MEMORANDUM OF AGREEMENT
Between the
Centers for Disease Control and Prevention, (CDC)
Coordinating Centers for Infectious Diseases (CCID)
National Center for Preparedness, Detection and Control of Infectious Diseases (NCPDCID)
Division of Healthcare Quality Promotion (DHQP)
Immunization Safety Office (ISO)
and the
Health Resources and Services Administration (HRSA)
Healthcare Systems Bureau/Division of Vaccine Injury Compensation (HSB/DVIC)

I. **PURPOSE:** This project will enable CDC and HRSA to exercise the two options for the HRSA Vaccine Injury Compensation Program contract. Option #1 adds two more vaccines for study: hepatitis A and meningococcal conjugate vaccine. Funding Option #2 adds MMR and DTaP vaccines, together and as component vaccines, such as rubella and tetanus and diphtheria toxoids.

II. **PERIOD OF AGREEMENT:** This agreement shall become effective immediately upon signature of both parties. This agreement is approved for Fiscal Year 2009 and may continue during Fiscal Year 2010, subject to availability of funds.

III. **ESTIMATED COST AND METHOD OF BILLING:** The estimated cost associated with this agreement for FY2009 is $735,000.00. Funding information will be provided through IAA modification as soon as the CAN information is available. The transfer of funds will be accomplished via on-line payment and collection system. The following accounts will be involved:

	From CDC/ISO	To HRSA
ALC	75090421	75030030
Appropriation:	7590943	7570350
CAN:		
DUNS:	927645465	044007990
EIN:	586051157	26-1821540
Obj Cl:	25308	25308
Amount:	$732,000	$732,000
Agreement No.		

IV. **AUTHORITY:** This agreement is made under Section 601 of the Economy Act of 1932, as amended (31 U.S.C. 1535 and 1536); and Section 301 of the PHS Act and the National Childhood Vaccine Injury Act of 1986, as amended, 42 U.S.C. 300aa-10 et seq.

V. **TERMS AND CONDITIONS:** This project is funded under the American Recovery and Reinvestment Act (ARRA). The receiving agency shall follow the Interim Rules prescribed in FAR Case 2009-009, Reporting Requirements, FAR Case 2009-010, American Recovery and Reinvestment Act of 2009 (the Recovery Act)–Publicizing Contract Actions;; FAR Case 2009-011-Whistleblower Actions; and FAR Case 2009-0101- GAO/IG Access, as published in the Federal Register on March 31, 2009 until such time the Final FAR Rules are promulgated.

VI. **MODIFICATION/CANCELLATION:** This agreement may be cancelled by either party upon 60 days written notice to the other party.

VII. **CONTACT INFORMATION:**

CDC/ISO

Bonita Johnson
CDC/CCID/NCPDCID/DHQP
Immunization Safety Office
1600 Clifton Rd, Mailstop D-26
Atlanta, GA 30333
Phone: (404) 639-8683

CDC/Budget	Jerry Robinson CDC/Financial Management Office 1600 Clifton Rd, Mailstop C-12 Atlanta, GA 30333 Phone: (404) 639-3439
HRSA	Kay Cook HRSA/HSB/DVIC 5600 Fishers Lane, Room 11C-26 Rockville, MD 20857 Phone: (301) 443-6768

VIII. APPROVAL

CDC:

_____ _____

Rima Khabbaz, M.D — Date
Director
NCPDCID/CCID

HRSA:

_____ _____

Geoffrey Evans, MD — Date
Director
HSB/DVIC/HRSA

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Health Resources and Services Administration (HRSA)
Healthcare Systems Bureau/Division of Vaccine Injury Compensation (HSB/DVIC)

I. **PURPOSE:** An ad hoc expert committee of the Institute of Medicine (IOM) will review the epidemiological, clinical, and biological literature, and additional evidence, regarding adverse health events associated with eight specific vaccines covered by the Vaccine Injury Compensation Program. Each of the vaccines reviewed represents an independent effort, although all vaccines will be reviewed by a single expert committee. A contract between HRSA and IOM will allow for review of vaccines against four infections: varicella, influenza (both TIV and live attenuated influenza virus), hepatitis B and HPV (tasks 2a-d, 3a-d, 4a-d; option packages 1, 2, 3, 4, 9, 10, 11, 12, 17, 18, 19, and 20 as indicated in the HRSA/IOM contract).

