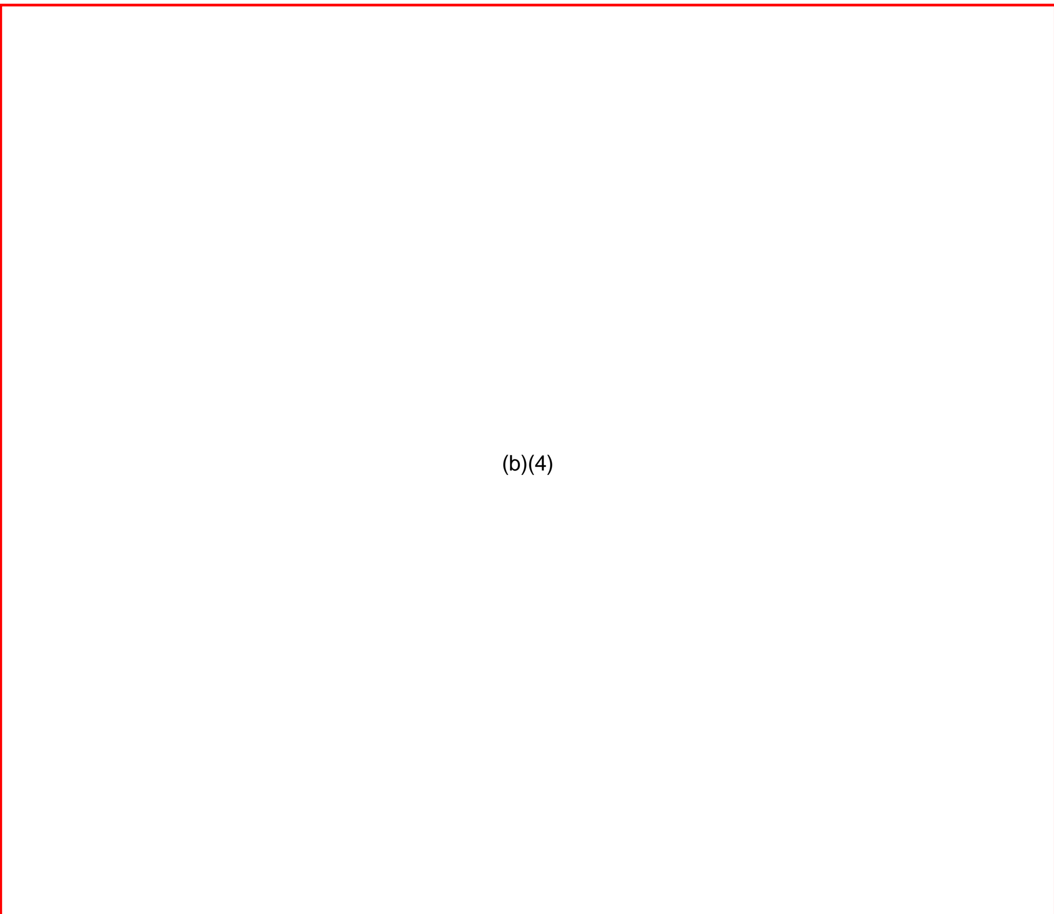
PI: **Smith, Angela B**	Title: American Urological Association's Quality Improvement Summit: Opioid Stewardship in Urology	
Received: 05/01/2018	FOA: PA16-453 Clinical Trial:Optional	Council: 10/2018
Competition ID: FORMS-E	FOA Title: AHRQ CONFERENCE GRANT PROGRAMS (R13)	
1 R13 HS026679-01	Dual:	Accession Number: 4166241
IPF: 401501	Organization: AMERICAN UROLOGICAL ASSOCIATION	
Former Number:	Department:	
IRG/SRG: ZHS1 HSR-T (02)	AIDS: N	Expedited: N
Subtotal Direct Costs (excludes consortium F&A) Year 1: 35,100	Animals: N Humans: N Clinical Trial: N Current HS Code: 10 HESC: N	New Investigator: N Early Stage Investigator: N

Senior/Key Personnel:	*Organization:*	*Role Category:*
Angela Smith M.D.	University of North Carolina	PD/PI



OMB Number: 4040-0001
Expiration Date: 10/31/2019

APPLICATION FOR FEDERAL ASSISTANCE

SF 424 (R&R)

3. DATE RECEIVED BY STATE	**State Application Identifier**

1. TYPE OF SUBMISSION*

❍ Pre-application ❍ Application ● Changed/Corrected Application

4.a. Federal Identifier

b. Agency Routing Number

2. DATE SUBMITTED

Application Identifier

c. Previous Grants.gov Tracking Number
GRANT12619635

5. APPLICANT INFORMATION — Organizational DUNS*: **0805676050000**

Legal Name*: **American Urological Association**
Department:
Division:
Street1*: **1000 Corporate Boulevard**
Street2:
City*: **Linthicum**
County:
State*: **MD: Maryland**
Province:
Country*: **USA: UNITED STATES**
ZIP / Postal Code*: **21090-2260**

Person to be contacted on matters involving this application
Prefix: **Ms.** First Name*: **Suzanne** Middle Name: **Boland** Last Name*: **Pope** Suffix:
Position/Title: **Director**
Street1*: **1000 Corporate Boulevard**
Street2:
City*: **Linthicum**
County:
State*: **MD: Maryland**
Province:
Country*: **USA: UNITED STATES**
ZIP / Postal Code*: **21090-2260**
Phone Number*: **410-689-4026** Fax Number: Email: **spope@auanet.org**

6. EMPLOYER IDENTIFICATION NUMBER *(EIN) or (TIN)** **430691437**

7. TYPE OF APPLICANT* **M: Nonprofit with 501C3 IRS Status (Other than Institution of Higher Education)**

Other (Specify):
Small Business Organization Type ❍ Women Owned ❍ Socially and Economically Disadvantaged

8. TYPE OF APPLICATION*

● New ❍ Resubmission
❍ Renewal ❍ Continuation ❍ Revision

If Revision, mark appropriate box(es).
❍ A. Increase Award ❍ B. Decrease Award ❍ C. Increase Duration
❍ D. Decrease Duration ❍ E. Other *(specify)*:

Is this application being submitted to other agencies?* ❍ Yes ● No What other Agencies?

