United States Government
Interagency Agreement (IAA) – Agreement Between Federal Agencies
General Terms and Conditions (GT&C) Section

IAA Number 14FED1408970 (GT&C #) - 0000 - (Order #) 01 (Amendment/Mod #)

DEPARTMENT AND/OR AGENCY			
1.		Requesting Agency of Products/Services	Servicing Agency Providing Products/Services
	Name	Centers for Disease Control and Prevention	Consumer Product Safety Commission
	Address	1600 Clifton Road NE, Mailstop A-24 Atlanta, GA 30333	4330 East West Highway, Room 502D Bethesda, MD 20814-4408

2. **Servicing Agency Agreement Tracking Number** (Optional) CPSC-IAG-01-1163 Mod #63

3. **Assisted Acquisition Agreement** Yes ☑ No ☐

4. **GT&C Action** (Check action being taken)

☐ New

☑ **Amendment** – Complete only the GT&C blocks being changed and explain the changes being made.

Changing from single order to multiple order.

☐ **Cancellation** – Provide a brief explanation for the IAA cancellation and complete the effective End Date.

5. **Agreement Period** Start Date 04-30-2015 (MM-DD-YYYY) End Date 09-30-2019 (MM-DD-YYYY) of IAA or effective cancellation date

6. **Recurring Agreement** (Check One) A Recurring Agreement will continue, unless a notice to discontinue is received.

Yes ☑ If Yes, is this an: Annual Renewal ☑

Other Renewal ☐ State the other renewal period: _____

No ☐

7. **Agreement Type** (Check One) ☐ Single Order IAA ☑ Multiple Order IAA

8. **Are Advance Payments Allowed for this IAA** (Check One) ☐ Yes ☑ No

If Yes is checked, enter Requesting Agency's Statutory Authority Title and Citation

Note: Specific advance amounts will be captured on each related Order.

United States Government
Interagency Agreement (IAA) – Agreement Between Federal Agencies
General Terms and Conditions (GT&C) Section

IAA Number 14FED1408970 - 0000 - 01
GT&C # Order # Amendment/Mod #

9. Estimated Agreement Amount (The Servicing Agency completes all information for the estimated agreement amount.)
(Optional for Assisted Acquisitions)

Direct Cost	$525,000.00
Overhead Fees & Charges	$175,000.00
Total Estimated Amount	$700,000.00

Provide a general explanation of the Overhead Fees & Charges
$225 for adverse drug event-related case reporting and quality assurance
$35,000 for administrative costs of programming support, delivering data, improving quality assurance, and evaluation activities

10. STATUTORY AUTHORITY

a. Requesting Agency's Authority (Check One)

Franchise Fund	Revolving Fund	Working Capital Fund	Economy Act (31 U.S.C. 1535/FAR 17.5)	Other Authority
☐	☐	☐	☑	☐

Fill in Statutory Authority Title and Citation for Franchise Fund, Revolving Fund, Working Capital Fund, or Other Authority

b. Servicing Agency's Authority (Check One)

Franchise Fund	Revolving Fund	Working Capital Fund	Economy Act (31 U.S.C. 1535/FAR 17.5)	Other Authority
☐	☐	☐	☑	☐

Fill in Statutory Authority Title and Citation for Franchise Fund, Revolving Fund, Working Capital Fund, or Other Authority

11. Requesting Agency's Scope (State and/or list attachments that support Requesting Agency's Scope.)

See Attachment

12. Roles & Responsibilities for the Requesting Agency and Servicing Agency (State and/or list attachments for the roles and responsibilities for the Requesting Agency and the Servicing Agency.)

See Attachment

United States Government
Interagency Agreement (IAA) – Agreement Between Federal Agencies
General Terms and Conditions (GT&C) Section

IAA Number 14FED1408970 - 0000 - 01
GT&C # Order # Amendment/Mod #

13. Restrictions (Optional) (State and/or attach unique requirements and/or mission specific restrictions specific to this IAA).

14. Assisted Acquisition Small Business Credit Clause (The Servicing Agency will allocate the socio-economic credit to the Requesting Agency for any contract actions it has executed on behalf of the Requesting Agency.)

15. Disputes: Disputes related to this IAA shall be resolved in accordance with instructions provided in the Treasury Financial Manual (TFM) Volume I, Part 2, Chapter 4700, Appendix 10; Intragovernmental Business Rules.

16. Termination (Insert the number of days that this IAA may be terminated by written notice by either the Requesting or Servicing Agency.)

30

If this agreement is canceled, any implementing contract/order may also be canceled. If the IAA is terminated, the agencies shall agree to the terms of the termination, including costs attributable to each party and the disposition of awarded and pending actions.

If the Servicing Agency incurs costs due to the Requesting Agency's failure to give the requisite notice of its intent to terminate the IAA, the Requesting Agency shall pay any actual costs incurred by the Servicing Agency as a result of the delay in notification, provided such costs are directly attributable to the failure to give notice.

17. Assisted Acquisition Agreements – Requesting Agency's Organizations Authorized To Request Acquisition Assistance for this IAA. (State or attach a list of Requesting Agency's organizations authorized to request acquisition assistance for this IAA.)

