



April 12, 2017

Mr. Bryce Jones
Grants Management Specialist
U.S. Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20857

Dear Mr. Jones:

RE:	PAR-16-378	Grant Application Cover Letter
	Opportunity Title:	FDA Scientific Conference Grant Program (R13)
	Offering Agency:	Food & Drug Administration
	CFDA Number:	93.103
	CFDA Description:	Food and Drug Administration Research
		Opportunity Number: PAR-16-378
	Corresponding FDA Center:	Office of Regulatory Affairs (ORA)
	Title of Conference:	ISSC 2017 Biennial Conference Meeting
	Location of Conference:	Sheraton Hotel & Convention Center, Myrtle Beach, SC
	Principal Investigator:	Ken B. Moore, Executive Director
	Approximate Cost:	\$80,000

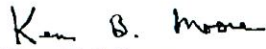
One of the highest priorities of the Interstate Shellfish Sanitation Conference (ISSC) is the development and management of the Guide for the Control of Molluscan Shellfish. This document is used by States in implementing State programs to ensure that raw molluscan shellfish is safe for human consumption. The FDA uses the document to audit State programs to determine compliance with the standards of the National Shellfish Sanitation Program (NSSP).

The ISSC has developed a process for review and modification of the requirements included in the Guide. The proposed changes are incorporated into a package which is shared with the Conference. The proposals are then assigned to the Task Forces and various committees that are appointed by the Chairman. The Executive Board Chairman appoints and assigns individuals to the various committees, subcommittees or work groups that deliberate the proposals submitted to the Conference. After the proposals are deliberated and voted upon by the delegates at the Conference, the Executive Office develops and submits the Summary of Actions by voting delegates to the USFDA. After the FDA evaluates the issues and concurs or rejects the proposal action, the Executive Office incorporates these proposal outcomes as new revisions to the NSSP Guide for the Control of Molluscan Shellfish in cooperation with FDA (ORA & CFSAN), NOAA and EPA.

Mr. Bryce Jones
April 12, 2017
Page 2 of 2

These actions are designed to provide a legislative mechanism by which states and the shellfish industry can affect national shellfish sanitation policy. This unique system allows stakeholders an opportunity to comment on proposed policy changes. This cooperative rule making process is very productive but requires a significant amount of effort and participation. This forum is complex and challenging and because participants represent many different interests.

Sincerely,

A handwritten signature in black ink that reads "Ken B. Moore". The signature is written in a cursive, slightly stylized font.

Ken B. Moore
Executive Director

/nsd

Grant Application Package

Opportunity Title:	FDA Scientific Conference Grant Program (R13)
Offering Agency:	Food and Drug Administration
CFDA Number:	93.103
CFDA Description:	Food and Drug Administration Research
Opportunity Number:	PAR-16-378
Competition ID:	
Opportunity Open Date:	08/01/2016
Opportunity Close Date:	10/12/2019
Agency Contact:	Bryce Jones Grants Management Specialist E-mail: bryce.jones@fda.hhs.gov Phone: 240-402-2111

This opportunity is only open to organizations, applicants who are submitting grant applications on behalf of a company, state, local or tribal government, academia, or other type of organization.

Application Filing Name: Interstate Shellfish Sanitation Conference

Select Forms to Complete

Mandatory

[SF424 \(R & R\)](#)

[PHS 398 Cover Page Supplement](#)

[Research And Related Other Project Information](#)

[Project/Performance Site Location\(s\)](#)

[Research and Related Senior/Key Person Profile \(Expanded\)](#)

[Research & Related Budget](#)

[PHS 398 Research Plan](#)

Optional

☐ [R & R Subaward Budget Attachment\(s\) Form 5 YR 30 ATT](#)

☐ [PHS 398 Inclusion Enrollment Report](#)

☐ [PHS Assignment Request Form](#)

Instructions

[Show Instructions >>](#)

This electronic grants application is intended to be used to apply for the specific Federal funding opportunity referenced here.

