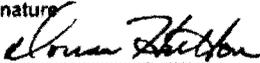


 <p style="text-align: center;">United States Environmental Protection Agency Washington, DC 20460</p> <p style="text-align: center;"><b>Interagency Agreement/ Amendment</b></p> <p style="text-align: center;"><b>Part 1 - General Information</b></p>		1. EPA IA Identification Number RW-81-92348701 - 0		2. Funding Location by Region EPA HQ					
		3. Other Agency IA ID Number (if known) CPSC-I-11-0011		4. Awarding Office IASSC East					
		5. Type of Action New		6. IA Specialist: Lenore Connell 202-564-5343 connell.lenore@epa.gov					
7. Name and Address of EPA Organization US Environmental Protection Agency IASSC East 1200 Pennsylvania Avenue, NW Mail code 3903R Washington, DC 20460			8. Name and Address of Other Agency Consumer Product Safety Commission 4330 East-West Highway, Rm. 502 Bethesda, MD 20814						
9. DUNS: 029128894		10. BETC: COLL		11. DUNS: 069287522					
12. BETC: DISB									
13. Project Title and Description Risk Assessment for Manufactured Nanoparticles Used in Consumer Products  The focus of the research under this agreement will be to develop tools to categorize and prioritize exposure potential for select products containing nanomaterials and to develop approaches and protocols to estimate and predict potential exposure pathways for selected product categories and to develop innovative approaches to estimate potential health risks.									
14. EPA Project Officer (Name, Address, Telephone Number) Michael McKittrick 1200 Pennsylvania Ave, NW (MC-8722P) Washington, DC 20460 703-347-8100 E-Mail: mckittrick.michael@epa.gov FAX: 703-347-8142			15. Other Agency Project Officer (Name, Address, Telephone) Treye Thomas 4330 East-West Highway, Suite 600 Bethesda, MD 20814 301-504-7738 E-Mail: tthomas@cpsc.gov FAX: 301-504-0079						
16. Project Period: 09/01/2011 to 09/30/2014			17. Budget Period: 09/01/2011 to 09/30/2014						
18. Scope of Work (See Attachment) See attached Scope of Work.									
19. Employer/Tax ID No. 520852695		20. CAGE No: 347A4		21. ALC: 88-01-0727					
22. Statutory Authority for Transfer of Funds and Interagency Agreement Toxic Substances Control Act (TSCA)					23. Other Agency Type Federal Agency				
24. Revise Reimbursable Funds and Direct Fund Cites (only complete if applicable)									
	Previous Funding		This Action		Amended Total				
Revise Reimbursable (In-house)					0				
Direct Fund Cites (contractor)					0				
Total					0				
	Previous Amount		Amount This Action		Total Amount				
25. EPA Amount					\$0				
26. EPA In-Kind Amount			\$1,556,300		\$1,556,300				
27. Other Agency Amount			\$500,000		\$500,000				
28. Other Agency In-Kind Amount					\$0				
29. Total Project Cost			\$2,056,300		\$2,056,300				
30. Fiscal Information									
Treas. Symbol	DCN	FY	Appropriation	Budget Org	PRC	Object Class	Site/Project	Cost Org	Ob/De-Ob Amt
681/20107		1112	CR	26T0X28	404FB2APV	0			443,695
681/20107		1112	CR	26T0Z28	404FB2APV	0			56,305
									500,000