DHQP, NCEZID, CDC

18. Assisted Acquisition Agreements – Servicing Agency's Organizations authorized to Provide Acquisition Assistance for this IAA. (State or attach a list of Servicing Agency's organizations authorized to provide acquisition for this IAA.)

CPSC, Bethesda, MD

19. Requesting Agency Clause(s) (Optional) (State and/or attach any additional Requesting Agency clauses.)

A. Travel under this agreement is subject to allowances authorized in accordance with Federal Travel Regulations, Joint Federal Travel Regulations, and/or Foreign Service Regulations.
B. Unless otherwise requested by the procuring agency, CDC will retain title to any equipment procured in order to provide service.

United States Government
Interagency Agreement (IAA) – Agreement Between Federal Agencies
General Terms and Conditions (GT&C) Section

IAA Number 14FED1408970 (GT&C #) - 0000 - (Order #) 01 (Amendment/Mod #)

20. Servicing Agency Clause(s) (Optional) (State and or attach any additional Servicing Agency clauses.)

21. Additional Requesting Agency and/or Servicing Agency Attachments (Optional) (State and or attach any additional Requesting Agency and or Servicing Agency attachments.)

22. Annual Review of IAA

By signing this agreement, the parties agree to annually review the IAA if the agreement period exceeds one year. Appropriate changes will be made by amendment to the GT&C and or modification to any affected Order(s).

AGENCY OFFICIAL

The Agency Official is the highest level accepting authority or official as designated by the Requesting Agency and Servicing Agency to sign this agreement. Each Agency Official must ensure that the general terms and conditions are properly defined, including the stated statutory authorities, and, that the scope of work can be fulfilled per the agreement.

The Agreement Period Start Date (Block 5) must be the same as or later than the signature dates.

Actual work for this IAA may NOT begin until an Order has been signed by the appropriate individuals, as stated in the Instructions for Blocks 37 and 38.

23.	Requesting Agency	Servicing Agency
Name	Beth P Bell, MD, MPH	Eddie Ahmad
Title	Director, NCEZID	Contracting Officer, CPSC
Telephone Number(s)	(404) 639-3967	(301) 504-7884
Fax Number	(404) 639-3936	(978) 244-8640
Email Address	bbell@cdc.gov	aahmad@cpsc.gov
SIGNATURE		
Approval Date	7/24/15	7/21/15

FMS Form 6-10 7600A

United States Government
Interagency Agreement (IAA) – Agreement Between Federal Agencies
Order Requirements and Funding Information (Order) Section

IAA Number 14FED1408970 - 0002 - _____
GT&C # Order # Amendment/Mod #

Servicing Agency's Agreement Tracking Number (Optional) CPSC-I-01-1163; MOD 6

PRIMARY ORGANIZATION/OFFICE INFORMATION

24.	Requesting Agency	Servicing Agency
Primary Organization Office Name	Centers for Disease Control and Prevention (CDC)	Consumer Product Safety Commission
Responsible Organization Office Address	1600 Clifton Road, MS A-24 Atlanta, GA 30333	4330 East West Highway, Room 502D Bethesda, MD 20814-4408

ORDER/REQUIREMENTS INFORMATION

25. Order Action (Check One)

☑ New

☐ Modification (Mod) List affected Order blocks being changed and explains the changes being made. For Example: for a performance period mod, state new performance period for this Order in Block 27. Fill out the Funding Modification Summary by Line (Block 26) if the mod involves adding, deleting or changing Funding for an Order Line.

☐ Cancellation Provide a brief explanation for Order cancellation and fill in the Performance Period End Date for the effective cancellation date.

26. Funding Modification Summary by Line	Line	Line	Line	Total of All Other Lines (attach funding details)	Total
Original Line Funding	$	$	$	$	$0.00
Cumulative Funding Changes From Prior Mods (addition (+) or reduction (-))	$	$	$	$	$ 0.00
Funding Change for This Mod	$	$	$	$	$ 0.00
TOTAL Modified Obligation	$ 0.00	$ 0.00	$0.00	$ 0.00	$0.00
Total Advance Amount (+)	$	$	$	$	$0.00
Net Modified Amount Due	$ 0.00	$0.00	$0.00	$ 0.00	$0.00

27. Performance Period
For a performance period mod, insert the start and end dates that reflect the new performance period.

Start Date 06-22-2015 MM-DD-YYYY End Date 06-21-2016 MM-DD-YYYY

IAA Order

IAA Number 14FED1408970 - 0002 - _____
GT&C # | Order # | Amendment/Mod #

Servicing Agency's Agreement Tracking Number (Optional) CPSC-I-

28. Order Line Funding Information — Line Number _____

	Requesting Agency Funding Information	Servicing Agency Funding Information
AFC	75-09-0421	61-00-0001
Component TAS	SP: / ATA: / AID: 075 / BPOA: 2015 / EPOA: 2015 / A: / MAIN: 0943 / SUB:	SP: / ATA: / AID: 061 / BPOA: 2015 / EPOA: 2015 / A: / MAIN: 0001 / SUB:
OR Current TAS format	75-15-0943	61-15-0100
BETC	DISB	COLL
Object Class Code (Optional)	25308	252E0
BPN	927645465	069287522
BPN + 4 (Optional)		
Additional Accounting Classification Information (Optional)	EIN 58-6051157 IAA 14FED1408970-02 CAN 939ZZXG 138,000.00	EIN: 520978750 Line of Accounting: 0100A15RSE 2015 1117900000 EXHR004310 252E0
Requesting Agency Funding Expiration Date (MM-DD-YYYY)	09-30-2015	
Requesting Agency Funding Cancellation Date (MM-DD-YYYY)	09-30-2020	

Project Number & Title: Adverse Effects Due To Therapeutic Drugs

Description of Products and/or Services, including the Bona Fide Need for this Order (State or attach a description of products/services, including the bona fide need for this Order.)

