AWARD NUMBER: W81XWH-18-1-0371

TITLE: Optical Imaging Falloposcope for Early Ovarian Cancer Detection: In Vivo Feasibility and Safety

PRINCIPAL INVESTIGATOR: Jennifer Barton, Ph.D.

CONTRACTING ORGANIZATION: The University of Arizona, Tucson, AZ

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6. AUTHOR(S)
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14. ABSTRACT

The goal of our project is to demonstrate that advanced imaging of the fallopian tubes and proximal ovary surface can be performed in women via a minimally invasive approach (no tissue cutting, endoscope introduced into the fallopian tube through a conventional hysteroscope), with no clinically relevant tissue damage, and in a reasonable period of time. We have completed the falloposcope system, tested, and obtained all certifications and human subjects approvals. Progress has been significantly delayed due to closure of clinical research at our hospital partner Banner University Medical Center, due to high volume of COVID-19 patients. This past performance period, we refined the falloposcopes and the image processing software. When the hospital re-opened recently, we recertified equipment. We went through operating room procedures, and are in the process of recruiting patients. We have received permission for a no-cost extension year and anticipate completing all statement of work items in the extension period.

15. SUBJECT TERMS

Endoscope, Fallopian Tube, Falloposcope, Fluorescence Imaging, Optical Coherence Tomography, Ovarian Cancer, Ovary, Uterine Tube

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
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TABLE OF CONTENTS

1. **INTRODUCTION:**

The purpose of this project is to demonstrate that advanced imaging of the fallopian tubes and proximal ovary surface can be performed in women via a minimally invasive approach (no tissue cutting, endoscope introduced into the fallopian tube through a conventional hysteroscope), with no clinically relevant tissue damage, and in a reasonable period of time (15 minutes or less). We are conducting two specific aims. In the first aim, we have built and certified a portable, operating room-ready falloposcope imaging system to improve upon our previous prototype. We have replaced large light sources with small fiber-coupled laser diodes, created a compact OCT system, rack mounted the hardware, built disposable, simplified but high performance falloposcopes, wrote improved software, and fully tested an operating room-ready, easily manufacturable, falloposcopy system. We have received all human subjects approvals and agreements with the hospital site. In the second aim, we will perform falloposcopy on twenty volunteers undergoing endometrial ablation with salpingectomy, and statistically assess the outcomes of performance of the falloposcope system as well as intra- and inter-patient image feature variability of the imaged tissue.

2. **KEYWORDS:**

Endoscope, Fallopian Tube, Falloposcope, Fluorescence Imaging, Optical Coherence Tomography, Ovarian Cancer, Ovary, Uterine Tube

3. **ACCOMPLISHMENTS:**

1. **What were the major goals of the project?**

The Statement of Work (with schedule modified per the last no cost extension request), together with the current percent complete, is give below. Tasks 1-5, which include all of Specific Aim 1, are complete. Task 6 associated with Specific Aim 2, is 55% complete, with 11 of 20 study subjects consented and imaged. Task 7, analysis, is 25% complete.

Specific Aim 1 Build and certify a portable, operating room (OR)-ready falloposcope imaging system	**Timeline**	**% Complete**
Major Task 1: *Build a portable MFI system*	Months	
Identify, order, and receive optimum laser wavelengths based on previous classification study and current availability power output, and cost.	1-3	100%
Combine lasers and couple into falloposcope MFI illumination fiber. Package into rack mount system.	3-9	100%
Convert proximal MFI imaging system from current microscope body to a compact cage mount system, affixed in instrument rack.	5-9	100%
Milestone Achieved: Functional, compact, portable MFI system.	9	*100%*
Major Task 2: *Incorporate a portable OCT system*		
Design a new OCT system with best available components, to meet resolution requirement of 5 μm axial. Order and receive components.	1-4	100%