If the Federal funding opportunity listed is not the opportunity for which you want to apply, close this application package by clicking on the "Cancel" button at the top of this screen. You will then need to locate the correct Federal funding opportunity, download its application and then apply.

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

1. TYPE OF SUBMISSION <input type="checkbox"/> Pre-application <input checked="" type="checkbox"/> Application <input type="checkbox"/> Changed/Corrected Application		3. DATE RECEIVED BY STATE <div style="border: 1px solid black; height: 20px; width: 100%;"></div>	
2. DATE SUBMITTED <div style="border: 1px solid black; padding: 2px;">04/12/2017</div>		State Application Identifier <div style="border: 1px solid black; height: 20px; width: 100%;"></div>	
Applicant Identifier <div style="border: 1px solid black; height: 20px; width: 100%;"></div>		4. a. Federal Identifier <div style="border: 1px solid black; height: 20px; width: 100%;"></div>	
5. APPLICANT INFORMATION		b. Agency Routing Identifier <div style="border: 1px solid black; height: 20px; width: 100%;"></div>	
Organizational DUNS: 8375182810000		c. Previous Grants.gov Tracking ID <div style="border: 1px solid black; height: 20px; width: 100%;"></div>	
Legal Name: Interstate Shellfish Sanitation Conference			
Department:		Division:	
Street1: 209 Dawson Road			
Street2: Suite 1			
City: Columbia		County / Parish: Richland	
State: SC: South Carolina		Province:	
Country: USA: UNITED STATES		ZIP / Postal Code: 29223-1740	
Person to be contacted on matters involving this application			
Prefix: Mrs.		First Name: Nancy	
Last Name: Daniel		Middle Name: S.	
Position/Title: Program Manager		Suffix:	
Street1: 209 Dawson Road			
Street2: Suite 1			
City: Columbia		County / Parish: Richland	
State: SC: South Carolina		Province:	
Country: USA: UNITED STATES		ZIP / Postal Code: 29223-1740	
Phone Number: 803-788-7559		Fax Number: 803-788-7576	
Email: ndaniel@issc.org			
6. EMPLOYER IDENTIFICATION (EIN) or (TIN): 52-1656630			
7. TYPE OF APPLICANT: M: Nonprofit with 501C3 IRS Status (Other than Institution of Higher Education)			
Other (Specify):			
Small Business Organization Type <input type="checkbox"/> Women Owned <input type="checkbox"/> Socially and Economically Disadvantaged			
8. TYPE OF APPLICATION: <input checked="" type="checkbox"/> New <input type="checkbox"/> Resubmission <input type="checkbox"/> Renewal <input type="checkbox"/> Continuation <input type="checkbox"/> Revision		If Revision, mark appropriate box(es). <input type="checkbox"/> A. Increase Award <input type="checkbox"/> B. Decrease Award <input type="checkbox"/> C. Increase Duration <input type="checkbox"/> D. Decrease Duration <input type="checkbox"/> E. Other (specify):	
Is this application being submitted to other agencies? Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> What other Agencies?			
9. NAME OF FEDERAL AGENCY: Food and Drug Administration		10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER: 93.103 TITLE: Food and Drug Administration Research	
11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT: Interstate Shellfish Sanitation Conference 2017 Biennial Meeting			
12. PROPOSED PROJECT: Start Date 08/01/2017 Ending Date 07/31/2018		13. CONGRESSIONAL DISTRICT OF APPLICANT All	

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

Prefix:	Mr.	First Name:	Kenneth	Middle Name:	B.
Last Name:	Moore			Suffix:	
Position/Title:	Executive Director				
Organization Name:	Interstate Shellfish Sanitation Conference				
Department:		Division:			
Street1:	209 Dawson Road				
Street2:	Suite 1				
City:	Columbia	County / Parish:	Richland		
State:	SC: South Carolina			Province:	
Country:	USA: UNITED STATES			ZIP / Postal Code:	29223-1740
Phone Number:	803-788-7559		Fax Number:	803-788-7576	
Email:	kmoore@issc.org				