I hereby certify that (a) this requirement represent a bona fide need of the fiscal years for which the appropriation was made and complies with the Anti-deficiency Act and (b) funds are committed for base period or first increment of performance of this acquisition

North American Industry Classification System (NAICS) Number (Optional)

Breakdown of Reimbursable Line Costs

Unit of Measure	Quantity	Unit Price	Total
			$ 0.00
Overhead Fees & Charges			X
Total Line Amount Obligated			$ 0.00
Advance Line Amount (-)			X
Net Line Amount Due			$ 0.00

OR

Breakdown of Assisted Acquisition Line Cost

Contract Cost	$ 120,500.00
Servicing Fees	$ 17,500.00
Total Obligated Cost	$ 138,000.00
Advance for Line (-)	X
Net Total Cost	$ 138,000.00

Assisted Acquisition Servicing Fees Explanation
$120,500.00 for adverse drug events related case reporting and quality assurance
$17,500.00 for administrative costs of programming support, delivering data, improving quality assurance

Type of Service Requirements

☑ Severable Service ☐ Non-severable Service ☐ Not Applicable

IAA Order

IAA Number 14FED1408970 - 0002 - _____
GT&C # | Order # | Amendment/Mod #

Servicing Agency's Agreement Tracking Number (Optional) CPSC-I-

28. Order Line Funding Information — Line Number _____

	Requesting Agency Funding Information							Servicing Agency Funding Information						
ALC	75-09-0421							61-00-0001						
Component TAS	SP	AFA	AID	BPOA	EPOA	A	MAIN	SUB	SP	AFA	AID	BPOA	EPOA	A	MAIN	SUB
			075	2015	2015		0949				061	2015	2015		0001	
OR Current TAS format	75-15-0949								61-15-0100							
BETC	DISB								COLL							
Object Class Code (Optional)	25308								252E0							
BPN	927645465								069287522							
BPN + 4 (Optional)																
Additional Accounting Classification Information (Optional)	EIN 58-6051157 IAA #14FED1408970-02 CAN 921HQ46-122,000 00								EIN 520978750 Line of Accounting 0100A15RSE 2015 1117900000 EXHR004310 252E0							

Requesting Agency Funding Expiration Date: 09-30-2015 (MM-DD-YYYY)

Requesting Agency Funding Cancellation Date: 09-30-2020 (MM-DD-YYYY)

Project Number & Title: Adverse Effects Due to Therapeutic Drugs

Description of Products and or Services, including the Bona Fide Need for this Order (State or attach a description of products services, including the bona fide need for this Order.)

I hereby certify that (a) this requirement represents a bona fide need of the fiscal year or years for which the appropriation was made and complies with the Anti-deficiency Act and (b) funds are committed for the base period or first increment of performance of this acquisition

North American Industry Classification System (NAICS) Number (Optional)

Breakdown of Reimbursable Line Costs

Unit of Measure	Quantity	Unit Price	Total
			$ 0.00
Overhead Fees & Charges			$
Total Line Amount Obligated			$ 0.00
Advance Line Amount (-)			$
Net Line Amount Due			$ 0.00

OR **Breakdown of Assisted Acquisition Line Cost**

Contract Cost	$ 104,500.00
Servicing Fees	$ 17,500.00
Total Obligated Cost	$ 122,000.00
Advance for Line (-)	$
Net Total Cost	$ 122,000.00

Assisted Acquisition Servicing Fees Explanation
$104,500.00 for adverse drug event-related case reporting and quality assurance
$17,500.00 for administrative costs of programing support delivering data improving quality assurance

Type of Service Requirements

☑ Severable Service ☐ Non-severable Service ☐ Not Applicable

IAA Order

IAA Number 14FED1408970 (GT&C #) - 0002 (Order #) - _____ (Amendment/Mod #) Servicing Agency's Agreement Tracking Number (Optional) CPSC-I-_____

29. Advance Information (Complete Block 29 if the Advance Payment for Products/Services was checked "Yes" on the GT&C.)

Total Advance Amount for the Order $_____ [All Order Line advance amounts (Block 28) must sum to this total.]

Revenue Recognition Methodology (according to SFFAS 7) (Identify the Revenue Recognition Methodology that will be used to account for the Requesting Agency's expense and the Servicing Agency's revenue)

☐ Straight-line – Provide amount to be accrued $_____ and Number of Months _____

☐ Accrual Per Work Completed – Identify the accounting posting period:

☐ Monthly per work completed & invoiced

☐ Other – Explain other regular period (bimonthly, quarterly, etc.) for posting accruals and how the accrual amounts will be communicated if other than billed. _____

30. Total Net Order Amount: $ 260,000.00

[All Order Line Net Amounts Due for reimbursable agreements and Net Total Costs for Assisted Acquisition Agreements (Block 28) must sum to this total.]