This agreement provides funding and direction for reviews of 4 additional vaccines: hepatitis A, meningococcal conjugate vaccine, and measles-mumps rubella vaccine, and DTaP vaccines, together and as component vaccines, such as rubella and tetanus and diphtheria toxoids. These are Tasks 2e-h, 3e-h, and 4e-h, referred to in the original contract as Option Packages 5, 6, 7, 8, 13, 14, 15, 16, 21, 22, 23, and 24.

The committee will make conclusions on the evidence bearing on causality and the evidence regarding the biological mechanisms that underlie specific theories for how a specific vaccine is related to a specific adverse event. The project entails four distinct tasks, which are the same conceptually regardless of the number of vaccines to be covered. The first task will explore a framework for categorizing evidence regarding biological mechanisms. The second task will focus on identifying the epidemiological literature bearing on the causal relation between the specific vaccine-adverse event relations under study.
The third task will involve accumulating and reviewing the evidence on specific biological mechanisms of relevance. The fourth task will involve the development, review, and release of the consensus report.

II. **PERIOD OF AGREEMENT:** This agreement shall become effective immediately upon signature of both parties. This agreement is approved for funding beginning fiscal year 2009 through fiscal year 2011.

III. **ESTIMATED COST AND METHOD OF BILLING:** The estimated cost associated with this agreement is $735,000.00. Funding information will be provided through IAA modification as soon as the CAN information is available. The transfer of funds will be accomplished via on-line payment and collection system. The following accounts will be involved:

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V. **TERMS AND CONDITIONS**: This project is funded under the American Recovery and Reinvestment Act (ARRA). The receiving agency shall follow the Interim Rules prescribed in FAR Case 2009-009,

Reporting Requirements, FAR Case 2009-010, American Recovery and Reinvestment Act of 2009 (the Recovery Act)–Publicizing Contract Actions;; FAR Case 2009-011-Whistleblower Actions; and FAR Case 2009-0101- GAO/IG Access, as published in the Federal Register on March 31, 2009 until such time the Final FAR Rules are promulgated. The HRSA has discussed the ARRA terms and conditions with the National Academy of Sciences (NAS) and NAS are in agreement to accept these terms and conditions. The resulting task order shall incorporate the ARRA terms and conditions.

VI. MODIFICATION/CANCELLATION: This agreement may be cancelled by either party upon 60 days written notice to the other party.

VII. CONTACT INFORMATION:

CDC/ISO	Bonita Johnson CDC/CCID/NCPDCID/DHQP Immunization Safety Office 1600 Clifton Rd, NE, Mailstop D-26 Atlanta, GA 30333 Phone: (404) 639-8683
CDC/Budget	Jerry Robinson CDC/Financial Management Office 1600 Clifton Rd, NE, Mailstop C-12 Atlanta, GA 30333 Phone: (404) 639-3439
HRSA	Kay Cook HRSA/HSB/DVIC 5600 Fishers Lane, Room 11C-26 Rockville, MD 20857 Phone: (301) 443-6768

VIII. APPROVAL

CDC:

_____ _____

Rima Khabbaz, M.D — Date
Director
NCPDCID/CCID

HRSA:

_____ _____

Geoffrey Evans, MD — Date
Director
HSB/DVIC/HRSA

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Division of Healthcare Quality Promotion (DHQP)
Immunization Safety Office (ISO)
and the
Food and Drug Administration
Center for Biologics Evaluation and Research
Division of Epidemiology
Office of Biostatistics and Evaluation