15. ESTIMATED PROJECT FUNDING

a. Total Federal Funds Requested	25,000.00
b. Total Non-Federal Funds	0.00
c. Total Federal & Non-Federal Funds	25,000.00
d. Estimated Program Income	0.00

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

a. YES	<input type="checkbox"/> THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:
	DATE: <input type="text"/>
b. NO	<input checked="" type="checkbox"/> PROGRAM IS NOT COVERED BY E.O. 12372; OR
	<input type="checkbox"/> 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 (Disclosure of Lobbying Activities) or other Explanatory Documentation

<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>
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19. Authorized Representative

Prefix:	Mrs.	First Name:	Nancy	Middle Name:	S.
Last Name:	Daniel			Suffix:	
Position/Title:	Program Manager				
Organization:	Interstate Shellfish Sanitation Conference				
Department:		Division:			
Street1:	209 Dawson Road				
Street2:	Suite 1				
City:	Columbia	County / Parish:	Richland		
State:	SC: South Carolina			Province:	
Country:	USA: UNITED STATES			ZIP / Postal Code:	29223-1740
Phone Number:	803-788-7559		Fax Number:	803-788-7576	
Email:	ndaniel@issc.org				

Signature of Authorized Representative

Date Signed

Nancy S Daniel

04/12/2017

20. Pre-application

<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>
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21. Cover Letter Attachment PA-16-378 ISSC Application Cover Letter 04-

<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>
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PHS 398 Cover Page Supplement

OMB Number: 0925-0001
Expiration Date: 10/31/2018

1. Human Subjects Section

Clinical Trial? ☐ Yes ☒ No

*Agency-Defined Phase III Clinical Trial? ☐ Yes ☐ No

2. Vertebrate Animals Section

Are vertebrate animals euthanized? ☐ Yes ☒ No

If "Yes" to euthanasia

Is method consistent with American Veterinary Medical Association (AVMA) guidelines? ☐ Yes ☐ No

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

3. *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)

4. 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://stemcells.nih.gov/research/registry/>. Or, if a specific stem cell line cannot be referenced at this time, please 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):

PHS 398 Cover Page Supplement

5. Inventions and Patents Section (RENEWAL)

*Inventions and Patents: Yes ☐ No ☐

If "Yes" then answer the following:

*Previously Reported: Yes ☐ No ☐

6. Change of Investigator / Change of Institution Section

☐ Change of Project Director / Principal Investigator

Name of former Project Director/Principal Investigator:

Prefix:

*First Name:

Middle Name:

*Last Name:

Suffix:

☐ Change of Grantee Institution

*Name of former institution:

RESEARCH & RELATED Other Project Information

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

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

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 of the United States or partnerships with international collaborators? ☐ Yes ☒ No

6.a. If yes, identify countries:

6.b. Optional Explanation:

7. Project Summary/Abstract

8. Project Narrative

9. Bibliography & References Cited

10. Facilities & Other Resources

11. Equipment

12. Other Attachments ☐

The Interstate Shellfish Sanitation Conference (ISSC) adopts uniform procedures, incorporated into the National Shellfish Sanitation Program (NSSP), and implemented by all shellfish control authorities. The ISSC gives state shellfish programs, current and comprehensive sanitation guidelines to regulate the harvesting, processing, and shipping of shellfish. The Biennial Meeting provides a forum for shellfish control authorities, the shellfish industry, and academic community to resolve major issues concerning shellfish sanitation.

One of the highest priorities of the Interstate Shellfish Sanitation Conference (ISSC) is the development and management of the Guide for the Control of Molluscan Shellfish. This document is used by States in implementing State programs to ensure that raw molluscan shellfish is safe for human consumption. The FDA uses the document to audit State programs to determine compliance with the standards of the National Shellfish Sanitation Program (NSSP).