Part II - Approved Budget				EPA IAG Identification Number RW-61-92348701 - 0
31. Budget Categories	Itemization of All Previous Actions	Itemization of This Action	In-Kind Itemization of This Action	Itemization of Total Project Cost to Date
(a) Personnel				\$0
(b) Fringe Benefits				\$0
(c) Travel				\$0
(d) Equipment		\$0		\$0
(e) Supplies				\$0
(f) Procurement / Assistance		\$443,695	\$1,556,300	\$1,999,995
(g) Construction				\$0
(h) Other				\$0
(i) Total Direct Charges	\$0	\$443,695	\$1,556,300	\$1,999,995
(j) Indirect Costs:	\$0	\$56,305		\$56,305
Charged - Amount Rate: 12.69% Base: \$ Not Charged: Funds-In: Not charged by EPA Amount \$				
(k) Total (EPA Share 75.68 %) (Other Agency Share 24.32 %)	\$0	\$500,000	\$1,556,300	\$2,056,300
<b>32. How was the IDC Base calculated?</b>				
33. Is equipment authorized to be furnished by EPA or leased, purchased, or rented with EPA funds? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No (Identify all equipment costing \$1,000 or more)				
34. Are any of these funds being used on extramural agreements? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No				
Type of Extramural Agreement Grant				
Contractor/Recipient Name (If known)	Total Extramural Amount Under This Project		Percent Funded by EPA (if known)	
University of Southern California	1999995 Total \$ 1,999,995.00		0	
<b>Part III - Funding Methods and Billing Instructions</b>				
<b>35. (Note: EPA Agency Location Code (ALC) - 68010727)</b>				
<input type="checkbox"/> Disbursement Agreement	Request for repayment of actual costs must be itemized on SF 1080 and submitted to the Financial Management Office, Cincinnati, OH 45288-7002:			
<input type="checkbox"/> Repayment	<input type="checkbox"/> Monthly <input type="checkbox"/> Quarterly <input type="checkbox"/> Upon Completion of Work			
<input type="checkbox"/> Advance	Only available for use by Federal agencies on working capital fund or with appropriate justification of need for this type of payment method. Unexpended funds at completion of work will be returned to EPA. Quarterly cost reports will be forwarded to the Financial Management Center, EPA, Cincinnati, OH 45268-7002.			
<input type="checkbox"/> Allocation Transfer-Out	Used to transfer obligational authority or transfer of function between Federal agencies. Must receive prior approval by the Office of Comptroller, Budget Division, Budget Formulation and Control Branch, EPA Hdqtrs. Forward appropriate reports to the Financial Reports and Analysis Branch, Financial Management Division, PM-226F, EPA, Washington, DC 20460.			
36. <input checked="" type="checkbox"/> Reimbursement Agreement	<input checked="" type="checkbox"/> Repayment <input type="checkbox"/> Advance			
<input type="checkbox"/> Allocation Transfer-In				
Other Agency's Billing Address (Include ALC or Station Symbol Number)			Other Agency's Billing Instructions and Frequency	
61-00-0001				

<b>Part IV - Acceptance Conditions</b>		EPA Identification Number  RW-61-92348701 - 0
37. Terms and Conditions (See attached terms and conditions, Attachment B)		
<b>Part V - Offer and Acceptance</b>		
<p>Note: A) For Fund-out actions, the agreement/amendment must be signed by the other agency official in duplicate and one original returned to the Grants and IA Management Division for Headquarters agreements or to the appropriate EPA Regional IA administration office within 3 calendar weeks after receipt or within any extension of time that may be granted by EPA. The agreement/amendment must be forwarded to the address cited in item 29 after acceptance signature.</p> <p>Failure to return the properly executed document within the prescribed time may result in the withdrawal of offer by EPA. Any change to the agreement/amendment by the other agency after the document is signed by the EPA Award Official, which the Award Official determines to materially alter the agreement/amendment, shall void the agreement/amendment.</p> <p>B) For Funds-In actions, the other agency will initiate the action and forward two original agreements/amendments to the appropriate EPA program office for signature. The agreements/amendments will then be forwarded to the appropriate EPA IA administration office for signature on behalf of the EPA. EPA will return one original copy after acceptance returned to the other agency after acceptance.</p>		
EPA IA Administration Office (for administrative assistance)		EPA Program Office (for technical assistance)
38. Organization/Address	39. Organization/Address	
U.S. Environmental Protection Agency IASSC East 1200 Pennsylvania Avenue, NW Mail code 3903R Washington, DC 20460	US Environmental Protection Agency ORD - Office of Research and Development 1200 Pennsylvania Ave, NW (MC-8722P) Washington, DC 20460	
Award Official on Behalf of the Environment Protection Agency		
40. Digital signature applied by EPA Award Official   FOR Frank N. Roth - Chief Fellowship IA & SEE Branch Michelle Messick - AO delegate		Date 09/20/2011
Authorizing Official on Behalf of the Other Agency		
41. Signature 	Typed Name and Title Donna Hutton, Contracting Official	Date 9/20/2011

**IA Terms and Conditions**

1. Should disagreements arise on the interpretation of the provisions of this agreement or amendments and/or revisions thereto, that cannot be resolved at the operating level, the area(s) of disagreements shall be stated in writing by each party and presented to the other party for consideration. If agreement or interpretation is not reached within 30 days, the parties shall forward the written presentation of the disagreement to respective higher officials for appropriate resolution.

If a dispute related to funding remains unresolved for more than 30 calendar days after the parties have engaged in an escalation of the dispute, disputes will be resolved in accordance with instructions provided in the Treasury Financial Manual (TFM) Volume I, Part 2, Chapter 4700, Appendix 10, available at <http://www.fms.treas.gov/tfm/index.html>.

2. If CPSC cancels the order, the Environmental Protection Agency (EPA) is authorized to collect costs incurred prior to cancellation of the order plus termination costs, up to the total payment amount provided for under the agreement.

