

Assisted Reproductive Technology (ART) Program Reporting System

OMB Control Number 0920-0556

Revision Request

Supporting Statement: Part A

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Section 2(a) of the Federal Clinic Success Rate and Certification Act (FCSRCA) requires that each Assisted Reproductive Technology (ART) program shall annually report to the Secretary through the CDC: (1) pregnancy success rates achieved by such ART program, and (2) the identity of each embryo laboratory used by such ART program and whether the laboratory is certified or has applied for such certification under the Act. The ART data collection includes patient demographics, medical history and infertility diagnoses, clinical information pertaining to the ART procedure, and outcome information on resultant pregnancies and births.

CDC's primary objective in developing the ART reporting system is to publish the mandated annual pregnancy success rates report for Congress and provide accurate ART information needed by consumers. The clinic-specific profile data are required to provide consumers with general information about each ART program. 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. 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 based on outcomes for clients with similar characteristics.

ART reporting system is population-based as the respondents for this data collection activity are clinics that provide ART services in the U.S. and its territories. Clinics report both clinic-specific information and ART cycle-specific information to CDC through the National ART Surveillance System (NASS), a Web-based management information system. The cycle-specific profile data are organized with one record per cycle.

Overview

The Centers for Disease Control and Prevention (CDC) is currently approved to collect information needed to determine the annual pregnancy success rate of each clinic that provides assisted reproductive technology (ART) services (“*Assisted Reproductive Technology Program Reporting System*,” OMB No. 0920-0556, exp. 8/31/2015). This data collection is required by The Fertility Clinic Success Rate and Certification Act (FCSRCA), Section 2(a) of P.L. 102-493(42 USC 263 (a)-1) which mandates ART clinics to submit information to CDC and requires CDC to publish pregnancy success rates. A clinic’s pregnancy success rate for a given calendar year (January 1 – December 31) is the number of live births resulting from ART procedures initiated by the clinic in that calendar year. Cycles initiated during a calendar year need to be reported by December 15 of the following calendar year. For example, ART cycles initiated between January 1, 2013, and December 31, 2013, need to be reported by December 15, 2014. This schedule allows sufficient time for all ART pregnancies conceived in 2013 to have reached completion, and for clinic personnel to compile and report information about the ART cycles and outcomes.

CDC seeks OMB approval to continue information collection for three years, with changes. This revision request describes a transition plan for implementing modified reporting requirements during this approval period.

1. In 2015, information collection and reporting will continue as previously approved.
2. In 2015, CDC will conduct outreach and training activities to prepare clinics for modified reporting requirements that will go into effect on January 1, 2016. Modifications to the currently approved data items are needed to accurately describe current ART technologies and medical practices, and to accurately calculate the pregnancy success rate of each ART clinic. These changes are needed to provide the best information for consumers to evaluate the potential outcomes of individual procedures.
3. In 2015, CDC will test, deploy, and provide end-user training for a new and improved web-based data collection system to support the updated reporting requirements.
4. Beginning January 1, 2016, and thereafter, ART clinics will be required to collect information about ART procedures and outcomes according to the updated reporting requirements. The first report prepared according to the revised standards will be published by CDC in 2018.
5. During the three-year period of this OMB approval, the estimated annualized burden to respondents will increase due to:
 - a. A projected increase in the number of responding ART clinics;
 - b. A projected increase in the average number of ART procedures performed by each clinic;
 - c. A projected increase in the number of data elements needed to accurately describe each ART procedure; and
 - d. A one-time adjustment for training and preparatory activities associated with deploying the new web-based data collection system.

A. Justification

A.1. Circumstances Making the Collection of Information Necessary

Assisted Reproductive Technology (ART) encompasses a wide variety of medical treatments and procedures undertaken to establish pregnancy. These procedures include all treatments which involve the handling of human oocytes or embryos (e.g., in vitro fertilization, gamete intrafallopian transfer, and zygote intrafallopian transfer). Success rates are variable and are thought to be influenced by a variety of factors including the type of procedure(s) performed; characteristics of the patient, gestational carrier, egg donor or sperm donor; and characteristics of the laboratory support services. In response to concerns about data quality and comparability of ART outcomes, Congress enacted the Fertility Clinic Success Rate and Certification Act (FCSRCA) of 1992, (Public Law 102-493, **Attachment A1**). Key features of the Act include:

