing to faculty-led research projects.

The proposed project has generated a great deal of student enthusiasm among students enrolled in the Electrical and Computer Engineering (ECE) and Mechanical Engineering majors, and four qualified students have already expressed a strong desire to participate in the work. Additionally, student workers with relevant areas of concentration and skills will help with organizing control and treatment group patient information, developing, designing, testing, and refining motivational messages and gamification features, translating in Spanish and recording motivational messages (English and Spanish), and collecting data on uses and perceptions of T-COM as well as perceptions of patient-provider communication.

b). Research time allocation and course release

At TCNJ, 25% of faculty time each semester is reserved for non-teaching activities under the standard teacher-scholar model and does not appear in the personnel budget.

c). SOSA course release

TCNJ faculty members may apply for a Support of Scholarly Activity (SOSA) grant, a highly competitive TCNJ award that provides an additional 25% release time (1 course release per year) for 2 years. At any given time, approximately 35% of full-time faculty receive release time through this award mechanism. Dr. Pearlstein was awarded a SOSA grant for the 2015-2017 cycle and has an application pending for the 2019-2021 cycle. Dr. Brodersen was awarded a SOSA grant for the 2011-2012, 2013-2015, and 2018-2020 cycles, and will apply again for the 2020-2022 cycle. Dr. Hu was awarded SOSA grants for the 2010-2012, 2012-2014, and 2017-2018 cycles, and will apply again in the future.

Equipment

Dr. Pearlstein's Intelligent Media Processing Laboratory (IMPL) is fully equipped for the activities involved in the proposed work, namely embedded systems engineering, test and handoff to manufacturing, multimedia creation and evaluation, and development of cloud database and computing applications. The following equipment housed by the IMPL is directly accessible for this project:

- Four (4) high-performance, high capacity, Linux workstations—These are used for research in media processing, electronic design automation (EDA) tools including printed circuit board design, and software development. An extensive installation of MATLAB software is supported for advanced analysis of images and signals.
- Four (4) High-performance Windows workstations—These are used for embedded system development, cloud computing development, printed circuit board design using Autodesk Eagle, and mechanical part design using SolidWorks.
- Three (3) Raspberry Pi Linux systems—These are used for prototyping intelligent embedded systems.
- One (1) 55" LG OLED TV—This is one of the most accurate displays commercially available. It is used for image and graphic creation and evaluation, and group presentations.
- One (1) ChromaATE Color Analyzer—It is used for analyzing the accuracy of electronic displays.
- Microphone, amplifier, loudspeakers—These are used for audio capture, enhancement, editing and evaluation.
- National Instruments VirtualBench—This is an integrated device, which provides 100 MHz oscilloscope, logic analyzer, protocol analyzer, signal generator, spectrum analyzer, and triple programmable power supplies.
- Miscellaneous breadboards, microcontrollers, sensors, actuators, switches, field-programmable gate array development systems, and Bluetooth, Wi-Fi, and long-range wireless embedded network development systems.

The Department of Electrical and Computer Engineering (ECE) owns an array of sophisticated equipment for test and measurement of signals, capable of operation at frequencies beyond 5 GHz. The ECE Department also owns a Tenney Environmental Test Chamber that will be used to verify proper operation of our devices over a specified range of environmental conditions. The ECE labs include a stockroom with thousands of common discrete and integrated components that can be used for experimentation.

A common machine shop is available within the School of Engineering, which houses CNC mills, lathes, drill presses, sheet metalworking equipment, and plastic processing equipment. Rapid prototyping equipment for 3D printing of parts and quick-turnaround printed circuit board manufacturing is also available, and will be used as needed.

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator			
Prefix: Dr.	First Name*: Larry	Middle Name	Last Name*: Pearlstein
Position/Title*	Associate Professor		
Organization Name*	COLLEGE OF NEW JERSEY		
Department:	Electrical & Comp Engineering		
Division:			
Street1*:	PO BOX 7718		
Street2:	2000 Pennington Road		
City*:	Ewing		
County:	Mercer		
State*:	NJ: New Jersey		
Province:			
Country*:	USA: UNITED STATES		
Zip / Postal Code*:	086280718		
Phone Number*:	6097712529		
	Fax Number: 6096375135		
E-Mail*:	pearlstl@tcnj.edu		
Credential, e.g., agency login: PEARLSTL			
Project Role*:	PD/PI		
Other Project Role Category:			
Degree Type:	Ph.D.		
Degree Year:	1987		
Attach Biographical Sketch*:	File Name:	Larry_Pearlstein_biosketch.pdf	
Attach Current & Pending Support:	File Name:		

PROFILE - Senior/Key Person				
Prefix:	First Name*: Ivy	Middle Name	Last Name*: Pearlstein	Suffix:
Position/Title*:	Clinical Educator			
Organization Name*:	The College of New Jersey			
Department:	Nursing			
Division:				
Street1*:	PO BOX 7718			
Street2:	2000 Pennington Road			
City*:	Ewing			
County:	Mercer			
State*:	NJ: New Jersey			
Province:				
Country*:	USA: UNITED STATES			
Zip / Postal Code*:	086280718			
Phone Number*:	6097712591		Fax Number: 6097715159	
E-Mail*:	pearlsi1@tcnj.edu			
Credential, e.g., agency login:	PEARLSI1			
Project Role*:	Co-Investigator		Other Project Role Category:	
Degree Type:	RN, MSN, APN		Degree Year: 1998	
Attach Biographical Sketch*:	File Name:	Ivy_Pearlstein_biosketch.pdf		
Attach Current & Pending Support:	File Name:			

PROFILE - Senior/Key Person				
Prefix:	First Name*: Donka	Middle Name	Last Name*: Brodersen	Suffix:
Position/Title*:	Associate Professor			
Organization Name*:	The College of New Jersey			
Department:	Economics			
Division:				
Street1*:	2000 Pennington Road			
Street2:				
City*:	Ewing			
County:	Mercer			
State*:	NJ: New Jersey			
Province:				
Country*:	USA: UNITED STATES			
Zip / Postal Code*:	086280718			
Phone Number*:	6097712260		Fax Number: 6095375129	
E-Mail*:	mirtchev@tcnj.edu			
Credential, e.g., agency login:	MIRTCHEV			
Project Role*:	Co-Investigator		Other Project Role Category:	
Degree Type:	Ph.D.		Degree Year: 2008	
Attach Biographical Sketch*:	File Name:	Donka_Brodersen_biosketch.pdf		
Attach Current & Pending Support:	File Name:			

PROFILE - Senior/Key Person				
Prefix: Dr.	First Name*: Yifeng	Middle Name	Last Name*: Hu	Suffix: Ph.D
Position/Title*:	Associate Professor			
Organization Name*:	The College of New Jersey			
Department:	Communication Studies			
Division:				
Street1*:	2000 Pennington Road			
Street2:				
City*:	Ewing			
County:	Mercer			
State*:	NJ: New Jersey			
Province:				
Country*:	USA: UNITED STATES			
Zip / Postal Code*:	086280718			
Phone Number*:	6097712373		Fax Number: 6096375187	
E-Mail*:	hu@tcnj.edu			
Credential, e.g., agency login: HU@TCNJ.EDU				
Project Role*:	Co-Investigator		Other Project Role Category:	
Degree Type:	Ph.D.		Degree Year: 2007	
Attach Biographical Sketch*:	File Name:	Yifeng_Hu_Biosketch.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: Larry A. Pearlstein

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

POSITION TITLE: Associate Professor, Department of Electrical and Computer Engineering

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
Drexel University, Philadelphia, PA	BSEE	5/1982	Electrical Engineering
Princeton University, Princeton, NJ	MA, MS, PhD	8/1984 5/1987	Electrical Engineering

A. Personal Statement

My role in this project will be to lead the development of the technology components required by the research project. Specifically I will be responsible for development of the T-COM, a portable device that serves as a breath carbon monoxide sensor and two-way communication link for audio, text and telemetry data. I will also be responsible for provisioning of the cloud database and web server, and creating the backend web page application, which allows the clinician to monitor clients and control interactions via a user-friendly portal. My work will involve the design of printed circuit boards and 3D printed enclosures, as well as various forms of software. The software will include embedded code running on the device, and the web application code that builds pages and code for managing text and audio messaging.

I will work closely with the rest of the team. I will collaborate with Dr. Hu to help ensure that the human factors are appropriately considered, and that the device will be attractive, engaging and easily understandable by the intended user. I will collaborate with Ms. Pearlstein regarding the technical requirements of the device, and with Dr. Brodersen regarding the bill-of-materials cost targets, and plans for ramping manufacturing (post pilot study).

My educational background is in Electrical Engineering, with a concentration in digital signal processing. Specifically, I have a strong background in embedded systems, with experience in industry, teaching and research, and have supervised successful projects involving networked applications based on a cloud database and website builder. I have over 25 years of industrial experience involved in the development of connected computerized electronics devices. As part of my industry experience I managed an international team of PhD-level researchers, leading to publication of our work, and development of state-of-the-art electronic chips that shipped in millions of digital television receivers and personal computers. I have taught courses including digital design, embedded systems and advanced electronics. I perform research in multimedia, and I am the Director of the Intelligent Media Processing Laboratory at TCNJ. I have mentored students in research and supervised a number of Senior Design Projects. I have been granted more than 70 US patents, and I have published conference papers and journal articles.

Selected Publications

Pearlstein, Larry, S. Maxwell, and A. Aved, "Adaptive prediction resolution video coding for reduced DRAM bandwidth", to appear in Elsevier Integration, the VLSI Journal, 2018.

Sorek, Noam, and L. Pearlstein. "Methods and systems for enhanced viewing of a display device." U.S. Patent No. 9,459,474. 4 Oct. 2016.

Pearlstein, Larry, A.J. Aved, and I. Patel, "Video coding layer optimization for target detection," 2016 IEEE Applied Imagery Pattern Recognition Workshop (AIPR), IEEE, 2016.

Pearlstein, Larry, M. Kim, and W. Seto, "Convolutional neural network application to plant detection, based on synthetic imagery," 2016 IEEE Applied Imagery Pattern Recognition Workshop (AIPR), IEEE, 2016.

B. Positions and Honors

Positions

1986-1987	Ass't. Prof. of Elect. Eng., University of Delaware, Newark DE.
1987-1989	VP Engineering, BioAutomation, Bridgeport, PA.
1989-1990	Lead Scientist, Computer Sciences Corporation, Moorestown, NJ.
1990-2000	Chief Researcher, Hitachi America, Princeton, NJ.
2000-2014	System-on-chip Architect and Technical Director, ATI/AMD/Broadcom, Yardley, PA.
2014-present	Assoc. Prof. of Elect. & Comp. Eng., The College of New Jersey, Ewing, NJ

Honors

1982	First Honors (of 129 EE students), Drexel University
1982-1987	National Science Foundation Graduate Fellow, Princeton University, Princeton, NJ
1998	Hitachi America President's Award
2018	Promoted to Senior Member status by Institute of Electrical and Electronic Engineers

C. Contributions to Science

I participated in the ISO MPEG international standardization activity that led to the development of MPEG audio and video coding standards, which radically transformed how people create, distribute and play audio and video. I was the Chairman of the ATSC T3/S6 Specialists Group on Video Coding, which developed the standard for digital TV in North America to replace the analog system that had been in use for about 55 years.

I developed the architecture for a family of low-cost audio/video compression chips that enabled standard personal computers to act as digital video recorders (DVRs). I led the development of algorithms and hardware/software implementation of motion compensated frame-rate conversion, which enabled digital television sets to display low frame-rate movies with smooth motion on a flat panel display.

I developed technologies for high performance video processing using heterogeneous multiprocessing, and for low cost implementation of video decoders. I developed algorithms for reducing the DRAM bandwidth requirements for video decoders.

D. Additional Information: Research Support and/or Scholastic Performance

My research has been supported by The College of New Jersey via a grant for Support Of Scholarly Activity (SOSA), covering 2015-2016. I also received support for my research on Deep Learning from the Air Force Research Laboratory for 2016-2017.

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: Pearlstein, Ivy

eRA COMMONS USER NAME (credential, e.g., agency login): PEARLSI1

POSITION TITLE: Clinical Educator

EDUCATION/TRAINING BSN, University of Pennsylvania, MSN, La Salle University

INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	Completion Date MM/YYYY	FIELD OF STUDY
University of Pennsylvania, Philadelphia, PA	BSN	05/1980	Nursing
La Salle University, Philadelphia, PA	MSN	05/1998	Nursing, Adult Nurse Practitioner Certification
The College of New Jersey, Ewing, New Jersey	Postmasters	05/ 2006	Family Nurse Practitioner Certification

A. Personal Statement

I have worked as a nurse in a variety of settings including primary care, retail health and intensive care units. I have seen first hand the effects of smoking on patients. I have taken care of patients after heart attacks, on oxygen, ventilators, some who recovered and many who did not. I have seen some patients who recovered resume smoking as soon as they left the hospital. I have also cared for patients who quit smoking but still recovered from the chronic nature of the disease caused by smoking. I became curious about those that were able to quit smoking. I began asking patients how they did it and most often the reply was, "Cold turkey," referring to having no help at all. I began to ask the cardiologists and pulmonologists in the ICU if they told their patients to quit smoking and they replied with a resounding "Yes" but when I asked how they assisted their patients to quit the answer was a silent shrug, as if they did not believe it was possible to help a smoker to quit. It was not until after becoming a Nurse Practitioner that I had the opportunity to work with addiction psychiatrists on a clinical trial that I learned about Motivational Interviewing. I began to see that it was possible to use this powerful technique to engage patients in their quit process, even if they were ambivalent, by guiding them to find their strengths and using those strengths to achieve their health goal. Experience with this clinical trial enabled me to conceive of and lead the iQuit clinical trial at HiTOPS adolescent Health center.