Assemble components on compact breadboard with robust mounting hardware, test functionality, affix in instrument rack	4-9	100%
Milestone Achieved: Functional, compact, portable OCT system.	9	*100%*
Major Task 3: *Build disposable falloposcopes*		
Refine the specifications for a GRIN lens to replace the original 3 element design	1-3	100%
Specify, order, obtain and test multi-durometer endoscope sheath designs from a disposables OEM (Vention Medical – Sunnyvale, CA)	1-6	100%
Build 30 disposable final-design falloposcopes, 10 for sterilization survivability, testing and spares; 20 for the feasibility and safety study	6-18	100%
Test endoscopes for mechanical and optical properties, physician usability, sterilization survivability	12-18	100%
Milestone Achieved: 30 endoscopes built; 20 ready for human pilot trial	18	*100%*
Major Task 4: *Rack assemble and write integrating software, test system*		
Assemble all components on a rack that can be cleaned/draped prior to entry, and upon leaving, the OR	9-14	100%
Write integrating software in LabVIEW	4-14	100%
Confirm functionality of the falloposcope system: size/portability, data acquisition, software interface	14-16	100%
Milestone Achieved: Portable falloposcope system complete and functionality tested.	16	*100%*
Specific Aim 2 Perform a safety and feasibility study in women		
Major Task 5: *Obtain certifications and approvals*		
Submit UA IRB approval and related material for DoD's HRPO approval	14-18	100%
Receive UA IRB approval and HRPO approval before initiating human subjects/HAS related studies	18	100%
Certify falloposcope system with standard clinical engineering review for electrical safety, laser safety, materials, sharp edges, etc. to be used in humans at the BUMC Ob/Gyn operating room	16-18	100%
Milestone(s) Achieved: All certifications/ permissions in place to begin human study	18	*100%*
Major Task 6: *Recruit, consent, and image 20 volunteers*		
Recruit volunteers from the pool at BUMC undergoing cervical dilation with salpingectomy.	33-57	55%
After cervical dilation, introduce the falloposcope through the hysteroscope, and advanced to image the right and left fallopian tubes in a non-significant risk study.	33-57	55%
Milestone Achieved: 20 volunteers imaged	57	*55%*

Major Task 7: ***Analyze data***		
Analyze data relating to success of the procedures (e.g. ability to enter the ostium, timing)	36-57	40%
Analyze data relating to imaging (e.g. intra- and inter-volunteer variation in image intensities as a function of wavelength)	36-58	30%
Evaluate tissue grossly for evidence of damage by the falloposcope. Obtain representative histological sections and examine for microscopic evidence of damage and confirm the normal status of the tissue.	36-59	25%
Write final manuscripts and reports	42-60	10%
Milestone Achieved: Analysis and manuscripts complete	60	*25%*

2. **What was accomplished under these goals?**

Our major delay with this project was the inability to conduct human subjects testing due to closure of Banner-University Medical Center to research. We are pleased to report that we have begun the study and have consented and imaged 11 or 20 research subjects. Readying the system for used in the operating room, testing, calibrating, and sterilizing falloposcopes, performing the imaging during a 15 minute pause in the standard of care surgery, obtaining and imaging samples of fallopian tubes from the surgically removed specimens, and performing histology/image analysis have occupied our efforts this year. We have also made some procedural and equipment refinements to made imaging quicker and more robust.

Photographs of imaging in the operating room are included below in Figure 1, example images are in Figure 2. Subjects ranged in age from 35 to 75 years old. All were at normal risk for ovarian cancer and were having a cervical dilation and salpingectomy, per inclusion criteria. We have been able to obtain at least a partial set of images of the fallopian tubes in most subjects. We were unsuccessful in some cases, due to fallopian tube obstruction or benign conditions such as polyps. We are now focusing on younger patients as they are both more relevant to our ultimate patient population, and less likely to have obstructions/polyps. We have also modified our introducing catheter to enable better reach of the ostium, and we are including a second camera so we can image hysteroscopically and laparoscopically at the same time.

Ex vivo sections of fallopian tube have been successfully imaged, and histology is ongoing. We are continuing our evaluation of images and histology. So far, we do not see any significant damage to the tubes. Histology has shown that the lumen diameter of the tube may be extremely small, even sub-mm in some cases, confirming that the 0.8mm diameter of our instrument is needed and appropriate.