31. Attachments (State or list attachments.)

☐ Key project and/or acquisition milestones (Optional except for Assisted Acquisition Agreements)

See attached SOW

☐ Other Attachments (Optional)

BILLING & PAYMENT INFORMATION

32. Payment Method (Check One) [**Intra-governmental Payment and Collection (IPAC)** is the Preferred Method.] If IPAC is used, the payment method must agree with the IPAC Trading Partner Agreement (TPA).

☐ Requesting Agency Initiated IPAC ☑ Servicing Agency Initiated IPAC

☐ Credit Card ☐ Other – Explain other payment method and reasoning _____

33. Billing Frequency (Check One)

[An Invoice must be submitted by the Servicing Agency and accepted by the Requesting Agency BEFORE funds are reimbursed (i.e., via IPAC transaction)]

☐ Monthly ☐ Quarterly ☑ Other Billing Frequency (include explanation) Upon receipt of IPAC

34. Payment Terms (Check One)

☐ 7 days ☑ Other Payment Terms (include explanation): As the services are completed or upon receipt of IPAC

IAA Order

IAA Number 14FED1408970 - 0002 - _____
GT&C # Order # Amendment/Mod #

Servicing Agency's Agreement Tracking Number (Optional) CPSC-I-

35. Funding Clauses/Instructions (Optional) (State and/or list funding clauses/instructions.)

CDC FUNDING INFORMATION IS ATTACHED.

36. Delivery/Shipping Information for Products (Optional)

Agency Name	
Point of Contact (POC) Name & Title	
POC Email Address	
Delivery Address /Room Number	
POC Telephone Number	
Special Shipping Information	

APPROVALS AND CONTACT INFORMATION

37. PROGRAM OFFICIALS
The Program Officials, as identified by the Requesting Agency and Servicing Agency, must ensure that the scope of work is properly defined and can be fulfilled for this Order. The Program Official may or may not be the Contracting Officer depending on each agency's IAA business process.

	Requesting Agency	Servicing Agency
Name	Kimberley A. Dobson	Eddie Ahmad
Title	Principal Management Official	Contracting Officer
Telephone Number	(404) 639-4048	(301) 504-7884
Fax Number	(404) 639-2647	(978) 244-8640
Email Address	ihj6@cdc.gov	aahmad@cpsc.gov
SIGNATURE	Kimberley A Dobson	
Date Signed	6/10/2015	

38. FUNDING OFFICIALS - The Funds Approving Officials, as identified by the Requesting Agency and Servicing Agency, certify that the funds are accurately cited and can be properly accounted for per the purposes set forth in the Order. The Requesting Agency Funding Official signs to obligate funds. The Servicing Agency Funding Official signs to start the work, and to bill, collect, and properly account for funds from the Requesting Agency, in accordance with the agreement.

	Requesting Agency	Servicing Agency
Name	Beth Bell, MD MPH	James Baker
Title	Director, NCEZID	Budget Officer
Telephone Number	(404) 639-3667	(301) 504-7575
Fax Number	(404) 693-3936	
Email Address	bbell@cdc.gov	jbaker@cpsc.gov
SIGNATURE		
Date Signed		7/21/2015

IAA Order

IAA Number 14FED1408970 - 0002 - _____
GT&C # / Order # / Amendment/Mod #

Servicing Agency's Agreement Tracking Number (Optional) CPSC-I-

CONTACT INFORMATION

FINANCE OFFICE Points of Contact (POCs)
The finance office points of contact must ensure that the payment (Requesting Agency), billing (Servicing Agency), and advance/accounting information are accurate and timely for this Order.

39.	Requesting Agency (Payment Office)	Servicing Agency (Billing Office)
Name	Barry Taylor	Debbie Young
Title	CDC, Financial Management Ofiice-Travel	Agency Payment Officer
Office Address	1600 Clifton Road, NE MS C-12 Atlanta, GA 30333	P.O. Box 25710, Fed Aviation Admin Oklahoma City, OK 73125
Telephone Number	(404) 718-8074	(405) 954-7467
Fax Number		
Email Address	btaylor@cdc.gov	C-AMZ-CPSC-Accounts Payable@faa.gov
Signature & Date (Optional)		

40. ADDITIONAL Points of Contacts (POCs) (as determined by each Agency)
This may include CONTRACTING Office Points of Contact (POCs).