9. NAME OF FEDERAL AGENCY*
Agency for Health Care Research and Quality

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER
TITLE:

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT*
American Urological Association's Quality Improvement Summit: Opioid Stewardship in Urology

12. PROPOSED PROJECT

Start Date*	Ending Date*
08/01/2018	**06/14/2019**

13. CONGRESSIONAL DISTRICTS OF APPLICANT
MD-002

SF 424 (R&R) APPLICATION FOR FEDERAL ASSISTANCE

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

Prefix: **Dr.** First Name*: **Angela** Middle Name: Last Name*: **Smith** Suffix: **M.D.**

Position/Title:

Organization Name*: **University of North Carolina**

Department:

Division:

Street1*: **2107 Physicians Office Building**

Street2: **Campus Box 7235**

City*: **Chapel Hill**

County:

State*: **NC: North Carolina**

Province:

Country*: **USA: UNITED STATES**

ZIP / Postal Code*: **27599-7235**

Phone Number*: **919-966-2574** Fax Number: Email*: **angela_smith@med.unc.edu**

15. ESTIMATED PROJECT FUNDING

a. Total Federal Funds Requested*	$35,100.00
b. Total Non-Federal Funds*	(b)(4)
c. Total Federal & Non-Federal Funds*	
d. Estimated Program Income*	

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

a. YES ❍ THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:

DATE:

b. NO ● PROGRAM IS NOT COVERED BY E.O. 12372; OR

❍ PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

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

● I agree*

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

18. SFLLL or OTHER EXPLANATORY DOCUMENTATION File Name:

19. AUTHORIZED REPRESENTATIVE

Prefix: First Name*: **Suzanne** Middle Name: **Boland** Last Name*: **Pope** Suffix:

Position/Title*: **Director**

Organization Name*: **American Urological Association**

Department:

Division:

Street1*: **1000 Corporate Boulevard**

Street2:

City*: **Linthicum**

County:

State*: **MD: Maryland**

Province:

Country*: **USA: UNITED STATES**

ZIP / Postal Code*: **21090-2260**

Phone Number*: **410-689-4026** Fax Number: Email*: **spope@auanet.org**

Signature of Authorized Representative*
Suzanne B Pope

Date Signed*
05/01/2018

20. PRE-APPLICATION File Name:

21. COVER LETTER ATTACHMENT File Name: **1239-AUA Cover letter QI Summit.pdf**

424 R&R and PHS-398 Specific
Table Of Contents

SF 424 R&R Cover Page. 1
  Table of Contents. 3
Performance Sites. 4
Research & Related Other Project Information. 5
  Project Summary/Abstract(Description). 6
  Project Narrative. 7
Research & Related Senior/Key Person. 8
Research & Related Budget Year - 1. 89
Budget Justification. 92
Research & Related Cumulative Budget. 94
PHS398 Cover Page Supplement. 95
PHS 398 Research Plan. 97
  Specific Aims. 98
  Conference Plan. 99
  PHS Human Subjects and Clinical Trials Information. 107

OMB Number: 4040-0010
Expiration Date: 10/31/2019

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: **American Urological Association**
Duns Number: **0805676050000**
Street1*: **1000 Corporate Boulevard**
Street2:
City*: **Linthicum**
County: **Anne Arundel**
State*: **MD: Maryland**
Province:
Country*: **USA: UNITED STATES**
Zip / Postal Code*: **21090-2260**
Project/Performance Site Congressional District*: **MD-002**

Additional Location(s) File Name:

OMB Number: 4040-0001
Expiration Date: 10/31/2019

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 ❍ No

If YES, check appropriate exemption number: _1 __ 2 __ 3 __ 4 __ 5 __ 6 __ 7 __ 8 If NO, is the IRB review Pending? ❍ **Yes** ❍ **No**

IRB Approval Date:

Human Subject Assurance Number

2. Are Vertebrate Animals Used?* ❍ Yes ● No

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ❍ Yes ❍ No

IACUC Approval Date:

Animal Welfare Assurance Number

3. Is proprietary/privileged information included in the application?* ● Yes ❍ No

4.a. Does this project have an actual or potential impact - positive or negative - on the environment?* ❍ Yes ● No

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ❍ Yes ❍ No

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*	**1235-Project Summary Abstract_AUA 5 1 18.pdf**
8. Project Narrative*	**1236-Project Narrative 5 1 18.pdf**
9. Bibliography & References Cited	
10.Facilities & Other Resources	
11.Equipment	

Project Summary/Abstract:

Opioid Stewardship in Urology

The American Urological Association (AUA) is requesting an AHRQ Conference Grant to support convening a Quality Improvement Summit on Opioid Stewardship in Urology, with discussion focusing on: post-operative pain management strategies, physician-led interventions in opioid stewardship, policy and outreach work related to the opioid epidemic, and the identification and management of patients at high-risk for opioid related issues in the peri-operative period. The AUA's Quality Improvement Summits address quality issues, define clinical problems, facilitate information exchange on quality efforts by clinicians across disciplines and care settings, and educate urology practitioners, primary care physicians, and specialists about developing patient-centered quality improvement programs. For its 2018 summit, the AUA will convene a multi-disciplinary panel of speakers to take part in a collaborative effort dedicated to reducing the impact of urologic surgery and subsequent pain management strategies on the current opioid epidemic.