3. **What opportunities for training and professional development has the project provided?**

The PI, Jennifer Barton, had opportunities to present the work on this project at the following events: a National Academy of Engineering workshop on Mar 30, 2022, Invited speaker at the Optica Biophotonics Conference, Apr 25, 2022, featured speaker at the University of Arizona College of Engineering Dean's Dinner (for national supporters) on May 1, 2022, Danish Technical University invited seminar (Sept 20, 2022). Additionally, she presented her work to three groups of undergraduate students as a guest lecture in classes throughout the 2021-2022 academic year.

Student Andrew Rocha presented his work engineering the software and developing the clinical standard operating procedures at the Biophotonics Summer School, Jun 11-18, 2022. Additionally 2 MD/PhD students and 4 grad/undergrad students had the opportunity to pass all required training, requirements and enter the operating room to observe, or assist with, the imaging.

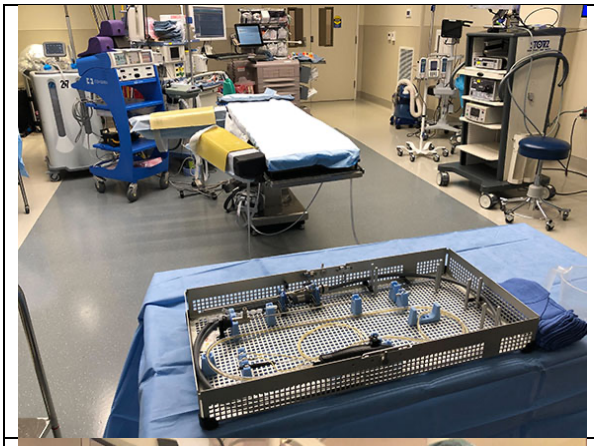
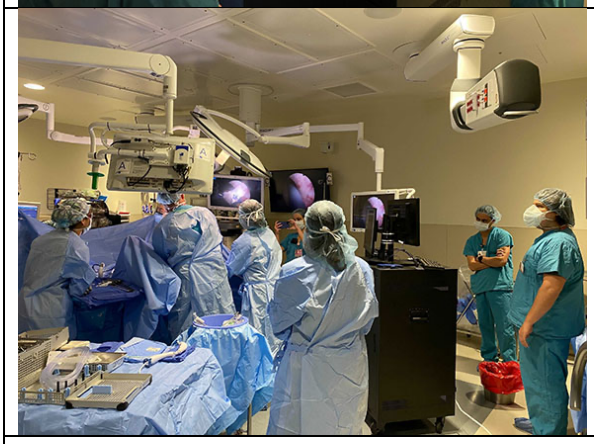
	Sterile falloposcope has been unwrapped and uncovered by the circulator as the operating room is prepared. Bed is prepared for patient and study subject.
	Handoff of falloposcope fibers from sterile surgeon (Dr. Heusinkveld, left) to Dr. Barton lab student to connect to the instrumentation cart.
	Monitor of the falloposcope cart displaying status as surgery commences.
	Room monitors show the hysteroscopic view of the falloposcope's introducing catheter docking with the ostium of the fallopian tube.

Figure 1. Imaging in the operating room- descriptions to the right of each image.