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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:
DUNS Number:
* Street1:
Street2:
* City: County:
* State:
Province:
* Country:
* ZIP / Postal Code: * Project/ Performance Site Congressional District:

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:
DUNS Number:
* Street1:
Street2:
* City: County:
* State:
Province:
* Country:
* ZIP / Postal Code: * Project/ Performance Site Congressional District:

Additional Location(s)

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator					
Prefix:	Mr.	* First Name:	Kenneth	Middle Name:	B.
* Last Name:	Moore	Suffix:			
Position/Title:	Executive Director	Department:			
Organization Name:	Interstate Shellfish Sanitation Conference	Division:			
* Street1:	209 Dawson Road				
Street2:	Suite 1				
* City:	Columbia	County/ Parish:	Richland		
* State:	SC: South Carolina	Province:			
* Country:	USA: UNITED STATES	* Zip / Postal Code:	29223-1740		
* Phone Number:	803-788-7559	Fax Number:	803-788-7576		
* E-Mail:	kmoore@issc.org				
Credential, e.g., agency login:	KBMOORE				
* Project Role:	PD/PI	Other Project Role Category:			
Degree Type:	MA				
Degree Year:	1987				
* Attach Biographical Sketch	PAR-16-378 Biosketch Ken Moo	Add Attachment	Delete Attachment	View Attachment	
Attach Current & Pending Support		Add Attachment	Delete Attachment	View Attachment	

PROFILE - Senior/Key Person 1					
Prefix:	Mrs.	* First Name:	Nancy	Middle Name:	S.
* Last Name:	Daniel	Suffix:			
Position/Title:	Program Manager	Department:			
Organization Name:	Interstate Shellfish Sanitation Conference	Division:			
* Street1:	209 Dawson Road				
Street2:	Suite 1				
* City:	Columbia	County/ Parish:	Richland		
* State:	SC: South Carolina	Province:			
* Country:	USA: UNITED STATES	* Zip / Postal Code:	29223-1740		
* Phone Number:	803-788-7559	Fax Number:	803-788-7576		
* E-Mail:	ndaniel@issc.org				
Credential, e.g., agency login:	NSDANIEL				
* Project Role:	Other (Specify)	Other Project Role Category:	Authorized Representative		
Degree Type:	Diploma				
Degree Year:	1970				
Attach Biographical Sketch	PAR-16-378 Biosketch Nancy D	Add Attachment	Delete Attachment	View Attachment	
Attach Current & Pending Support		Add Attachment	Delete Attachment	View Attachment	

Delete Entry

Next Person

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Senior/Key Person 2			
Prefix:	Ms.	* First Name:	Cathy
		Middle Name:	C.
* Last Name:	Mantooth	Suffix:	
Position/Title:	Administrative Assistant	Department:	
Organization Name:	Interstate Shellfish Sanitation Conference	Division:	
* Street1:	209 Dawson Road		
Street2:	Suite 1		
* City:	Columbia	County/ Parish:	Richland
* State:	SC: South Carolina	Province:	
* Country:	USA: UNITED STATES	* Zip / Postal Code:	29223-1740
* Phone Number:	803-788-7559	Fax Number:	803-7887576
* E-Mail:	issc@issc.org		
Credential, e.g., agency login:			
* Project Role:	Other (Specify)	Other Project Role Category:	Administrative Assistant
Degree Type:			
Degree Year:			
Attach Biographical Sketch	PAR-16-378 Biosketch Cathy M	Add Attachment	Delete Attachment View Attachment
Attach Current & Pending Support		Add Attachment	Delete Attachment View Attachment
Delete Entry		Next Person	

PROFILE - Senior/Key Person 3			
Prefix:	Mr.	* First Name:	William
		Middle Name:	J.
* Last Name:	Eisele	Suffix:	
Position/Title:	Meeting Office Manager	Department:	
Organization Name:	Interstate Shellfish Sanitation Conference	Division:	
* Street1:	280 Old Tuckahoe Road		
Street2:			
* City:	Woodbine	County/ Parish:	
* State:	NJ: New Jersey	Province:	
* Country:	USA: UNITED STATES	* Zip / Postal Code:	08270-3132
* Phone Number:	609-628-2758	Fax Number:	803-788-7576
* E-Mail:	beisele@comcast.net		
Credential, e.g., agency login:			
* Project Role:	Other Professional	Other Project Role Category:	Office Manager
Degree Type:	BS		
Degree Year:	1965		
Attach Biographical Sketch	PAR-16-378 Biosketch Bill Ei	Add Attachment	Delete Attachment View Attachment
Attach Current & Pending Support		Add Attachment	Delete Attachment View Attachment
Delete Entry		Next Person	