	Requesting Agency	Servicing Agency
Name	Nancy Gallagher	Tom Schroeder
Title	Principal Management Official	Statistician, Director
Office Address	1600 Clifton Road NE, MS A-24 Atlanta, GA 30333	4330 East West Highway, Room 502D Bethesda, MD 20814-4408
Telephone Number	(404) 639-4675	(301) 504-7431
Fax Number	(404) 639-4045	(301) 504-0038
Email Address	NGallaghef@cdc.gov	tschroeder@cpsc.gov
Signature & Date (Optional)	NM Gallagher	THOMAS SCHROEDER Digitally signed by THOMAS SCHROEDER Dn: c=US, o=U.S. Government, ou=Consumer Product Safety Commission, cn=THOMAS SCHROEDER, 0.9.2342.19200300.100.1.1=61001000019872 Date: 2015.06.29 09:52:37 -04'00'
Name	Geneva Nathani	
Title	Senior Budget Analyst	
Office Address	1600 Clifton Road NE, MS A-24 Atlanta, GA 30333	
Telephone Number	(404) 639-3418	
Fax Number	(404) 639-4023	
Email Address	gnathani@cdc.gov	
Signature & Date (Optional)	6/10/15	
Name	Dan Budnitz	
Title	Director, Medication Safety Program	
Office Address	1600 Clifton Rd NE, MS A-24 Atlanta, GA 30333	
Telephone Number	(404) 639-4096	
Fax Number	(404) 639-4045	
Email Address	dbudnitz@cdc.gov	
Signature & Date (Optional)		

35. FUNDING CLAUSES/INSTRUCTIONS (OPTIONAL) (STATE AND/OR LIST FUNDING CLAUSES/INSTRUCTIONS).

T.C	FY	DOC.NO	CAN	TAS	O.C	BACS	AMOUNT
050	15	14FED1408970-0002	939ZZXG	75150943	25308	5614-RF-11-01	$138,000.00
050	15	14FED1408970-0002	921HQ46	75150949	25308	5614-A1-11-01	$122,000.00

ALC: 75090421 PERIOD OF PERFORMANCE: 06/22/2015-06/21/2016

The Funding on this order is only available to pay for work performed within the dates of the Period of Performance (POP). The funding cannot be used to pay for work performed prior to the start date of the POP or after the end date of the POP.

Funding for Interagency Agreement **14FED1408970-0002**
Title: All Adverse Effects Due to Therapeutic Drugs
Period of Performance: June 29, 2015 to June 28, 2016

I. Purpose

This agreement is to provide funding for the collection of adverse drug event-related injury and illness data in Fiscal Year 2015. Under this agreement between the Centers for Disease Control and Prevention (CDC) and the U.S. Consumer Product Safety Commission (CPSC), CDC will contribute to the cost of the National Electronic Injury Surveillance System (NEISS) and CPSC will to maintain or enhance the current scope of NEISS to accommodate the special interests and needs of CDC for adverse drug event-related injury and illness data for victims of all ages from October 1, 2014 through September 30, 2015. It is recognized that through a collaborative, long term commitment to the NEISS that both agencies benefit from program improvements, training, and cost sharing that assist in the timely assessment of injury/illness incidents and that foster future projects of common interest.

II. Background

CPSC contracts with hospital emergency rooms to collect injury/illness data for the data system known as NEISS. This system is used by CPSC to identify and measure the magnitude of the injury problems associated with consumer products that are treated in hospital emergency departments in the U.S. and its territories.

NEISS is a tri-level data collection system, with the capacity for collecting data at emergency departments, from telephone follow-up interviews with hospital staff and/or victims, and from in-depth interviews with injured/ill parties and/or witnesses at the sites where the injuries/illnesses occurred. One, two, or all three of these levels are used by CPSC as primary data collection tools.

Since 1978, other Federal Agencies have found it useful to share NEISS, including having CPSC expand the scope of the injuries collected or add to the list of variables to be collected. Agencies which have shared NEISS data through interagency agreements in the past include: Environmental Protection Agency (EPA), Centers for Disease Control and Prevention (CDC), National Highway Traffic Safety Administration (NHTSA), Food and Drug Administration (FDA), and the Bureau of Justice Statistics (BJS). Through interagency agreements with CDC in FY 2003 through FY 2014, CPSC expanded NEISS to include all adverse drug event-related incidents involving therapeutic use. In FY 2015, CPSC will also include adverse drug event-related incidents involving self-harm, assault, abuse, and undetermined intent of use.

CDC has a need to measure the number and rate of adverse drug-related injuries. NEISS has provided this information on an ongoing basis and in a timely and cost-effective manner. Under this agreement, CDC will contribute funds towards the cost of NEISS contracts in return for sharing of data from this system.

III. Scope of Work

A. Under the terms of this agreement, CPSC agrees to effect modifications to NEISS to meet the needs of CDC in collecting adverse drug event-related injury and illness data. These modifications were put in place in past agreements dating most recently back to FY96. These modifications expanded the scope of data collected through the NEISS system to include adverse drug event-related injuries and illnesses regardless of product involvement, added CDC special study variables to the NEISS surveillance system for adverse drug event-related cases, and established a system whereby CDC is routinely provided with adverse drug event-related data collected through the NEISS system. This agreement covers adverse drug event-related injuries and illnesses to victims of all ages who are treated in the CDC hospital sub-sample (nominally 63 hospitals) of the entire NEISS hospital emergency department sample (nominally 100 hospitals) from October 1, 2014 through September 30, 2015.