The 2018 Summit will provide a unique and timely opportunity to accelerate the application of evidence into practice by bringing together physicians, researchers, and professional societies spanning the disciplines of urology, broader surgical specialties, alternative medicine, pain management, anesthesiology, and psychiatry/ addiction medicine around the shared goal of improving care delivery as it relates to opioid prescription and use in the peri-operative period. Specific aims include the following:

- Provide an overview of the opioid epidemic in the context of surgical management of urologic diseases
- Provide pragmatic information for steps that can be taken by urologists to influence the opioid epidemic at the individual patient level
- Delineate roles urologists can play in broader settings (e.g., across healthcare system or communities) in combating the opioid epidemic
- Establish a list of priorities for future work in opioid and pain management by AUA and other interest parties
    - Research and develop procedure-specific guidance
    - Develop physician and patient-facing educational programs and materials

Project Narrative:

Opioid Stewardship in Urology

The United States is faced with the growing public health challenge of treating patients suffering with pain while preventing the potential harms associated with the use and misuse of opioids that has led to the current opioid epidemic. While opioids are known to be effective for managing post-operative pain and make up the majority of prescriptions for pain control after surgery, nearly 2 million patients each year develop opioid dependence following a first dose of an opioid following surgical or dental care. In this context, the American Urological Association (AUA) is working to increase awareness of this issue and provide its members nationwide with an evidence-based action plan to reduce the impact of urologic surgery as a potential contributor to opioid-related disorders, and, as a foundational step, the AUA is convening a multi-stakeholder Quality Improvement Summit to address these topics, bringing together experts from urology, broader surgical specialties, anesthesia, pain management, addiction medicine, and several relevant public service organizations to discuss a variety of topics including: post-operative pain management strategies, physician-led interventions in opioid stewardship, policy and outreach work related to these topics, the identification and management of patients at high-risk for opioid related issues in the peri-operative period.

OMB Number: 4040-0001
Expiration Date: 10/31/2019

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: Dr. **First Name*:** Angela **Middle Name** **Last Name*:** Smith **Suffix:** M.D.

Position/Title*:
Organization Name*: University of North Carolina
Department:
Division:
Street1*: 2107 Physicians Office Building
Street2: Campus Box 7235
City*: Chapel Hill
County:
State*: NC: North Carolina
Province:
Country*: USA: UNITED STATES
Zip / Postal Code*: 27599-7235

Phone Number*: 919-966-2574 **Fax Number:**

E-Mail*: angela_smith@med.unc.edu

Credential, e.g., agency login: (b)(6)

Project Role*: PD/PI **Other Project Role Category:**

Degree Type: **Degree Year:**

Attach Biographical Sketch*: **File Name:** 1240-Smith.pdf

Attach Current & Pending Support: File Name:

Tracking Number: GRANT12619712 Funding Opportunity Number: PA-16-453 . Received Date: 2018-05-01T14:47:17.000-04:00

Pages 10 through 89 redacted for the following reasons:
- -
(B)(4) Key personel/resumes

OMB Number: 4040-0001
Expiration Date: 10/31/2019

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

ORGANIZATIONAL DUNS*: 0805676050000

Budget Type*: ● Project ❍ Subaward/Consortium

Enter name of Organization: American Urological Association

Start Date*: 08-01-2018 **End Date*:** 06-14-2019 **Budget Period: 1**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .	Dr.	Angela		Smith	M.D.	PD/PI			0.45		0.00	0.00	0.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: **Total Senior/Key Person** **0.00**

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*

Total Number Other Personnel **Total Other Personnel**

Total Salary, Wages and Fringe Benefits (A+B) **0.00**

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

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

ORGANIZATIONAL DUNS*: 0805676050000

Budget Type*: ● Project ❍ Subaward/Consortium

Organization: American Urological Association

Start Date*: 08-01-2018 **End Date*:** 06-14-2019 **Budget Period:** 1

C. Equipment Description

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

Equipment Item	Funds Requested ($)*
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name:

D. Travel

D. Travel	Funds Requested ($)*
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs

E. Participant/Trainee Support Costs	Funds Requested ($)*
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	14,000.00
4. Subsistence	
5. Other:	
Number of Participants/Trainees — **Total Participant Trainee Support Costs**	**14,000.00**

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

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

ORGANIZATIONAL DUNS*: 0805676050000
Budget Type*: ● Project ❍ Subaward/Consortium
Organization: American Urological Association

Start Date*: 08-01-2018 **End Date*:** 06-14-2019 **Budget Period:** 1

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	100.00
2. Publication Costs	500.00
3. Consultant Services	6,000.00
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	8,000.00
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Speaker fee	5,000.00
9 . Postage - meeting materials	1,500.00
Total Other Direct Costs	**21,100.00**

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	**35,100.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)*
Total Indirect Costs			

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)*
Total Direct and Indirect Institutional Costs (G + H)	**35,100.00**

J. Fee	Funds Requested ($)*

K. Total Costs and Fee	Funds Requested ($)*
	35,100.00

L. Budget Justification* File Name: 1234-Budget Justification 050118.pdf
(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

2018 QUALITY IMPROVEMENT SUMMIT

"OPIOID STEWARDSHIP IN UROLOGY"

BUDGET JUSTIFICATION

This grant application requests partial support to convene a full-day summit on December 8, 2018 at the American Urological Association (AUA) Headquarters in Linthicum, Maryland. This summit will focus on educating urologists and other providers about the opioid epidemic as related to the surgical management of urologic diseases and the role of providers in combatting the epidemic while managing the pain of their patients.

The AUA has negotiated corporate discounted lodging rates at a nearby hotel in Linthicum. The Standard Operating Procedures under which the Conventions and Meetings Department of the AUA operates dictate that all venues and hotels meet federal ADA guidelines. A meeting planner from the AUA Conventions and Meetings Department will be assigned to the summit to coordinate activities, such as registration and faculty travel, and to interact with the hotel staff as necessary to ensure a smooth event. Additionally, the summit itself will be held in AUA office space; therefore, no costs are associated with meeting space rental.

Several AUA staff members as well as members of the AUA Board of Directors will attend the summit. While the full budget provided below includes staff and faculty meals, lodging and other travel expenses, and other logistical costs, they are exclusive of the amount requested from AHRQ. We are requesting $35,100 in support for this summit to cover travel expenses for speakers, meeting supplies, consultants, and speaker fees, if needed. Travel expenses are estimated from $400–$800 per speaker based on past AUA Quality Improvement Summits and current travel costs. We estimate $1875 in revenue from registration fees. The AUA is prepared for additional expenses related to promotional efforts and attendee meals which are not covered under this grant opportunity.