To ensure proper performance of this form; after adding 20 additional Senior/ Key Persons; please save your application, close the Adobe Reader, and reopen it.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Moore, Kenneth B.		POSITION TITLE	
eRA COMMONS USER NAME (credential, e.g., agency login) KBMOORE		Executive Director	
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	MM/YY	FIELD OF STUDY
Francis Marion University, Florence, SC	BS	06/76	Biology
Webster University, St. Louis, MO	MA	05/87	Public Administration
Webster University, St. Louis, MO	MA	05/87	Business Administration

Please refer to the application instructions in order to complete sections A, B, C, and D of the Biographical Sketch.

A. Personal Statement

B. Positions and Honors

1993 – Present

Executive Director, Interstate Shellfish Sanitation Conference, Columbia, SC.

- The Interstate Shellfish Sanitation Conference is a public health organization which fosters and promotes shellfish sanitation through the cooperation of state and federal control agencies, the shellfish industry, and the academic community.

2007 – 2010

Legislative and External Liaison, SC Department of Health and Environmental Control, Columbia, SC.

- Served as assistant to the Deputy Commissioner of Health Regulations which provides oversight in regulations for health care facilities in the State of South Carolina.

1983 – 1993

Manager, Water Quality & Shellfish Sanitation Division, SC Department of Health & Environmental Control, Columbia, SC.

- Managed the statewide shellfish sanitation program and the State Law Enforcement Unit. Reviewed field activities such as sanitary survey reports for growing area classification, received certification for all shellfish processing facilities and developed annual plan to ensure compliance with NSSP guidelines.

C. Selected Peer-reviewed Publications

D. Research Support

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Nancy S. Daniel		POSITION TITLE	
eRA COMMONS USER NAME NSDANIEL		Program Manager	
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
Brookland-Cayce High School, Cayce, SC SC Real Estate School, Columbia, SC	Diploma Certified	1970 1997	Business Property Management

Please refer to the application instructions in order to complete sections A, B, and C of the Biographical Sketch.

A. Personal Statement

B. Positions and Honors

Notary Public State of South Carolina

2003 – Present

Interstate Shellfish Sanitation Conference, Columbia, SC

- Program Manager

1999 – 2003

General Physics Corporation, Aiken, SC

- Business Development & Marketing Assistant

1996 – 1999

Mid-America Apartment Communities (Woodwinds), Aiken, SC

- Property Manager

1994 – 1996

Charter Rivers Behavioral Health System, West Columbia, SC

- Executive Assistant & Medical Staff Credentialing

1992 - 1994

Kimberly Clark Corporation, Beech Island, SC

- Computer Specialist & Lab Assistant

1970 – 1992

State of South Carolina Budget and Control Board Office of Executive Director, Columbia, SC

- Administrative Assistant

State of South Carolina Criminal Justice Academy, Columbia, SC (1979 – 1983)

- Training Department Administrative Assistant

C. Selected Peer-Reviewed Publications (in chronological order).

D. Research Support

Principal Investigator/Program Director (Last, First, Middle): **Moore, Ken B.**

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME William J. Eisele, Jr.		POSITION TITLE ISSC Program Chair and Conference Office Manager	
eRA COMMONS USER NAME			
EDUCATION/TRAINING (<i>Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.</i>)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY
University of Missouri, Columbia, MO	BS	1961-1965	Forest Management

1985 to Present

Interstate Shellfish Sanitation Conference

- Biennial Conference Office Manager

1982 to Present

ISSC Executive Board

- Vice-Chairman, Regulatory Region II Representative; Executive Committee, Task Force I Advisor

1965- 2002

NJ Dept of Environmental Protection

- 1970 -2002 Last position Chief of the Bureau of Marine Water Monitoring 1985-2002 (Retired 2002)
Various FDA sponsored training courses concerning Shellfish Sanitation and Shellfish Growing Water Classification

1966 – 1969

US Army Officer Candidate School Signal Corps

1966 -1969

USAREUR Germany

- Honorable Discharge 1969 as 1st Lt.