My primary role in the proposed project relates to implementation of the proposed clinical trial at the Henry J. Austin Federally Qualified Health Center in Trenton, NJ. It will be my responsibility to train the tobacco dependence counselors and providers to use the device and the portal as well as to enroll patients and treat them for tobacco dependence. I will oversee personnel at the site to ensure that patient consents are obtained correctly and ethically, and that these consent forms are stored in a secure location, that the pilot study is carried out as planned, and any concerns are addressed. I will be a study resource for the staff at the health center and will monitor usage of the portal. I will assist with creating the motivational messages, which will be automatically sent via the T-COM device to patients in response to their CO readings. I will be available to respond to patients when they send messages or need assistance through their T-COM. I will assist with creation and administration of final study questionnaires for patients and data analysis at the conclusion of the pilot study.

Select Publications

Pearlstein I., & Friedman S. (2009). Reduction of Cigarette Smoking via iQUIT: A Web-Based Program Using Podcasting and Text Messaging in Adolescents. *Journal of Adolescent Health*, 44(2):S24.

Williams JM, Steinberg ML, Zimmermann MH, Gandhi KK, Lucas GE, Gonsalves DA, Pearlstein I, Mccabe P, Galazyn M, & Salsberg E. (2009). Training psychiatrists and advanced practice nurses to treat tobacco dependence. *Journal of the American Psychiatric Nurses Association*, 15(1):50-58.

B. Positions and Honors

Positions and Employment

2017-present	Clinical Educator, The College of New Jersey
2013-2017	Nurse Practitioner Rediclinic, Langhorne, PA, staff inservice on smoking cessation counseling in a retail health clinic
2016	Nurse Practitioner of the Year, RediClinic, Philadelphia District
2006-2013	Health Center Director, HiTOPS Adolescent Health Center, Preceptor for NP students
2005	Nurse Practitioner in a multicenter-randomized trial of buprenorphine-naloxone versus clonidine for opioid detoxification
2001-2010	Nurse Practitioner, clinician at Mercer County Tobacco Dependence Program, Trenton, NJ

Other Experience and Professional Memberships

2001	Member, ANA, AANP
2006	Member Sigma Theta Tau, National Nursing Honor Society
2010	Invited lecturer at NLN Annual conference on topic of vaping

Honors

2015	Nurse Practitioner of the year at Rediclinic
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C. Contribution to Science

I had the opportunity to work at HiTOPS Adolescent Health Center in Princeton, NJ, where I innovated tobacco treatment for adolescents and young adults who were smokers. This work was supported by a grant from the American Legacy Foundation, which helped me develop the iQuit Program in 2008. iQuit was a tailored quit program for young people using text messaging (which was novel at the time) and podcasting (which was virtually unknown at the time) to deliver a seven part smoking cessation program in English and Spanish. The pilot program followed 60 patients for 6 months and demonstrated improved quit rates and reductions in cigarette use. This program was shared at the Annual conference of the Society of Adolescent Medicine in San Antonio, Texas.

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: Brodersen, Donka Mirtcheva

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

POSITION TITLE: Associate Professor of Economics

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
American University in Bulgaria, Bulgaria	B.S.	05/2001	Applied Economics, Business Administration
University of Illinois at Chicago	M.A.	05/2003	Economics
University of Illinois at Chicago	Ph.D.	05/2008	Economics

A. Personal Statement

I have the expertise, leadership abilities, and motivation to successfully support the team and carry out the proposed project. As a health economist, my primary area of research is health behavior. I worked under Frank J. Chaloupka as a member of his research group, which focused on smoking cessation and obesity. Dr. Chaloupka is an internationally renowned health economist, known for his work on the economics of tobacco control. I have published work on health behavior, including obesity, smoking, and other health conditions. My areas of research have overlapped with research in public health, nursing, medicine, sociology, psychology, and education, and I have experience in the statistical analysis techniques used in those fields. As a health economist, my experience has been primarily with large secondary datasets. As a faculty researcher, I have also had experience with small-scale survey data collection and primary data analysis, as well as IRB applications. My research interests in health behavior, especially those focusing on program evaluation for low-income population, strongly align with the proposed research project on decreasing health disparities by offering a smoking cessation trial program for low-income population in Trenton, NJ. I have experience working with excellent students from the College as collaborators, research assistants, independent study students, and students from my Health Economics classes, which include majors in Economics, Public Health, and others. I have found that the quality of work of our students often matches that of graduate students.

My primary role in the proposed project relates to data collection and analysis. I will take the lead on designing the patient survey questions; obtaining IRB approval; merging the data from the patient surveys, electronic records, and device; cleaning the data; and performing data analysis to evaluate the effectiveness of the treatment (comparisons between treatment and control groups) and the effectiveness of the motivational messages and gamification features (comparisons within the treatment group). I will also contribute toward completion of various other tasks, such as creating effective motivational messages, organizing the Spanish student translators of the messages and the student actors to create the audio messages, and overseeing various logistics in the process of completing the project (e.g., meeting bill-of-materials cost targets, plans for ramping manufacturing post pilot study).

Selected Publications*

- Powell, L.M., Slater, S., **Mirtcheva D.**, Bao, Y. & Chaloupka, F. (2007). Food store availability and neighborhood characteristics in the United States. *Preventive Medicine*, 44(3), 189-195.**
- Mirtcheva, D.M.** & Powell, L.M. (2013). National School Lunch Program Participation and Child Body Weight. *Eastern Economic Journal*, 39(3), 328-345. doi:10.1057/eej.2012.14.
- Chiswick, Barry R., & **Mirtcheva, D.M.***** (2013). Religion and child health: Religious affiliation, importance, and attendance and health status among American youth. *Journal of Family and Economic Issues*, 34(1), 120-140. doi: 10.1007/s10834-012-9312-5.
- Matthew, P. & **Brodersen, D.M.** (2017). Income Inequality and Health Outcomes in the United States: An Empirical Analysis. *Social Science Journal*, forthcoming, <https://doi.org/10.1016/j.soscij.2018.05.001>.

Notes: * Mirtcheva and Brodersen refer to the same person

** 963 Google Scholar citations as of 10-8-2018

*** First author (author names listed alphabetically).

B. Positions and Honors

Positions and Employment

- 2001-2005 Graduate Student Instructor, University of Illinois at Chicago, Chicago, IL
2002-2006 Faculty and Teaching Assistant, Rush University-Medical Center, Chicago, IL
2006 Visiting Summer Instructor, Governors State University, University Park, IL
2008-2013 Assistant Professor, The College of New Jersey, Ewing, NJ
2013-present Associate Professor, The College of New Jersey, Ewing, NJ.

Other Experience and Professional Memberships

- 2004-2009 Member, Illinois Economic Association
2006-2009 Member, Midwest Economic Association
2009-present Member, Eastern Economic Association
2013-present Member, American Economic Association
2018-present Liaison, Committee on the Status of Women in the Economics Profession.

Honors

- 2016-present Phi Kappa Phi faculty.

C. Contribution to Science

My scholarly work comprises applied research spanning across three main distinct areas: health behavior economics, the economics of religion, and welfare economics. More specifically, in my research I have examined health behaviors, such as obesity, smoking, and other health conditions. Much of my research focuses on low-income populations. For example, we merged data on food stores with neighborhood characteristics (such as race, ethnicity, socioeconomic status, population size) and found that the availability of chain supermarkets is much lower in low-income neighborhoods than middle-income neighborhoods (75% fewer, $p<0.01$), and in predominantly African American urban zipcodes than White urban zipcodes (41% fewer, $p<0.01$) (Powell et al. 2008). I have found that income disparities are highly correlated with health. In a recent study, we found that income inequality has significant relationships with behavioral, physical, and mental health outcomes, and often the impact on low-income individuals is slightly smaller than on the high-income group, suggesting that economic policies to address the rising income inequality in the United States might serve to also address some of our nation's most troubling health statistics (Matthew & Brodersen, 2017). I have also worked on welfare program evaluation. In another paper, we found that participation in the National School Lunch Program (NSLP), a program for low-income students, is associated with higher body weight among girls, but not boys; however, the relationship between school lunches and child body weight was not found to be causal, suggesting that school lunches per se were not the culprit (Mirtcheva & Powell 2013). My research interests strongly align with the proposed research project on decreasing health disparities by offering a smoking cessation trial program for low-income population in Trenton, NJ.

Overall, I have six (6) papers published in academic journals, numerous conference presentations, and two (2) invited presentations. The College of New Jersey's competitive Support of Scholarly Activity program has supported my research in 2011-2012, 2013-2015, and 2018-2020, and the Mentored Undergraduate Summer Experience (MUSE) program has supported my research work with student-collaborators in 2008 and 2009.

D. Additional Information: Research Support and/or Scholastic Performance

- 2005-2006 Chicago Center of Excellence in Health Promotion Economics fellowship, University of Illinois at Chicago and University of Chicago
- 2006-2008 Co-Investigator on a cooperative research grant from the Economic Research Service (ERS) at the U.S. Department of Agriculture, entitled "Diet, Weight, and USDA School Meal Participation." #58-5000-6-0036. \$31,803
- 2008 Baylor University and George Mason University scholarship for participation and presentation at the Graduate Workshop on Religion, Economics, & Politics, Alexandria, VA
- 2010-2013 The College of New Jersey's (TCNJ) Advancement Program (TAP) External Mentorship Grant award and Travel award. \$5,300. TAP is a National Science Foundation (NSF)-funded program to promote gender equity in professional advancement through mentorship, workshops, policy development, and rigorous evaluation in NSF-supported disciplines.

Ongoing Research Support

- 2018-2019 Curriculum Development Grant award, Global Religion Research Institute, University of Notre Dame, \$4,000
- 2018-2020 Support of Scholarly Activities (Faculty Resources Grant), The College of New Jersey.

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: Yifeng Hu

eRA COMMONS USER NAME (credential, e.g., agency login): HU@TCNJ.EDU

POSITION TITLE: Associate Professor, Chair, Department of Communication Studies

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
Renmin University of China, Beijing, China	B.A.	06/2000	Journalism
Chinese University of Hong Kong, Hong Kong	M.Phil.	08/2002	Communication
Pennsylvania State University, University Park, PA	Ph.D.	06/2007	Mass Communication

A. Personal Statement

I have the expertise, leadership, training, and motivation necessary to successfully carry out the proposed research project. I have a broad background in new media and health communication, with training and expertise in a variety of research methods such as survey, experiment, in-depth interview and focus groups. My major research interests focus on the uses and effects of new media and emerging technologies in a variety of health communication contexts. I have published in top tier journals and presented at various academic conferences scholarly pieces related to uses and effects of new media and emerging technologies in a variety of health communication contexts, ranging from online health source credibility, to influences of online health search on provider-patient relationship, to motivations and benefits of mental health blogging in a larger public health setting.

As a researcher specializing in new media and health communication, my major role in this collaborative project is to connect and balance technology and the human element. Specifically, I will be in charge of these tasks: 1) use the approach of motivational interviewing in behavioral health intervention to create motivational messages to be delivered via the enhanced CO Monitor to patients seeking smoking cessation based on their individual progress; 2) design gamification features for the monitor, specifically different types of rewards such as point systems, badges/medals, and animated feedback to engage users; 3) conduct overall and feature specific usability testing through focus groups and one-on-one interviews; and 4) craft survey questions for both providers and patients regarding their uses and perceptions of the device as well as their perceptions of provider-patient communication. In addition, I will contribute my expertise from other health intervention programs that I have worked on to ensure that the intervention is designed and administered properly throughout the whole process.

Recently, I have been heavily involved in two interdisciplinary research projects that can shed lights on this project in many ways. Gamification has gained increased attention in health intervention and education. In summer 2018, through internal grants and a grant from New Jersey Department of Health, I successfully led and administered a project on designing an interactive and engaging video game with narrative immersion to promote mindful drinking among college freshmen. I collaborated with a team of faculty and student workers from Communication, Public Health, and Interactive Multimedia. The team produced a pilot video game and

did multiple usability tests. Based on the feedback, we are further developing the program which has the potential to be adopted by The College of New Jersey as its mandatory alcohol education program for incoming freshmen in 2019. Another health intervention project that I am leading, funded by The College of New Jersey's Mini Engagement Grant, is a campus-wide, mixed-media social marketing campaign to reduce excessive alcohol consumption. As a result of these experiences, I am aware of the importance of frequent communication among project members and of constructing a realistic research plan, timeline, and budget.