1. Requirement for all ART clinics to report pregnancy success rate data in a standardized manner to the Secretary of the Department of Health and Human Services through the Centers for Disease Control and Prevention (CDC). In addition, ART programs are required to report the identity of each embryo laboratory used by the program and whether the laboratory was certified (see Sec. 2 (a)(1) and 2(a)(2)). Information must be reported to CDC annually.
2. Requirement for CDC to publish and disseminate the pregnancy success rate(s) for each responding clinic and the certification information for embryo laboratories used by the clinic. CDC is also required by the law (see Sec. 6 (1)(A) and 6(1)(B)) to publish the name of each ART clinic that fails to report its information to CDC.
3. Guidance on definitions and principles used to produce reports on pregnancy success rates. Sections 2 (b)(1) and 2(b)(2) describe basic terms and calculations used to determine pregnancy success rates. Section 2 also acknowledges that various factors may affect success rates and directs [CDC] to take these factors into account when developing definitions associated with reporting.
4. Requirement for CDC to consult with appropriate consumer and professional organizations in the development of definitions used in conjunction with the required reporting to CDC and the calculation of success rates, overall and for individual consumers.

The first ART program data were submitted to CDC in 1995, establishing the National ART Surveillance System (NASS). On September 1, 2000, CDC published an informational Notice in the Federal Register, “Reporting of Pregnancy Success Rates from Assisted Reproductive Technology Programs” (see **Attachment C7a**). This Notice provided background information about FCSRCA and a technical appendix to clarify: (I) which entities are subject to FCSRCA reporting requirements, (II) the reporting process, (III) data items and definitions, and (IV) content of published reports. Because it includes content (e.g., applicability of FCSRCA requirements, content of published reports) that is outside the scope of the NASS Users’ Manual

(a procedures document), this Notice has been a key reference document for ART programs. CDC plans to publish an updated Notice upon receipt of OMB approval of proposed changes to the ART program reporting system. A draft of updated content for the Notice is included as **Attachment C7b** (Draft Updated NASS Reporting Requirements).

Currently, ART clinics continue to report information to CDC through the electronic NASS information management system. Screen shots of the current NASS are provided in **Attachment C1a (Current)**; submission instructions are provided in **Attachment C2**; and the NASS Users' Manual is provided in **Attachment C3**. The medical director of each clinic, or a designee, is required to submit ART cycle information to CDC annually by an established deadline and to verify by signature that the data reported are accurate. Clinics that fail to submit the required materials by the deadline are considered noncompliant with the federal reporting requirements. These clinics will be identified as non-reporters in CDC's annual ART report and on CDC's website, <http://www.cdc.gov/art>. The text of the FCSRCA (Public Law 102-493) is included as **Attachment A1**. CDC is authorized to conduct data collection under section 301 of the Public Health Service Act (42 U.S.C. 241) (**Attachment A2**).

Three types of information are reported to CDC:

- I. Information needed to identify the reporting clinic (e.g., clinic name and address, name of embryo laboratory used, and services provided).
- II. Information needed to produce and interpret ART success rates. This information is submitted as one record per ART cycle, where 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. This information includes clinical information pertaining to the ART procedure, outcome information on resultant pregnancies and births, and information on factors that may affect outcomes, such as de-identified patient demographics, medical history, diagnosis of infertility, etc.
- III. An optional feedback survey at the end of the data submission for each reporting year (see **Attachment C4**). Participation in the feedback survey is voluntary. The purpose of the feedback survey is to obtain insight into NASS usability issues as well as respondents' perspectives on the usefulness of the information collection. No information is collected directly from the patients who utilize the clinics.

As required by FCSRCA, CDC disseminates information submitted by clinics through ART reports, surveillance summaries, and supplemental publications. The core publication is an annual ART report that includes an aggregate summary of information reported by ART clinics (or programs), and specific information about each reporting clinic with cross-tabulations of pregnancy success rate according to the characteristics of specific ART procedures and selected patient demographics such as maternal age. Importantly, the report also includes guidance about how to interpret the information provided in the data tables. Together, the data tables and guidance provide actionable information that can inform decision making by ART providers, consumers, and the public.