1965 - 1970

NJ Dept of Health Bureau of ShellFish Control -Sanitarian

National Indicator Study Member

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Cathy Mantooth		POSITION TITLE Administrative Assistant	
eRA COMMONS USER NAME (credential, e.g., agency login)			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	MM/YY	FIELD OF STUDY
Midlands Technical College Winthrop University		06/00-04/01 08/96-06/97	Accounting/Business Mathematics/Education

A. Personal Statement

I am an administrative assistant with the Interstate Shellfish Sanitation Conference. I have an extensive background in many clerical and financial duties. I am capable of providing all clerical assistance needed by others working on this project.

B. Positions and Honors

2005-2013 Insurance Underwriter, Columbia Underwriters, Inc., West Columbia, SC
 2004-2005 Accounts Payable Clerk, PPM, Carolina, Columbia,, SC
 2002-2004 Support Services Manager, Carolina Care Plan, Columbia, SC
 2001-2002 Renewal Coordinator, Carolina Care Plan, Columbia, SC
 2000-2001 Contract Issuance Coordinator, Carolina Care Plan, Columbia, SC
 1998-2000 Accounts Payable Clerk, WB Guimarin & Assoc., Columbia, SC
 1998-1998 Receptionist, WB Guimarin & Assoc., Columbia, SC

C. Selected Peer-reviewed Publications

D. Research Support

RESEARCH & RELATED BUDGET - Budget Period 1

OMB Number: 4040-0001
Expiration Date: 6/30/2016

ORGANIZATIONAL DUNS:

8375182810000

Enter name of Organization:

Interstate Shellfish Sanitation Conference

Budget Type: ☒ Project

☐ Subaward/Consortium

Budget Period: 1

Start Date: 08/01/2017

End Date: 07/31/2018

A. Senior/Key Person

Prefix	First	Middle	Last	Suffix	Base Salary (\$)	Months			Requested Salary (\$)	Fringe Benefits (\$)	Funds Requested (\$)
						Cal.	Acad.	Sum.			
Mr.	Kenneth	B.	Moore		0.00	12.00	0.00	0.00	0.00	0.00	0.00
Project Role: PD/PI											
Mrs.	Nancy	S.	Daniel		0.00	12.00	0.00	0.00	0.00	0.00	0.00
Project Role: Program Manager / Authorized Representative											
Mr.	William	J.	Eisele		0.00	2.00	0.00	0.00	0.00	0.00	0.00
Project Role: Office Manager											
Ms.	Cathy	C.	Mantooth		0.00	12.00	0.00	0.00	0.00	0.00	0.00
Project Role: Administrative Assistant											

Additional Senior Key Persons:

Add Attachment

Delete Attachment

View Attachment

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

Total Senior/Key Person

0.00

B. Other Personnel

Number of Personnel	Project Role	Months			Requested Salary (\$)	Fringe Benefits (\$)	Funds Requested (\$)
		Cal.	Acad.	Sum.			
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						

Total Number Other Personnel

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

0.00

C. Equipment Description

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

Equipment item	Funds Requested (\$)
None	0.00

Additional Equipment:

Total funds requested for all equipment listed in the attached file

Total Equipment	0.00
-----------------	------

D. Travel

	Funds Requested (\$)
1. Domestic Travel Costs (Incl. Canada, Mexico and U.S. Possessions)	25,000.00
2. Foreign Travel Costs	0.00
Total Travel Cost	25,000.00

E. Participant/Trainee Support Costs

	Funds Requested (\$)
1. Tuition/Fees/Health Insurance	0.00
2. Stipends	0.00
3. Travel	0.00
4. Subsistence	0.00
5. Other	0.00
None	0.00
Total Participant/Trainee Support Costs	0.00