Related to my scholarly work, I have designed and developed an advanced undergraduate course, New Media and Health Communication, since I joined The College of New Jersey. Attracting students from various disciplines, this course is now a key offering in the new public health major and Master of Public Health program and required for all who concentrate in the health communication track. With my research and teaching expertise in new media and health communication, I have been invited to teach a similar graduate-level course at Mailman School of Public Health, Columbia University. The proposed project will be a great case study for topics such as wearables and self-tracking and gamification for health in my classes. Students feedback and participation in this project will in turn benefit the project.

Selected Publications and Research Products:

1. Hu, Y. (Forthcoming). Helping is healing: A social dimension of mental health blogging. *Journal of Communication in Healthcare*. [REFEREED]
2. Hu, Y., & Fishburn J., Newell G., Capria, K. L., Cheng, E., & Laureano, N. (2018). "Fresh Start" - An Interactive Video Game With Narrative Immersion to Promote Mindful Drinking Among College Freshmen. Presentation at the 2018 Interdisciplinary Research Forum, The College of New Jersey.
3. Hu, Y. (2015). Health communication research in the digital age: A systematic review. *Journal of Communication in Healthcare*, 8(5), 260-288. [REFEREED]
4. Hu, Y., & Sundar, S. S. (2010). Effects of online health sources on credibility and behavioral intentions. *Communication Research*, 37(1), 105-132. [REFEREED] *

* Top journal in the communication field. Cited by 287 times on Google Scholar as of October 08, 2018.

B. Positions and Honors

Positions and Employment

2005-2006	Lecturer, College of Communications, Pennsylvania State University
2007-2016	Assistant Professor, Department of Communication Studies, School of the Arts and Communication, The College of New Jersey
2016-present	Associate Professor, Department of Communication Studies, School of the Arts and Communication, The College of New Jersey
2018-present	Adjunct Faculty, Department of Socialmedical Sciences, Mailman School of Public Health, Columbia University
2018-present	Chair, Department of Communication Studies, School of the Arts and Communication, The College of New Jersey.

Current Professional Membership

2018-present Founding Member, Society for Health Communication

Honors

- University Practicum Scholarship, Renmin University of China, 1996 – 1997.

- University Top Student Scholarship (the highest GPA in the School of Journalism & Communication), Renmin University of China, 1996 – 1997.
- People's Daily Award (the highest GPA in the School of Journalism & Communication), Renmin University of China, 1997 – 1998.
- University Exceptional Student Fellowship (one of five selected from all the students in the university), Renmin University of China, 1998 – 1999.
- Graduate Fellowship, Chinese University of Hong Kong, 2000 – 2002.
- Graduate Fellowship, Pennsylvania State University, 2002 – 2005.
- Top Student Paper Award, the 2nd Chinese Communication Symposium, Shanghai, China, 2002.
- Top Student Paper Award, Chinese Communication Association, USA, 2003.
- 2nd Place, the 18th Annual Graduate Exhibition Competition, Pennsylvania State University, March 2003.
- Top Student Paper Award, Communication Technology & Policy Division, Association for Education in Journalism and Mass Communication, Kansas City, MO, July 2003.
- 2nd Place, Graduate Student Paper Competition, College of Communications, Pennsylvania State University, 2006.
- Top Panel Award, "Elevating Traditional Theories to Study New Media Environment," the 83th annual conference of the Central States Communication Association, Minneapolis, MN, April, 2014.

C. Contribution to Science

1. My early publications involve online health search and users' perceptions of information credibility, behavioral intention, and provider-patient communication. By providing empirical evidence through strictly designed experiments and surveys of large number of participants, this body of work has added to the literature on health information technology and its impacts in human behavior and relationships. Below are two examples of this line of studies where I served as the sole or primary investigator.

- a. Hu, Y., & Sundar, S. S. (2010). Effects of online health sources on credibility and behavioral intentions. *Communication Research*, 37(1), 105-132. [REFEREED]

Online health information comes from a variety of sources. A $2 \times 2 \times 5$ full-factorial experiment ($N = 555$) examined the direct and combined influences of original sources (doctors vs. laypersons) and selecting sources (technology-based sources) on perceived credibility of—and behavioral intentions toward—health information. It revealed that online health seekers perceive different levels of credibility of the same health information and their behavioral intentions differ due to different sources. The effect was mediated by perceived level of gatekeeping and perceived information completeness. The analysis also yielded a three-way interaction between message, original source, and selecting source on perceived credibility, suggesting the operation of an appropriateness heuristic when evaluating source combinations for less relevant health topics. Theoretical and practical implications are discussed, leading to the proposal of a new online source typology.

- b. Hu, Y. (2010, November). *Competitor or collaborator? Effects of online health search on physician visit*. Paper presented at the 138th annual meeting of the American Public Health Association, Denver, CO.

A survey of 205 participants showed that online health search does not discourage patients from visiting their physicians, and building up trust is more important than worrying about patients' increased knowledge and power. The research implies that there is a beneficial effect on patient healthcare satisfaction when patients supplement doctor visits with independent research online. The only factor associated with a decline in the physician-patient relationship is when physicians feel that their authority is threatened. Providers should use this finding to their own benefits. They should encourage their patients to do online health search, which would strengthen provider-patient relationship, ultimately resulting in better health outcomes of patients.

2. In addition to the contributions described above, my other line of prior research focused on technology use and effects in human communication. For example, I led a team of graduate students and explored the relationship between the amount of Instant Messenger (IM) use and the level of perceived intimacy between friends. A survey using systematic sampling (N=138) showed that the amount of IM use was positively associated not only with verbal intimacy, but also with affective and social intimacy. Findings are consistent with the relationship liberated perspective of computer-mediated communication, and suggest that IM promotes rather than hinders intimacy. Moreover, frequent conversation via IM actually encourages the desire to meet face-to-face. Through another experimental study, my collaborators and I developed a theoretical model for which social effects of cell phone usage in public places documented in observational studies can be empirically tested. These studies emphasized the importance of being mindful of human factors while studying technology usage.
- a. Banjo, O., Hu, Y., & Sundar, S. S. (2008). Cell phone usage and social interaction with proximate others: Ringing in a theoretical model. *The Open Communication Journal*, 2, 127-135. [REFEREED]
 - b. Hu, Y., & Sundar, S. S. (2006). Computer-mediated communication (CMC). In J. J. Arnett (Ed.), *Encyclopedia of children, adolescents, and the media* (pp. 200-202). Thousand Oaks, CA: Sage. [INVITED]
 - c. Hu, Y., Wood, J. F., Smith, V., & Westbrook, N. (2004). Friendship through IM: Examining the relationship between instant messaging and intimacy. *Journal of Computer-Mediated Communication*, 10(1), Article 6. [REFEREED] **
 - d. Hu, Y. (2004). Interpersonal communication in virtual reality: Romantic ICQ. *Communication & Management Research*, 3(2), 31-66. [REFEREED]

** Top journal in the communication field. Cited by 276 times on Google Scholar as of October 08, 2018.

From 2000 to 2018, I have published 19 academic journal articles and book chapters, 21 conference presentations, and six (6) invited speeches. The College of New Jersey's competitive Support of Scholarly Activity (SOSA) program has supported my research in 2010-2012, 2012-2014, and 2017-2018, and the Mentored Undergraduate Summer Experience (MUSE) program has supported my research work with student collaborators in 2011 and 2018.

D. Additional Information: Research Support and/or Scholastic Performance

Ongoing Research Support

- TCNJ Engagement Mini-Grant (\$2,000) 2018-2019

A Campus-Wide, Mixed-Media Social Marketing Campaign to Reduce Excessive Alcohol Consumption

Completed Research Support

- New Jersey Department of Health (\$8,364) *** 2018

An Interactive Video Game with Narrative Immersion to Promote Mindful Drinking Among College Freshmen

*** The Division of Mental Health and Addiction Services partnered with The College of New Jersey in "Supporting Students in Recovery through Recovery Housing and Supports to Prevent and Reduce Substance Abuse on College Campuses".

- Mentored Undergraduate Summer Experience (MUSE): 2011; 2018
- Support of Scholarly Activities (SOSA) Award: 2010-2012; 2012-2014; 2017-2018
- Sabbatical Leave: 2015-2016

PHS 398 Cover Page Supplement

OMB Number: 0925-0001

Expiration Date: 03/31/2020

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)

PHS 398 Cover Page Supplement

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. 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. 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

5. 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 Modular Budget

OMB Number: 0925-0001
 Expiration Date: 03/31/2020

Budget Period: 1			
Start Date: 07/01/2019		End Date: 06/30/2020	
A. Direct Costs			
Direct Cost less Consortium Indirect (F&A)*			Funds Requested (\$)
Consortium Indirect (F&A)			150,000.00
Total Direct Costs*			<hr/> 150,000.00
B. Indirect (F&A) Costs			
Indirect (F&A) Type	Indirect (F&A) Rate (%)	Indirect (F&A) Base (\$)	Funds Requested (\$)
1. Salary & Wages	64.10	94,232.88	60,403.28
2.			
3.			
4.			
Cognizant Agency (Agency Name, POC Name and Phone Number)	Department of Health and Human Services Jeffrey Warren (212) 264-2069		
Indirect (F&A) Rate Agreement Date	05/31/2016	Total Indirect (F&A) Costs	<hr/> 60,403.28
C. Total Direct and Indirect (F&A) Costs (A + B)		Funds Requested (\$)	210,403.28

PHS 398 Modular Budget

Cumulative Budget Information	
1. Total Costs, Entire Project Period	
Section A, Total Direct Cost less Consortium Indirect (F&A) for Entire Project Period (\$)	150,000.00
Section A, Total Consortium Indirect (F&A) for Entire Project Period (\$)	0.00
Section A, Total Direct Costs for Entire Project Period (\$)	150,000.00
Section B, Total Indirect (F&A) Costs for Entire Project Period (\$)	60,403.28
Section C, Total Direct and Indirect (F&A) Costs (A+B) for Entire Project Period (\$)	210,403.28
2. Budget Justifications	
Personnel Justification	Personnel_Justification.pdf
Consortium Justification	
Additional Narrative Justification	

Personnel Justification

Personnel Costs

The personnel who will work on the proposed project include:

- Larry Pearlstein (PD/PI, Electrical and Computer Engineering): 3.75 person months
Dr. Pearlstein's role in this project will be to lead the development of the technology components required by the research project. Specifically he will be responsible for development of the T-COM, a portable device that serves as a breath carbon monoxide sensor and two-way communication link for audio, text and telemetry data. He will also be responsible for provisioning of the cloud database and web server, and creating the backend web page application, which allows the clinician to monitor clients and control interactions via a user-friendly portal. His work will involve the design of printed circuit boards and 3D printed enclosures, as well as various forms of software. The software will include embedded code running on the device, and the web application code that builds pages and code for managing text and audio messaging.
- Ivy Pearlstein (Co-Investigator, Nursing): 4.8 person months
Ms. Pearlstein's primary role in the proposed project relates to implementation of the proposed clinical trial at the Henry J. Austin Federally Qualified Health Center in Trenton, NJ. She will train the tobacco dependence counselors and providers to use the device and the portal as well as to enroll patients and treat them for tobacco dependence. She will also oversee personnel at the site to ensure that patient consents are obtained correctly and ethically, and that these consent forms are stored in a secure location, that the pilot study is carried out as planned, and any concerns are addressed. Ms. Pearlstein will be a study resource for the staff at the health center and will monitor usage of the portal. She will assist with creating the motivational messages, which will be automatically sent via the T-COM device to patients in response to their CO readings. She will be available to respond to patients when they send messages or need assistance through their T-COM. Finally, she will assist with creation and administration of final study questionnaires for patients and data analysis at the conclusion of the pilot study.
- Yifeng Hu (Co-Investigator, Communication Studies): 4.5 person months
Dr. Yifeng Hu's primary role in this project is to connect and balance technology and the human element. Specifically, she will be responsible for the following tasks: 1) use the approach of motivational interviewing in behavioral health intervention to create motivational messages to be delivered via the enhanced CO Monitor to patients seeking smoking cessation based on their individual progress; 2) design gamification features for the monitor, specifically different types of rewards such as point systems, badges/medals, and animated feedback to engage users; 3) conduct overall and feature specific usability testing through focus groups and one-on-one interviews; and 4) craft survey questions for both providers and patients regarding their uses and perceptions of the device as well as their perceptions of provider-patient communication. In addition, she will contribute her expertise from other health intervention programs that she has worked on to ensure that the intervention is designed and administered properly throughout the whole process.
- Donka Brodersen (Co-Investigator, Economics): 3.75 person months
Dr. Donka Brodersen's primary role in the proposed project relates to data collection and analysis. She will take the lead on designing the patient survey questions; obtaining IRB approval; merging the data from the patient surveys, electronic records, and device; cleaning the data; and performing data analysis to evaluate the effectiveness of the treatment (comparisons between treatment and control groups) and the potential effectiveness of the motivational messages and gamification features (comparisons within the treatment

group). She will also contribute toward completion of various other tasks, such as creating effective motivational messages, organizing the Spanish student translators of the messages and the student actors to create the audio messages, and overseeing various logistics in the process of completing the project (e.g., meeting bill-of-materials cost targets, plans for ramping manufacturing post pilot study).

