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CPSC-IAG-05-1083; MOD #9

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration



INTERAGENCY AGREEMENT

1. IAG NO. (FDA) 224-07-6010		2. TYPE OF AGREEMENT <input type="checkbox"/> New <input checked="" type="checkbox"/> Mod <input type="checkbox"/> Administrative <input type="checkbox"/> No Cost Ext		3. MODIFICATION NO. 9	
4. TITLE OF PROJECT Emergency department visits for injuries related to medical devices: data collection and processing to				5. SECURITY CLAUSE APPLIES <input type="checkbox"/> Yes (See attached) <input checked="" type="checkbox"/> No	
6. DESCRIPTION OF WORK ATTACHED see attached				7. AMOUNT \$36,000.00	
8. NAME AND ADDRESS OF PARTICIPATING FEDERAL AGENCY Consumer Product Safety Commission 4330 East West Highway Bethesda, MD 20814			9. LIAISON TO PARTICIPATING FEDERAL AGENCY a. Name: Mannon Boudreault b. Phone No.: (310) 504 - 6996 c. E-mail: m.boudreault@cpsc.gov d. FAX No.: () -		
10. NAME AND ADDRESS OF PARTICIPATING FDA UNIT FDA CDRH/OSB 10903 New Hampshire Ave., WO66, Rm. 2312 Silver Spring, MD 20903			11. LIAISON TO PARTICIPATING FDA UNIT a. Name: Donna Schwartz b. Phone No.: (301) 796 - 6004 c. E-mail: donna.schwartz@fda.hhs.gov d. FAX No.: (301) 847 - 8124		
12. PERIOD OF AGREEMENT FROM 10/1/09 THROUGH 9/30/10					

This agreement may be terminated by either party upon a thirty day advance written notice. If this Agreement is funded by the FDA, FDA will retain title for any equipment procured under this agreement, unless otherwise justified in the statement of work.

13. AUTHORITY (FDA)

- Economy Act approved June 30, 1932, as amended by 31 U.S.C. 1535
- Section 301 of the Public Health Service Act (42 USC 241)
- Other (specify):

14. AUTHORITY (Other Agency)

This agreement is made under the authority of Section 29 (c) and 29 (e) of the Consumer Product Safety Act in U.S.C. 2078 (c) and 29 (e).

15. FDA FUNDING INFORMATION

Increase from \$ 0.00 by \$ 36,000.00 to \$ 36,000.00

Decrease from \$ _____ by \$ _____ to \$ 0.00

R09592 6998986
223901-40 25.38
75100600
CPSC, TIN: 520978750
US Treas Code:
6190100
DUNS: 069287570
Iag: 09592076010DE14

16. Administrative billing requirements will comply with GAO Policy and Procedures, Title 7, Section 8.4

Billing IPAC system FDA A/C 75380999 Other Agency A/C 61-00-0001

SF 1080 - FDA Accounting (HFA-129) 5650 Fishers Lane, Rockville, MD 20857

17. PARTICIPATING AGENCY FUNDING INFORMATION (This block must be completed if funding is being provided to the FDA)

- Note a. Legal authority for the acquisition of supplies/services exists within your agency
- b. This action does not conflict with any other agency's authority or responsibility

18. PARTICIPATING AGENCY IS

- Required to sign
- Not required to sign

19. FDA APPROVAL

BY: Michelle Howley
Director, DASG/OAGS
4/12/2010
FOIA 3443 (102)

20. PARTICIPATING AGENCY ACCEPTANCE

NAME: Donna Hutton, CPSC Contracting Officer
TITLE: Contracting Officer 5/5/10

Interagency Agreement
between the
U.S. Food and Drug Administration,
Center for Devices and Radiological Health
and the
U.S. Consumer Product Safety Commission
224-07-6010

Note: This IAG should be processed expeditiously to allow sufficient time for necessary data collection during this fiscal year.

I. Objective

Under this agreement between the Center for Devices and Radiological Health (CDRH) and the Consumer Product Safety Commission (CPSC), CDRH will contribute to the cost of the National Electronic Injury Surveillance System (NEISS) and CPSC will maintain and add to the current scope of NEISS to accommodate the special interests of CDRH that pertain to the collection of medical device-associated injury data.

II. Background

CPSC contracts with hospital emergency departments to collect injury data from emergency department records for the National Electronic Injury Surveillance (NEISS) system. This system is used by CPSC to identify and measure the magnitude of injury problems associated with consumer products that are treated in hospital emergency departments in the U.S. and its territories. Since 1978, other federal agencies have found it useful to have CPSC expand the scope of injury data collected by NEISS for their purposes. This agreement will enable CDRH to obtain data on adverse events associated with medical devices from NEISS.

III. Statement of Work

Under the terms of this agreement, CDRH will contribute funds to offset the cost of NEISS contracts in return for sharing of data from this system.

Under the terms of this agreement CPSC will:

1. Deliver to hospital coders instructional materials for identifying and coding medical device-associated injuries as provided by CDRH and approved by CPSC, including printed instructions, coding examples, and background materials.
 2. Provide training with CDRH for hospital coders in the abstraction of information from hospital emergency department records of interest to CDRH for the NEISS primary screen.
 3. Collect all medical device case primary screen data from October 1, 2009 through September 30, 2010 and provide CDRH with this data.
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Clause:

FDA/CDRH plans to continue the project into FY 2011 and will actively pursue continued funding for the project for FY 2011.

IV. Estimated Cost and Conditions of Payment

Under the terms of this agreement, funding from CDRH will be paid to CPSC in FY 2010 immediately upon receipt of the signed interagency agreement and billing statements.

\$36,000.00

V. Information Safeguards

CDRH shall comply with the Privacy Act in using and storing information related to this agreement. CDRH agrees that the identity of any injured person, and of any person who treated an injured person, shall not, without the consent of person identified, be included in any report of information made available by CDRH to any of the public. CDRH 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 unless the Commission is notified, and the Commission complies with Section 6 (b) of the CPSA (15 U.S.C. 2055).

VI. Method of Payment

FDA/CDRH agrees to contribute \$36,000.00 to the cost of the NEISS to accommodate CDRH plans as specified herein in fiscal year 2010 upon billing through the OPAC system. Upon receipt of OPAC statement, FDA/CDRH will make payment to:

CPSC: Debbie Hodge
Director of Division of Finance, CPSC
4330 East West Highway, Rm. 522-A
Bethesda, MD 20814-4408
