Assisted Reproductive Technology (ART) Program Reporting System

OMB Control Number 0920-0556

Revision Request

Supporting Statement: Part A

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Abstract

As required by the Fertility Clinic Success Rate and Certification Act (FCSRCA), CDC currently collects information from all clinics that offer assisted reproductive technology (ART) services, and reports this information as specified in the Act. OMB approval for information collection is scheduled to expire 9/30/2009 (OMB No. 0920-0556), and CDC seeks to renew OMB approval for an additional three years. This Revision request includes minor wording changes to improve the clarity of the question concerning pre-implantation genetic diagnosis (PGD), and an increase in the total estimated burden hours due to an increase in the estimated number of responses.

A. Justification

A.1. Circumstances Making the Collection of Information Necessary

In 2002, two million women of reproductive age were infertile. A number of factors have been associated with infertility, including pelvic inflammatory disease and other modifiable factors (e.g., male factor, environment, tobacco use). In the U.S., as elsewhere, technological advances such as assisted reproductive technology procedures have increasingly been used to overcome infertility. In 2006, there were 138,198 ART cycles reported and 41,343 live-birth deliveries resulting from ART procedures performed in the U.S. and its territories. A total of 54,656 infants were born in 2006 resulting from cycles reported. The total number of infants born is greater than the number of live-birth deliveries because more than one infant may be born during a live-birth delivery (e.g., twins).

The first infant conceived with ART in the U.S. was born in 1981. As ART use increased throughout the 1980s, there was growing concern about the quality of ART information that infertility patients were receiving.

In response to concerns about data quality and comparability, Congress enacted the Fertility Clinic Success Rate and Certification Act (FCSRCA, or Public Law 102-493) in 1992, mandating that all ART clinics report success rate data to the federal government in a standardized manner.

Public Law 102-493, and specifically sections 2(a), 2(b), 2(c), 6 and 8 thereof, established specific definitions and reporting requirements.

CDC is currently approved to conduct the required information collection through the ART Program Reporting System (OMB No. 0920-0556, exp. 9/30/2009), and seeks to extend OMB approval for a period of three years. CDC is authorized to conduct data collection under section 301 of the Public Health Service Act (42 U.S.C. 241) **(Attachment A1)**. The text of the FCSRCA (Public Law 102-493) is included as **Attachment A2**.

Privacy Impact Assessment

Overview of the Data Collection System

The respondents for this data collection activity are clinics that provide ART services in the U.S. and its territories. Respondents have the option to upload ART data directly into a secure, web-based data collection system (the National ART Surveillance System, NASS; see **Attachment C**), or to transmit NASS-compatible files that have been extracted from other medical record systems. NASS collects both ART cycle-specific and clinic-specific data from all responding clinics. CDC employs a contractor to operate and maintain NASS.

The medical director of each clinic, or a designee, is required to submit data annually by an established deadline and to verify by signature that the data reported are accurate. All clinics that fail to submit the required materials by the deadline are considered to not be in compliance with the federal reporting requirements. These clinics are listed as non-reporting clinics in the ART annual report. No information is collected directly from the patients who utilize the clinics.

NASS does not collect direct identifiers such as patient name, patient street address, or social security number (SSN). This information and other directly identifiable data remain with each individual clinic. Because information contained in the database could indirectly identify the patients or link sensitive information with the clinic, an Assurance of Confidentiality has been granted to safeguard the confidentiality of the information collected in NASS and the information maintained by the clinics. **(Attachment E1).**

Items of Information to be Collected

The ART data collected includes patient demographics, medical history and infertility diagnoses, clinical information pertaining to the ART procedure, and outcome information on resultant pregnancies and births. The cycle-specific profile data are organized with one record per cycle. Multiple cycles from a single patient are not linked. An ART cycle is considered to begin when a woman starts taking ovarian stimulatory drugs or starts ovarian monitoring with the intent of having embryos transferred into the uterus. Clinics submit clinic-specific profile data such as clinic name and address, name of embryo laboratory used, and services provided.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

NASS is a web-based data collection system. Access to the website is restricted to approved users. NASS does not involve any content directed to children of any age. The NASS website does not contain any links to any other websites.