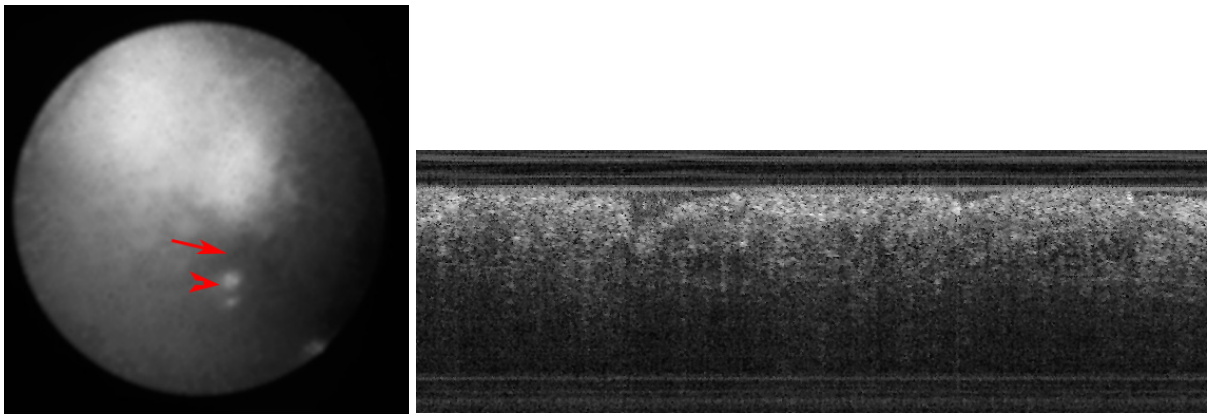


Figure 2. (Left) Reflectance image in the fallopian tube, showing lumen of tube (arrow) and very small growth in the tube (arrowhead). Right, optical coherence tomography image of the fallopian tube.

4. **How were the results disseminated to communities of interest?**
The PI has been an active member of the National Institutes of Health Early Detection Research Network, where she has presented work on this project and a separately funded project to develop a cell-collecting fallopian endoscope. She and her students have given lab tours and talks to 2 industry groups and 3 groups of community members interested in gynecological cancers.

5. **What do you plan to do during the next reporting period to accomplish the goals?**
In our second no-cost extension year, we will consent and image the remaining 9 subjects. We will finalize histology and perform qualitative and quantitative analysis of the imaging data and write additional manuscripts.

4. **IMPACT:**

1. **What was the impact on the development of the principal discipline(s) of the project?**
Detailed standard parts list and operating procedures (SOPs) for construction of the falloposcope were published with graduate student Kelli Kiekens' dissertation. Additional SOPs for imaging in the operating room have also been developed. Our improved designs for the falloposcope, involving a modular multi-lumen extrusion, ferrule, coating, functional handle, and rack design are a model that other groups can follow when developing miniature endoscopes. Several of the techniques for producing and assembling are unique as far as we are aware.

2. **What was the impact on other disciplines?**
Nothing to report.

3. **What was the impact on technology transfer?**
The University of Arizona has received the patent on the falloposcope technology (filed during a previous contract W81XWH-13-1-0131), WO2016126879A1 *Falloposcope and method for ovarian cancer detection*. A patent application has been filed on improvements to the falloposcope created in part under this contract: WO2021050537A1 *Cell-collecting falloposcope and method for ovarian cancer detection*. The investigators continue to talk with potential licensees in medical device industry. This work, showing feasibility *in vivo*, is instrumental in attracting attending of potential licensees.

4. **What was the impact on society beyond science and technology?**
Nothing to Report.

5. **CHANGES/PROBLEMS:***:*

1. **Changes in approach and reasons for change**
   Aside from the delay in the in vivo test previously reported, there have been no changes.

2. **Actual or anticipated problems or delays and actions or plans to resolve them**
   We are optimistic that Banner- University Medical System will remain open to research throughout any possible winter surge in COVID-19 cases. We are attempting to complete recruitment as soon as possible.

3. **Changes that had a significant impact on expenditures**
   None.

4. **Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**
   Human subjects protocols are approved and current. Electrical safety certification is current. Laboratory biosafety approval is current.

6. **PRODUCTS:**

1. **Publications, conference papers, and presentations**.
   "OCT and Multispectral Imaging of the Human Fallopian Tube," Invited talk Optica Biophotonics Conference, virtual, Apr 25, 2022,

2. **Other publications, conference papers, and presentations.**
   "Advanced Endoscopic Imaging for Early Cancer Detection," National Academy of Engineering workshop, Tucson, AZ, Mar 30, 2022,
   "Early detection of cancer with multi-modal endoscopes," Danish Technical University, Copenhagen, Denmark, Sept 20, 2022.
   Poster by student Andrew Rocha "Technology Development and Fabrication Techniques for Low Cost Multimodal Microendoscopes," Biophotonics Summer School, Ven, Sweden, Jun 12, 2022.

3. **Website(s) or other Internet site(s)**
   None.