I. **PURPOSE:** This interagency agreement (IAA) establishes a cooperative relationship with the Centers for Disease Control and Prevention (CDC), Immunization Safety Office (ISO), and the Food and Drug Administration (FDA), Center for Biologics Evaluation and Research, Office of Biostatistics and Evaluation, Division of Epidemiology through which the agencies will collaborate on conducting active safety surveillance for vaccines including those to be licensed in the future. CDC and FDA have a common goal of ensuring the safety of vaccines, which they do utilizing a variety of tools. This agreement sets forth the understanding of both agencies with respect to their rights and responsibilities in the utilization of one of these tools, the Rapid Cycle Analysis (RCA).

The mission of the Division of Epidemiology, Office of Biostatistics and Evaluation, Center for Biologics Evaluation and Research at the FDA is to provide epidemiologic and pharmacovigilance expertise to assure the safety and effectiveness of biologic products through post-marketing safety surveillance and research, review of pharmacovigilance plans and other regulatory submissions, and the collaborative development of regulatory, risk communication, and risk management actions. The Food and Drug Administration Amendments Act of 2007 (FDAAA) states that postmarketing safety activities should include "developing and using improved adverse-event data-collection systems, including information technology systems" and "developing and using improved analytical tools to assess potential safety problems, including access to external data bases". FDAAA also recommends to "develop methods to obtain disparate data sources..." and "develop validated methods for the establishment of a postmarket risk identification and analysis system to link and analyze safety data from multiple sources, with the goals of including, in aggregate" at least 25 million individuals by July 1, 2010 and 100 million individuals by July 1, 2012. In addition, FDAAA states that for the establishment of the postmarket risk identification and analysis system, procedures be established and maintained to "to provide for active adverse event surveillance" using a number of data sources including "private sector health-related electronic data (such as pharmaceutical purchase data and health insurance claims data)".

The mission of the Centers for Disease Control, NCPDCID, DHQP, ISO, is to "To assure and enhance the safety of immunization of children, adolescents and adults through monitoring, evaluation, and prevention." Within ISO, the Vaccine Safety Datalink project conducts post marking evaluations of vaccine safety. Established in 1990, the project has created an infrastructure allowing for high quality research and surveillance. The VSD is a collaborative project between CDC and eight participating Managed Care Organizations (MCOs), in which researchers are able to monitor and conduct studies assessing adverse events following immunization (AEFIs) within a population of 8.8 million members annually (3% of the US population) In 2005 , VSD developed statistical methodologies to conduct near real time post marketing surveillance for newly licensed vaccines. The system created is referred to as Rapid Cycle Analysis (RCA), which is an active surveillance system that routinely assesses possible associations between vaccines and pre-defined potential adverse events. Through RCA, the observed number of suspected adverse events is compared to the expected number of events, determined from a variety of sources. When conducting RCA, researchers are on alert for a "signal", which is generated if the expected rate of adverse events is significantly greater than the control rate adjusting for sequential methods and other factors. The VSD provides scientific expertise and resources as the primary mechanism for population-based evaluations of vaccine safety in the United States, and may serve as a model for other patient safety collaborative research projects.

Comment [jg1]: Are we officially with NCPDCID or with OCSO? Might be better to just say CDC, ISO.

CDC and FDA, through their complementary expertise and resources, can achieve efficiency and synergy in conducting active safety surveillance of newly licensed vaccines and vaccines that will be licensed in the near future.