CDC, the data collection contractor, and partner organizations, such as the Society for Assisted Reproductive Technology (SART), engage in ongoing dialogue to identify opportunities for improvement in NASS. In this Revision request, CDC outlines plans to implement revised reporting requirements for ART cycles initiated on or after January 1, 2016. The proposed changes will affect select reporting requirements, data definitions, NASS variables, and reporting procedures. The revised reporting requirements are necessary to keep pace with current medical practice and the rapidly changing technologies of ART treatments and procedures. The revised reporting requirements also incorporate new or modified fields that are needed to calculate pregnancy success rate(s), taking into account important factors related to the diverse consumer population (see FCSRCA Section 2(b)), and that can be used to inform decision making by consumers and health care providers. Proposed changes for ART cycles initiated on or after January 1, 2016, are summarized in **Attachment C5** (Overview of Changes to NASS Data Elements) and **Attachment C6** (Detailed List of Changes to NASS Data Elements). During the 60-day comment period, a total of 7 comments were received. See **Attachment B2** (Summary of Public Comments and CDC response). The revised data elements will be reported through an updated NASS interface (see **Attachment C1b**-NASS Screens-Proposed starting 2016).

Changes will be implemented in stages over the three-year period of this revision request.

- In 2015, information collection will continue as previously approved; however, CDC will conduct outreach and training with ART clinics and stakeholders to prepare for phased implementation of revised reporting requirements. Changes to the web-based reporting system are being coordinated with changes in the content of the submissions. The current NASS web-application and the underlying backend database (developed in 2003) will be redesigned and migrated to a new platform to accommodate the new or modified variables, revised content, and improved security features; it will also incorporate skip patterns and pre-filled information and an updated graphical user interface. CDC will provide technical assistance to clinics, as needed, on the updated data definitions as well as deployment and use of the new submission system.
- On January 1, 2016, ART clinics will begin to collect information according to the revised standards and enter 2016 data into the updated electronic submission system. CDC will continue to provide technical assistance as needed.

As CDC and clinics gain experience with the revised reporting requirements, minor changes to NASS data definitions or similar technical adjustments may be proposed. Non-substantive changes will be submitted to OMB through the Change Request mechanism. CDC will also provide OMB with a copy of the revised NASS Users' Manual when its content is finalized.

A.2. Purpose and Use of Information Collection

CDC's primary objective in developing the ART reporting system is to make timely and relevant ART success rate information available to Congress, the states, and the public. For the convenience of specific audiences, information is disseminated in a variety of formats and

communication channels, however, all publications are available to all members of the public. CDC produces an annual Fertility Clinic Success Rates Report, which a key publication available to Congress, individual clinics, consumers, the states, and the general public. This report provides clinic-specific profile data needed to provide consumers with general information about each ART program, by clinic name and location. In addition, for each ART program, the report provides a table which displays tabulated results of pregnancy success rates for all reported ART procedures at the individual clinic. The detailed ART cycle-specific profile data are used to ensure that success rate calculations for each clinic are based on standardized data definitions and methodology.

CDC also publishes an annual National Summary Report using pooled data presented as graphs and charts to provide an in-depth picture of the type, number, and outcomes of ART cycles performed in the United States. CDC also uses the pooled data to publish an annual ART Surveillance Summary (MMWR) with state-specific information on ART procedures and their outcomes. These reporting formats are primarily used by states for state-based surveillance and to inform maternal and child health programs.

The information compiled by CDC for the required clinic-specific reports provides additional opportunities for secondary analysis and supplemental publications. These activities allow CDC and others to examine events or outcomes that are too rare to be published annually – for example, due to small sample sizes, some annual estimates would be unstable, or presentation of information could present a risk to patient privacy. Findings from secondary analyses are typically disseminated through special-purpose journals for health care providers, epidemiologists, and other professional groups. These contributions facilitate public discussion about a variety of issues that are integral to ART success rate reporting and are not specific to individual clinics, such as the definition of outcome measures or factors that influence ART success rates.

Some recent examples of supplemental publications that have allowed CDC to disseminate findings for small population subgroups, emerging treatment options, and rare outcomes include:

- Publications on small population subgroups (by medical diagnosis):
 - Kawwass JF, Crawford S, Session DR, Kissin DM, Jamieson DJ; National ART Surveillance System Group. Endometriosis and assisted reproductive technology: United States trends and outcomes 2000-2011. *Fertil Steril*. 2015 Jun;103(6):1537-43.
 - Grigorescu V, Zhang Y, Kissin DM, Sauber-Schatz E, Sunderam M, Kirby RS, Diop H, McKane P, Jamieson DJ. Maternal characteristics and pregnancy outcomes after assisted reproductive technology by infertility diagnosis: ovulatory dysfunction versus tubal obstruction. *Fertil Steril*. 2014 Apr;101(4):1019-25.
 - Kawwass JF, Crawford S, Kissin DM, Session DR, Boulet S, Jamieson DJ. Tubal factor infertility and perinatal risk after assisted reproductive technology. *Obstet Gynecol*. 2013 Jun;121(6):1263-71.
- Publications on ART treatment options:
 - Boulet SL, Mehta A, Kissin DM, Warner L, Kawwass JF, Jamieson DJ. Trends in use of and reproductive outcomes associated with intracytoplasmic sperm injection.