- Student workers: 7.5 person months

The proposed study will incorporate TCNJ undergraduate students as important research contributors. TCNJ offers a wealth of degree programs through the College's seven schools: Arts and Communication; Business; Education; Engineering; Humanities and Social Sciences; Nursing, Health, and Exercise Science; and Science. TCNJ employs a teacher-scholar model, and one of its five signature experiences is "undergraduate research, mentored internships, and field experiences." Such a model is immensely valuable to the students, since faculty provide hands-on experience to students in their laboratories conducting research activities and incorporate their research directly into the classroom. Many students are highly skilled in their respective areas of concentration and obtain valuable experience while contributing to faculty-led research projects. The proposed budget includes 850 hours of student work for developing system design and software for the T-COM device in Year 1. Additionally, 450 hours of student work (230 in Year 1 and 220 in Year 2) will be devoted to organizing control and treatment group patient information, developing, designing, testing, and refining motivational messages and gamification features, translating in Spanish and recording motivational messages (English and Spanish), and collecting data on uses and perceptions of T-COM as well as perceptions of patient-provider communication.

PHS 398 Research Plan

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

Research Plan - Specific Aims

Standard tobacco dependence treatment includes repeat visits to a provider's office. Low-income individuals may face significant barriers to utilizing such treatment due to copay costs, transportation difficulties, inability to take time off from work, and language barriers [1]. Thus there is a critical need to provide a tobacco dependence program that can reach low-income individuals remotely and on their schedules, which would strengthen patient adherence to treatment, reduce barriers to communication with providers, and improve provider monitoring of patient progress. Until this need is met, smoking rates among the low-socioeconomic status (SES) population are likely to remain high, prolonging health disparities for millions of low-income individuals and imposing a high cost on society.

The long term goal of this study is to reduce smoking among vulnerable low-SES populations. The objective of this R21 application is to develop, implement, and evaluate a novel telehealth intervention for improving smoking cessation at a Federally Qualified Health Center (FQHC), which serves socioeconomically disadvantaged individuals. The proposed study will pursue three specific aims: (1) Develop technology that incorporates an affordable bilingual mHealth device and telemetry, allowing for remote access in the acquisition, visualization, and monitoring of biomedical CO data, and contemporaneous patient self-reporting; (2) Compare smoking outcomes, retention rates, and patient-provider communication between the treatment group and the control group; and (3) Analyze the potential effectiveness of engagement with the device, including measuring CO levels, reading/listening to motivational messages, and interacting with gamification components, on improving smoking outcomes within the treatment group.

Specifically, we expect to achieve three main outcomes. First, the newly developed portable mHealth technology will help low-SES patients overcome barriers in accessing smoking cessation treatment by offering them remote access to their providers in a direct, easy-to-use, cost-effective format. It will also provide patients with visualization of their CO levels, so they will gain a better understanding of the harm to their bodies caused by smoking and be able to monitor their process of recovery, both of which are expected to increase their likelihood of success in smoking cessation. This new technology will also assist providers through access to telemetry data in monitoring a large number of patients simultaneously, resulting in economies-of-scale in resource use. Second, a significantly higher fraction of the treatment group are expected to decrease their smoking rates as compared with the control group who receive the standard tobacco cessation. Third, engagement with the device features, such as taking CO levels, reading/listening to motivational messages, and interacting with gamification components, is expected to positively correlate with improved patient outcomes, as these patients will actively participate in their treatment. The language-appropriate motivational messages and entertaining gamification rewards on the device are expected to result in high retention rates of patients in the smoking cessation process and greater success in quitting smoking.

This project is innovative in several ways. It proposes a novel concept of a single device that combines CO monitoring, motivational messaging and gamification rewards, with cloud-based data storage and applications for generating and sending customized content to patients. Next, the proposed mHealth technology tailors the device to low-SES populations by reducing both the direct cost (no requirement to provide smartphone, no copayment from office visits) and indirect cost (opportunity cost of time) of tobacco dependence treatment. In addition, the proposed treatment adapts motivational messaging based on objective measures of progress. Finally, there are no published studies describing telehealth services for smoking cessation that involve cloud data and an integrated system of providers. If this study proves successful with low-income individuals, it could be easily scalable to a tiered-system that will treat millions of patients enrolled at hundreds of FQHCs nationwide, complement or even radically transform standard tobacco dependence treatment for any income group, and be readily applicable to a wide variety of other health conditions.

Research Strategy - 1. Significance

As the leading cause of preventable death in the United States, smoking takes 480,000 lives every year [2], and burdens the nation annually with \$170 billion in direct medical costs and \$156 billion in lost productivity [2,3]. Thus smoking imposes not only significant health risks on the individual, but also a heavy economic toll on society. There has been a decrease in smoking prevalence from 50% in the 1950s to 15.5% in 2016 [3,4]. Much of the progress has been attributed to tobacco treatment, which has been cited as the “gold standard” in terms of return on investment in health care spending [4]. Yet, this effective treatment has not reached all population groups to the same extent, as cigarette smoking remains at 25.3% among the segment of the population living below the poverty level [3]. Low-income individuals may face significant barriers to utilizing such treatment due to infrequent provider appointments, transportation difficulties, inability to take time off from work, and language barriers [1]. Even existing personal carbon monoxide (CO) devices (i.e., CO Smartphone Systems such as SmokerLyzer, which are wired to a smartphone) may not be appropriate for low-income patients who may not have the disposable income for a smartphone device or data plan [5]. These and other barriers result in low adherence and retention rates for low-income persons who enter treatment for tobacco dependence. Thus there is a critical need to provide a smoking cessation program that can reach low-income individuals remotely and on their schedules, strengthen patient adherence to treatment, and reduce barriers to communication, while allowing providers to frequently monitor patient progress. The proposed research addresses this need by developing a portable device, which incorporates a novel combination of personal carbon monoxide monitoring, two-way texting, motivational messaging, and engaging gamification features. Gamification is defined as “the use of game-like rewards and incentives, paired with desired behaviors, to increase motivation and sustain habits of individuals over time” [6]. There is evidence as to the efficacy of gamification in improving desired outcomes regarding health and health behaviors [7-9].

This device will be specifically tailored to low-SES populations with its simplicity and ease of use, multilingual support, and absence of any requirement for the user to have access to Wi-Fi, a smartphone or a data plan. The device will also include a built-in wireless modem to connect patients and providers through a portal and allow providers frequent access to patient data. This mHealth intervention can readily be scalable to reach millions of patients, and lead to reduced costs via the use of automated messaging in conjunction with tightly managed contingent of specially trained telehealth providers.

2. Innovation - This project proposes the development of a novel standalone portable device, T-COM (The College of New Jersey CO Monitor), to be used in tobacco dependence treatment that combines CO monitoring, enhanced visualization of biomedical data, motivational messaging, gamification features, built-in wireless communication, and interaction with cloud computing. Specifically, the proposed study offers five (5) innovative features. First, a significant attribute that distinguishes our study from prior approaches is the incorporation of wireless communication within our compact and simple to use mHealth device, eliminating the reliance on, or interaction with, a user-provided smartphone or Wi-Fi access point. This device is thus tailored to the needs of low-SES patients, who may not own a modern smartphone, or may be unable to afford a broad data plan or unlimited text messaging. Second, a cloud-based application will adapt and send tailored motivational messages based on automated analysis of their CO readings and other patient-entered data.

The T-COM will present language-appropriate (English and Spanish) motivational messages, at a fifth-grade reading level. Third, the T-COM will incorporate the use of gamification, a novel intervention strategy, which has been increasingly utilized to raise intrinsic motivation through engaging users in fun and enjoyable activities [7-9]. Gamification features such as rewards and incentives will be aligned with each patient’s trend in CO levels to motivate and engage patients in the smoking cessation program. Fourth, another innovation of the T-COM is to incorporate important Behavioral Change Techniques (BCTs) in the messaging and gamification features. BCTs have been successfully utilized in wearable devices for managing physical activity and obesity [10], however there are no published studies that incorporate BCTs with gamification features in a

patient-centered, portable device used in smoking cessation programs. Specifically, we will use BCTs for designing rewards, goal-setting messages, and machine-generated messages, all aligned with the traditional motivational interviewing approach. Finally, this is the first study to describe telehealth services for smoking cessation that involve cloud data or an integrated system of providers.

3. Approach - Overall Strategy. As a Federally Qualified Health Center (FQHC), the Henry J. Austin (HJA) clinic, located in downtown Trenton, NJ, provides primary care to uninsured or underinsured low-income patients. This population includes those who are at high risk for smoking and smoking-related illnesses. Our strategy involves identifying eligible patients and randomizing them to control and treatment groups. The control group will receive standard smoking cessation intervention, and the treatment group will receive the T-COM device-based intervention. Patients will be followed for the duration of the study to measure the extent to which they were successful in reducing their smoking, and were engaged in the process. Specifically, we expect to achieve three main outcomes. First, the newly developed portable mHealth technology will help low-SES patients overcome barriers in accessing smoking cessation treatment by offering them remote access to their providers in a direct, easy-to-use, cost-effective format. It will also provide patients with visualization of their CO levels, so they will gain a better understanding of the harm to their bodies caused by smoking and be able to monitor their process of recovery, both of which are expected to increase their likelihood of success in smoking cessation. This new technology will also assist providers through access to telemetry data in monitoring a large number of patients simultaneously, resulting in economies-of-scale in resource use. Second, the treatment group is expected to have significant higher decrease in their smoking rates, increase in their retention rates, and improved patient-provider relationship as compared with the control group. Third, engagement with the device features (taking CO levels, reading/listening to motivational messages, and interacting with gamification components) is expected to positively correlate with improved patient outcomes. **Experimental Design.** This study is characterized as an individually randomized group-treatment control trial (IRGT), as patients will receive at least some of their treatment through a common change agent (Ivy Pearlstein, Co-Investigator and Family Nurse Practitioner) in the provider office. Qualifying patients for the study are 18-85 years old, current everyday smokers, and interested in quitting in the next 30 days. The study will mainly recruit patients from the population coming to the clinic. In addition, eligible participants will be actively recruited using social media pages, posters at the clinic, outreach sites (such as libraries, churches, train station, food pantries), and through the Athena patient portal, and interested participants will be advised to contact the clinic for the first office visit in order to enroll.

For this study, the control and treatment groups will have a convenience sample of 30 patients each, as limited by time and resource constraints. We make the conservative estimate that three (3) eligible patients present themselves out of the roughly 100 total patients seen at the FQHC in a typical week. Over the nine (9) month period (39 weeks) of the enrollment, we expect to see, on average, 117 eligible patients. Combining these estimates, we calculate the probability of a random patient being eligible to participate in the study at 0.03. Assuming that 100% of eligible patients are willing to enroll, the resulting binomial distribution suggests that the probability of successfully enrolling (at least) 60 patients is >99%. If we assume that only 70% are willing to enroll, then there is 99.4% chance of enrolling 60 patients within the nine-month recruitment period. We expect that the monetary incentive (a raffle of three gift cards of \$100 each), combined with very low intrinsic disincentives and high potential health benefits, will encourage a willingness-to-enroll rate close to 100%. Upon routine assessment, patients are asked a series of questions about their medical history, including whether or not they smoke and number of cigarettes smoked per day. If eligible participants are willing to enroll in the study, they must read and sign an informed consent form for participation for the duration of the study. The consent form also informs patients of the benefits and possible risks related to their participation in the study. To the extent possible, patients will be matched a priori based on gender and race to achieve the best balance in the control group or the treatment group.

Both the “control” and “treatment” groups will receive the standard practice of smoking cessation treatment with an initial assessment at their first FQHC visit. The “control” group will schedule follow-up visits once a month in the 3-month study period. Patients will have their CO-level measured and receive provider advice on quitting smoking upon their subsequent visits to the clinic, and any prescription smoking cessation medications. At their first visit the “treatment” group will be given their T-COM, and instructions for daily use. The “treatment” group will be invited to contact their provider via the T-COM for monthly check-in’s if needed. Patients will receive motivational messages and virtual rewards based on their CO levels. A trained smoking cessation counselor will monitor the web-based portal and contact the patient as needed using the T-COM. Both the “control” and “treatment” groups will receive a final assessment at the end of the study.

The research team will train staff and providers who are involved in smoking cessation counseling to instruct the patients in the use of the T-COM device, access and monitor patients’ progress via the web-based portal, and conduct follow-up counseling through telephone booster sessions upon a patient’s request and need. It should be noted that all employees of this FQHC receive annual HIPAA training. At the participating FQHC, a professional language line is used for non-English speaking patients, which will be available for this study.