FDA and CDC each bring specific expertise to the pursuit of postmarketing adverse event detection. FDA scientists with the mandate of regulating and licensing new vaccines and other biologics have recognized the importance for conducting active safety surveillance of vaccines. CDC investigators have a long history of conducting high quality vaccine safety research, conduct active surveillance in order to protect the public's health. CDC and FDA roles with respect to the conduct of Rapid Cycle Analysis will be as follows:

1. CDC will continue to be primarily responsible for directing the activities of the Vaccine Safety Datalink (VSD). Active surveillance for new vaccines and new vaccine recommendations is conducted through VSD's rapid cycle analysis (RCA) system. CDC will provide staff to lead regular conference calls and meetings of VSD investigators, primarily review VSD proposals, approval all proposals, analyze VSD data and produce regular reports of events under surveillance. CDC will share preliminary findings from the RCA with FDA on a regular basis. I

2. VSD investigators will lead all rapid cycle analysis projects and decisions made for any RCA will be made through a collaborative decision making process among the VSD investigators, CDC, and FDA. In the event of a public health concern that is not already being monitored within an ongoing RCA project, the decision to add the outcome to a study will be based on feasibility, plausibility and timeliness of the issue.

2. FDA will designate a "Vaccine Safety Datalink liaison" (and alternate) who will be the FDA's main point of contact and participate in regular conference calls and meetings for both ongoing projects of the VSD and RCAs. It is important for the liaison to understand that RCA is just one part of the VSD project and to fully understand the project, full participation is needed. In regards to RCA projects, the FDA liaison, Director of the Division of Epidemiology, or their designee may appoint an FDA expert on specific vaccines and adverse events to participate in conference calls and meetings to develop RCA protocols, which include identifying outcomes for monitoring, assisting in outcome definitions for monitoring of vaccines, creating chart abstraction tools, and providing clinical and epidemiological guidance.

3. CDC will coordinate the review of proposals for any RCA as well as proposals for VSD. FDA's VSD liaison will be included in the rotating list of reviewers. CDC will provide final approval to all VSD proposals, including RCA proposals.

4. CDC and FDA will determine priorities for RCA projects. Decisions will be based on feasibility of conducting projects within the VSD health plan population.

5. CDC, with guidance from FDA, will work to develop standard approaches for incorporating findings from active surveillance from the VSD in policy and regulatory decisions.

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III. ESTIMATED COST AND METHOD OF BILLING: The estimated cost associated with this agreement is $_____.00. Funding information will be provided through IAA modification as soon as the CAN information is available. The transfer of funds will be accomplished via on-line payment and collection system. The following accounts will be involved:

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ALC	75090421	75030030
Appropriation:	7590943	7570350
CAN:		
DUNS:	927645465	044007990
EIN:	586051157	26-1821540
Obj Cl:	25308	25308
Amount:	_____	_____

Agreement No.

IV. **AUTHORITY:** This Agreement is entered into under the inherent and specific authorities for both agencies to execute their legal missions. In this regard, the agencies recognize the importance of interagency cooperation and collaboration in their mission areas.

CDC and FDA are the agencies within HHS responsible for achieving optimal prevention of human infectious diseases through immunization and prevention against adverse reactions to vaccines (42 U.S.C. § 300aa–1). CDC, FDA Office of Biologics Research and Review, and other agencies are responsible for coordinating and providing direction in several areas of vaccine safety including but not limited to vaccine research to prevent adverse reactions to vaccines (42 U.S.C. § 300aa–2(a)(1)), the safety and efficacy testing of vaccines (42 U.S.C. § 300aa–2(a)(3) and for evaluating the need for and the effectiveness and adverse effects of vaccines and immunization activities (42 U.S.C. § 300aa–2(a)(7))

V. **MODIFICATION/CANCELLATION:** This agreement may be cancelled by either party upon 60 days written notice to the other party.