- JAMA. 2015 Jan 20;313(3):255-63.
- Kissin DM, Kawwass JF, Monsour M, Boulet SL, Session DR, Jamieson DJ; National ART Surveillance System (NASS) Group. Assisted hatching: trends and pregnancy outcomes, United States, 2000-2010. *Fertil Steril*. 2014 Sep;102(3):795-801.
 - Steinberg ML, Boulet S, Kissin D, Warner L, Jamieson DJ. Elective single embryo transfer trends and predictors of a good perinatal outcome--United States, 1999 to 2010. *Fertil Steril*. 2013 Jun;99(7):1937-43.
 - Marsh C, Farr S, Chang J, Kissin D, Grainger D, Posner S, Macaluso M, Jamieson D. Trends and Factors Associated with Day 5 Embryo Transfer, Assisted Reproductive Technology Surveillance, United States, 2001 – 2009. *Human Reproduction*. 2012 Aug;27(8):2325-31.
- Publications on rare outcomes:
 - Kawwass JF, Kissin DM, Kulkarni AD, Creanga AA, Session DR, Callaghan WM, Jamieson DJ; National ART Surveillance System (NASS) Group. Safety of assisted reproductive technology in the United States, 2000-2011. *JAMA*. 2015 Jan 6;313(1):88-90.
 - Kanter JR, Boulet SL, Kawwass JF, Jamieson DJ, Kissin DM. Trends and correlates of monozygotic twinning after single embryo transfer. *Obstet Gynecol*. 2015 Jan;125(1):111-7.
 - Perkins KM, Boulet SL, Kissin DM, Jamieson DJ; National ART Surveillance (NASS) Group. Risk of ectopic pregnancy associated with assisted reproductive technology in the United States, 2001-2011. *Obstet Gynecol*. 2015 Jan;125(1):70-8.
 - Kissin DM, Zhang Y, Boulet SL, Fountain C, Bearman P, Schieve L, Yeargin-Allsopp M, Jamieson DJ. Association of assisted reproductive technology (ART) treatment and parental infertility diagnosis with autism in ART-conceived children. *Hum Reprod*. 2015 Feb;30(2):454-65.
 - Fountain C, Zhang Y, Kissin DM, Schieve LA, Jamieson DJ, Rice C, Bearman P. Association between assisted reproductive technology conception and autism in California, 1997-2007. *Am J Public Health*. 2015 May;105(5):963-71.

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. As outlined in the FCSRCA, Sections 2 (b)(1) and 2(b)(2), these various factors may affect success rates and thus CDC is directed to take these factors into account when developing definitions associated with reporting.

ART technologies and other medical practices change over time. The updated NASS variables will allow CDC to more effectively report ART effectiveness and safety in a manner that is consistent with current practice: these changes will allow CDC to keep pace with future advances in the field, improve data quality and comparability by standardizing definitions. The updates are also essential for reducing the likelihood of misclassification or under-reporting of information used to calculate pregnancy success rates.

CDC also uses the data to monitor information that may affect ART treatment outcomes. Other data may not be released to protect the ART patient's confidentiality, but may be included in periodic supplemental publications once sufficient years of data have accumulated. A detailed list of changes to NASS data elements and justification is summarized in **Attachment C6**. The list of proposed NASS variables, information on the reasons for collecting these variables in accordance with FCSRCA (whether they are used in calculation of success rates or may affect success rates), and dissemination and publication plan are summarized in **Attachment C8a**. The list of measures of ART success, as well as detailed success rate calculations, are summarized in **Attachment C8b**. In addition, this unique population-based database is used for epidemiological studies to address safety and efficacy issues related to ART treatment for improving maternal and child health outcomes (**Attachment D**). The CDC Institutional Review Board (IRB) approved the use of the NASS information for epidemiological studies (**Attachment E1**).