Based on the above assumptions, we calculate an approximate shortfall of $10100 even if this R13 application is funded at the requested amount. The AUA stands firm in its support of this summit and will cover the costs for staff travel, meals, meeting logistics, and miscellaneous expenses. Other than potential AHRQ funding, the AUA will be the sole source of support for the meeting.

Full Budget:

REVENUES:		
Government Grants	$35100	
Registration Fees	(b)(4)	
TOTAL REVENUES		
EXPENSES:		
Speakers: • Air Travel • Parking and Ground Transportation • Lodging • Meals		
Speaker fee		
Consultant Services		
Supplies		
Publication Costs		
Conference Services		
Postage		
Staff Lodging and Meals		
Promotional Costs		
Food, Beverage and Banquet		
TOTAL EXPENSES		
NET INCOME/(DEFICIT)		

RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals ($)
Section A, Senior/Key Person	
Section B, Other Personnel	
Total Number Other Personnel	
Total Salary, Wages and Fringe Benefits (A+B)	
Section C, Equipment	
Section D, Travel	
1. Domestic	
2. Foreign	
Section E, Participant/Trainee Support Costs	
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	(b)(4)
5. Other	
6. Number of Participants/Trainees	
Section F, Other Direct Costs	
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Other 1	
9. Other 2	
10. Other 3	
Section G, Direct Costs (A thru F)	**35,100.00**
Section H, Indirect Costs	
Section I, Total Direct and Indirect Costs (G + H)	**35,100.00**
Section J, Fee	
Section K, Total Costs and Fee (I + J)	**35,100.00**

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 Research Plan

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

Introduction	
1. Introduction to Application (for Resubmission and Revision applications)	
Research Plan Section	
2. Specific Aims	**1237-AUA Specific Aims EK050118_mn Final.pdf**
3. Research Strategy*	**1238-QI Summit 18 5 1 18.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	
10. Resource Sharing Plan(s)	
11. Authentication of Key Biological and/or Chemical Resources	
Appendix	
12. Appendix	

Specific Aims

Each day, more than 115 Americans die from opioid-related overdose and an additional 1,000 people are treated in emergency departments for opioid-related morbidity. Sales of prescription opioids in the U.S. nearly quadrupled between 1999 and 2014 with similar increases seen in the number of opioid-related deaths over the same period. Current data show that approximately 30% of patients prescribed opioids for chronic pain misuse them, and roughly 10% of those individuals will develop an opioid-use disorder. It has also been reported that 80% of heroin users' pathway to opioid misuse began with prescription opioids.

It is estimated that the opioid epidemic has cost the U.S. over $1 trillion from 2001-2017 with an additional $500 billion expected by 2020. Related healthcare costs reached $215 billion over the same period, largely due to emergency room visits and associated field-based emergency medical services and Naloxone use. A disproportionate share of this cost has been carried by Medicaid in recent years. On top of the staggering direct financial burden of opioid misuse, there are devastating ripple effects on families and communities surrounding individuals with opioid use disorders.

Whereas the majority of existing policy and public health initiatives focus on the important downstream consequences of opioid use disorders, there has historically been a paucity of efforts focused on upstream prevention. A recently emerging body of evidence suggests previously a previously underappreciated substantial contribution of prescribing related to surgery and other acute conditions as an upstream driver of the opioid epidemic. For instance, new chronic use of opioids among previously opioid-naïve patients is more common than conventional postoperative complications.

While a broad consensus exists regarding the need for judicious opioid prescribing, available data highlight substantial heterogeneity in post-operative opioid prescribing patterns, even among patients receiving similar surgeries, and emphasize the growing need for greater patient and physician education on the appropriate use of opioids, alternative pain management strategies, and options for management of the impact of opioid dependence with continued efforts towards the decrease of its prevalence. Consequently, the American Urological Association (AUA) recognizes the growing need for physician-led stewardship of pain management. With the vast majority of opioid prescriptions address the need for pain management following a surgical encounter, the attendees of the QI Summit represent a specialty with tremendous potential for positive impact on the growing problem from a patient care perspective through appropriate prescribing practices and the related reduction of the growing costs needed to treat opioid misuse.

The Summit will provide a unique and timely opportunity to accelerate the application of evidence into practice by bringing together physicians, researchers, and professional societies spanning the disciplines of urology, pain management, anesthesiology, psychiatry/addiction medicine, and complementary and alternative medicine, around the shared goal of improving care delivery with a specific focus on pain management and opioid utilization for patients under the care of urologic surgeons.

Specific Aims for this Quality Improvement Summit include the following:

1. Provide an overview of the opioid epidemic in the context of surgical management of urologic diseases
2. Provide pragmatic information for steps that can be taken by urologists to influence the opioid epidemic
3. Delineate roles urologists can play in combating the opioid epidemic
4. Establish a list of priorities for future work in opioid and pain management by AUA and other interest parties

Aligned with AHRQ's mission, the conference will provide a vehicle to disseminate health services research to relevant stakeholder communities and facilitate the engagement of urologists in an interdisciplinary network for future collaborations. These collaborations will develop and disseminate tools to support the systematic implementation of policies and programs that improve the quality, effectiveness, and safety of heath care.

Conference Plan

The 2018 American Urological Association (AUA) Quality Improvement Summit, "Opioid Stewardship in Urology," will be held December 8, 2018 at the AUA headquarters in Linthicum, Maryland, a centralized location on the east coast near a major airport hub to enable ease of travel for non-local attendees, including participants from various medical institutions, governmental agencies, and other interested stakeholders.