Data Collection. Data will be collected through patient medical records, T-COM devices, and surveys. The initial (baseline) and final (at the conclusion of the study period) patient data will be obtained from relevant information manually transcribed from the Athena Electronic Medical Records (EMR) system. For the control group, similar information will be obtained at each follow-up visit. Variables extracted include demographic data, vital signs, height and weight, oxygenation level, blood glucose readings for diabetic patients, smoking status, readiness to quit in the next month, screening for depression, anxiety and insomnia and CO reading. T-COM data will be uploaded directly to the cloud database upon patient T-COM use. The T-COM data include the CO readings, ratings of CO monitoring experience and gaming features, and other patient data, such as patient-reported number of cigarettes smoked in a given day, number of motivational messages received and viewed, patient’s reported mood, smoking cravings, and new smoking triggers. Patients in the treatment group will complete a survey to gather user impressions on device acceptability.

Specific Aims & Methodologies

Aim 1: Develop technology that incorporates an affordable bilingual mHealth device and telemetry, allowing for remote access in the acquisition, visualization, and monitoring of biomedical CO data, and contemporaneous patient self-reporting. T-COM device - consists of hardware and associated software. The envisioned role of the T-COM in our proposed study imposes the following requirements on the device:

- ease of use—should be responsive, appealing and accessible to those with little prior experience operating high-tech devices, those with limited visual acuity, and those with limited education, and have maximal battery life
- minimal thickness, size, and weight and capable of being integrated into a wearable form factor
- accurate measurement, transmission, and visualization of breath CO readings
- delivery of interactive gamification features
- delivery of motivational text and audio messages
- user entry and transmission of status (e.g., cigarettes smoked, smoking cessation medication taken, mood)
- reminders to take smoking cessation medication (e.g., Chantix, nicotine patches)
- bilingual support—English and Spanish
- capability for two-way audio, to allow patient convenient access to telehealth providers
- use of commonly available wireless links, such as 3G networks
- high reliability under a wide range of environmental conditions
- low manufacturing cost when produced in high volume.

There does not currently exist a commercial, off-the-shelf solution to meet this set of requirements. We will design the T-COM and procure assembly of 50 units to cover the treatment group, with spares for

demonstration, continued development, and replacement for any failures. Figure 1 presents a concept graphic depicting a physical form factor for the T-COM. The hardware design will make use of modern tools for electronic design automation, which enable design capture, system simulation, and verification, and hook to automated manufacturing. The T-COM will be developed using low-cost, readily available components. A block diagram of the T-COM hardware design is shown in Figure 2, where adjacent block boundaries are used to represent electronic interfaces. We have identified viable components for all of the major functions that are consistent with the requirements. Our conservative cost estimate for the bill-of-materials, based on publicly available pricing, is between \$50 and \$60 (in production quantities), and is dominated by the cost of the 3G Modem module, at \$25.69. We are confident in predicting that this cost can be reduced significantly with maturing technology, and with price negotiation in a competitive environment. The cost estimate for assembly and test is \$5 per unit, in production volume. T-COM software will be developed under close collaboration among our experts in tobacco dependence, software development, communication/gamification, and graphical art to satisfy the stated requirements and gain strong user acceptance.

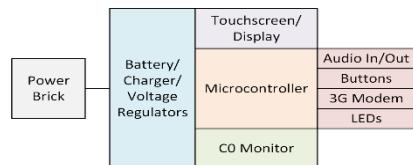


Figure 1 - Concept graphic of T-COM form factor. Figure 2 - Block diagram of T-COM electronics.

Cloud database and web-based portal. Patient data, in the form of CO measurements, patient-generated text messages, patient self-reporting, and usage statistics, will be transmitted via secure links to a HIPAA-compliant cloud database, such as Amazon AWS S3. We will also use cloud computing to host a web-based portal application, which will be used by authorized personnel to browse patient information, examine historical trends, respond to notifications and communicate with patients. The portal will allow providers to read and write text messages exchanged with patients, and record and listen to audio messages. It will allow providers to initiate live voice calls with patients, who would participate in the calls using their T-COM devices. Figure 3 shows a high-level diagram of the end-to-end system, from T-COM to web-based portal. An additional feature of the cloud computing application stack is a module to transmit customized text and audio motivational messages, notifications, and reminders, based on patient data including CO measurements, status reports, and overall usage statistics.

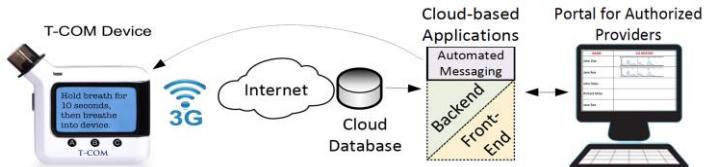


Figure 3 - High-level diagram of our end-to-end system, from T-COM to portal for authorized providers.

Evaluating Aim 1. The success of Aim 1 relates to meeting the stated requirements on the T-COM hardware and software. This will be evaluated via a conventional electronic design verification process (pass/fail) and comparison between actual manufacturing cost and target cost (meets/does not meet). In addition, the multi-disciplinary design team will verify that the device implementation meets expectations in terms of usability and aesthetics. Additionally, focus group usability testing will be conducted to elicit pre-rollout feedback for device refinement.

Aim 2: Compare smoking outcomes, retention rates, and patient-provider communication between the treatment group and the control group. The T-COM displays the daily CO reading as well as a history of prior CO readings giving patients a visual representation of the harm from smoking. Authorized providers, smoking cessation counselors, and research team members can view the CO history via the web-based portal. Adjustments to medications can be made and concerns answered via the T-COM. Active use of the T-COM is

expected to result in increased retention in the treatment program. Greater provider response to the patient and the automated motivational messaging will enhance the patient-provider communication thus increasing patient satisfaction.

Evaluating Aim 2. Smoking outcomes measures include: change (final - initial values) in: CO level, number of cigarettes smoked, Fagerström score. Retention rates will be defined by completion of the study, i.e. attending the final visit. A modified Patient-Doctor Relationship Questionnaire (PDRQ-9) [11] will be used to measure patient-provider communication, which includes patients' perceptions on provider trust, provider helpfulness, understanding, easy access, etc. Specifically, we will test the following hypotheses:

H1: the treatment group using T-COM will have a greater improvement in smoking outcomes than the control group.

H2: the treatment group using T-COM will have higher retention rates than the control group.

H3: the treatment group using T-COM will have a greater satisfaction with patient-provider communication.

Aim 3: Analyze the potential effectiveness of engagement with the device, including measuring CO levels, reading/listening to motivational messages, and interacting with gamification components, on improving smoking outcomes and retention rates within the treatment group. Research team members will develop an array of motivational messages tailored to cover a range of different scenarios for user CO reading trends and patient's responses to prompts. For example, if the patient's CO level goes down, the patient may receive messages such as "Good work! You are on your way to reaching your goal." In addition, this study will include the gamification feature of virtual rewards, such as points, badges, and medals, which have been found to provide stronger motivation than tangible rewards and currency [12].

Evaluating Aim 3. Success will be determined by a positive correlation between level of engagement and improvement in smoking outcomes in the treatment group. Engagement will be measured as frequency of CO level measurements, reading/listening to motivational messages, and collection of virtual rewards. Specifically, we will test the following hypothesis:

H4: higher engagement (frequency of CO level measurements, reading/listening to motivational messages, collection of virtual rewards) will be associated with greater improvement in smoking outcomes for the treatment group.

Data Analysis. Based on mean smoking cessation rates from a prior study of 14% for control group and 23% for treatment group [13], the calculated effect size is 0.6 and the power is 74.3% (at significance level 0.05). For all outcomes we will use the Mann-Whitney means comparison, as a non-parametric robust test for significance between the control and treatment groups, and Spearman correlations between the outcome variables and engagement. Additional analyses will be performed stratifying the sample by factors, such as gender, age, race, and ethnicity, as appropriate.

The analysis of intervention success, measured as smoking cessation, retention rates, and improved patient-provider communication, will rely on pretest-posttest comparisons between the control and treatment groups. Specifically, using Mann-Whitney test, we will examine if the two groups were in fact equivalent upon random assignment at the beginning of the study by comparing their baseline demographics, biomedical indicators, including CO levels, and Fagerström scores. If the two groups are equivalent at baseline, then differences in the three smoking outcomes (smoking status, CO levels, and Fagerström scores) post-intervention will be indicative of a causal effect of the intervention. We will also analyze how closely related are the three smoking outcomes by examining the Spearman's correlation between them.

Resource Sharing Plans. The PI and Co-Investigators will adhere to the principles for sharing research resources outlined in the NIH Grants Policy Statement (Availability of Research Results) and the NIH Research Tools Policy (Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources). We will also share protocols and additional published data upon request. All design data, including mechanical design, printed circuit board design, embedded coding, user interface design, and cloud applications will be made available for public download at github.com.

Potential Problems and Alternative Strategies. We anticipate challenges in implementing the T-COM and associated cloud computing applications. In any complex digital system there will be bugs introduced at the time of design and initial implementation. This likelihood will be addressed by the creation of thorough verification plans for both the T-COM and cloud computing applications. The verification procedures will include randomized, automated tests, as well as tests directed at exercising the most extreme conditions under which the system is required to operate. Any areas of failure (i.e., design bugs) will be fixed.

It may be evident that some component choices were unsatisfactory only after an initial prototype is verified. For example, a display could provide insufficient brightness, or a touch-screen could be of poor quality. There are multiple sources for each of the T-COM components, and we will rapidly select and design-in an alternative component. Modern electronic system design, printed circuit board fabrication, and manufacturing systems permit very rapid turnaround. For example, a printed circuit board design can typically be modified in under one hour, and revised board designs can be instantly transferred via the Internet to a fabrication facility for delivery in less than one week.

In spite of our efforts to anticipate human factors, maintain simplicity, and provide easy access to help, we may receive constructive feedback during initial evaluation of our device by a focus group or device roll-out. Accordingly, we will produce rapid “re-spins” of our device for reevaluation. We will update the mechanical design (i.e. case and physical layout of user-facing components) via the use of computer aided design and manufacturing tools (CAD/CAM), and 3D printing. We will update user interface elements by modifying the software and device flash memory. We will perform any needed updates to printed circuit boards (PCBs) via CAD/CAM tools, and rapid turnaround PCB fabrication.

The data collection process and analysis could also present challenges. Although we anticipate enrolling 60 patients (30 each in the control and treatment groups), attrition is a possibility. Despite training and reference card instructions, patients and providers may still have difficulty using the device. We plan to address this with telephone instructional booster sessions for those patients who are not responding to prompts.

Timeline. A timeline of our planned project activities is as follows:

Month	Tasks
0	Develop consent form, obtain IRB approval from TCNJ and HJA.
1-6	Hire student workers. Develop and design T-COM device, software, and integration with cloud database. Test with focus group. Create and translate (English and Spanish) motivational messages and gaming rewards. Develop a training module for nursing students and counselors, set up electronic database to recruit & record patients. Prepare and place a recruitment flyer in provider's office.
7-12	Develop cloud-based applications, a thorough plan for cloud computing application design verification, automated system for sending out custom-selected text and audio messages to patients. Test and refine motivational messages and gamification features with focus groups and one-on-one interviews. Provider portal is fully operational. Develop written instruction cards for T-COM patients. Train staff and providers on T-COM and portal use.
13-21	Recruitment and enrollment of patients, data collection, entry, incorporate relevant EMR data into study database, and do preliminary analysis. Start write-up.
22-24	Finalize data analysis and write-up. Study closure: initiate 3-4 journal articles and R01 grant application for randomized trial.

Future directions. Potential additional features include a 9-1-1 button on the device and adding additional languages (e.g., Haitian Creole). Given the value of social support for patients going through the quit process, another device feature that might be added is social networking, so that users may communicate with each other in a gamified, engaging manner. Our long-term vision is to add trained telehealth counselors for 24/7 patient support, to create a fully scalable tiered telehealth system that could readily be deployed nationwide. With modified sensors and therapeutic motivational messaging on the T-COM platform, our approach could be repurposed for treating a wide array of chronic conditions, such as alcohol and opioid addiction, diabetes, obesity, heart disease, and high blood pressure.

PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001 and 0925-0002

Expiration Date: 03/31/2020

Are Human Subjects Involved	<input checked="" type="radio"/> Yes	<input type="radio"/> No
Is the Project Exempt from Federal regulations?	<input type="radio"/> Yes	<input checked="" type="radio"/> No
Exemption Number	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7 <input type="checkbox"/> 8	
Other Requested Information		

Human Subject Studies

Study#	Study Title	Clinical Trial?
1	An Innovative mHealth Tool for Tobacco Dependence Treatment Utilizing an Enhanced CO Monitor with Motivational Messaging and Gamification Features	Yes

Section 1 - Basic Information (Study 1)

OMB Number: 0925-0001 and 0925-0002

Expiration Date: 03/31/2020

1.1. Study Title *

An Innovative mHealth Tool for Tobacco Dependence Treatment Utilizing an Enhanced CO Monitor with Motivational Messaging and Gamification Features

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

2.2. Eligibility Criteria

Qualifying patients must be between 18-85 years old, current everyday smokers, and interested in quitting in the next 30 days.