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

Since 2004, clinics have submitted ART cycle information electronically through NASS, a web-based data management system (**Attachment C1a**). Respondents also have the option of transmitting NASS-compatible electronic files that can be uploaded into the NASS database if they prefer to do so. CDC's 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 Fertility Clinic Success Rates Report. Once the national data set of individual ART cycles is finalized, the data collection contractor additionally compiles an *aggregate* clinic-level data set of clinic statistics and submits this file to CDC electronically.

An updated and improved electronic management and reporting system will be deployed during the period of this clearance request. Reorganized data entry screens with conditional data entry logic have been designed to reduce respondent burden and improve data quality (**Attachment C1b**).

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

The Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA) 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.

Some clinics that are required to report information to CDC are also members of SART, a professional association. These clinics are required to report cycle-specific data to SART as a condition of their membership. As a courtesy to these clinics and to SART, CDC accepts submissions from SART's Clinical Outcome Reporting System (CORS) on behalf of its member clinics. This arrangement allows clinics to use one transmission (to SART) for two purposes:

SART membership (which is not required by the federal government) and fulfillment of federal reporting requirements (which is required under FCSRCA). However, the information available to SART does not include information about clinics that are not SART members, and is not a substitute for required reporting to CDC under FCSRCA.

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 secure 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 as non-reporters in the annual ART Fertility Clinic Success Rates Report.

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. 79, No. 139, pages 42328-42329) was published on July 21, 2014 (**Attachment B1**). During the 60-day comment period, a total of 7 comments were received. See **Attachment B2** for public comments and responses. This attachment includes the original public comments and a summary of the comments with CDC's responses, in table form. A narrative summary of the comments and CDC's responses is provided below.

In response to public comments regarding estimated burden, CDC acknowledges that there is an additional burden for the first year of this transition associated with making the appropriate software modifications that was not represented in the Federal Register Notice published on July 21, 2014. In order to minimize the impact of this burden on clinic operations, clinics will have a full calendar year to implement changes, as the new data collection system will be implemented on January 1, 2016. We have also recalculated the burden for the first year to include the fixed burden associated with changes to the data collection systems in each clinic (see Table 12-1).

With regard to the addition of variables that were considered to go beyond the scope of the Fertility Clinic Success Rate and Certification Act of 1992, CDC feels that the modifications to the NASS data elements are essential to keep pace with changes in medical practice, to ensure that reported success rates reflect standardized definitions, and to provide additional insight into factors that may affect success rates. Additional variables regarding maternal and infant outcomes, such as maternal morbidity, delivery methods, and detailed neonatal-associated variables and neonatal morbidity were suggested. Many of the suggested data elements are only available through vital records (i.e. birth certificates, fetal death certificates) and NASS does not collect information from birth certificates. Thus, collection of these additional variables is not feasible as part of this effort. In general, method of delivery is usually only available through either the birth certificate or from the OB-Gyn care providers; however, method of delivery was added to the data collection as CDC agrees this information could be reliably reported by the patient.

In regards to comments on duplication of ART data collection by SART, while CDC is required to collect and report pregnancy success rates achieved by each ART program under the FCSRCA, Section 2(a) of Public Law 102-493, the collection of ART outcomes by SART is not required by this law.

- b) The field of ART is a rapidly developing medical science. The ART data collection instruments, variables, and definitions are periodically reviewed and updated as new knowledge concerning ART methods and techniques becomes available. Therefore, professional and consumer groups and individuals are consulted to confirm the validity of the new or revised data collection tools.

The representatives of these organizations, listed below, consulted with CDC on ART topics

American Society for Reproductive Medicine (ASRM):

Rebecca Sokol, M.D., M.P.H.
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American Urological Association

Ajay Nangia, MBBS, F.A.C.S.
University of Kansas Hospital and Medical Center
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Society of Assisted Reproductive Technology (SART):

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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

A. 10.1 Privacy Impact Assessment Information

Overview of the Information Collection System

The respondents for this data collection activity are clinics that provide ART services in the U.S. and its territories. Clinics report both clinic-specific information and ART cycle-specific information to CDC through the National ART Surveillance System (NASS), a Web-based management information system. Access to the website is restricted to approved users and does not contain any links to any other websites. NASS does not involve any content directed to children of any age.

Clinic staff extract the clinical data from patient medical records and either upload the de-identified clinical data into NASS directly or export data from other electronic medical record systems into NASS-compatible data files. Patients do not directly enter data into the NASS.