Under the terms of this agreement CPSC shall:

1. Deliver to hospital coders instructional materials for identifying and coding all adverse drug event-related injuries and illnesses (including those from self-harm, assault, abuse, and undetermined intent as well as therapeutic use) as provided by CDC and approved by CPSC, including printed instructions, background materials, posters, etc.
2. From time to time (e.g., during visits by CPSC staff to hospitals), provide to current hospital coders within the CDC hospital sub-sample informal training and review on identifying all adverse drug event-related injury and illness cases and recording adverse drug event-related information.
3. At the time of hiring, provide training to new hospital coders within the CDC hospital sub-sample on identifying all adverse drug event-related injury and illness cases and recording adverse drug event-related information.
4. Provide CDC with all in-scope adverse drug event-related injury and illness data from the CDC hospital sub-sample, including standard NEISS data variables and CDC special study variables for adverse drug event-related cases.
5. CPSC will monitor the data collection process and perform routine quality assurance and quality control procedures on CDC adverse drug event-related case variables in addition to the standard NEISS variables.
6. CPSC will collect additional quality assurance data on CDC adverse drug event-related case variables for up to 8 hospitals selected by mutual agreement of CPSC and CDC.
7. CPSC will routinely provide these data to CDC monthly in a file format (e.g., SAS) and on electronic media that are mutually agreeable. For special studies or to meet other unusual data needs, including collection of self-harm, assault, abuse, and undetermined intent cases, CPSC will provide CDC the data electronically at more frequent intervals up to weekly.
7. Finalized data will be provided to CDC yearly, and CPSC will provide a statistical weighting factor for each case based on the CDC sub-sample and statistical support, as necessary, to enable the calculation of national estimates and error terms associated with the estimates.
8. Quarterly, CPSC will provide CDC with a list of changes, if any, in hospitals participating in the CDC sub-sample (including hospital number, name, address, and CPSC regional coordinator), dates of participation/case submissions if not the full quarter, hospital strata, and the number of standard NEISS and adverse drug event-related cases entered during the

quarter. CPSC will maintain an up-to-date CDC sample design document detailing sample design changes, monthly hospital participation, and assigned statistical weights and annually provide a revised copy to CDC.

9. CPSC will notify CDC in advance of major changes to the sample design, variables collected, variable coding schemes, and other factors that materially influence the collection or analysis of the NEISS data.
10. CPSC will modify the CDC special study data collection tool and variables to streamline data collection and allow collection of self-harm, assault, abuse, and undetermined intent cases.

B. CDC will be responsible for analysis of any of the data resulting from this agreement. CPSC will provide consultation on matters concerning the data collection, quality control, sample design, injury/illness estimates, sampling errors and questionnaire design.

D. CDC will be responsible for public release of NEISS data that are identified as adverse drug event-related cases including printed and/or electronic dissemination of data. Public release of data shall exclude hospital and case identifiers, and other NEISS date variables that identify an individual calendar day, and consumer product or manufacturer identifiers as described in Section XVI. Information Safeguards.

IV. Period of Performance

This agreement is approved from the date of signature for both agencies through June 21, 2016
Period of Performance June 29 2015, June 28, 2016
This agreement is severable

V. Estimated Costs

Estimated costs are $260,000. This cost estimate is broken down into the following sub-categories:

$90,000 for adverse drug event-related case reporting and quality assurance
$75,000 for new coder training materials, updating data collection module, and modified programming support
$30,000 for training session for coders
$15,000 for additional case reporting and quality assurance beginning July 1, 2015
$15,000 for quality assurance site visits
$35,000 for administrative costs of programming support, delivering data, improving quality assurance, and evaluation activities

TOTAL: $260,000

The distribution of funds within the categories may be modified as needed by CPSC to complete the collection of the CDC adverse drug event-related injury and illness data through NEISS.

VI. Funding

All funds provided by CDC in this agreement must be obligated by the performing agency by the end of the fiscal year in which the funds expire. Any unobligated but expired funds may not be used to fund

services in subsequent periods. The CDC Financial Management Office (FMO) must be notified of any unobligated funds pertaining to this agreement at least 60 days before the end of the fiscal year so that the agreement can be amended to reduce the obligated amount when appropriate. The notification must be provided to the address cited below (in paragraph VIII).

VII. Conditions of Payment (including under a Continuing Resolution)

Under terms of this agreement, CDC will affect the transfer of $260,000 to CPSC in Fiscal Year 2015 immediately upon receipt of this signed Interagency Agreement and billing statements.

VIII. Accounting and Billing Information

Funds for this project for FY2015 in the amount not to exceed $260,000.00 will be transferred to CPSC via IPAC using the following account data:

	From	CAN	To
Agency	CDC		CPSC
Appropriation	75150949	921HQ46	0100A15RSE-20151117900000-
	75150943	939XXZG	EXHR004310-252E0
EIN	586051157		US Treas Code: 6150100
ALC	75090421		61-00-0001
DUNS#	927645465		069287522
TIN			520978750
CAN	921HQ46, 939ZZXG		
	5-6PP9ALG		
Object Class	25308		252E0
Amount	$260,000.00		$260,000.00

When billing CDC through the IPAC system, CPSC will reference agreement number CDC 14FED1408970-02; CPSC-IAG-01-1163 Mod #63.