The contractor may use session and/or persistent cookies to quickly determine whether the respondents' (clinics) browser has the cookie option turned on. Cookies are not used as tracking technologies or for "remember me" logins.

A.2. Purpose and Use of Information Collection

CDC's primary objective in developing the ART reporting system was to publish the mandated annual surveillance report for Congress and provide accurate ART information needed by consumers. The Congressional report includes the annual ART report, *ART Success Rates, National Summary and Fertility Clinic Reports*. In addition, this unique population-based database is used for epidemiological studies to address important questions regarding assisted reproductive technologies, including safety and efficacy issues, birth weight, and preterm delivery **(Attachment D)**. The CDC Institutional Review Board (IRB) approved the use of the NASS information for epidemiological studies **(Attachment E)**.

The information collected in NASS also provides benefits to ART consumers by serving as a standardized resource for high-quality information about ART procedures and outcomes. Standardized reporting of outcome information for all clinics offering assisted reproductive services is the best way to ensure that consumers have access to accurate information that they need to make informed decisions about infertility treatment.

Privacy Impact Assessment Information

The purpose of the ART data collection is for ART programs to fulfill annual reporting requirements of the Fertility Clinic Success Rate and Certification Act, Section 2(a) of P.L. 102-483(42 USC 263 (a)-1). As mentioned in section A.2 above, information collected is also used by CDC to publish the annual ART Success Rates report as mandated by law and other statistical summaries of epidemiologic analyses of the data. The detailed cycle-specific profile data are required to ensure that the calculation of the success rates is based on the characteristics and outcomes of individual procedures. The clinic-specific profile data are required to provide the consumers with general information about each ART program, in addition to the success rates of ART procedures performed by the program.

Annual NASS data delivered to CDC in identifiable form (IIF) includes patient donor, live born child, and gestational carrier birth dates, patient zip code, state, and country of residence, patient race/ethnicity, and two optional identifier fields. The optional identifier fields are designed to assist clinics in a limited capacity to differentiate between the NASS generated IDs with the same patient birth date. Because they are not required, optional identifier fields may be delivered to CDC blank. Each clinic is responsible for the method(s) it uses to link its cycle-specific NASS data records to the medical records maintained for clinical care.

Information about any individual patient will not be disclosed in any reports, statistical summaries, or to unauthorized entities. Unauthorized disclosure of the IIF data captured in the

NASS and delivered to CDC could have adverse effects such as public embarrassment to the patients utilizing ART and public relations problems for clinic directors. To prevent a breach of confidentiality, security controls are in place in NASS, including user identifications and password protection. Unique user IDs and passwords are required for clinics to gain access to NASS and to submit their annual ART data. Passwords must be of sufficient complexity to prevent unauthorized access and passwords must be changed per the security protocol at a specified interval. Each clinic must have a primary and secondary security point of contact identified by the clinic's medical director.

The medical director, or a designee, must inform the contractor when key personnel leave the clinic or move to another clinic so that their NASS access can be deactivated. Time out logs are also used to automatically log out of a session that remains idle for a specified period of time. Data are encrypted using Transport Layer Security (TLS) during transmission to the NASS.

A.3. Uses of Improved Information Technology and Burden Reduction

Since 2004, clinics have submitted ART cycle information electronically through NASS, the web-based data management system **(Attachment C)**. Respondents also have the option to transmit NASS-compatible electronic files that can be uploaded into the database if they prefer to do so. The data collection contractor conducts data quality control checks and works with CDC and the clinics to reconcile any discrepancies or errors, and to update or improve future data collected in NASS to ensure that the clinic-level statistics meet the requirements of the fertility clinic tables section of the annual ART report. Once the national data set of individual ART cycles is finalized, the data collection contractor additionally compiles an *aggregate*-level data set of clinic statistics and submits this file to CDC electronically.

