



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration

CPSC-IAG-03-1312



OS

INTERAGENCY AGREEMENT

1. IAG NO. (FDA) 224-03-6005	2. TYPE OF AGREEMENT <input checked="" type="checkbox"/> New <input type="checkbox"/> Mod <input type="checkbox"/> Administrative <input type="checkbox"/> No Cost Ext.	3. MODIFICATION NO.
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4. TITLE OF PROJECT
Emergency department visits for injuries related to medical devices: data collection and

5. DESCRIPTION OF WORK - ATTACHED See Attached	6. AMOUNT processing to support surveillance. \$34,000.00
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7. NAME AND ADDRESS OF PARTICIPATING FEDERAL AGENCY Consumer Product Safety Commission 4330 East West Highway Bethesda, MD 20814	LIAISON NAME: Phil Travers	PHONE NO. (301) 504-7447
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8. NAME AND ADDRESS OF PARTICIPATING FDA UNIT CDRH/OSB/DPS 1350 Piccard Drive, Room 330B Rockville MD 20850	LIAISON NAME: Donna M. Schwartz	PHONE NO. (301) 594-2805
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9. PERIOD OF AGREEMENT FROM: 7/1/2003 THROUGH: 9/30/2003

This agreement may be terminated by either party upon a thirty day advance written notice.

10. 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) _____

11. AUTHORITY (Other Agency) This agreement is made under the authority of Section 29(c) and 29(e) of the Consumer Product Safety Act 15 U.S.C. 2078 (c) and (e)

12. FDA FUNDING INFORMATION
 Increase from \$0 by 34,000 to 34,000 R-9556 3-6997446 25.38 7530600 22390L-40
 Decrease from _____ by _____ to _____ CPSC: 03 PS EXOB 4310 11179 259e

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

14. Billing: Billing: OPAC system FDA ALC 75060099 Other Agency ALC 61-00-0001
 _____ SF 1080 - FDA Accounting (HFA-120) 5600 Fishers Lane, Rockville, MD 20857

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

16. PARTICIPATING AGENCY IS
 Required to sign Not required to sign

17. FDA ACCEPTANCE
 NAME: Rosemary Springer
 TITLE: Grants Management Office, FDA
 DATE: 8/1/03

17. PARTICIPATING AGENCY ACCEPTANCE
 NAME: Donna Hutton
 TITLE: Contracting Officer
 DATE: 7/30/03

2003 JUL 31 A 10:59
OFAS ACQUISITIONS

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

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 rooms to collect injury data from emergency room records for the system known as NEISS. 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, background materials, etc.
2. Provide training with CDRH for hospital coders in the abstraction of information from hospital emergency room records of interest to CDRH for the NEISS primary screen.

3. Collect and provide CDRH with three months of all medical device case primary screen data compiled after the completion of training and distribution of instructional materials to hospital coders.

Clause:

FDA/CDRH plans to continue the project into FY 2004 and will actively pursue continued funding for the project for FY 2004.

IV. Estimated Cost and Conditions of Payment

Under the terms of this agreement funding from CDRH will be paid to CPSC in FY 2003 immediately upon receipt of the signed interagency agreement and billing statements in the amount of \$34,000.00.

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 \$34,000.00 in advance to the cost of the NEISS to accommodate CDRH plans as specified herein in fiscal year 2003 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