2.3. Age Limits	Min Age: 18 Years	Max Age: 85 Years
2.4. Inclusion of Women, Minorities, and Children	Attachment_2.4.pdf	
2.5. Recruitment and Retention Plan	Attachment_2.5.pdf	
2.6. Recruitment Status	Not yet recruiting	
2.7. Study Timeline	Attachment_2.7.pdf	
2.8. Enrollment of First Subject	09/01/2020	Anticipated

Attachment 2.4.

1. Inclusion of Women and Minorities

Planned distribution of subjects and recruitment. The study is an individually randomized group-treatment control trial (IRGT) available to a large low-income population, which is not otherwise constrained in terms of gender and race/ethnicity. In other words, no plans are made to systematically exclude patients based on gender, race, or ethnicity. The study utilizes a sample of convenience, based on the eligible patients who seek service in the clinic for the duration of the study. As such, no planned distribution of subjects by sex/gender, race, and ethnicity is expected. To recruit patients for the study, the research team will create and post a bilingual flyer (English and Spanish) in the waiting room of the clinic.

Existing datasets and resources. Demographic and health information from the clinic electronic medical records system for patients enrolled in the study will be manually typed into the portal database.

2. Inclusion of Children

N/A

Attachment 2.5: Recruitment and Retention Plan

Recruitment Plan. The study will mainly recruit patients from the population coming to the clinic. In addition, eligible participants will be actively recruited using social media pages, posters at the clinic, outreach sites (such as libraries, churches, train station, food pantries), and through the Athena patient portal, and interested participants will be advised to contact the clinic for the first office visit in order to enroll.

Both control and treatment group patients will fill out the consent form, which would inform study participants of the 3-month duration of the study, and that patients are expected to come back for a provider office visit at the end of the period. After the initial assessment, the control group patients may have up to 3 monthly follow-up visits, whereas treatment group patients are expected to have a follow-up visit at the end of the study period.

Retention Plan. The control group patients will be encouraged at each follow-up visit to complete the study. In order to retain patients, the study will offer a drawing to win 1 of 3 gift cards (\$100 each) for the patients who complete the study. It is expected that the motivational messages and virtual rewards from the gamification features of the T-COM device will further improve retention rates.

Attachment 2.7. Study Timeline

Month	Tasks
0	Develop consent form, obtain IRB approval from TCNJ and HJA.
1-6	Hire student workers. Develop and design T-COM device, software, and integration with cloud database. Test with focus group. Create and translate (English and Spanish) motivational messages and gaming rewards. Develop a training module for nursing students and counselors, set up electronic database to recruit & record patients. Prepare and place a recruitment flyer in provider's office.
7-12	Develop cloud-based applications, a thorough plan for cloud computing application design verification, automated system for sending out custom-selected text and audio messages to patients. Test and refine motivational messages and gamification features with focus groups and one-on-one interviews. Provider portal is fully operational. Develop written instruction cards for T-COM patients. Train staff and providers on T-COM and portal use.
13-21	Recruitment and enrollment of patients, data collection, entry, incorporate relevant EMR data into study database, and do preliminary analysis. Start write-up.
22-24	Finalize data analysis and write-up. Study closure: initiate 3-4 journal articles and R01 grant application for randomized trial.

Inclusion Enrollment Reports

IER ID#	Enrollment Location Type	Enrollment Location
The study does not have any IERs		

Section 3 - Protection and Monitoring Plans (Study 1)

- 3.1. Protection of Human Subjects Attachment_3.1.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
If yes, describe the single IRB plan
- 3.3. Data and Safety Monitoring Plan Attachment_3.3.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 Attachment_3.5.pdf

Attachment 3.1. Protection of Human Subjects

1. Risks to Human Subjects

a. Human subjects involvement, characteristics, and design

The overall study design is an individually randomized group-treatment control trial (IRGT), where patients at a Federally Qualified Health Center (FQHC) in Trenton, NJ, will be assigned to either the control group (30 patients) or the treatment group (30 patients). Qualifying patients must be between 18-85 years old, current everyday smokers, and interested in quitting in the next 30 days. Patients will be included regardless of gender, race, and ethnicity until enrollment is complete.

b. Study Procedures, Materials, and Potential Risks

The “control” group will receive the standard practice of smoking cessation treatment at their initial FQHC visit upon enrollment and follow-up visits in the 3-month study period. Patients will have their CO-level measured and receive provider advice on quitting smoking upon their regular visit to the clinic and any prescription smoking cessation medications. At each follow-up visit, the providers will offer counseling and alter the medication as needed. Both groups will have the initial assessment during their first visit and a final assessment at the end of the study. At the first visit, the “treatment” group will also be given their T-COM, and instructions for daily use. Patients will receive motivational messages and virtual rewards based on their CO levels.

Relevant intake information will be obtained from the Athena Electronic Medical Records (EMR) upon the patient’s initial and follow-up visits and manually entered into a password-secured computer. The private identifiable information collected includes contact and demographic information. Patients’ initial CO reading will be manually entered into the portal as well.

For the control group, the subsequent CO readings from each visit will be manually entered into the portal. For the treatment group, all data from the T-COM will be linked to the portal. The T-COM data include the CO readings, and other patient data, such as patient-reported number of cigarettes smoked in a given day, and number of motivational messages. Both groups will complete an exit survey recording changes in their smoking behavior at the conclusion of the study period. Patients in the treatment group will also complete a survey to gather user impressions on device acceptance.

Potential risks for the patients may include withdrawal symptoms from quitting smoking and breach of private information. The physical consequences of withdrawal are the same for the treatment and control group as well as for alternative tobacco dependence treatments. The consequences of withdrawal symptoms from quitting can be managed by providing patient contact information for providers. The consequences of a breach of private information could cause embarrassment, jeopardize insurability, and potentially result in loss of employment. The research team will take great efforts to mitigate those risks by limiting access to the portal and using password protected access to the portal.

2. Adequacy of Protection Against Risks

a. Informed Consent and Assent

Qualifying patients (between 18 and 85 years old, current everyday smokers, interested in quitting in the next 30 days) will be asked to read and sign a consent form for participation for the duration of the study during their office visit to Henry J. Austin FQHC in Trenton, NJ. If patients choose to participate in the study, they will have the option to sign the printed consent form at that time, or bring the signed form back at their earliest convenience. The consent form will inform patients of the purpose of the study, duration, expectations on their participation, benefits and possible risks related to their participation in the study. For adult subjects not able to consent we will assess each situation individually and make our best effort to obtain consent from their legally authorized representative.

b. Protection Against Risk

The research team is taking steps to minimize the risks noted above. As part of the standard tobacco dependence care, both control and treatment group patients will be offered prescriptions of first-line smoking cessation medications (e.g., Chantix or nicotine patches), which are designed to mitigate withdrawal symptoms. In order to protect confidential health information, patient names and addresses will be stored separately from patient data, and will be linked via a numerical patient ID, created for this study. All patient information and collected data will be encrypted, and will only be accessible to authorized users via an audited, time-limited session login. The file linking the study ID with the patient name and other identifying information will be kept on a secure password-protected computer. Initial and follow-up assessments will take place in an exam room for protection of patient privacy. It should be noted that all employees of this FQHC receive annual HIPAA training.

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

The benefits of the research to the study participants is the potential to improve health, lengthen life, and reduce illness or disability by quitting smoking. The benefits from quitting outweigh the risks to the subjects of temporary withdrawal symptoms, such as irritability, impatience, decreased mental alertness, fatigue, and depression. Randomly assigned participants in the treatment group will receive a T-COM device that has the potential to radically transform tobacco dependence treatment. If this study proves successful, it could be easily scalable to treat millions of patients, and be readily applicable to a wide variety of other health conditions.

4. Importance of the Knowledge to be Gained

Tobacco dependence treatment has been considered the “gold standard” in terms of return on investment in health care spending. Smoking affects 15.5% of the population and 25.3% of persons living below the poverty level. There is a critical need to provide a tobacco dependence program that can reach low-income individuals, and thus reduce health disparities. This could save millions of lives and save millions of dollars in health care costs. The great benefits gained by this treatment far outweigh the minimal risks this treatment presents.

Attachment 3.3. Data and Safety Monitoring Plan

The overall framework for the Data and Safety Monitoring Plan (DSPM) includes designating Ivy Pearlstein as the study monitor. As a Family Nurse Practitioner (FNP), Mrs. Pearlstein is a licensed prescriber. Her other qualifications are included in her biosketch. She will monitor patient calls regarding any medication issues and any specific events that might preclude participants from continuing, such as unrelated illness, hospitalization, or accident. If there is a medication-related issue (e.g. medication washout, allergic reactions, drug interactions, discontinuation/stoppage of medication, use of rescue medications), patients will be advised to stop the medication in question and call Mrs. Pearlstein immediately. All study participants will sign an informed consent form upon enrolling in the study, which will provide Mrs. Pearlstein's office number, 609-278-5900, which is the HJA's answering service available 24-7. If a study participant calls regarding the study, the provider-on-call will inform Mrs. Pearlstein. If it is a true emergency, the patient will be advised to contact the nearest emergency room.

The study monitor will manage and report any Adverse Events (AEs), including Serious Adverse Events (SAEs), and unanticipated problems (UPs) to the PD/PI; Dr. Rachael Evans, the HJA Chief Medical Officer (CMO); the IRB at TCNJ and HJA FQHC; the NIBIB; the NIH Office of Biotechnology Activities; and the FDA. Reports will be submitted to the monitoring entity annually or more frequently if required. An Excel spreadsheet with AE reporting will be kept by the study monitor. We will follow the NIMH guidelines for reporting events (<https://www.nimh.nih.gov/funding/clinical-research/nimh-reportable-events-policy.shtml>):

Reportable Event	When is Event Reported to the NIMH	Reported By
IRB/ISM/DSMB/OHRP/FDA Suspensions or Terminations	Any suspension or termination of approval must include a statement of the reason(s) for the action and must be reported promptly to the NIMH PO within 3 business days of receipt.	Regulatory or Monitoring Entity and Investigator
Deaths related to study participation	Deaths must be reported immediately (no later than within 5 business days) of the principal investigator first learning of the death.	Investigator
Unexpected Serious Adverse Events related to study participation	Reported to the NIMH PO within 10 business days of the study team becoming aware of the SAE.	Investigator
Unanticipated Problems Involving Risks to Subjects or Others	Reported to the NIMH PO within 10 business days of the investigator learning of the event.	Investigator
Serious or Continuing Noncompliance	Reported to the NIMH PO within 10 business days of IRB determination	Institution

Adverse Event	For all AEs and SAEs that are deemed expected and/or unrelated to the study, a summary should be submitted to the NIMH PO with the annual progress report.	Investigator
Protocol Violations	With the annual progress report.	Investigator

To protect privacy, all in-person interviews will take place in a private room. The research team will take great efforts to mitigate any breaches of privacy information by limiting access to the portal and using password protected access to the portal.

3.5. Overall Structure of the Study Team

Larry Pearlstein (PD/PI, Electrical & Computer Engineering): My role in this project will be to lead the development of the technology components required by the research project. Specifically I will be responsible for development of the T-COM, a portable device that serves as a breath carbon monoxide sensor and two-way communication link for audio, text and telemetry data. I will also be responsible for provisioning of the cloud database and web server, and creating the backend web page application, which allows the clinician to monitor clients and control interactions via a user-friendly portal. My work will involve the design of printed circuit boards and 3D printed enclosures, as well as various forms of software. The software will include embedded code running on the device, and the web application code that builds pages and code for managing text and audio messaging. I will work closely with the rest of the team. I will collaborate with Dr. Hu to help ensure that the human factors are appropriately considered, and that the device will be attractive, engaging and easily understandable by the intended user. I will collaborate with Ms. Pearlstein regarding the technical requirements of the device, and with Dr. Brodersen regarding the bill-of-materials cost targets, and plans for ramping manufacturing (post pilot study).

Donka Brodersen (Co-Investigator, Economics): My primary role in the proposed project relates to data collection and analysis. I will take the lead on designing the patients' survey questions; obtaining IRB approval; merging the data from the patient surveys, electronic records, and device; cleaning the data; and perform data analysis to evaluate the effectiveness of the treatment and the effectiveness of the motivational messages and gamification features. I will also contribute with various other tasks, such as creating factual motivational messages, organizing the student actors and translators of the messages, and overseeing various logistics in the process of completing the project.