The Summit will provide a unique and timely opportunity to accelerate the application of evidence into practice by bringing together physicians, researchers, and professional societies spanning the disciplines of urology, pain management, anesthesiology, psychiatry/addiction medicine, and complementary and alternative medicine, around the shared goal of improving care delivery with a specific focus on pain management and opioid utilization for patients under the care of urologic surgeons. In 2016, the U.S. Food and Drug Administration (FDA) launched an Opioid Action Plan, part of which tasked the National Academies of Sciences, Engineering, and Medicine to convene a committee to identify actions needed in response to the growing opioid epidemic.[1] The committee's report highlighted the public health challenge involved in treating those suffering with pain while preventing the potential harms associated with the use and/or misuse of opioids. These challenges are particularly salient in the management of peri-operative pain, where opioid medications have well-defined efficacy, but have also been increasingly recognized to be associated with prolonged opioid use in a considerable number of patients who were opioid naïve prior to surgery.[2] Further still, it is possible that surplus opioids provided in well-intended peri-operative prescriptions may represent a source of opioids in the community that can eventually be diverted for less appropriate use. Given the potential for such prescriptions to contribute to the broader opioid epidemic, there are opportunities to augment understanding within the surgical community as to the current state of evidence for various pain control strategies, investigate opportunities for surgeons and other care-providers to reduce the risk of opioid dependence or diversion of prescribed medication, and to define areas where future research can improve the care patients receive from urologic surgeons. We anticipate this meeting will provide actionable information to AUA members and also establish partnerships between stakeholder organizations that will facilitate needed ongoing clinical and organizational improvement activities aimed at improving the quality of patient care.

Conference Objectives

1. Provide an overview of the opioid epidemic in the context of surgical management of urologic diseases
2. Provide pragmatic information for steps that can be taken by urologists to influence the opioid epidemic
3. Delineate roles urologists can play in combating the opioid epidemic
4. Establish a list of priorities for future work in opioid and pain management by AUA and other interest parties
    a. Research and develop procedure-specific opioid prescribing guidelines
    b. Develop physician and patient-facing educational programs and materials

Scientific Need, Timeliness, and Usefulness to the Practice, Research, and Policy Community

Growing Need for Physician-Led Stewardship of Pain Management

In 2010, nearly 50 million surgical and non-surgical procedures were performed in the U.S.[3] Following surgery, improper pain management can lead to recovery delays and result in longer hospital stays and future chronic pain issues. As such, over 280 million of the nearly 4 billion prescriptions dispensed in 2012 were for opioids, and more than a third (36.5%) of all prescriptions written by surgeons were for opioids.[4] While opioids make up a majority of prescriptions for the treatment of postoperative pain, 2 million people had a substance use disorder involving prescription pain relievers in 2015 alone.[5] The available data highlight substantial heterogeneity in post-operative opioid prescribing patterns, even among patients receiving similar surgeries,[2,6,7] and emphasize the growing need for greater patient and physician education on the appropriate use of opioids, alternative pain management strategies, and options for management of the impact of opioid dependence with continued efforts towards the decrease of its prevalence.

Mitigating Opioid Harms: An Impetus for Stewardship of Opioid Prescribing

Each day, more than 115 Americans die from opioid-related overdose; an additional 1,000 people are treated in emergency departments for opioid-related morbidity.[8] Sales of prescription opioids in the U.S. nearly quadrupled between 1999 and 2014 with similar increases seen in the number of opioid-related deaths over the same period.[9] Currently, nearly 3 million people in the U.S. are living with opioid-use disorders, including dependence, misuse, and addiction. Current data show that approximately 30% of patients prescribed opioids for chronic pain misuse them, and roughly 10% of those individuals will develop an opioid-use disorder. It is also reported that 80% of heroin users first misused prescription opioids.

According to analysis by Altarum, a non-profit health research institute, the opioid epidemic has cost the U.S. over $1 trillion from 2001-2017 with an additional $500 billion expected by 2020. Related healthcare costs reached $215 billion over the same time period, largely due to emergency room visits and associated ambulance and Naloxone use.[10] A disproportionate share of this cost has been carried by Medicaid in recent years. Aside from the financial burden posed by opioid misuse is the emotional and physical burden experienced by those with use disorders and that of their families and surrounding communities.

With the vast majority of opioid prescriptions originating in a need for pain management following a surgical encounter, the attendees of the QI Summit represent a specialty with tremendous potential for positive impact on the growing problem from a patient care perspective through appropriate prescribing practices and the related reduction of the growing costs needed to treat opioid misuse.

Current Stewardship Initiatives and Areas of Further Need

While a broad consensus exists regarding the need for modest opioid prescribing, studies continue to demonstrate wide variation in opioid prescribing trends. In a large national sample of over 350,000 Medicare patients, rates of opioid prescribing varied widely between physicians practicing within the same surgery department.[11] The results demonstrated that an increased likelihood of receiving an opioid for even a single encounter had the potential to drive future long-term opioid use and increased negative outcomes among the elderly. There have additionally been recent publications on issues of unused/excess opioids following surgery and the lack of awareness on appropriate storage and disposal. Bicket et al. reviewed a population of 810 unique patients who underwent various surgical procedures. Of those patients, 67%-92% reported unused opioids while the authors noted that safe storage and/or disposal of unused prescription opioids were low.[12] It is estimated that 40%-70% of opioid pills prescribed following surgery remain unconsumed, thus providing a large supply for diversion into the community.[12,13]

Such studies illustrate the continued need for further educational intervention to close the growing gap in prescribing practices with additional opportunities for improvement utilizing tools designed to provide practice-based audit and feedback. The American Medical Association (AMA) and the American College of Surgeons (ACS) have both developed resources on this issue and how physicians can take action. The AMA convened a task force that developed a variety of resources, including continuing medical education (CME) courses on opioids and addiction. The ACS further developed a statement on the Opioid Abuse Epidemic in June 2017 to advocate for surgeon stewardship. Many such existing strategies focus on the downstream consequences of opioid misuse, but there is a clear need for education on surgical prescribing practices and prevention opportunities. The Summit will provide a much-needed multidisciplinary platform for physicians and other important stakeholders to discuss the issue and brainstorm further ways to promote such physician stewardship in everyday practice.