When funds are provided to the performing agency in advance of services being performed or goods being delivered, the performing agency is required to provide, within 15 days of the end of each quarter, statements of obligations and expenditures made during the quarter. These statements are also provided to the address below:

CDC, FMO
Attn: IPAC Desk
1600 Clifton Road, MS D-06
Atlanta, GA 30333

IX. Equipment

If equipment is procured by CPSC to accomplish the program's goals and objectives using funds provided by this interagency agreement, CDC will retain title to the equipment, with the exception of

equipment procured in support of the overall NEISS project for which CPSC shall retain title of equipment.

X. **Travel**

Travel under this agreement is subject to allowances authorized in accordance with the Federal Travel Regulations, Joint Federal Travel Regulations, and/or Foreign Service Regulations.

XI. **Conflict with Existing Agreements**

There is no duplication or conflict with existing agreements, policy, or statue.

XII. **Program Contacts**

CDC:
Daniel Budnitz
DHQP/NCDPCID/CCID/CDC
1600 Clifton Rd, NE, MS-A-24
Atlanta, GA 30333
(404) 639-4096
DBudnitz@cdc.gov

CPSC:
Tom Schroeder
CPSC
4330 East West Highway, Rm 502D
Bethesda, MD 20814-4408
(301) 504-7431
TSchroeder@cpsc.gov

XIII. **Budget Contacts**

CDC:
Geneva Nathani
Budget Analyst
1600 Clifton Rd, NE, MS-A-07
Atlanta, GA 30333
(404) 639-3418
gnathani@cdc.gov

CPSC:
James Baker
Budget Officer
4330 East West Highway
Betherda, MD 20814-4408
(301) 504-7575
jbaker@cpsc.gov

XIV. **Modification and Cancellation**

This agreement may be modified by mutual consent of both parties or canceled upon 30 days advance written notice by either party.

XV. **Authority**

This agreement is entered into under Section 601 of the Economy Act, as amended (31 U.S.C. 1535) and the Consumer Product Safety Act.

XVI. Information Safeguards

CDC shall comply with the Privacy Act in using and storing information related to this agreement. CDC shall provide CPSC with written assurances satisfactory to CPSC that the identity of any injured/ill person, and of any person who treated an injured/ill person, shall not be included in any report or information made available by CDC to any member of the public. CDC also agrees that it shall not disclose information compiled under this agreement to the public if the information describes a consumer product in such a manner that will permit the public to ascertain readily the identity of the manufacturer or private labeler of a consumer product under the authority of the Commission unless the Commission is notified, and the Commission complies with Section 6(b) of the CPSA (15 U.S.C. 2055).

CDC shall maintain all publicly accessible NEISS data records through internet file downloads, web-based query systems, or other electronic mechanisms such that individuals or NEISS hospitals are not directly or indirectly identifiable. CDC shall refer all public requests for hospital identities to CPSC. CDC shall provide CPSC, at their discretion, the opportunity to review for up to 30 days all bulk NEISS adverse drug event-related data prior to intended release via internet file downloads, web-based query systems, or other electronic mechanisms.

CDC shall be considered the originating agency for all adverse drug event-related injury and illness cases, including basic NEISS case data and any supplemental data collected. CDC shall serve as the CDC center responsible for employing adequate and effective security controls to protect the confidentiality, availability, and integrity of adverse drug event-related NEISS data, including all data shared with other organizations. CDC shall ensure, prior to the sharing of any data, that the recipient organization affords the appropriate equivalent level of security controls as maintained by CDC, the originating agency. Since data security remains the responsibility of CDC, procedures shall be agreed to in advance that provide for the security controls of the recipient organization.

Because individual NEISS case information for adverse drug event-related injuries and illnesses are considered extremely sensitive and public release of the NEISS data may harm the affected patient, CDC, as the originating agency shall establish agreements with recipient agencies that consider and apply all appropriate management, operational, and technical security controls including physical security needs, such as whether personal information is so sensitive that it should be kept in an approved security container, or whether access to where the information is located should be limited; personnel security needs, such as additional controls over individuals who have access to data; network security, including encryption for data in transit and protection for data at rest; and procedures for the retention and timely destruction of identifiable records. CDC shall provide CPSC a period of up to 30 days to review and provide comment on the privacy and security implications of new data sharing agreements. Once appropriate interagency data sharing agreements have been established between CDC and recipient agencies, CDC may, at its discretion, authorize CPSC to provide NEISS adverse drug event-related case data directly to the recipient agency.

From time to time, CPSC may be contracted by other agencies to collect supplemental information on specific cases that include adverse drug event-related injuries and illnesses. Because the activities of the contracting agency and subsequent release of the adverse drug event-related data collected has the potential to harm individual patients and compromise CDC's ability to continue to collect adverse drug event-related injury and illness data through NEISS, CPSC shall provide CDC a period of up to 30 days to review and provide comment on the privacy and security implications of the new data collection. CPSC shall ensure that agreements with contract agencies include provisions requiring the contracting agencies to apply all appropriate management, operational, and technical security controls including physical security needs, personnel security needs, network security, and procedures for the retention and timely destruction of directly or indirectly identifiable records. Additionally, CPSC shall make a reasonable effort to ensure that CDC have, at their discretion, a period of up to 30 days for review of products arising from such agreements that include adverse drug event-related case information and that are intended for public release. The CDC review shall not prohibit data release nor shall it be implied to indemnify CPSC or other agencies in the event of public release of personal identifiers through their data release mechanisms.

