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,

including metropolitan Atlanta. Control infants are randomly selected from birth certificates or birth hospital records. Mothers of case and control infants are interviewed using a computer-assisted telephone interview. The interview is estimated to take one hour. A maximum of thirty-six hundred interviews are planned, 2,700 cases and 900 controls, resulting in a maximum interview burden of 3,600 hours for all Centers.

Parents are also asked to collect cheek cells from themselves and their infants for DNA testing. The collection of cheek cells by the mother, father, and infant is estimated to take about 10 minutes per person. Each person will be asked to rub 1 brush inside the left cheek and 1 brush inside the right cheek for a total of 2 brushes per person. Collection of the cheek cells takes approximately 1–2 minutes, but the estimate of burden is 10 minutes to account for reading and understanding the consent form and specimen collection instructions and mailing back the completed kits. The anticipated maximum burden for collection of the cheek cells is 1,800 hours.

Information gathered from both the interviews and the DNA specimens will be used to study independent genetic and environmental factors as well as gene-environment interactions for a broad range of carefully classified birth defects.

There are no costs to the respondents other than their time. The total estimated annualized burden is 5,400 hours.

ESTIMATED ANNUALIZED BURDEN TABLE

Respondents	Number of respondents	Number of responses per respondent	Avg. burden per response (In hours)
NBDPS case/control interview	3,600	1	1
Biologic Specimen Collection	10,800	1	10/60

Dated: November 13, 2008.

Maryam I. Daneshvar,

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–09–09AE]

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 404–639–5960 and send comments to Maryam I. Daneshvar, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to *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

Chagas Disease knowledge, attitude, practices (KAP) study of physicians—New—Coordinating Center for Infectious Disease (CCID), National Center for Zoonotic, Vector-borne, and Enteric Diseases (NCZVED), Division of Parasitic Diseases (DPD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Division of Parasitic Diseases is proposing a knowledge, attitudes, and practices (KAP) study to determine the level of physician awareness and understanding of Chagas disease. Chagas disease is a blood-borne parasitic disease, found only in the Americas, and spread through contact with the triatomine bug. Chagas disease can also be contracted through blood transfusion, organ transplantation, and from mother to child congenitally. This disease is not spread through person-to-person contact. Chagas disease can cause serious heart and stomach illness; for some patients, treatment with antiparasitic medications prevents these serious complications and may eliminate the infection. The hypothesis of this research study is that there will be a dramatic Chagas disease knowledge deficit among physicians. In the first 20 months of blood donor screening for Chagas disease, at least 624 positive blood donors were identified. Currently, only about 10% of blood donors with Chagas disease are receiving treatment medication. It is suspected that most physicians are not familiar with this disease and this may negatively impact patient care: (1) When positive blood donors see their healthcare provider, (2) when organs and tissues are transplanted unknowingly from infected donors, and (3) when infected mothers give birth to babies without screening for Chagas disease. This KAP study will survey physicians in areas where there may be more patients with Chagas disease. The survey will be sent to all physician members of several partner organizations. Results will be analyzed in order to develop physician education material. That material will then be sent to all members. Subsequently, a second follow-up survey, very similar to the initial one, will be sent in order to determine levels of knowledge change. The data collected by this study will allow DPD to understand, and consequently develop and appropriately target medical educational material to address, Chagas disease knowledge deficits of physicians.

There is no cost to respondents other than their time.