F. Other Direct Costs

	Funds Requested (\$)
1. Materials and Supplies	0.00
2. Publication Costs	0.00
3. Consultant Services	0.00
4. ADP/Computer Services	0.00
5. Subawards/Consortium/Contractual Costs	0.00
6. Equipment or Facility Rental/User Fees	0.00
7. Alterations and Renovations	0.00
8. None	0.00
9. None	0.00
10. None	0.00
Total Other Direct Costs	
	0.00

G. Direct Costs

Total Direct Costs (A thru F)	Funds Requested (\$)
	25,000.00

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base (\$)	Funds Requested (\$)
None			0.00
Total Indirect Costs			0.00

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

None

I. Total Direct and Indirect Costs

Total Direct and Indirect Institutional Costs (G + H)	Funds Requested (\$)
	25,000.00

J. Fee

Funds Requested (\$)
0.00

K. Budget Justification

(Only attach one file.)

FAR 16-378 ISSC Budget Justification.F

Add Attachment

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View Attachment

The Interstate Shellfish Sanitation Conference (ISSC) expects approximately 200 – 250 Biennial Meeting registrants at \$520.00 to \$620.00 (approximately \$104,000.00 to \$124,000.00). This amount may be lower than projected due to budget constraints of the various participating states, industry members, consumers, and academic parties. Participants have paid their own travel, registration lodging, and meals in the past. The FDA Small Conference Grants funds are being requested to facilitate meeting attendance of State Voting Delegates, Task Force members, and Committee members whose attendance might otherwise be denied due to budget constraints.

PHS 398 Research Plan

OMB Number: 0925-0001
Expiration Date: 10/31/2018

Introduction

1. Introduction to Application
(Resubmission and Revision)

[Add Attachment](#)[Delete Attachment](#)[View Attachment](#)

Research Plan Section

2. Specific Aims

PAR 16-378 ISSC Specific Ai

[Add Attachment](#)[Delete Attachment](#)[View Attachment](#)

3. *Research Strategy

PAR 16-378 ISSC Research St

[Add Attachment](#)[Delete Attachment](#)[View Attachment](#)

4. Progress Report Publication List

[Add Attachment](#)[Delete Attachment](#)[View Attachment](#)

Human Subjects Section

5. Protection of Human Subjects

[Add Attachment](#)[Delete Attachment](#)[View Attachment](#)

6. Data Safety Monitoring Plan

[Add Attachment](#)[Delete Attachment](#)[View Attachment](#)

7. Inclusion of Women and Minorities

[Add Attachment](#)[Delete Attachment](#)[View Attachment](#)

8. Inclusion of Children

[Add Attachment](#)[Delete Attachment](#)[View Attachment](#)

Other Research Plan Section

9. Vertebrate Animals

[Add Attachment](#)[Delete Attachment](#)[View Attachment](#)

10. Select Agent Research

[Add Attachment](#)[Delete Attachment](#)[View Attachment](#)

11. Multiple PD/PI Leadership Plan

[Add Attachment](#)[Delete Attachment](#)[View Attachment](#)

12. Consortium/Contractual Arrangements

[Add Attachment](#)[Delete Attachment](#)[View Attachment](#)

13. Letters of Support

[Add Attachment](#)[Delete Attachment](#)[View Attachment](#)

14. Resource Sharing Plan(s)

[Add Attachment](#)[Delete Attachment](#)[View Attachment](#)

15. Authentication of Key Biological and/or
Chemical Resources

[Add Attachment](#)[Delete Attachment](#)[View Attachment](#)

Appendix

16. Appendix

[Add Attachments](#)[Delete Attachments](#)[View Attachments](#)

Specific Aims:

PAR-16-378

The Interstate Shellfish Sanitation (ISSC) proposes to work cooperatively with FDA/CFRAN to enhance the National Shellfish Sanitation Program (NSSP). To accomplish this, the ISSC will:

