

Data Sharing and Use Agreement Form for the Study of Thimerosal and Autism Public Use Data Set

Requestor Name _____
Affiliation _____
Mailing Address _____
Telephone Number _____
EMAIL Address _____

Proposed Use(s) (Please use this space to briefly describe the primary and any secondary objectives of the included proposal. In addition, please provide a brief justification on how using this dataset can address the question):

The data covered under this agreement are the data that were generated from the study titled “*Prenatal and Infant Exposure to Thimerosal from Vaccines and Immunoglobulins and Risk of Autism*” (hereafter referred to as the *Study of Thimerosal and Autism*¹). This study was conducted for the Immunization Safety Office, CDC and the data set contains all of the variables used in the analysis. The purpose of the study was to evaluate the effect, if any, that thimerosal exposure from

¹ Price, C.S., Thompson, W.W., Goodson, Ph.D., B., Weintraub, E.S., Croen, L.A., Hinrichsen, V.L., Marcy, M., Robertson, A., Eriksen, E., Lewis, E., Bernal, P., Shay, D., Davis, R.L., DeStefano, F. Prenatal and Infant Exposure to Thimerosal from Vaccines and Immunoglobulins and Risk of Autism. *Pediatrics* published online: September 13, 2010 (doi: 10.1542/peds.year.2010-0309)

vaccines and immune globulins during the first seven or twenty months of life might have on subsequent performance on a battery of autism outcomes.

In accepting this agreement, I also agree to the following terms and conditions of data use:

1. I will not use, nor permit others to use, the data in any manner except that explicitly stated in The Data Sharing and Use Agreement form for the Study of Thimerosal and Autism Public Use Data Set.
2. I will require others in the organization that use the data to sign this agreement and will submit the signed agreements to CDC.
3. I will not attempt any linkage or combination of the *Study of Thimerosal and Autism* data to any other data set for any other purpose.
4. I will not re-release, share, provide access to, or otherwise make the *Study of Thimerosal and Autism* data available to any other party for any reason whatsoever. I agree to refer all requests for access to the data to the Immunization Safety Office at CDC.
5. I agree to make no attempt to learn the identity of any person included in these data. I also agree to use the *Study of Thimerosal and Autism* data for statistical reporting and analysis only.
6. I understand that CDC and Abt Associates Inc. have de-identified the *Study of Thimerosal and Autism* data set to the best of their ability, in accordance with standards for de-identification set forth in the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (45 C.F.R. Parts 160 and 164). I agree that I will not attempt, in any way, to re-identify any person included in these data..
7. I agree to make no disclosure or use of the identity of a person discovered inadvertently (or by any other means) and will advise the Immunization Safety Office at CDC of any such discovery in writing within two (2) business days of the date of discovery. If such a discovery is made, the information that would identify the individual will be safeguarded or destroyed as requested by CDC.
8. **I also agree to the following security procedures prior to receiving the data:**
 - a. **I will password protect any permanent analysis files, such as those produced by SAS or other statistical analysis package.**
 - b. **I will treat all the *Study of Thimerosal and Autism* data at my desk or worksite as confidential materials and not give other persons access to it.**
 - c. **I will keep all hard copies of analysis and data runs containing small cells, defined herein as any combination of race, ethnicity, geography, age, and/or gender that results in five (5) or fewer cases per cell, locked in my desk when they are no longer necessary to my analysis. Furthermore, I will review all printed or electronic output and delete or blackout any direct or indirect identifiers and any small cells. In addition, for public reporting of results of my analysis on the *Study of Thimerosal and Autism* data, I agree not to report information on any small cells.**
 - d. **I have received IRB approval for the proposed research, and have attached the approved IRB protocol and approval letter.**
9. I agree not to imply or state, in either written or oral form, that interpretations based on the data are those of the original data sources or of CDC.

- 10. I agree to acknowledge, in all reports and published manuscripts using these data, the associated public use data set documentation (see footnote 2 for suggested citation)² and the previously published manuscript for the study (see footnote 1)**
11. I agree to provide to CDC for review a courtesy copy of any publications or other public disseminations of the findings of my analysis prior to their release.
12. I understand that the following federal laws may pertain to this data; that these laws allow for criminal and civil penalties for disclosure and violation of confidentiality; that I am solely responsible for compliance with these and other applicable federal laws; and that I will also investigate and comply with any relevant state laws that might pertain to this data. The applicable laws include but are not limited to:
- a. Human subjects common rule 45 CFR § 46
 - b. Assurances of Confidentiality
Section 308(d) of the
Public Health Service Act
42 USC 242 m(d)
 - c. Privacy Act 5 USC § 552a; 45 CFR § 5b
 - d. HIPAA Privacy Rule, 45 C.F.R. Parts 160 and 164

Any failure by the Requestor to abide by terms of this Agreement constitutes a breach of this Agreement and may result in CDC obtaining any remedy authorized by law including, but not limited to, specific performance and cancellation of the Agreement, which will require the Requestor to return all data obtained hereunder and the destruction, under the supervision of CDC, of all copies of data in the Requestor's possession, as well as in the possession of any of the Requestor's employees, agents, assigns, and subcontractors. In any action brought by CDC under this Agreement in which CDC prevails, CDC shall be entitled to its attorney's fees and court costs. This provision applies to the extent permitted by Federal law.

SIGNATURE: _____ TITLE: _____

ORGANIZATION: _____

This signed data sharing agreement along with the proposed research protocol and IRB approval documentation can be emailed to publicdataset@cdc.gov with the following subject line: (request for data from the: *Study of Thimerosal and Autism*).

² Price, C.S., He, Y. (2010) The Study of Thimerosal and Autism: Data Set Documentation. Bethesda MD: Abt Associates, Inc; Prepared for the National Immunization Program Centers for Disease Control and Prevention Atlanta, GA