4. **Technologies or techniques**
   We developed detailed Standard Operating Procedures for fabrication and testing of the falloposcope, as well as working in the operating room. Many of these techniques will be applicable to others wanting to build similar miniature endoscopes and perform studies. All SOPs were included in previous graduate student Kelli Kieken's dissertation, which has been published and is available to the community.

5. **Inventions, patent applications, and/or licenses**
   A patent was filed on improvements to the falloposcope created in part under this contract: *Cell-Collecting Falloposcope and method for Ovarian Cancer Detection* PCT/US20/49927, WO2021050537A1.
   The original falloposcope patent was finally issued: *Falloposcope and method for ovarian cancer detection*, J Barton, U Utzinger, T Tate, M Keenan, J Black, US Patent 10,939,864, WO2016126879A1.

6. **Other Products**
N/A

7. **PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS**

1. **What individuals have worked on the project?**

Name:	Jennifer Barton
Project Role:	Principal Investigator
Researcher Identifier (e.g. ORCID ID):	0000-0003-4897-9361
Nearest person month worked:	1
Contribution to Project:	Dr. Barton performed roles of project leadership, overseeing personnel, and contributing to design, building and testing of the endoscope.
Funding Support:	This project

Name:	Andrea Aguirre, M.D.
Project Role:	Co-I, physician
Researcher Identifier (e.g. ORCID ID):	0000-0001-9853-6185
Nearest person month worked:	1
Contribution to Project:	Dr. Aguirre aided with design and testing of the falloposcope and human subjects protocol.
Funding Support:	This project

Name:	William Drake
Project Role:	Research Technician, Undergraduate Research Assistant
Researcher Identifier (e.g. ORCID ID):	0000-0002-1189-0526
Nearest person month worked:	4
Contribution to Project:	Mr. Drake built and tested endoscopes and wrote operating room procedures.
Funding Support:	This project

Name:	Dominique Galvez
Project Role:	Graduate Research Assistant

Researcher Identifier (e.g. ORCID ID):	0000-0002-7716-7250
Nearest person month worked:	1
Contribution to Project:	Ms. Galvez assisted with building and testing endoscopes.
Funding Support:	This project

Name:	John Heusinkveld, M.D.
Project Role:	Co-I, physician
Researcher Identifier (e.g. ORCID ID):	0000-0002-5708-2647
Nearest person month worked:	1
Contribution to Project:	Dr. Heusinkveld aided with design and testing of the falloposcope and human subjects protocol.
Funding Support:	This project

Name:	Photini Faith Rice
Project Role:	Research Specialist
Researcher Identifier (e.g. ORCID ID):	0000-0001-7100-4023
Nearest person month worked:	4
Contribution to Project:	Ms. Rice assisted with the technical development of the falloposcope system, obtained certifications and assisted with writing the human subjects protocol.
Funding Support:	This project

Name:	Andrew Rocha
Project Role:	Graduate Student
Researcher Identifier (e.g. ORCID ID):	0000-0002-9030-7609
Nearest person month worked:	7
Contribution to Project:	Mr. Rocha performed optical and mechanical design and assembled and tested endoscopes.
Funding Support:	This project

Name:	Mary Reed
Project Role:	Project Coordinator
Researcher Identifier (e.g. ORCID ID):	0000-0002-7647-4419
Nearest person month worked:	1
Contribution to Project:	Ms. Reed performed clinical coordination services, including obtaining Banner hospital approvals, sterilization assurance, clinical engineering, and contract coordination.
Funding Support:	This project

Name:	Denise Roe
Project Role:	Co-investigator
Researcher Identifier (e.g. ORCID ID):	NIH Commons: deniseroe
Nearest person month worked:	1
Contribution to Project:	Dr. Roe provided statistical support in determining the experimental design and type of analysis to perform.
Funding Support:	This project

2. **Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**
Currently Active, New, and Ended support for all key personnel is given below.