Current Engagement of the Urology Community in Opioid Prescription Stewardship

The urology practice community and AUA are actively engaged in stewardship activities related to the use of opioids both post-operatively and for chronic pain. Most notably, the AUA promoted the Centers for Disease Control and Prevention Guideline for Prescribing Opioids for Chronic Pain and continues to promote patient and physician education on appropriate use. Additionally, at its 2018 Annual Meeting, the AUA will convene many educational courses on opioid use and abuse. Topics include opioid overdose in patients with chronic flank pain, opioid use in early recovery after surgery for a radical cystectomy, opioid prescribing guidelines for

the urologic surgery patient, perioperative opioid-sparing analgesia strategies, and variation in opioid prescribing patterns for various urologic surgeries,

The Summit will also build on AUA's development of an official position statement on opioid prescribing and facilitate a more in-depth analysis and discussion of the issues. Plans are also in place to further promote this effort, which expands on the AUA's Choosing Wisely Statement that recommends, "Don't continue opioid analgesia beyond the immediate postoperative period; prescribe the lowest effective dose and number of doses required to address the expected pain." As surgical specialists, urologists recognize the important role they play in stemming the overuse of prescription opioids and welcome guidance and educational opportunities.

Tools for Improvement

To address the issue postoperatively, physicians at the University of Michigan developed the Opioid Prescribing Engagement Network (OPEN) in 2016 as a statewide initiative in partnership with academic and community clinicians, scientists, large payers, policy makers, state health officials, and community members. The project aimed to prevent new opioid-related morbidity and mortality in the community by (1) limiting the influx of opioids, and (2) facilitating the disposal of opioids. Initial efforts included the successful creation of prescribing guidelines across 72 hospitals, implementation of innovative options for opioid deactivation and disposal within the home, and creation of a community opioid return event (CORE) toolkit for community partners to participate in statewide opioid disposal drives. While the program was met with initial success, further opportunities remain to expand this program and further demonstrate effectiveness in reducing excess opioids in the community.

The QI Summit has the potential to create tools to instill deeper physician understanding of opioid-related risk/benefits and alternative strategies that can limit the need for peri-operative opioids. Through the exchange of ideas on how physicians can serve as better stewards in prescribing these medications, efforts can focus on the reduction of surplus medications making their way into communities. On a policy level, insights will be shared into physician-led policy initiatives to address the opioid crisis with attendees leaving with a greater understanding of how to engage local and state governments to address the opioid issue. Finally, the QI Summit will help establish plans for future research into urology-specific pain management strategies designed to better address patient pain while mitigating opioid-related risks.

Potential Opportunities for Alternative Pain Management

Many patients are unaware of both the possibility of postsurgical chronic opioid use and the potential for use of alternative pain management strategies that avoid or delay the use of opioids. In a systematic review of over 5,000 studies, alternative strategies such as electrotherapy, acupuncture, continuous passive motion, preoperative exercise, and cryotherapy showed the potential to reduce and/or delay opioid use for pain.[14] There remains a tremendous opportunity for further research in this space. While opioids are the most commonly prescribed tool for pain management, such research suggests that alternative strategies exist and can be used effectively to treat post-operative pain. Drs. Margaret Rukstalis Meghan Sperandeo will be present at the QI summit to discuss further research in this space and promote opportunities for the safe use of alternative strategies in practice.

Emerging Federal Activity and the Timeliness of the Summit

CMS is acutely aware of the growing opioid epidemic, which was officially declared as a "public health emergency" by the current presidential administration as of October 2017. As such, CMS is currently finalizing a number of policies for 2019 to further help Medicare plan sponsors prevent and combat prescription opioid overuse. For opioid naïve patients, CMS is calling on all Part D sponsors to limit initial opioid prescription fills for the treatment of acute pain to no more than a 7 days' supply. For high-risk users, CMS is expanding the Overutilization Monitoring System (OMS), which identifies those patients considered at high risk. For chronic

opioid users, CMS will implement real-time safety alerts at the time of dispensing as a step to engage patients and prescribers about overdose risk and prevention.

Likewise, the FDA has shown great concern about the growing epidemic of opioid abuse.[15] As such, the agency has developed a comprehensive plan with steps aimed towards reducing the impact of opioid abuse in families and communities. The FDA has committed to working closely with advisory committees when making labeling decisions, enhancing safety labeling, requiring new data, and seeking to improve treatment of addiction and pain.

The CDC has committed to fighting the opioid epidemic and supporting communities in their continued efforts to collect data, respond to overdoses, and provide care to those in need within the community.[16] The CDC's Prevention for States and Data-Driven Prevention Initiative aims to enhance the Prescription Drug Monitoring Program (PDMP) within clinical and public health settings. It is the goal of the CDC's Enhanced State Opioid Overdose Surveillance Program to support and build the capacity of states to monitor the epidemic and improve the timeliness and quality of surveillance data focused on both fatal and non-fatal opioid overdose.

Success of Prior AUA Quality Improvement Summits

The AUA Quality Improvement and Patient Safety (QIPS) Committee previously led three successful interdisciplinary QI Summits. The first was at AUA headquarters on January 25, 2014 and focused on complications associated with prostate needle biopsies. This inaugural summit garnered 53 attendees, including representation from urology, research, CMS, and infectious disease. For the 2016 Summit held April 2, 2016 at the AUA headquarters, AUA partnered with the Society for Medical Decision Making (SMDM) and focused on shared decision making and prostate cancer. This event brought in 63 attendees, including representatives from AUA and SMDM. The 2017 summit on stewardship in imaging jointly promoted by AUA, the American College of Emergency Physicians (ACEP) and the American College of Radiology (ACR) drew over 50 attendees. Various publications focused on meeting proceedings were published and widely disseminated following all summits by the AUA and partner organizations. Recordings from all summits were also made publicly available via the AUA website.

The proposed 2018 summit is projected to draw in an even larger audience with multi-disciplinary representation from urology, pain management, anesthesiology, and addiction medicine. We also will plan to make the summit available to AUA members for remote web access to increase dissemination where travel precludes attendance.

AUA Quality Improvement Summit Agenda

7:30 – 8:00 AM **Registration and Breakfast**
8:00 – 8:15 AM **Opening Remarks:** Robert Flanigan, MD, AUA President
8:15 – 9:00 AM **Keynote: The Opioid Epidemic and Role of Physicians and Prescription Pharmaceuticals:** *Chad Brummett, MD, University of Michigan*

9:00 – 10:00 AM **Session 1: Understanding Postoperative Pain**

- *Pathophysiology of post-operative pain, role of opioids, non-opioid alternatives in management of post-operative pain (Brooke Chidgey, MD, University of North Carolina)*
- *Post-operative opioids and their role in the opioid epidemic (Chad Brummett, MD, University of Michigan)*
- *Alternative pain management strategies using mindfulness, naturopathy, acupuncture (Meghan Sperandeo, ND, National University of Natural Medicine)*
- *Cognitive behavioral therapy and non-pharmacologic approaches to pain management (Margaret Rukstalis, MD, Wake Forest School of Medicine)*

10:00 – 11:00 AM **Session 2: Physician-led Multicomponent Interventions in Opioid Stewardship**

- *Procedure-specific guidelines (Richard J. Barth, MD, Dartmouth University)*
- *Reclamation efforts (Jonah Stulberg, MD, PhD, MPH, Northwestern Medicine)*

- *Expectation setting (Behfar Ehdaie, MD, Memorial Sloan Kettering)*
- *Urologist perspective (Vernon Pais, MD, Dartmouth; Benjamin Davies, MD, UPMC, Matthew Nielsen, University of North Carolina)*

11:00 – 12:00 PM **Session 3: Policy and Outreach**

- *Outreach (Jennifer Waljee, MD, MPH, MS, University of Michigan)*
- *Policy Change/Legislature (Greg Murphy, MD, North Carolina General Assembly)*
- *FDA Safe Use Initiative (Scott Winiecki, MD, Food and Drug Administration)*

12:00 – 1:00 PM **Lunch**

1:00 – 2:00 PM **Session 4: Identifying and Managing High-Risk Patients in the Pre-operative Setting**

- *Helping patients who develop opioid dependence after surgery/ A surgeon's role in managing patients who develop opioid misuse disorders (Margaret Rukstalis, MD – Associate Professor, Psychiatry and Behavioral Medicine, Substance Addiction and Abuse Center, Wake Forest School of Medicine*
- *The role of pain specialists with high-risk patients (Brooke Chidgey - Assistant Professor of Anesthesiology, University of North Carolina)*

2:00 – 3:00 PM **Session 5: Challenging Cases and Discussion** *(Moderator: Tudor Borza, University of Michigan)*

3:00 – 3:30 PM **Closing Remarks**: Timothy Averch, MD, Quality Improvement and Patient Safety Committee Chair

Planning Process

Executive Committee: The 2018 QI Summit was first discussed in 2017 as a topic to follow up on the QIPS Committee's plan to release a position statement on opioid prescribing. Following approval by QIPS and the S&Q Council, the AUA Board of Directors was informed of the topic in February 2018. The Committee has an established working relationship via biweekly conference calls and biannual face-to-face meetings in planning conference logistics and enforcing the mission of this conference.

Conference Chairs: Angela Smith, MD, MS, is Assistant Professor of Urology at the UNC School of Medicine, and Gregory Auffenberg, MD, MS is a Clinical Instructor of Urology at Memorial Sloan Kettering Cancer Center.

Internal Speakers: Robert C. Flanigan, MD, AUA President, will provide introductory remarks. Chairs Gregory Auffenberg and Angela Smith will provide a brief overview of the agenda for the day summarizing key background material included in this proposal. Closing remarks will be provided by Timothy Averch, MD.

External Speakers: The agenda will be broken down into five major sessions. Session 1 will provide attendees with an understanding of postoperative pain and management strategies. The discussion lead by Brooke Chidgey, MD; Chad Brummett, MD; Meghan Sperandeo, ND; and Margaret Rukstalis, MD will begin with an overview of post-operative pain and the role of post-operative opioids in the opioid epidemic. Discussion will then focus on alternative pain management strategies and cognitive behavioral therapy and non-pharmacologic approaches to pain management. Session 2 will focus on physician-led multicomponent interventions in opioid stewardship. Drs. Richard Barth, Jonah Stulberg, Behfar Ehdaie, Vernon Pais, Benjamin Davies, and Matthew Nielsen will discuss procedure-specific guidelines and provide a unique look at the opioid epidemic from a urology perspective. Session 3 will turn to policy and outreach. Drs. Jennifer Waljee and Greg Murphy will look at outreach and legislature, while FDA representative Dr. Scott Winiecki will discuss the FDA Safe Use Initiative. Session 4 will educate attendees on the identification and management of high-risk patients in the preoperative setting. Dr. Rukstalis will discuss a surgeon's role in managing patients who develop opioid misuse disorders, and Dr. Brooke Chidgey will speak on the role of pain specialists in the treatment of high-risk patients. Session 5 will close out the day with an interactive discussion of challenging cases in pain management to be led by Dr. Tudor Borza.

Anticipated Audience: The AUA is the leading professional society for Urology with over 20,000 members globally, including 15,000 from the US. We anticipate AUA members to be the primary audience for this conference. We anticipate approximately 100 attendees, including 70 registrants, 15 presenters (urology and out-of-specialty experts), and 15 AUA officers and staff.

Conference Evaluation: The conference will be evaluated through multiple mechanisms: (1) Participants will rate each session for content, organization, and relevance on 5-point Likert scales; (2) Successful compilation and dissemination of consensus statements; (3) Publication of conference proceedings in *Urology Practice* in 2018; and (4) in the long term, building on the interdisciplinary collaboration between stakeholders to advance the care and science of opioid use in medicine.

ANTICIPATED CONFERENCE PRODUCTS

CONFERENCE PROCEEDINGS	Following the QI Summit, a proceedings paper will be published in *Urology Practice,* an official journal of the AUA focusing on clinical trends, challenges, and practice applications.
RESEARCH AGENDA	The collaborative nature of the summit will provide unique opportunity for practitioners to generate consensus on the optimal clinical practices related to opioid prescribing and pain management and establish an adequate research agenda to further these recommendations.
PROVIDER TOOLKIT	The QIPS Committee is dedicated to supporting efforts generated from the QI Summit through a QI project focused on a provider toolkit for urologists and other physicians to lead efforts to improve safety, and quality related to opioid prescribing for urologic procedures and surgery.
INTERDISCIPLINARY NETWORK	The development of the 2018 QI Summit has fostered a strong collaboration between AUA, Anesthesiology, and other disciplines involved in the care of high-risk patients, which will continue following the summit to further the goal of stewardship of opioids in urology.

Conference Outreach / Dissemination*:* Conference proceedings will be published in a 2019 issue of *Urology Practice*, which will be made "open access." For a wider interdisciplinary outreach, the executive summary of the proceedings will be jointly e-published in target specialty journals. Video recording of the conference presentations as well as slides and other meeting materials will be made available online. Additionally, the AUA will make use of social media to broadly disseminate meeting information to members of AUA and other non-affiliated stakeholders.

Priority Populations*:* According to the National Institute on Drug Abuse, as of 2014, prescription drug misuse and abuse is increasing among older adults. Such patients are more likely to experience issues with opioids due to increased medication sensitivity and slower metabolism. Drug misuse is also elevated in this population

due to higher rates of pain, sleep disorders, anxiety, and cognitive decline. Additionally, the Department of Defense Health Related Behaviors reported that 1.3% of active duty personnel described prescription drug misuse in the preceding 12 months. Hence, improvements in care and education targeting such patients are likely to be of disproportionate benefit to these populations.

Other Sources of Support: Primary support is requested from AHRQ and secondary support from other sources. AUA will cover all additional costs.

Promotional Plan*:* Visibility and promotion of the conference will be achieved through a multi-prong approach including internet news sources, monthly ads in leading national journals of urology care, an aggressive marketing campaign by the AUA marketing manager and other urology stakeholders, widespread dissemination of educational papers and videos, and preconference networking.

Past Conferences: To our knowledge, there have been no similar collaborative, multi-disciplinary meetings or conferences focusing on the opioid epidemic in urologic care. Our conference will consolidate and advance the work of stakeholders from across the continuum of care for such patients.

REFERENCES

[1] Committee on Pain Management and Regulatory Strategies to Address Prescription Opioid Abuse: The Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use. https://www.nap.edu/read/24781/chapter/1. Published: July 13, 2017. Accessed April 9, 2018.

[2] Brummett CM, Waljee JF, Goesling J et al: New persistent opioid use after minor and major surgical procedures in US adults. JAMA Surg 2017; e170504.

[3] Hall MJ, Schwartzman A, Zhang J et al: Ambulatory surgery data from hospitals and ambulatory surgery centers: United States, 2010. Natl Health Stat Report 2017; 1.

[4] Levy B, Paulozzi L, Mack KA et al: Trends in opioid analgesis-prescribing rates by specialty, U.S., 2007-2012. Am J Prev Med 2015; **49:** 409.

[5] Center for Behavioral Health Statistics and Quality: Key substance use and mental health indicators in the United States: Results from the 2015 National Survey on Drug Use and Health. http://www.samhsa.gov/data/. Accessed April 30, 2018.

[6] Hill MV, McMahon ML, Stucke RS et al: Wide variation and excessive dosage of opioid prescriptions for common general surgical procedures. Ann Surg 2017; **265**:709.

[7] Wunsch H, Wijeysundera DN, Passarella MA et al: Opioids prescribed after low-risk surgical procedures in the United States, 2004-2012. JAMA 2016; **315**: 1654.

[8] National Institute on Drug Abuse: Opioid overdose crisis. https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis. Published March 2018. Accessed: April 11, 2018.

[9] Centers for Disease Control and Prevention: Vital signs: overdoses of prescription opioid pain relievers — United States, 1999—2008. MMWR 2011; **60**;1487.

[10] Altarum: Economic toll of opioid crisis in U.S. exceeded $1 trillion since 2001. https://altarum.org/about/news-and-events/economic-toll-of-opioid-crisis-in-u-s-exceeded-1-trillion-since-2001. Published: February 13, 2018. Accessed: April 9, 2018.

[11] Barnett ML, Olenski AR, Jena AB: Opioid-prescribing patterns of emergency physicians and risk of long-term use. N Eng J Med 2017; **376:** 663.

[12] Bicket MC, Long JJ, Pronovost PJ et al: Unused after surgery: a systematic review. JAMA Surg 2017; **152:** 1066.

[13] 100 million opioids not utilized by patients following removal of third molars. J Calif Dent Assoc 2016; **44:** 727.

[14] Tedesco D, Gori D, Desai KR et al: Drug-free interventions to reduce pain or opioid consumption after total knee arthroplasty: a systematic review and meta-analysis. JAME Surg 2017; **152:** e172872.

[15] US Food and Drug Administration: FDA Opioids Action Plan. https://www.fda.gov/drugs/drugsafety/informationbydrugclass/ucm484714.htm Published: April 2018. Accessed: April 30, 2018.

[16] Centers for Disease Control and Prevention: Understanding the epidemic. https://www.cdc.gov/drugoverdose/epidemic/index.html. Published: August 2017. Accessed: April 30, 2018.

PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001 and 0925-0002

Expiration Date: 03/31/2020

Are Human Subjects Involved	❍ Yes	● No
Is the Project Exempt from Federal regulations?	❍ Yes	❍ No
Exemption Number	❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑ 6 ❑ 7 ❑ 8	
Does the proposed research involve human specimens and/or data	❍ Yes	● No
Other Requested information		