CDC, as the originating agency, shall be notified in a timely fashion of all adverse drug event-related data requests under the Freedom of Information Act (FOIA) or other applicable court order. Routine FOIA requests specific to only adverse drug event-related case information shall be referred to CDC for disposition. Requests for mixed data including more than just adverse drug event-related case information shall be responded to by CPSC with the opportunity for CDC to provide comment on the releasibility of the adverse drug event-related case data.

The provisions in this section, Information Safeguards, shall not in any way prohibit or limit the use of the NEISS adverse drug event-related injury and illness data by CPSC staff in fulfillment of their agency mission and responsibilities. CPSC shall make a reasonable effort to ensure that CDC have, at their discretion, a period of up to 30 days for review of products that include significant adverse drug event-related case information and that are intended for public release. The CDC review shall not prohibit data release nor shall it be implied to indemnify CPSC.

Approved and Accepted for Consumer Product Safety Commission:

Signature: _____ Date: 7/21/15

Name: Eddie Ahmad
Title: Contracting Officer
Address: Division of Procurement Services
U.S. Consumer Product Safety Commission
4330 East West Highway, Room 523
Bethesda, Maryland 20814
Phone: 301-504-7884

Approved and Accepted for CDC:

Signature: Frederick Pestorius -S Digitally signed by Frederick Pestorius -S DN: c=US, o=U.S. Government, ou=HHS, ou=CDC, ou=People, 0.9.2342.19200300.100.1.1=1000378508, cn=Frederick Pestorius -S Date: 2015.07.22 14:01:03 -04'00' Date: 07/22/2015

Name: for Beth Bell, MD, MPH
Title: Director, NCEZID
Address: 1600 Clifton Road, NE, MS-C-12
Atlanta, Georgia 30333
Phone: 404-639-3967

Determination and Findings (D&F)
Regarding Interagency Agreement Request
Between the Centers for Disease Control and Prevention
National Center for Emerging Zoonotic and Infectious Disease
Division of Healthcare Quality Promotion
And
Consumer Product Safety Commission: **(14FED1408970-0002)**

1. Nature and/or description of the action being approved.

The purpose of the project titled: "Adverse Events due to Therapeutic Drugs (ADEs)" is public health monitoring of serious adverse effects from medications. The U.S. Consumer Product Commission (CPSC) will provide timely ADE data from the National Electronic Injury Surveillance System (NEISS) to CDC. This system is unique in the capacity to provide timely, detailed, and nationally representative data on adverse drug events treated in emergency agreement. In summary, this activity supports CDC's goals of integrating and enhances existing surveillance systems to detect, monitor, report, and evaluate public health threats and to prevent adverse events in patients.

2. This D&F is based on the provisions of the Economy Act, 31 U.S.C. 1535.
   The total value of Order 0002 is $260,000.00.
3. It is agreed that DHQP will participate in the scientific and technical oversight of the project in conjunction with the CPSC. The CPSC will be responsible for fiscal management of the project. (This project does not involve human subjects research).

4. The interagency acquisition is in the best interest of the Government and the services cannot be obtained as conveniently or economically by contracting directly with a private source.

5. If the Economy Act order requires contract action by the servicing agency, the D&F must also include a statement that at least one of the following circumstances applies:

6. The Contracting Officer has determined that the use of (Consumer Product Safety Commission (CPSC) is best procurement approach based on the following:

   a. CPSC currently has an appropriate vehicle in place that allows for recruitment of skilled, knowledgeable individuals whose expertise has historically resulted in the successful completion of critical research projects for the agency. Use of this existing relationship is in the best interest of taxpayers because of minimal overhead costs and reduced time investment by CDC personnel.

   b. DHQP has been the requesting organization for multiple years with NEISS/CPSC and has expertise with administering the agreement throughout the acquisition lifecycle.
   c. The IAA is an existing mechanism that has been successfully managed by the CDC for many years.

7. Signature: The D&F must be signed either by the official who signs the IAA request, or an individual acting with the authority of the IAA signer, or a higher authority. The Contracting Officer must also sign the D&F in concurrence.

Signatures:

Date: 6/10/15

Nancy Gallagher
Principal Management Official
Division of Healthcare Quality Promotion
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention

Date: 6/19/15

Beth P. Bell, MD, MPH
Director
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention

Amanda E. Haynes

Date: 6/23/2015

Amanda Haynes
Contracting Officer
Procurements and Grants Office
Centers for Disease Control and Prevention

CONTRACTING OFFICER REVIEW SHEET

SOLICITATION NO. _____

CONTRACT NO. CPSC-IAG-01-1163, MOD 63

SPECIALIST Kessler

CONTRACTING OFFICER _____

SUBMISSION DATE: 7-21-15 URGENT REQUEST:
YES ✓ NO _____

SPECIALIST COMMENTS: For your signature, $60K Reimbursable

CONTRACTING OFFICER'S REVIEW

REVIEW DATE:

APPROVED:

DISAPPROVED:

APPROVED AS NOTED: