William Blumenthal,

General Counsel.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0263]

Agency Information Collection Request; 30-Day Public Comment Request

AGENCY: Office of the Secretary.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed information collection request for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request, including your address, phone number, OMB number, and OS document identifier, to *Sherette.funncoleman@hhs.gov*, or call the Reports Clearance Office on (202) 690–5683.

Written comments and recommendations for the proposed information collections must be directed to the OS Paperwork Clearance Officer at the above e-mail address within 30 days.

Proposed Project: Protection of Human Subjects: Assurance Identification/IRB Certification/ Declaration of Exemption Form Extension—OMB No. 0990–0263—Office for Human Research Protections.

Abstract: The Federal Policy for the Protection of Human Subjects, known as the Common Rule, requires that before engaging in non-exempt human subjects research that is conducted or supported by a Common Rule department or agency, each institution must: (1) Hold an applicable assurance of compliance [Section 103(a)]; and (2) certify to the awarding department or agency that the application or proposal for research has been reviewed and approved by an IRB designated in the assurance [Sections 103(b) and (f)]. The Office for Human Research Protections is requesting a three-year extension of the Protection of Human Subjects: Assurance Identification/IRB Certification/ Declaration of Exemption Form. That form is designed to promote uniformity among departments and agencies, and to help ensure common means of ascertaining institutional review board certifications and other reporting requirements relating to the protection of human subjects in research. Respondents are institutions engaged in research involving human subjects where the research is supported by HHS. Institutional use of the form is also relied upon by other federal departments and agencies that have codified or follow the Federal Policy for the Protection of Human Subjects (Common Rule). There are an estimated total of 70,000 health or human research studies supported each year, meaning an average of 7 certifications per institution annually, requiring an estimated one-half hour per certification for a total burden of 35,000 hours. Data is collected as needed.

ESTIMATED ANNUALIZED BURDEN IN HOURS FOR IRB CERTIFICATION BURDEN

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Protection of Human Subjects: Assurance Identification/IRB Certification/Declaration of Exemption	10,000	7	0.5	35,000

John Teeter,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–08–0010]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–5960 or send an e-mail to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–6974. Written comments should be received within 30 days of this notice.

Proposed Project

The National Birth Defects Prevention Study (NBDPS)—Revision—National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Address the following criteria provided in 5 CFR 1320.5(a): 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, which is being requested for OMB clearance for three additional years. Its primary purpose is to describe the spatial and temporal patterns of birth defects occurrence and serves as an early warning system for new Teratogens. In 1997, the Birth Defects Risk Factor Surveillance (BDRFS) study, a case-control study of risk factors for selected birth defects, became the National Birth Defects Prevention Study (NBDPS). The major components of the study did not change.

The NBDPS is a case-control study of major birth defects that includes cases identified from existing birth defect surveillance registries in nine states,