- (1) Plan and facilitate regularly scheduled ISSC meetings to discuss NSSP changes. This activity includes development and submission of Summary of Actions by voting delegates to the USFDA and meetings of the ISSC Executive Board and *Vibrio* related committees (reports available).
- (2) Improve information exchange and transfer among States, Federal agencies, industry, and consumers by: Maintaining a web site for continuous accessibility to molluscan shellfish related information. The website has an extensive amount of information related to the NSSP useful for state regulators and consumers and is regularly updated. The ISSC website is linked to the USFDA web site to provide easy access for FDA information. Providing annual updates of ISSC/FDA activities at regional shellfish sanitation conferences. Enhancing communication capabilities using electronic information capabilities for alerting states of illness outbreaks and recalls associated with molluscan shellfish. Assisting states by distributing supplemental ICSSL listings. Assisting FDA with distribution of the NSSP Guide for the Control of Molluscan Shellfish. Development of new revisions of the NSSP Guide for the Control of Molluscan Shellfish in cooperation with FDA Office of Seafood. Continuing to work collectively with FDA and the Conference of Food Protection to address concisely molluscan shellfish issues in the implementation of the FDA Food Code. Interact with States and the USFDA in resolving problems between States or between FDA and a State regarding conformity to the NSSP by continuing to utilize the ISSC unresolved issue process to resolve state non-compliance with the NSSP and facilitating discussion between parties to achieve resolution.
- (3) Communicate procedures and policy statements to guide States in executing the NSSP by coordinating State review of FDA's Molluscan Shellfish Compliance Program as requested and providing technical assistance to States regarding NSSP implementation.
- (4) Interact with States in developing uniform and effective evaluation criteria by providing technical assistance to States regarding NSSP implementation and continuing development of criteria for determining state program compliance and effectiveness.
- (5) Provide program auxiliary support in facilitating FDA, State, and shellfish industry involvement in technical training, research, and consumer. Continuing support of efforts for research into more appropriate bacteriological water quality indicators; continuing to review Laboratory Methodology for incorporation into the National Shellfish Sanitation Program; and continued participation in Interagency Task Force on Shellfish Growing Waters to address Shellfish growing water issues with Federal agencies.
- (6) Interact with FDA, States and the shellfish industry to continue development and implementation *Vibrio* illness reduction strategies.
- (7) Obtain information from States and industry to provide consistent and coordinated input to FDA in the implementation of the NSSP Model Ordinance.
- (8) Provide funding and technical support for research efforts to assess levels of pathogens in retail oysters (work plan available).
- (9) Other: The ISSC will gather information from FDA and National Marine Fisheries on international participation in the NSSP; co-sponsor the International Shellfish Restoration Conference; and coordinate with other research and technology entities to encourage information exchange for improving the NSSP. Develop an awareness program to address unusual and intentional contamination of shellfish. The Program will address acts of terrorism and natural disasters.

One of the highest priorities of the Interstate Shellfish Sanitation Conference (ISSC) is the development and management of the Guide for the Control of Molluscan Shellfish. This document is used by States in implementing State programs to ensure that raw molluscan shellfish is safe for human consumption. The FDA uses the document to audit State programs to determine compliance with the standards of the National Shellfish Sanitation Program (NSSP).

The ISSC has developed a process for review and modification of the requirements included in the Guide. The proposed changes are incorporated into a package which is shared with the Conference. The proposals are then assigned to the Task Forces and various committees that are appointed by the Chairman. The Executive Board Chairman appoints and assigns individuals to the various committees, subcommittees or work groups that deliberate the proposals submitted to the Conference. After the proposals are deliberated and voted upon by the delegates at the Conference, the Executive Office develops and submits the Summary of Actions by voting delegates to the USFDA. After the FDA evaluates the issues and concurs or rejects the proposal action, the Executive Office incorporates these proposal outcomes as new revisions to the NSSP Guide for the Control of Molluscan Shellfish in cooperation with FDA Office of Seafood, NOAA and EPA.

These actions are designed to provide a legislative mechanism by which states and the shellfish industry can affect national shellfish sanitation policy. This unique system allows stakeholders an opportunity to comment on proposed policy changes. This cooperative rule making process is very productive but requires a significant amount of effort and participation. This forum is complex and challenging and because participants represent many different interests.