BARTON, J.K.
REMAINED ACTIVE
W81XWH1810371 (Barton) 07/15/18-07/14/23 (NCE) 1.2 calendar
US Army Medical Research Acquisition Activity (total cost)
Optical Imaging Falloposcope for Early Ovarian Cancer Detection: in vivo Feasibility and Safety
The purpose of this project is to test the feasibility of an imaging-only endoscope that traverses the uterus and fallopian tubes to the ovary, to detect early ovarian cancer.
SUBJECT GRANT

ENDED
1R01EB020605 (Barton) 9/15/16 – 6/30/22 (NCE) 1.8 calendar
NIH/NIBIB
Advanced Salpingoscope for Minimally-Invasive Imaging of the Fallopian Tubes
The goal of this project is to build an endoscope that can image the ovaries and fallopian tubes with wide field, optical coherence tomography, and multiphoton microscopy, but accessing through the vagina wall.

R21CA229707 (Barton) 09/01/18-08/31/21 0.6 calendar
NIH/NCI
Molecular and Imaging Assessment of Fallopian Tube Health

The overall goal of this project is to show ex vivo proof of principle of a combined method for differentiating fallopian tubes of normal risk, high risk, and ovarian cancer patients.

T32HL007955 (Barton) 4/1/00 - 6/30/22 (NCE) 1.2 calendar
NIH/NHLBI
Cardiovascular Biomedical Engineering
Barton is the Program Director for this grant, which funds pre-doctoral student training in the field of cardiovascular biomedical engineering.

3P30CA023074 (Sweasy PI, Barton prog. co-leader) 7/14/16 - 6/30/22 0.6 calendar
NIH/NCI
University of Arizona Cancer Center – Cancer Center Support Grant
This is the overall Arizona Cancer Center support grant. Dr. Barton is Leader of the Cancer Imaging and Engineering Innovative Working Group.

ECCS-1828132 (Zhang, Barton co-I) 10/1/2018-9/30/2021 0 Calendar
NSF
MRI: Development of Integrated Multi-Access Entangled Photon Sources and Single-Photon Detector Array Instrument for Interdisciplinary Quantum Information Research.
This grant will develop novel quantum sources and detectors for distribution and use around the University of Arizona. Barton's role is to evaluate quantum entangled photons for use in biomedical imaging applications.

5U01CA200469 (Shih PI, Barton sub PI) 10/01/2-19-3/31/2-22 (NCE) 0.6 Calendar
NIH/NCI
Development of in vitro diagnostic multivariate assay
Barton is subcontract PI on this pilot project funded by the Early Detection Research Network. This pilot grant funds an endoscope with cell collecting capability and ability to visualize fluorescent contrast agent targeted to STIC lesions.

NEWLY FUNDED

R43CA254531 (Black PI, Barton Subcontract PI) 12/01/2021-8/01/2022 1.2 Calendar
NIH/NCI (total subcontract)
Outpatient Screening for Early-Stage High-Grade Serous Ovarian Cancer in Higher Risk Women (SBIR Phase I)
The purpose of the subcontract was to assist with testing an introducing device being developed for a falloposcope that can seek early signs of ovarian cancer

R01CA260399 (Barton PI) 01/01/2022-12/31/2026 1.2 Calendar
NIH/NCI (total cost)
Ovarian Cancer Detection with Blood- and Imaging-Based Biomarkers
The purpose of this study is to perform a study which develops a first-line blood biomarker and a second-line fluorescence imaging and cell collection endoscope.

R01CA260399S1 (Barton PI) 07/01/2022-12/31/2024 0 Calendar
NIH/NCI (total cost)
Ovarian Cancer Detection with Blood- and Imaging-Based Biomarkers, Diversity Supplement
The purpose of this supplement is provide training to Ms. Dominique Galvez to extend work on image quality of the falloposcope being developed in the parent grant.

1R21EB033454 (Cao PI, Barton Co-I) 07/01/2022-12/31/2024
NIH/NIBIB (total cost)
WARE-Care: a novel RF-based system to assess and prevent falling

The purpose of this study is to develop a non-invasive and non-obtrusive method to detect human movement and predict falls.

HEUSINKVELD, J.
REMAINED ACTIVE
W81XWH1810371 (Barton, Heusinkveld Co-I) 07/15/18-07/14/23 (NCE) 0.6 calendar
US Army Medical Research Acquisition Activity (total cost)
Optical Imaging Falloposcope for Early Ovarian Cancer Detection: in vivo Feasibility and Safety
The purpose of this project is to test the feasibility of an imaging-only endoscope that traverses the uterus and fallopian tubes to the ovary, to detect early ovarian cancer.
SUBJECT GRANT

ENDED
R21CA229707 (Barton, Heuskinveld Co-I) 09/01/18-08/31/21 0.48 cal. y2-3
NIH/NCI
Molecular and Imaging Assessment of Fallopian Tube Health
The overall goal of this project is to show ex vivo proof of principle of a combined method for differentiating fallopian tubes of normal risk, high risk, and ovarian cancer patients.

NEWLY FUNDED
None

AGUIRRE, A.
REMAINED ACTIVE
W81XWH1810371 (Barton, Aguirre Co-I) 07/15/20-07/14/23 (NCE) 0.6 calendar
US Army Medical Research Acquisition Activity (Total Cost)
Optical Imaging Falloposcope for Early Ovarian Cancer Detection: in vivo Feasibility and Safety
The purpose of this project is to test the feasibility of an imaging-only endoscope that traverses the uterus and fallopian tubes to the ovary, to detect early ovarian cancer.
SUBJECT GRANT

NEWLY FUNDED, ENDED
None

ROE, D.
REMAINED ACTIVE
W81XWH1810371 (Barton, Roe Co-I) 7/15/18 – 7/14/23 (NCE) 0.23 calendar
US Army Medical Research Acquisition Activity (Total Cost) (y3 only)
Optical Imaging Falloposcope for Early Ovarian Cancer Detection: In Vivo Feasibility and Safety.
The goal of this study is to test the feasibility of a minimally invasive, inexpensive, and highly sensitive falloposcope, which will allow the testing for the first time in vivo, or in a living person.
SUBJECT GRANT

U01CA214254 (Roe Site PI) 08/01/2019-07/31/2023 0.65 calendar
NIH/NCI
Noncoding RNA Biomarkers for Noninvasive and Early Detection of Pancreatic Cancer
This project is innovative as it will use NGS-based miRNA-Sequencing for discovery of cell-free and exosomal miRNA biomarkers in matched tissue and plasma samples, and validate these in multiple, well-characterized cohorts of patients with PNs and PDAC vs. controls

R25HL126140 (Garcia, Roe Co-I) 9/15/2014 – 12/31/2023 0.60 calendar
NIH/NHLBI
Arizona Pride-25: Translational Approaches to Health Disparities in the Lung.

The goal of this project is to have sustained reductions in health disparities through impactful basic, behavioral, clinical, and social sciences research and an impactful increase in the proportion of successful next generation UBR research leaders.

P30CA023074 (Sweasy, Roe Core lead) 07/01/2016 – 06/30/2027 NIH/NCI 3.36 calendar
Arizona Cancer Center – Cancer Center Support Grant.
The major goal of this project is to provide organizational infrastructure for the promotion of interdisciplinary research and the collective use of resources.

R01CA241709 (Karellas, Roe Co-I) 06/1/2019 – 05/31/2024 NIH/NCI 0.24 calendar
Upright, Low-dose, High-resolution, 3D Breast CT.
The goal of this project is to design, develop and clinically evaluate a new generation of breast CT that will use upright patient positioning similar to mammography, but without breast compression, and at radiation dose similar to mammography to provide full 3D images of the breast.

P01CA229112 (Curiel-Lewandrowski, Roe Core Leader) 09/10/2019-08/31/2024 1.20 calendar NIH/NCI
Targeted Prevention for Non-Melanoma Skin Cancer
Core B – Biostatistics and Bioinformatics Core
The overall goal of this grant is to identify, develop, and clinically evaluate novel non-melanoma skin cancer chemopreventive agents, biomarker discovery and to evaluate these candidate agents in early human studies.

R01CA245920 (Altbach, Roe Co-I) 12/01/2019 – 11/30/2024 NIH/NCI 0.36 calendar
Advancing MRI Technology for Early Diagnosis of Liver Metastases
We expect our proposal to yield technology improvements that will increase precision of care and outcomes in patients with metastatic malignancies, in particular those with colorectal cancer.

41010481702/1U01CA214254-01 (Goel, Roe Site PI) 0/801/2019– 07/31/2023 Beckman Res. Inst. of The City of Hope 0.99 calendar
Noncoding RNA Biomarkers for Noninvasive and Early Detection of Pancreatic Cancer
Dr. Roe will contribute to this project by providing statistical design, oversight of statistical analyses, assistance in the reporting of results to investigators as well as assistance in manuscript preparation.

R01CA253302 (Bea, Roe Co-I) 07/01/2020 – 06/30/2023 NIH/NCI 1.20 calendar
Adipose and Lean Soft Tissue Depots, Cancer Risk and Mortality in Postmenopausal Women
This study will inform etiological understanding, improve risk assessment, and, most importantly, enhance our ability to target interventions and cancer prevention efforts.

R01MD014127-01A1 (Gachupin, Roe Co-I) 04/13/2020 – 12/31/2024 NIH/NIMHD 1.20 calendar

Achieving American Indian Youth Energy and Mental Health Balance.
The goal of this project is to develop and test a culturally relevant, community-led intervention that incorporates the principles of Mind-Body Medicine (MBM) skills training and parental/caregiver engagement to support AI youth in achieving healthy lifestyle choices and in reducing risk for obesity and related metabolic diseases.

R03HD102403 (Farland) 04/01/2021-03/31/2023 0.48 calendar

NIH/NICHD
Infertility and Risk of Breast, Gynecologic, and Colorectal Cancer
Infertility is a common public health problem that may increase a woman's risk for cancer (breast, ovarian, endometrial, colorectal). Within the Women's Health Initiative, a prospective cohort of over 160,000 women followed for 25 years, we will combine data on infertility history and specific infertility diagnoses to evaluate the relationship between infertility and the risk of hormone-related cancers.

R21CA245411 (Ibrahim, Roe Co-I) 01/01/2021-12/31/2022 0.48 calendar
NIH/NCI
Repurposing Sulfasalazine in a Two-Arm Phase Two Double-Blind Randomized Clinical Trial for the Adjunct Management of Breast Cancer-Induced Bone Pain
We will assess whether sulfasalazine will improve both of our primary and secondary outcomes. Our primary outcome is reduction in the opioids used. The secondary outcome is reduction in pain and improvement of the quality of life (SA1). Secondly, we will assess the levels of serum glutamate and IL-6, TNF-alpha and tumor markers before and after treatment with sulfasalazine and placebo (SA2).

NEWLY FUNDED
1R01CA251729 (Roe Co-I) 08/10/2021-07/31/2026 0.6 calendar
NIH/NCI
Unraveling the regulatory circuits that drive Merkel cell carcinoma
We will analyze dynamic protein and genomic measurements to understand how normal cells can acquire neuroendocrine and metastatic features, because reversing this process could lead to new cancer therapies.

1R01CA258436 (Roe Co-I) 04/01/2022-03/31/2027 3.0 calendar
NIH/NCI
Role of FSH in postmenopausal obesity and breast cancer
This study is focused on the topic of postmenopausal shifts in follicle stimulating hormone (FSH) and how FSH relates to obesity development and breast cancer risk.

1R21CA263132 (Roe Co-I) 04/01/2022 – 03/31/2024 0.36 calendar
NIH/NCI
DNA Methylation, Liquid Biopsy, and Pancreatic Cancer
The objective of this proposal is to validate our liquid biopsy approach and demonstrate its utility.

1R01CA246482 (Roe Co-I) 07/01/2022 – 06/30/2-2026 1.3 calendar
Ethnicity and Lung Cancer Survival: A Test of the Hispanic Sociocultural Hypothesis
This is a multisite, two-study, mixed-methods investigation to evaluate the Hispanic Health Paradox by investigating whether the observed Hispanic survival advantage is mediated by ethnic differences.

ENDED
None

3. **What other organizations were involved as partners?**
Nothing to Report.

8. **SPECIAL REPORTING REQUIREMENTS**
N/A

9. **APPENDICES:**
None