VI. **CONTACT INFORMATION:**

CDC/ISO	Bonita Johnson CDC/CCID/NCPDCID/DHQP Immunization Safety Office 1600 Clifton Rd, NE, Mailstop D-26 Atlanta, GA 30333 Phone: (404) 639-8683
CDC/Budget	Jerry Robinson CDC/Financial Management Office 1600 Clifton Rd, NE, Mailstop C-12 Atlanta, GA 30333 Phone: (404) 639-3439
FDA	**(Insert FDA Management/Admin contact info here)**

IV. **APPROVAL:**

CDC:

_____ _____

Denise Cardo, M.D
Director
DHQP/NCPDCID/CCID

Date

FDA:

_____ _____

Date

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	From CDC/ISO	To HRSA
ALC	75090421	75030030
Appropriation:	7509100942	7570350
CAN:	9-3886903	
DUNS:	927645465	044007990
EIN:	586051157	26-1821540
Obj Cl:	25308	25308
Amount:	$735,000	$735,000
Agreement No.	FY2009-CDC-07	

IV. **AUTHORITY:** This agreement is made under Section 601 of the Economy Act of 1932, as amended (31 U.S.C. 1535 and 1536); and Section 301 of the PHS Act and the National Childhood Vaccine Injury Act of 1986, as amended, 42 U.S.C. 300aa-10 et seq.

V. **TERMS AND CONDITIONS:** This project is funded under the American Recovery and Reinvestment Act (ARRA). The receiving agency shall follow the Interim Rules prescribed in FAR Case 2009-009,

Reporting Requirements, FAR Case 2009-010, American Recovery and Reinvestment Act of 2009 (the Recovery Act)–Publicizing Contract Actions;; FAR Case 2009-011-Whistleblower Actions; and FAR Case 2009-0101- GAO/IG Access, as published in the Federal Register on March 31, 2009 until such time the Final FAR Rules are promulgated. The HRSA has discussed the ARRA terms and conditions with the National Academy of Sciences (NAS) and NAS are in agreement to accept these terms and conditions. The resulting task order shall incorporate the ARRA terms and conditions.

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CDC/Budget	Jerry Robinson CDC/Financial Management Office 1600 Clifton Rd, NE, Mailstop C-12 Atlanta, GA 30333 Phone: (404) 639-3439
HRSA	Kay Cook HRSA/HSB/DVIC 5600 Fishers Lane, Room 11C-26 Rockville, MD 20857 Phone: (301) 443-6768

VIII. **APPROVAL**

CDC:

_____ _____

Rima F. Khabbaz, M.D — Date
Director
NCPDCID/CCID

HRSA:

_____ _____

Geoffrey Evans, MD — Date
Director
HSB/DVIC/HRSA

April 3, 2009

2nd Training Session for AARA (HAI & 317)

Century Center, 2500, room 1200/1201, 8:30-12:30 pm

Presenters: Elmira Benson and Tom Chapel

Elmira Benson – Overview and Reporting for Grants, Financial Management

Purpose today is to inform program staff of requirements

FMO will provide supplemental module for grants and contracts

Funds are for two years. All funds must be obligated by 9/30/2010 but this does not mean activities should end.

Firm-fixed contracts are highly encouraged (Contractor bears risk and with cost reimbursement contracts, the Government bears greater risk)

Everything we do with ARRA funds must be transparent (posting @ FedBizOpps, grants.gov, recovery, gov). Also Public Affairs Office must sign off on all announcements prior to posting at FedBizOpps

Beginning 7/10/09 – huge recipient reporting requirements will be posted directly to recovery.gov (Salaries for top 10 Officers must be posted, if 80% federally funded)
Note: For vaccine programs, this reporting requirement already exists and the majority of program funds are not federal sources.

CDC ORAC office will be established by May 2009

AARA specific CANS will be created by FMO

317 funds will come directly to CDC and HAI funds via HHS

Grants Post-Award for >25k. OIG will conduct pre-award site visit for new grantees within 6 months of award. PGO (in conjunction with program) will conduct post-award site visit.

Contracts: Encourage firm fixed price; increased notification requirements; must include economic impact, strategy and job creation for acquisitions. Contract options must be posted at FedBizOpps and sole source actions on recovery.gov