**CPSC-I-11-0011**  
**INTERAGENCY AGREEMENT (IA)**  
**BETWEEN THE**  
**U.S. CONSUMER PRODUCT SAFETY COMMISSION**  
**AND THE**  
**U.S. ENVIRONMENTAL PROTECTION AGENCY**

**I. INTRODUCTION**

The U.S. Consumer Product Safety Commission (CPSC) and the U.S. Environmental Protection Agency (EPA) hereby agree that the EPA, subject to the terms and conditions herein, shall support preliminary research to improve our understanding of potential exposures to nanomaterials that may be released from consumer products. This research effort will also be supported by regulatory agencies within the United Kingdom (UK). The focus of the research under this agreement will be to develop tools to categorize and prioritize exposure potential for select products containing nanomaterials and to develop approaches and protocols to estimate and predict potential exposure pathways for selected product categories and to develop innovative approaches to estimate potential health risks.

**II. TITLE**

Risk Assessment for Manufactured Nanoparticles Used in Consumer Products  
(RAMNUC)

**III. BACKGROUND**

Congress has requested that the federal agencies participating in the National Nanotechnology Initiative (NNI) collaborate on international nanotechnology research. This project is part of a research collaboration between the US EPA and agencies in the UK, where the countries agreed to solicit proposals for research into the environmental health and safety implications of nanomaterials and fund the most relevant studies under the EPA Science to Achieve Results (STAR) grants program. The STAR grants program and process is used by other agencies such as the National Institutes for Occupational Safety and Health (NIOSH) because it has a well developed mechanism for the solicitation of research proposals, extensive peer review of submitted proposals, and oversight of funded projects. The studies selected for funding were subject to extensive peer review at a 2010 meeting in London, UK that was conducted jointly with similar agencies within the UK. CPSC staff attended the London meeting and actively participated in the grant review and selection process, along with other internationally known experts in nanotechnology environmental health and safety issues who served as members of the moderating panel.

One particular research proposal was ranked very highly in the selection process that proposed to quantify exposure to consumers and to develop risk models to

predict potential health effects. The CPSC staff member in addition to other reviewers considered the proposal worthy of consideration because it would provide data to support the missions of all funding parties. The initial EPA commitment was to fund 2 research proposals, however, because the importance of the subject matter, consumer product and environmental exposures, EPA has made a commitment to award a third grant and fund the proposed study. The EPA requested that CPSC and the UK agencies also provide funding for this grant, because of the relevance to their respective missions. EPA expects that funding this research will not only leverage resources internationally from multiple governmental organizations, it will also expedite scientific innovation and international science collaboration. The research will be conducted through a collaborative effort of highly qualified experts at consortium of universities in the U.S. and the U.K., thus supporting academic research and the development of researchers with expertise in nanomaterial exposure science.

This research effort will provide a systematic, multidisciplinary approach, including both experimental and computational tools and projects, for predicting potential human and environmental risks associated with the use of selected consumer products that contain zinc oxide, silver and cerium dioxide nanoparticles.

The third grant was awarded to the University of Medicine and Dentistry of New Jersey in 2010. This grant is funded incrementally, and the CPSC funds are needed to continue the funding of this research.

#### **IV. PURPOSE AND OBJECTIVES**

The overall objective of this project is to determine whether the nanoparticle exposures to humans and organisms resulting from consumer product and environmental exposures will substantially differ in both physicochemical and toxicological properties from nanoparticles that are newly synthesized in the laboratory or incorporated directly into a product. These differences may have significant consequences with respect to nanoparticle bioavailability and other toxicity measures. This study will test these measures in in vitro and in vivo experiments, and produce mechanism-based results relating toxic effects to nanoparticle physicochemical properties. The results of the study will be placed into source-to-exposure and dose-effects modeling systems allowing for extrapolation in nanoparticle risk assessment.

#### **V. STATEMENT OF WORK**

To address the objectives of the research effort, the EPA grantee will conduct the following activities:

1. Synthesize the three (3) selected nanoparticles and compare their physicochemical properties to properties of the nanoparticles incorporated in consumer products at the point of exposure.
2. Conduct a set of laboratory-controlled experiments to simulate realistic use of consumer sprays incorporating selected nanoparticles, and determine potential inhalation exposures.
3. Investigate the effects of nanoparticles as synthesized and as incorporated in consumer products, on cellular, molecular and immune reactivity using in vitro models of primary mammalian and human cell lines.
4. Examine the cellular reactivity and distribution of the selected nanoparticles as synthesized and incorporated in consumer products, the airways and lungs and compare to effects for nanoparticles administered by inhalation or pharyngeal aspiration, assessed both acutely and chronically.
5. Refine and customize computational modules for selected nanoparticles as synthesized and as incorporated in consumer products, by integrating the data to be obtained in this study and relevant extant data as input to the modules. These modules are developed to predict the environmental fate and transport, population exposure, toxicokinetics and toxicodynamics, cellular and inhalation toxicity. These modules will be amenable to extrapolation and generalization and will be used to complete a generalized risk assessment.