A.4. Efforts to Identify Duplication and Use of Similar Information

The Fertility Clinic Success Rate and Certification Act directs CDC to collect data from all ART clinics and report their success rates. The only source of population-based, procedure-level ART data is the clinic data collected through NASS. Although some states include a small amount of information about the use of ART on birth certificates, such information is simplistic (e.g., the birth certificate might address "Was this child conceived using ART? Yes/no)," non-standard variables and inconsistent definitions of ART are used, and some states collect no information on ART at all. Collection of the required ART data in compliance with FCSRCA and the publication of the annual report are not conducted anywhere else within CDC or within the Department of Health and Human Services.

A.5. Impact on Small Businesses or Other Small Entities

This data collection system impacts all ART clinics, including some that are small businesses. The NASS data collection elements are the absolute minimum required for the intended use of the data. In an effort to minimize the burden of this data collection system, the contractor has

developed a web-based data collection system so information entered about a patient or clinic is not stored on the computer's hard drive or network drive, but instead on a server residing with the data collection contractor. ART programs that submit data through the Society for Assisted Reproductive Technology (SART) rather than directly to NASS may be charged fees by SART to use their services. ART programs that submit data through SART are SART member programs.

Prior to 2004, non-SART member clinics could only submit data through SART, and were charged fees. Currently, any ART program that chooses to submit data through NASS uses the system free of charge.

A.6. Consequences of Collecting the Information Less Frequently

FCSRCA establishes the frequency of data collection. The Act requires respondents to report data to CDC on an annual basis. Clinics that do not report are not in compliance with FCSRCA and are listed in the annual ART Success Rates Report as non-reporters.

A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This information collection fully complies with all guidelines of 5 CFR 1320.5.

A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. The 60-Day Federal Register Notice [Vol. 74, No. 8, pg. 1688-1689] was published on January 13, 2009 **(Attachment B)**. No public comments were received.

B. The field of ART is a rapidly developing medical science. Therefore, the CDC conducts on-going meetings with American Society for Reproductive Medicine (ASRM), ASRM's affiliate, the Society for Assisted Reproductive Technology (SART), and RESOLVE, the National Infertility Association, and The American Fertility Association. ASRM and SART are medical professional societies representing reproductive health professionals and clinics that perform ART in the U.S. RESOLVE and The American Fertility Association are national consumer organizations representing persons experiencing infertility. The representatives of these organizations, listed below, consult with CDC on ART topics.

ASRM:

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RESOLVE:

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Executive Director
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American Fertility Association:

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A.9. Explanation of Any Payment or Gift to Respondents

No payment or gifts will be provided to respondents.

A. 10. Assurance of Confidentiality Provided to Respondents

ART clinics provide direct patient services and thus require patient identifiers (name, SSN, medical record number) for health care and business purposes. These patient identifiers are not reported through NASS to CDC but NASS does collect demographic information that could contribute to the indirect identification of patients. For this reason, the confidentiality of information submitted by clinics to NASS is protected by an Assurance of Confidentiality under Section 308(d) of the Public Health Service Act. **(Attachment E1)**.

Preliminary review of this application determined that the Privacy Act applies. In addition to the demographic information described above, the database also contains particularly sensitive information such as number of pregnancies lost, use of donor eggs, sperm, or embryos. It is important to protect individual women and clinics from persecution or discrimination, which could occur, if identifiable and sensitive data were obtained by or disclosed to unauthorized individuals or organizations.

To safeguard and ensure the integrity of data while being accumulated, archived, and transmitted on behalf of, and to the CDC, the contractor and/or subcontractors shall ensure that all data is encrypted following the Data Encryption Standard (DES) or triple-DES encryption standard. The contractor shall either provide for the encryption of the data files as a whole, or can programmatically encrypt data items prior to being stored within the data files. It is recommended that the method chosen and implemented by the contractor utilize a key archival or recovery mechanism so files encrypted by lost or forgotten passwords or keys can be recovered.

All CDC and contractor personnel who have access to protected data are required to go through training on confidentiality protections and sign a nondisclosure agreement **(Attachment F and G).**

Privacy Impact Assessment Information

A. The preliminary determination is that the privacy act applies to the data collected and processed by the ART data collection system. Even though the ART data collection system does not collect patient name, SSN, or street address, it does collect sensitive information and a number of indirect identifiers. The SORN number is 09-20-0136, “Epidemiologic Studies and Surveillance of Disease Problems.”

Patient personally identifiable information (PII) is not shared or disclosed to public entities, external agencies, or other people or organizations outside the agency.

B. A contractor operates and maintains NASS. Administrator controls in place include regular backups, security training, completion of a security certification and accreditation (C&A), security plans, and policies. Access to NASS and the ART information collected is limited to contractor staff support the ART project. The project director grants rights and privileges to individuals based on their need to know and the particular requirements of assigned tasks. The contractor follows federal security requirements and adheres to all CDC security policies and regulations. Requirements for adherence to privacy provisions and policies, as well as instructions for destruction of ART data and files when the contract ends, are specified in the contract language.

Clinic directors and data entry personnel who are authorized to submit information to NASS are required to enter a valid user ID and password to gain access. The medical director must provide the data collection contractor the names and e-mail addresses of a primary and secondary security contact. User manuals are provided to clinics that include information for securing and protecting the information submitted to NASS.

All data files and project management files are stored off-site. Technical controls in place include user identification, passwords, firewalls, encryption, and an intrusion detection system. Physical access controls in place include guards, identification badges, key cards, and other security measures. The NASS is undergoing security risk assessment through CDC's Office of the Chief Information Security Officer (OCISO). A C&A for "Moderate" system risk is anticipated. C&A approval will certify that the system meets the CDC security measures required.

C. Patients do not directly enter data into the NASS. Clinic staff extract the data required for CDC to publish the mandated report from patient medical records and either upload the data into NASS directly or export data from other electronic medical record systems into NASS-compatible data files.

Informed consent for treatment is obtained from patients, before ART treatment begins, by the clinic providing ART services. Clinics specify in their informed consent that patient data is subject to reporting to CDC as required by FCSRCA. Patients volunteer their information and can refuse to sign the clinic's informed consent. Clinics are responsible for administering the informed consent to their patients and obtaining permission from patients for ART treatment and submission of their data to CDC.

D. Respondents are the ART clinics. Information collected is mandatory as specified in the FCSRCA. Clinics that do not report their ART data to CDC are not in compliance with FCSRCA and are listed in the annual report as non-reporters.

11. Justification for Sensitive Questions

Based on the legal requirements pertaining to ART, as described in section A.1, the ART surveillance system collects the following data for each ART procedure: 1) patient demographic information; 2) patient history; 3) ART cycle information; and 4) outcome information.

As mentioned in section A.8 above, CDC developed the data collection requirements after extensive consultation with professional and consumer organizations. There is consensus that the sensitive information collected is necessary to produce an accurate account of the effectiveness and safety of ART. Additionally, this information ensures the accuracy of the success rate estimate and the stability of any other estimates generated. Thus, the present data collection system represents a necessary and appropriate implementation of the general requirements set forth by Congress through the FCSRCA.

12. Estimates of Annualized Burden Hours and Costs

A. Burden Hours

Information collection is conducted annually. Respondents are clinics that provide ART services. Since July 2005, respondents have the option of entering information directly into the web-based NASS **(Attachment C)**, or of transmitting NASS-compatible files that can be uploaded into the database. Each clinic receives submission instructions in an annual letter **(Attachment C1)**. Instructions to respondents are provided in **Attachment C2**, NASS Users Manual.

The estimated number of respondents is 430, based on the number of clinics that provided information in 2006. Each ART cycle is considered one response. The average number of responses per respondent (321) was calculated by dividing the total number of ART cycles reported (approximately 138,000 in 2006) by the total number of respondents.

The average burden for reporting one ART cycle (37 minutes) is an average across clinics and includes time to gather records, follow-up with patients in the 30% of cycles that resulted in pregnancy and record pregnancy outcome data in the medical record, abstract data from records, enter data for each record into the software system, and compile a summary report of all cycles as required for submission to CDC.

Each year, approximately 8-10% of the reporting clinics are randomly selected for data validation (35 ART clinics were selected for validation in 2006). In each selected clinic, up to 50 cycles are selected for full data validation. Additionally, an abbreviated validation is performed on each cycle in which a multiple pregnancy occurred that was not selected randomly as part of the full data validation. A description of the full and abbreviated validation is included **(Attachment H).** The average burden for validation procedures was estimated at 23 minutes per cycle validated. By distributing the total burden associated with the validation process across all respondents, we arrived at an adjusted average burden per response of 39 minutes.

In Table A.12-1 (below), the average burden per respondent is calculated by multiplying the average number of responses per respondent (321 ART cycles) times the adjusted average burden per response (39 minutes). The total annualized burden hours are 89,720.

A. 12 – 1 Estimated Annualized Burden Hours

Respondents	No. of Respondents	No. of Responses (ART cycles) per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
ART Clinics	430	321	39/60	89,720

A substantial portion of the information collected for ART reporting through NASS is necessary for routine clinic operations, or is required as a condition of membership in SART (approximately 90% of reporting clinics are SART members who report cycle-specific data to SART on an annual basis).

However, because of the difficulty in distinguishing between the burden associated with FCSRCA reporting requirements, and the burden associated with data collection for the other purposes, the total burden estimate in this Information Collection Request reflects the total time commitment for collecting, validating, and reporting ART cycle information. In the absence of a requirement to submit the information to the Federal government, the burden of collecting this information would remain essentially unchanged for SART member clinics.

B. Estimated Annualized Cost to Respondents

Information for the NASS is collected by data entry clerks, nurses, lab technicians, and physicians. An average wage of $34.00 per hour was used to estimate the annualized cost to respondents for personnel effort associated with information collection and validation. The average wage was derived from the U.S. Office of Personnel Management 2008 General Schedule: Data entry clerks, GS-8 step 3, $18 per hour; Nurses, GS-12 step 6, $32 per hour; Lab Technicians, GS-11 step 7, $28 per hour; Physicians, GS-15 step 10, $59 per hour. The total annualized cost to respondents for both data entry and data validation is estimated to be $3,040,960. The average costs per respondent for data entry and data validation is $7,072 ($3,040,960/430 respondents).

A. 12 – 2 Annualized Cost to Respondents

Respondents	Total Burden (in hours)	Average Hourly Wage Rate	Respondent Cost
ART Programs* (data entry and data validation)	89,720	$34.00	$3,050,480

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no additional costs to respondents or record keepers.

14. Annualized Cost to the Federal Government

Estimates of annualized costs to the federal government are included in the following table.

A. 14 – 1 Annualized Cost to the Federal Government	
Assisted Reproductive Technology Epidemiology Surveillance Program	Annualized Cost
1. Contract	
Total labor	$145,300
Total other direct costs	$153,530
Total overhead	$168,218
General and administrative expense	$75,718
Fee @ 7%	$39,276
2. CDC Editorial Services (publication of the annual report and CD's)	$58,000
Subtotal	$640,042
CDC/NCCDPHP/DRH/WHFB FTEs	Salary
1. Epidemiologist, GS-601-13	$93,916
2. Epidemiologist, GS-601-13	$93,916

3. Statistician, GS-1529-13	$88,838
4. Public Health Analyst, GS-685-13	$86,147
Subtotal	$362,817
Total Federal Government Cost	**$1,002,859**

The contract for collecting ART information supports contractor personnel, facilities, equipment, supplies, and materials necessary to assist CDC with producing and publishing an annual report of pregnancy success rates and embryo laboratory certification status, as mandated by the Fertility Clinic Success Rate and Certification Act of 1992, (FCSRCA), P.L. 102-493, including monitoring clinic openings, closings, and reorganizations, maintaining data collection software, tracking data collection, conducting data management and analysis, conducting data validation visits and other quality assurance activities, and drafting the annual success rates report.

CDC staff members provide technical oversight and expertise, including analytic and scientific guidance, on NASS and to the contract staff. CDC staff members participate in reviewing annual validation plans and attend site visits. CDC staff also conducts scheduled calls to monitor the contractor's performance and ensure that project standards are met and that the data are of high quality, thus ensuring accurate reporting and generation of valid success rates. CDC staff listed in table A.14-1 dedicates approximately 100% of their time to these activities.

15. Explanation for Program Changes or Adjustments

We are requesting an increase of 17,407 burden hours. This increase in burden hours resulted from an increase in the number of responses (ART cycles) from 115,000 in 2004 to 138,030 in 2006 (see section 12.A.). The burden estimate for each response was revised from 37 minutes to 39 minutes per response, to include an adjustment for the data validation process. A minor wording change was made to the pre-implantation genetic diagnosis (PGD) question on the "Manipulation Techniques" NASS screen to improve clarity **(Attachment C3)**. The revised language identifies the genetic disposition of the parent(s) as one possible reason for selecting PGD and clarifies the language in the other categories. No other additions, deletions, or changes to the data collection instrument are proposed or requested.

16. Plans for Tabulation and Publication and Project Time Schedule

The ART reporting process includes data collection, validation, analysis, writing, editing and review, and publication. Table A. 16 – 1 presents the steps in this process with a timeline for the data flow. Altogether, there is an approximate two-year lag from when the last ART cycle of the year initiated is performed to the publication of the annual ART report. A detailed description

of the reporting process is provided below.

CDC uses a contractor to collect annual cycle-specific and clinic-specific data from all practicing assisted reproductive technology clinics in the U.S. and its territories. All U.S. clinics that perform ART are now required to submit data to contractor. All clinics that submit their data to this CDC-supported system are considered to be in compliance with FCSRCA.

In addition to data entry for each ART cycle, NASS includes programming that uses the cycle-level data to calculate key ART statistics for each clinic. The contractor develops this programming in conjunction with CDC to ensure that these clinic-level statistics meet the needs of the fertility clinic tables section of the annual ART report. Once the national data set of individual ART cycles is finalized, the contractor additionally compiles an *aggregate*-level data set of clinic statistics (clinic tables data set) and submits this file to CDC.

A. 16 – 1 Project Time Schedule

Activity	**Time Schedule**
ART Cycles are Performed	January-December, Year 0*
Data Collection and Data Management: Data collection materials distributed. Data submission instructions distributed. Clinics submit data to contractor. Data files compiled, checked for errors, cleaned and final data sets submitted to CDC.	 January, Year 0 By September, Year 1 December, Year 2 February-June Year 2
Data Validation: Contractor randomly selects clinics for validation and conducts site visits to all selected clinics.	March-June, Year 2
Data Analysis and Report Publication: CDC conducts data analysis. Contractor drafts report and sends to CDC. CDC staff review and edit report. Report reviewed and cleared by CDC science officer. Report published.	April-December, Year 2
Report released and disseminated	December, Year 2

*Year 0 refers to the year ART procedures were initiated, Years 1-2 refer to the years after the year ART procedures were initiated.

A.17. Reason(s) Display of OMB Expiration Date is Inappropriate.

No exceptions from display of expiration date are requested.

A. 18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exemptions to certification are sought.