Yifeng Hu (Co-Investigator, Communication Studies): My major role in this collaborative project is to connect and balance technology and the human element. Specifically, I will be in charge of these tasks: 1) use the approach of motivational interviewing in behavioral health intervention to create motivational messages to be delivered via the enhanced CO Monitor to patients seeking smoking cessation based on their individual progress; 2) design gamification features for the monitor, specifically different types of rewards such as point systems, badges/medals, and animated feedback to engage users; 3) conduct overall and feature specific usability testing through focus groups and one-on-one interviews; and 4) craft survey questions for both providers and patients regarding their uses and perceptions of the device as well as their perceptions of provider-patient communication. In addition, I will contribute my expertise from other health intervention programs that I have worked on to ensure that the intervention is designed and administered properly throughout the whole process.

Ivy Pearlstein (Co-Investigator, Nursing): My primary role in the proposed project relates to implementation of the proposed clinical trial at the Henry J. Austin Federally Qualified Health Center in Trenton, NJ. It will be my responsibility to train the tobacco dependence counselors and providers to use the device and the portal as well as to enroll patients and treat them for

tobacco dependence. I will oversee personnel at the site to ensure that patient consents are obtained correctly and ethically, and that these consent forms are stored in a secure location, that the pilot study is carried out as planned, and any concerns are addressed. I will be a study resource for the staff at the health center and will monitor usage of the portal. I will assist with creating the motivational messages, which will be automatically sent via the T-COM device to patients in response to their CO readings. I will be available to respond to patients when they send messages or need assistance through their T-COM. I will assist with creation and administration of final study questionnaires for patients and data analysis at the conclusion of the pilot study.

Section 4 - Protocol Synopsis (Study 1)

4.1. Brief Summary

Smoking, the leading cause of preventable death in the United States, affects 15.5% of the population and 25.3% of persons living below the poverty level. The conventional treatment for tobacco dependence consists of monthly provider office visits with counseling, nicotine replacement therapy, and prescription medication. Significant barriers to utilizing such treatment exist for low-socioeconomic status (SES) individuals due to infrequent provider appointments, transportation difficulties, inability to take time off from work, and language barriers. Thus there is a critical need to provide a tobacco dependence program that can reach low-income individuals remotely and on their schedules, which would strengthen patient adherence to treatment, reduce barriers to communication with providers, and improve provider monitoring of patient progress. The long term goal of this study is to reduce smoking among vulnerable low-SES populations. The objective of this R21 application is to develop, implement, and evaluate a novel telehealth intervention at a Federally Qualified Health Center (FQHC), which serves socioeconomically disadvantaged individuals. The proposed study will pursue three specific aims: (1) Develop technology that incorporates an affordable bilingual mHealth device and telemetry, allowing for remote access in the acquisition, visualization, and monitoring of biomedical CO data, and contemporaneous patient self-reporting; (2) Compare smoking outcomes, retention rates, and patient-provider communication between the treatment group and the control group; and (3) Analyze the potential effectiveness of engagement with the device, including measuring CO levels, reading/listening to motivational messages, and interacting with gamification components, on improving smoking outcomes within the treatment group. The research design involves a 3-month individually randomized group-treatment trial (IRGT). The ?control? group will receive the standard smoking cessation regimen. The ?treatment? group will be given our device, and instructed to measure their daily CO levels and provide status updates. Collected data will be automatically transmitted via a secure link to a cloud database that will be readily accessible to authorized providers. Patients will receive motivational messages, collect virtual rewards, and engage remotely on a frequent basis with their providers using their devices. The methods will include means comparisons between the control group and treatment group regarding the program effectiveness, and correlations between device engagement and program effectiveness within the treatment group. The proposed research aligns with both the NIH and NIBIB missions of developing scalable biomedical technologies and utilizing multidisciplinary approaches to improve health, lengthen life, and reduce illness and disability.

4.2. Study Design

4.2.a. Narrative Study Description

This individually randomized group-treatment control trial (IRGT) study will take place at a Federally Qualified Health Care Center in Trenton, NJ, where patients will receive at least some of their treatment through a common change agent in the provider office. For this trial study, we expect to have a convenience sample of 30 patients each in the control and treatment groups. As much as possible, patients will be matched a priori based on gender and race to achieve the best balance in the control group or the treatment group. The control group will receive standard smoking cessation intervention, and the treatment group will receive the T-COM device-based intervention. Patients will be followed for the duration of the study to measure the extent to which they were successful in reducing their smoking, and were engaged in the process. Our overarching goal is that the treatment group using the T-COM will quit smoking at a higher rate than the control group, as measured by lower Fagerstr?m scores and a greater reduction in CO levels. Qualified patients must be at least 18 years old, current everyday smokers, and interested in quitting in the next 30 days. Study participants must read and sign a consent form for participation for the duration of the study. Both the ?control? and ?treatment? groups will receive the standard practice of smoking cessation treatment with an initial assessment at their first FQHC visit upon enrollment. The ?control? group will schedule follow-up visits once a month in the 3-month study period. Patients will have their CO-level measured and receive provider advice on quitting smoking upon their subsequent visits to the clinic, and any prescription smoking cessation medications. At their first visit the ?treatment? group will be given their T-COM, and instructions for daily use. The ?treatment? group will be invited to contact their provider via the T-COM for monthly check-in?s if needed. Patients will receive motivational messages and virtual rewards based on their CO levels. A trained smoking cessation counselor will monitor the web-based portal and contact the patient as needed using the T-COM. Both the ?control? and ?treatment? groups will receive a final assessment at the end of the study. The research team will train staff and providers who are involved in smoking cessation counseling to instruct the patients in the use of the T-COM device, access and monitor patients? progress via the web-based portal, and conduct follow-up counseling through telephone booster sessions upon a patient?s request and need. It should be noted that all employees of this FQHC receive annual HIPAA training. At the participating FQHC, a professional language line is used for non-English speaking patients, which will be available for this study. Usability testing will be done for all of the features of the device through focus group and individual interviews prior to launching at the pilot site. Baseline data will be collected during the initial assessment and post-intervention data will be collected at the final assessment at the conclusion of the study period. Using Mann-Whitney test, we will examine if the control and treatment groups were matched appropriately at the beginning of the study by comparing their baseline demographics, biomedical indicators, including CO levels, and Fagerstr?m scores on smoking. We will also examine the correlation between CO levels and daily cigarette consumption through Spearman?s correlation. The potential effectiveness of patient engagement with the device on smoking cessation will be examined by analysis of Spearman?

s correlations between CO levels and frequency of patient usage of the device features (such as gamification rewards, number of messages, response rate to questions on device, frequency of CO measurement). To compare the smoking outcomes between the control and treatment groups, Mann-Whitney test will be utilized.

4.2.b. Primary Purpose

Device Feasibility

4.2.c. Interventions

Type	Name	Description
Device (including sham)	T-COM	This project proposes the development of a novel standalone portable device, T-COM (The College of New Jersey CO Monitor), to be used in tobacco dependence treatment that combines CO monitoring, enhanced visualization of biomedical data, motivational messaging, gamification features, built-in wireless communication, and interaction with cloud computing. Specifically, the proposed study offers 5 innovative features: (1) incorporation of wireless communication within our compact device, eliminating the reliance on, or interaction with, a user-provided smartphone or Wi-Fi access point. This device is thus tailored to the needs of low-SES patients, who may not own a modern smartphone, or may be unable to afford a broad data plan or unlimited text messaging. (2) Patients will receive tailored motivational messages based on automated analysis of their CO readings and other patient-entered data. A cloud-based application will adapt and send motivational messaging based on objective measures

4.2.d. Study Phase

Other

Develop portable device to be used in tobacco dependence treatment that combines CO monitoring, enhanced visualization of biomedical data, motivational messaging, gamification features, built-in wireless communication, and interaction with cloud computing

Is this an NIH-defined Phase III Clinical Trial?

 Yes No

4.2.e. Intervention Model

Parallel

4.2.f. Masking

 Yes No Participant Care Provider Investigator Outcomes Assessor

4.2.g. Allocation

Randomized

4.3. Outcome Measures

Type	Name	Time Frame	Brief Description
Primary	Smoking Status	baseline, posttreatment	Baseline and posttreatment measures are assessed during patient visit to provider office.
Primary	CO level	baseline, daily, posttreatment, Smoking= Yes, non-smoking(quit)= No	CO level measured on a scale from 0-100 ppm per exhaled breath. Baseline and posttreatment are measured during patient visit to provider office (control and treatment group); daily measures are taken on the personal device (treatment group).
Primary	Change in CO level	baseline, posttreatment	Measure calculated as the difference between posttreatment and baseline CO level.
Primary	Number of cigarettes smoked per day	baseline, daily, posttreatment	Baseline and posttreatment measures are assessed during patient visit to provider office (control and treatment group); daily measures are reported by the patient on personal device (treatment group).

Primary	Change in number of cigarettes smoked per day	baseline, daily, posttreatment	Baseline and posttreatment measures are assessed during patient visit to provider office (control and treatment group); daily measures are reported by the patient on personal device (treatment group).
Primary	Fagerström score	baseline, posttreatment	Baseline and posttreatment are measured during patient visit to provider office.
Primary	Change in Fagerström score	baseline, posttreatment	Measure calculated as the difference between posttreatment and baseline CO level.
Primary	Retention rate	posttreatment	Measure calculated as completion of the study, completion=yes, non-completion=no
Primary	Provider-Patient Communication	baseline, posttreatment	A modified Patient-Doctor Relationship Questionnaire (PDRQ-9) [11] will be used to measure provider-patient communication, which includes patients' perceptions on provider trust, provider helpfulness, understanding, easy access, etc.

4.4. Statistical Design and Power

Attachment_4.4.pdf

4.5. Subject Participation Duration

Approximately 3 months for control group, depending on patient schedule.

4.6. Will the study use an FDA-regulated intervention?

 Yes No

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

4.7. Dissemination Plan

Attachment_4.7.pdf

4.4. Statistical Design and Power

For the convenience sample, each of the treatment and control groups will have a size of 30 patients, as limited by the time and resource constraints. We make the conservative estimate that three (3) eligible patients present themselves out of the roughly 100 total patients seen at the FQHC in a typical week. An eligible patient is a self-reported current smoker, age 18-85, interested in quitting smoking in the next month. Over a nine (9) month period (39 weeks), we expect to see, on average, 117 eligible patients. Combining these estimates, we calculate the probability of a random patient being eligible to participate in the study at 0.03. Assuming that 100% of eligible patients are willing to enroll, the resulting binomial distribution suggests that the probability of successfully enrolling (at least) 60 patients is >99%. If we assume that only 70% are willing to enroll, then there is 99.4% chance of enrolling 60 patients within the nine-month recruitment period. We expect that the monetary incentive (a raffle of three gift cards of \$100 each), combined with very low intrinsic disincentives and high potential health benefits, will encourage a willingness-to-enroll rate close to 100%. Based on the mean smoking cessation rates from a prior study of 14% for the control group and 23% for the treatment group (Volpp et al. 2009), the calculated effect size is 0.6 and the power is 74.3% (at a significance level of 0.05).

For all outcome variables (smoking status, CO level, change in CO level, number of cigarettes smoked per day, change in number of cigarettes smoked per day, Fagerström score, change in Fagerström score, retention rates, provider-patient communication satisfaction), we will use the Mann-Whitney means comparison test for significance between the control and treatment group and Spearman correlations between engagement (frequency of taking CO level, frequency of reading/listening to motivational messages, frequency of interacting with gamification components) and outcome variables. Additional analyses will be performed stratifying the sample by factors such as gender, age, race, and ethnicity when appropriate.