#### **VI. EPA FURNISHED MATERIALS/EQUIPMENT**

The EPA agrees to furnish all necessary personnel, equipment, materials, services, and facilities to complete the objectives listed in Section V.

#### **VII. CONFIDENTIALITY REQUIREMENTS**

Results from this IA will not be distributed or released in any form until agreed upon by CPSC and EPA.

#### **VIII. REPORTING REQUIREMENTS**

EPA will provide an interim report at the end of each fiscal year beginning in FY 2011.

#### **IX. PERIOD OF PERFORMANCE**

The period of performance shall begin on the effective date and shall extend 36 months. This agreement may be modified or cancelled by mutual consent of CPSC and EPA.

**X. DELIVERY OR PERFORMANCE**

All deliverables required under the terms and conditions of this IA shall be provided to CPSC. The activities planned under this agreement are expressly subject to the availability of funds and other necessary resources of the parties. EPA neither commits nor makes any obligation of funds pursuant to this agreement. The following items shall be performed in accordance with the following schedule:

- a. An interim report summarizing all activities for FY11 will be submitted by September 30, 2011.
- b. Subsequent interim reports will be submitted by September 30, 2012 and September 30, 2013.
- c. A final report will be submitted no later than September 30, 2014.

**XI. DISAGREEMENTS**

In the event that the CPSC and EPA have a disagreement arising under this Interagency Agreement, then the parties shall cooperatively seek to resolve the disagreement by themselves. If the disagreement cannot be resolved between them, then the parties agree to seek the assistance of a third party in resolving the disagreement.

**XII. LIAISON OFFICERS**

- a. EPA PROJECT OFFICER  
Michael McKittrick, Ph.D.  
US EPA  
Ariel Rios Building  
1200 Pennsylvania Avenue, NW  
703-347-8100
- b. CPSC PROJECT OFFICER  
Treye A. Thomas, Ph.D.  
U.S. Consumer Product Safety Commission  
Office of Hazard Identification and Reduction  
4330 East West Highway  
Bethesda, MD 20814  
Phone: (301)504-7738  
[tthomas@cpsc.gov](mailto:tthomas@cpsc.gov)
- c. CPSC PAYMENT OFFICE  
CPSC Accounts Payable Branch, A-160  
PO Box 25710  
Oklahoma City, OK 73125

- d. AGENCY PAYMENT OFFICER  
Ms. Debbie Young  
PO Box 25710  
Oklahoma City, OK 73125

### **XIII. COST AND TRANSFER OF FUNDS**

The estimated cost is \$500K, provided with CPSC FY2011 funds.

EPA Administrative Point of Contact:

### **XIV. FUNDING AND ACCOUNTING DATA**

The transfer of funds shall be from CPSC to EPA through the On-Line Payment Collection (OPAC) system using the following accounting data:

**Transfer From:**

**CPSC**

Taxpayer ID Number (TIN): 520978750

Agency Location Code (ALC): 61-00-0001

DUNS: 069287522

US Treasury Code: 61-1-0100

ACCT. DATA: 0100A11DPS 2011 2370400000 EXHR004000 25310

AMOUNT: \$500,000.00

**Transfer To:**

**EPA**

Taxpayer ID Number (TIN): 520852695

Agency Location Code (ALC): 68011499

DUNS: 029128894

US Treasury Code: 3875F

### **XV. AUTHORITIES**

**FOR CPSC:**

Section 27(g) of the Consumer Product Safety Act, (15 U.S.C. 2076(g)).

**FOR EPA:**

Toxic Substances Control Act, Section 10(d) which authorizes the Administrator of EPA to be responsible for research aimed at the development, in cooperation with other Federal agencies, or monitoring techniques which may be used in the detection of toxic chemical substances.

APPROVED AND ACCEPTED FOR  
THE U.S. CONSUMER PRODUCT  
SAFETY COMMISSION

BY: Donna Hutton

SIGNATURE: *Donna Hutton*

TITLE: Contracting Officer

DATE: 9/20/11

APPROVED AND ACCEPTED  
FOR THE ENVIRONMENTAL  
PROTECTION AGENCY

BY: \_\_\_\_\_

SIGNATURE: *Michelle Messick* *JR*

TITLE: Frank Roth, Branch Chief  
Fellowship, IA&SEE's Branch

DATE: 9-20-11