

is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

### Proposed Project

Morbidity Monitoring Project (MMP)—New—National Center for HIV, STD and TB Prevention (NCHSTP), Centers for Disease Control and Prevention (CDC).

**Background and Brief Description:** This proposed data collection supplements the HIV/AIDS surveillance programs in 26 selected state and local health departments, which collect information on persons diagnosed with, living with, and dying from HIV infection and AIDS and will incorporate data elements from two data collections:

Supplement to HIV/AIDS Surveillance (SHAS) project (0920–0262) and the Adult/Adolescent Spectrum of HIV Disease (ASD). Both projects stopped data collection in 2004.

Although CDC receives surveillance data from all U.S. states, these supplemental surveillance data are needed to make estimates of key indicators, such as quality of HIV-related ambulatory care and the severity of need for HIV-related care and services. A large number of cities and states are heavily impacted by the HIV/AIDS epidemic, resulting in the need for population-based national estimates of HIV-related behaviors, clinical outcomes, and quality of HIV care.

This project will collect data on behaviors and clinical outcomes from a probability sample of HIV-infected adults receiving care in the U.S. Collection of data from interviews with HIV-infected patients will provide information on patient demographics, and the current levels of behaviors that may facilitate HIV transmission; sexual and drug use behaviors; patients' access to, use of and barriers to HIV-related secondary prevention services; utilization of HIV-related medical services; and adherence to drug

regimens. Collection of data from patient medical records will provide information on: demographics and insurance status; the prevalence and incidence of AIDS-defining opportunistic illnesses and co-morbidities related to HIV disease; the receipt of prophylactic and antiretroviral medications; and whether patients are receiving screening and treatment according to Public Health Service guidelines. No other Federal agency collects national population-based behavioral and clinical information from HIV-infected adults in care. The data will have significant implications for policy, program development, and resource allocation at the state/local and national levels.

CDC is requesting approval for a 3-year clearance for data collection. Data will be collected by 26 Reporting Areas (19 states, Puerto Rico and 6 separately funded cities). CDC estimates an average of 400 respondents per site, resulting in 10,400 respondents for the interview portion. There will be 2 medical record abstractors per site, resulting in 52 respondents for the medical record abstraction. Participation of respondents is voluntary and there is no cost to the respondents other than their time.

ESTIMATE OF ANNUALIZED BURDEN TABLE

Type of data collection	Number of sites	Average number of respondents/site	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Persons interviewed .....	26	400	10,400	1	45/60	7,800
Medical record abstractors .....	26	2	52	200	1	10,400
Total .....						18,200

Dated: June 21, 2005.

**Joan F. Karr,**

*Acting Reports Clearance Officer, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[60Day–05–0425X]

### Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the

Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–371–5983 and send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to [omb@cdc.gov](mailto:omb@cdc.gov).

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the

burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

### Proposed Project

The National Centers for Autism and Developmental Disabilities Research and Epidemiology (CADDRE) Study—New—National Center for Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

### Background and Brief Description

The Children's Health Act of 2000 mandated CDC to establish autism surveillance and research programs to address the number, incidence, correlates, and causes of autism and related disabilities. Under the

provisions of this act, CDC funded 5 CADDRE centers including the California Department of Health and Human Services, Colorado Department of Public Health and Environment, Johns Hopkins University, the University of Pennsylvania, and the University of North Carolina at Chapel Hill. CDC National Center for Birth Defect and Developmental Disabilities will participate as the 6th site. The multi-site, collaborative study will be an epidemiological investigation of possible causes for the autism spectrum disorders.

Data collection methods will consist of the following: (1) Medical and educational record review of the child participant; (2) medical record review of the biological mother of the child participant; (3) a packet sent to the participants with self-administered questionnaires and a buccal swab kit; (4) a telephone interview focusing on pregnancy-related events and early life history (biological mother and/or primary caregiver interview); (5) a child development interview (for case participants only) administered over the telephone or in-person; (6) a

developmental and physical exam of the child participant; (7) biological sampling of the child participant (blood and hair); and, (8) biological sampling of the biological parents of the child participant (blood only). OMB clearance is requested for the self administered questionnaires and buccal swab kit, the primary caregiver interview, and the child development interview. There is no cost to respondents other than their time.

#### ESTIMATE OF ANNUALIZED BURDEN HOURS

Survey	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)	Total burden (in hrs.)
<b>Cases:</b>				
—Self administered questionnaires and buccal swab kit .....	644	1	3.0	1932
—Primary caregiver interview .....	644	1	40/60	429
—Child development interview .....	644	1	3.0	1932
<b>Controls:</b>				
—Self administered questionnaires and buccal swab kit .....	1288	1	3.0	3864
—Primary caregiver interview .....	1288	1	40/60	859
—Child development interview .....	1288	1	1.0	1288
<b>Total .....</b>				<b>10,304</b>

Dated: June 21, 2005.

**Joan F. Karr,**

*Acting Reports Clearance Officer, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[60 Day-05-0010]

#### Proposed Data Collections Submitted for Public Comment and Recommendations

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CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an e-mail to [omb@cdc.gov](mailto:omb@cdc.gov).

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#### Proposed Project

The National Birth Defects Prevention Study (OMB 0920-0010)—Extension—The Division of Birth Defects and Developmental Disabilities (DBDDD), National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

#### Background and Brief Description

CDC has been monitoring the occurrence of serious birth defects and genetic diseases in Atlanta since 1967 through the Metropolitan Atlanta Congenital Defects Program (MACDP). The MACDP is a population-based surveillance system for birth defects in the 5 counties of Metropolitan Atlanta. Its primary purpose is to describe the spatial and temporal patterns of birth defects occurrence and serve as an early warning system for new teratogens. From 1993 to 1996, the Division of Birth Defects and Developmental Disabilities (DBDDD) conducted the Birth Defects Risk Factor Surveillance (BDRFS) study, a case-control study of risk factors for selected birth defects. Infants with birth defects were identified through MACDP and maternal interviews and clinical/laboratory tests were conducted on approximately 300 cases and 100 controls per year. Controls were selected from among normal births in the same population. In 1997 the BDRFS became the National Birth Defects Prevention Study (NBDDS). The major components of the study did not change.

The NBDDS is a case-control study of major birth defects that includes cases identified from existing birth defect