4.7. Dissemination

Shareable data will be made available to all researchers directly. Available data will be cited in all publications and annual progress reports. The PI and co-Investigators We will adhere to the principles for sharing research resources outlined in the NIH Grants Policy Statement (Availability of Research Results) and the NIH Research Tools Policy (Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources). Results from the proposed research will be published in appropriate peer-reviewed journals and such publications will be made readily available by depositing in online archives, such as ClinicalTrials.gov, PubMed Central or arXiv.org. Results from this research will also be presented at academic seminars (e.g., Interdisciplinary Research Forum at The College of New Jersey) and scientific conferences in Electrical and Computer Engineering, Nursing, Health Communication, Public Health, and Economics. We will also share protocols and additional published data upon request. All design data, including mechanical design, printed circuit board design, embedded coding, user interface design, and cloud applications will be made available for public download at <http://www.github.com>

Delayed Onset Studies

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

References

- [1] Blumenthal D.S. (2007). Barriers to the provision of smoking cessation services reported by clinicians in underserved communities. *The Journal of the American Board of Family Medicine*, 20(3):272-9.
- [2] U.S. Department of Health and Human Services. *The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General*. (2014). Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health [accessed Feb 22, 2018].
- [3] Jamal, A., Phillips, E., Gentzke, A.S., Homa, D.M., Babb, S.D., King, B.A., & Neff, L.J. (2018). Current cigarette smoking among adults—United States, 2016. *Morbidity and Mortality Weekly Report*, 67(2):53.
- [4] Tobacco Use and Dependence Guideline Panel. *Treating Tobacco Use and Dependence: 2008 Update*. (2008). Rockville (MD): US Department of Health and Human Services. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK63952/> [accessed Oct 2, 2018].
- [5] Herbeć, A., Perski, O., Shahab, L., & West, R. (2018). Smokers' views on personal carbon monoxide monitors, associated apps, and their use: An interview and think-aloud study. *International Journal of Environmental Research and Public Health*, 15(2): 288.
- [6] Lister, C., West, J. H., Cannon, B., Sax, T., & Brodegard, B. (2014). Just a Fad? Gamification in Health and Fitness Apps. *Journal of Medical Internet Research Serious Games*, 2(2):e9. doi:10.2196/games.3413.
- [7] Fiellin, L.E., Hieftje, K.D., Pendergrass, T.M., Kyriakides, T.C., Duncan, L.R., Dziura, J.D., Sawyer, B.G., Mayes, L., Crusto, C.A., Forsyth, B.W.C., & Fiellin, D.A. (2017). Video Game Intervention for Sexual Risk Reduction in Minority Adolescents: Randomized Controlled Trial. *Journal of Medical Internet Research*, 19(9):e314. doi:10.2196/jmir.8148.
- [8] Ingadottir, B., Blöndal, K., Thue, D., Zoega, S., Thylen, I., & Jaarsma, T. (2017). Development, Usability, and Efficacy of a Serious Game to Help Patients Learn About Pain Management After Surgery: An Evaluation Study. *Journal of Medical Internet Research Serious Games*, 5(2):e10. doi:10.2196/games.6894.
- [9] Majumdar, D., Koch, P.A., Lee, H., Contento, I.S., Islas-Ramos, A.L., & Fu, D.. (2013). "Creature-101": A Serious Game to Promote Energy Balance-Related Behaviors Among Middle School Adolescents. *Games for Health Journal: Research, Development, and Clinical Applications*, 2(5):280-290.
- [10] Mercer, K., Li, M., Giangregorio, L., Burns, C., & Grindrod, K. (2016). Behavior Change Techniques Present in Wearable Activity Trackers: A Critical Analysis. *JMIR mHealth uHealth*, 4(2):e40. doi:10.2196/mhealth.4461.
- [11] Porcerelli, J.H., Murdoch, W., Morris, P., & Fowler, S. (2014). The Patient-Doctor Relationship Questionnaire (PDRQ-9) in Primary Care: A Validity Study. *Journal of Clinical Psychology in Medical Settings*, 21(3):291-296.
- [12] Lewis, Z. H., Swartz, M. C., & Lyons, E. J. (2016). What's the Point?: A Review of Reward Systems Implemented in Gamification Interventions. *Games for Health Journal: Research, Development, and Clinical Applications*, 5(2):93-99.
- [13] Volpp, K.G., Troxel, A.B., Pauly, M.V., Glick, H.A., Puig, A., Asch, D.A., Galvin, R., Zhu, J., Wan, F., DeGuzman, J., Corbett, E. (2009). A randomized, controlled trial of financial incentives for smoking cessation. *New England Journal of Medicine*, 360(7):699-709.



October 11, 2018

Larry Pearlstein, Associate Professor
Department of Electrical & Computer Engineering
Armstrong, Room 159
The College of New Jersey
2000 Pennington Road
Ewing, NJ 08628

Dear Larry:

I am writing to offer my full support of the PA-18-389 grant application "An Innovative mHealth Tool for Tobacco Dependence Treatment Utilizing an Enhanced CO Monitor with Motivational Messaging and Gamification Features" (PI/PD Larry Pearlstein), proposed for September 1, 2019–August 31, 2021 to be carried out at The College of New Jersey with partial data collected at the Henry J. Austin Federally Qualified Health Center in Trenton, NJ.

My primary role in the proposed project relates to implementation of the proposed clinical trial at the Henry J. Austin Federally Qualified Health Center in Trenton, NJ. It will be my responsibility to train the tobacco dependence counselors and providers to use the device and the portal as well as to enroll patients and treat them for tobacco dependence. I will oversee personnel at the site to ensure that patient consents are obtained correctly and ethically, and that these consent forms are stored in a secure location, that the pilot study is carried out as planned, and any concerns are addressed. I will be a study resource for the staff at the health center and will monitor usage of the portal. I will assist with creating the motivational messages, which will be automatically sent via the T-COM device to patients in response to their CO readings. I will be available to respond to patients when they send messages or need assistance through their T-COM. I will assist with creation and administration of final study questionnaires for patients and data analysis at the conclusion of the pilot study.

Sincerely,

A handwritten signature in black ink that reads "Ivy Pearlstein, MSN, APN, FNP".

Ivy Pearlstein, MSN, APN, FNP
The College of New Jersey
School of Nursing, Health and Exercise Science
2000 Pennington, Rd, Ewing , NJ 08628
Pearlsi1@tcnj.edu



School of Business

October 14, 2018

Larry Pearlstein, Associate Professor
Department of Electrical & Computer Engineering
Armstrong, Room 159
The College of New Jersey
2000 Pennington Road
Ewing, NJ 08628

Dear Larry:

I am writing to confirm that I would be delighted to collaborate with you and our TCNJ colleagues Ivy Pearlstein and Yifeng Hu on the research proposed in your R21 application "An Innovative mHealth Tool for Tobacco Dependence Treatment Utilizing an Enhanced CO Monitor with Motivational Messaging and Gamification Features" (PA-18-389).

As we have spoken, my primary role in the proposed project relates to data collection and analysis. I will take the lead on designing the patient survey questions; obtaining IRB approval; merging the data from the patient surveys, electronic records, and device; cleaning the data; and performing data analysis to evaluate the effectiveness of the treatment (comparisons between treatment and control groups) and the effectiveness of the motivational messages and gamification features (comparisons within the treatment group). I will also contribute toward completion of various other tasks, such as creating effective motivational messages, organizing the Spanish student translators of the messages and the student actors to create the audio messages, and overseeing various logistics in the process of completing the project (e.g., meeting bill-of-materials cost targets, plans for ramping manufacturing post pilot study).

Yours sincerely,

A handwritten signature in black ink that reads "Donka M. Brodersen".

Donka Mirtcheva Brodersen, Ph.D.
Associate Professor, Department of Economics
The College of New Jersey
mirtchev@tcnj.edu
609-771-2260



October 15, 2018

Dr. Larry Pearlstein
Associate Professor, Department of Electrical and Computer Engineering
Room 159, Armstrong Hall
The College of New Jersey
2000 Pennington Rd
Ewing, NJ 08628

Dear Larry,

I am writing to offer my full support of the PA-18-389 grant application “An Innovative mHealth Tool for Tobacco Dependence Treatment Utilizing an Enhanced CO Monitor with Motivational Messaging and Gamification Features”, proposed for September 1, 2019–August 31, 2021 to be carried out at The College of New Jersey with partial data collected at the Henry J. Austin Federally Qualified Health Center in Trenton, NJ.

As a researcher specializing in new media and health communication, my major role in this collaborative project is to connect and balance technology and the human element. Specifically, I will be in charge of these tasks: 1) use the approach of motivational interviewing in behavioral health intervention to create motivational messages to be delivered via the enhanced CO Monitor to patients seeking smoking cessation based on their individual progress; 2) design gamification features for the monitor, specifically different types of rewards such as point systems, badges/medals, and animated feedback to engage users; 3) conduct overall and feature specific usability testing through focus groups and one-on-one interviews; and 4) craft survey questions for both providers and patients regarding their uses and perceptions of the device as well as their perceptions of provider-patient communication. In addition, I will contribute my expertise from other health intervention programs that I have worked on to ensure that the intervention is designed and administered properly throughout the whole process.

I look forward to our work together on this exciting proposal.

Sincerely,

A handwritten signature in black ink that reads "yifeng".

Yifeng Hu, Ph.D.
Associate Professor, Chair, Department of Communication Studies
609-771-2373 hu@tcnj.edu



School of Engineering
Steven Schreiner, Dean

October 11, 2018

Dear NIBIB Program Director and Reviewers:

I enthusiastically support Dr. Larry Pearlstein in the R21 submission to the NIH of the proposal “An Innovative mHealth Tool for Tobacco Dependence Treatment Utilizing an Enhanced CO Monitor with Motivational Messaging and Gamification Features.” He is an outstanding researcher and educator who meets all the eligibility requirements for NIH funding. His research plan described in this proposal is highly reflective of The College of New Jersey’s (TCNJ) mission and goals, as well as those of the School of Engineering.

TCNJ is a highly selective, primarily undergraduate residential public institution that has earned national recognition for its commitment to excellence. TCNJ is dedicated to fostering interdisciplinary and multidisciplinary collaboration, engaging undergraduates in authentic research, integrating original scholarship into the undergraduate curriculum, and supporting faculty to be active and accomplished “teacher-scholars” who deeply engage our students. Publication record and laboratory productivity are prime considerations for tenure and promotion.

Because of TCNJ’s commitment to and expectation for significant research, faculty like Dr. Pearlstein are assigned a reasonable teaching load of 6 courses per year (3 per semester). Professors with a record of research productivity may receive additional assistance from the internally-funded Support of Scholarly Activity (SOSA) program. Dr. Pearlstein has an application under consideration for a SOSA 2019-2021 award. The administration is fully supportive of Dr. Pearlstein’s intention to devote increased time and effort on this important NIH/NIBIB research project, especially given his role as director of the Intelligent Media Processing Laboratory.

Our mission requires faculty who pursue excellence in research and teaching, with emphasis on student-faculty collaboration and integration of advanced topics into curricula. I am very excited that Dr. Pearlstein is seeking funding to enable this highly interdisciplinary research at TCNJ, seeking to combine the College’s expertise in engineering, health communication, nursing, and health economics in this smoking cessation treatment project. It is vital that our engineering graduates be prepared for the current and future technical challenges of our nation. This work will foster interest in biomedical sensors, connected systems, and low-power design, as well as provide students with a broader view of how engineers can work together with other innovators to drive advances in health care. Over 30% of our School of Engineering graduates pursue advanced studies in top graduate programs around the nation and world.

We have found a very high level of interest among our students to get involved in the proposed work. If awarded, the NIBIB funding will be critically enabling, giving Dr. Pearlstein and his students the ability to create technology that will advance the state-of-the-art in mHealth for treating tobacco addiction. I am impressed with the proposal and feel the proposed work well suits the strengths of the Principal Investigator, his multidisciplinary collaborators, and our institution.

Accordingly, I give this project my most enthusiastic endorsement. Please feel free to contact me with any questions you may have about my support for this project or our engineering programs at TCNJ. This interest, coupled with the endorsement of this work by other departmental and school faculty members is likely to lead to additional innovative course development and collaborations within the College.

Sincerely,

A handwritten signature in black ink that reads "Steve Schreiner". The signature is fluid and cursive, with "Steve" on top and "Schreiner" below it.

Steve Schreiner, Ph.D., P.E.



This letter is in support of a proposed research project entitled, “An innovative mHealth tool for Tobacco dependence treatment utilizing an enhanced CO Monitor with motivational messaging and gamification features.”

The project is seeking funding from the NIH R21 grant program for the purpose of studying the effectiveness of a device for tobacco dependence treatment. It is understood that this study will be a clinical trial and participants will be recruited from the Henry J Austin patient population. This study must be approved by the Institutional Review Boards of Henry J Austin and The College of New Jersey prior to patient enrollment. Patients who elect to participate will sign a consent form. The study will be primarily conducted at Henry J Austin Health center by Ivy Pearlstein, MSN, FNP in conjunction with 3 professors at The College of New Jersey, Dr. Donka Brodersen, Dr. Yifeng Hu and Dr. Larry Pearlstein(PI).

Patients in the study will be enrolled over a 9 month period and followed for 3 months. Other staff at Henry J Austin that may assist with the study include Maggie Vasil, who does smoking cessation counseling with patients at Henry J Austin. BHCs may also be involved with counseling. The language line may be used for Spanish speaking patients. Patient data will be de-identified and all information kept confidential. Patients may stop participation in the study at any time. All steps have been taken to cause minimal harm to patients, no extra cost and no extra cost to Henry J Austin.

I have read the above information and my signature attests that I support this research project should it receive funding.

Name Rachael B. Evans, MD Title Chief Medical Officer
Signature RBE
Date 10/14/18

Resource Sharing Plan

Shareable data will be made available to all researchers directly. Available data will be cited in all publications and annual progress reports. The PI and Co-Investigators will adhere to the principles for sharing research resources outlined in the NIH Grants Policy Statement (Availability of Research Results) and the NIH Research Tools Policy (Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources). Results from the proposed research will be published in appropriate peer-reviewed journals and such publications will be made readily available by depositing in online archives, such as ClinicalTrials.gov, PubMed Central or arXiv.org. Results from this research will also be presented at academic seminars (e.g., Interdisciplinary Research Forum at The College of New Jersey) and scientific conferences in Electrical and Computer Engineering, Nursing, Health Communication, Public Health, and Economics. We will also share protocols and additional published data upon request. All design data, including mechanical design, printed circuit board design, embedded coding, user interface design, and cloud applications will be made available for public download at github.com.