Information to be Collected

Section 2(a) of FCSRCA requires that each ART program shall annually report to the Secretary through the CDC: (1) pregnancy success rates achieved by such ART program, and (2) the identity of each embryo laboratory used by such ART program and whether the laboratory was certified or had applied for such certification under the Act. It is important to note that ART success rates vary in the context of patient demographics and treatment characteristics. ART data collection includes age, pregnancy history, infertility diagnosis, number of embryos transferred, type of ART procedure, use of techniques such as intracytoplasmic sperm injection (ICSI), preimplantation genetic diagnosis (PGD), and outcome information on resultant pregnancies and births (see **Attachments C1a and C1b**). The pregnancy success rates and their imputations (including data elements used for the imputation) are presented in the annual ART Fertility Clinic Success Rates Report. In addition, information on embryo laboratory accreditations, certified from 1) College of American Pathologists (CAP); 2) The Joint Commission; or 3) New York State Tissue Bank Program (NYSTB) is also collected and presented as part of the annual ART Fertility Clinic Success Rates Report.

How Information Will Be Shared and for What Purpose

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

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

about any individual patient will not be disclosed in any reports, statistical summaries, or to unauthorized entities. Unauthorized disclosure of the information in identifiable form (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.

Impact on the Respondent's Privacy

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. A number of review procedures and security measures have been put in place to protect patient privacy. CDC's Institutional Review Board oversees certain types of data analysis conducted with this information collection (see IRB approval letter, **Attachment E1**), and 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 (see **Attachment E2**). 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.

Consent and Nature of Response

For FCSRCA-mandated reporting, respondents are ART clinics and annual reporting to CDC is required. No consent is obtained from patients whose medical information is recorded in the ART surveillance data files. A waiver of informed consent for the collection of data under the FCSRCA has been approved, based on the criteria described in Code of Federal Regulations, Title 45, Section 46.116. As such, it has been determined that the mandated reporting involves no more than minimal risk to the subjects and will not adversely affect the rights and welfare of the subjects. In addition, this information could not practicably be ascertained without the waiver or alteration.

How Information Will Be Secured

To prevent inadvertent disclosure, 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.

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. Time out logs are used to automatically log out of a session that remains idle for a specified period of time. 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. 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. Additional technical controls in

place include firewalls, encryption, and an intrusion detection system. Physical access controls in place include guards, identification badges, key cards, and other security measures. CDC's Office of Information Security Management has identified NASS as a moderate security risk for security certification and accreditation (C&A). A current certification and accreditation (C&A) of NASS is approved with authorization to operate (ATO) until 04/03/2017.

A contractor operates and maintains NASS. Administrator controls in place include regular backups, security training, completion of a security C&A, security plans, and policies. Access to NASS and the ART information collected is limited to contractor staff supporting 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.

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. Data are encrypted using Transport Layer Security (TLS) during transmission to the NASS.

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.

Privacy Act Determination

Preliminary review of this application determined that the Privacy Act applies. Even though the NASS 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."

A.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) treatment outcome information. The database also contains particularly sensitive information such as number of pregnancies lost, use of donor eggs, sperm, or embryos.

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.

A.12. Estimates of Annualized Burden Hours and Costs

a) Burden Hours

Respondents are clinics that provide ART services. Three types of burden are itemized in the burden table.

- I. The burden of reporting data used to calculate each clinic's annual pregnancy success rate (required; annual; see **Attachment C1a and Attachment C1b**).
- II. The burden of participating in a voluntary annual feedback survey (optional; annual; see **Attachment C4**).
- III. The burden of training and preparatory activities associated with implementing revised reporting procedures (required; one-time adjustment annualized over this 3-year clearance request; see Attachment C1b, Attachment 5, and **Attachment C6**).

I. Burden of Reporting ART Cycle Data

To calculate the burden of reporting information required by the FCSRCA, each ART cycle is considered one response. The average burden for reporting one ART cycle is an average across clinics and includes time to gather records, follow up with patients among the 30% of cycles that resulted in pregnancy, 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. The average number of responses per respondent (i.e., the average number of ART cycles reported by each clinic) is calculated by dividing the total number of ART cycles reported to CDC by the total number of respondents.

A number of factors used to estimate burden will change during this three-year clearance request as additional clinics report on ART services and CDC transitions to modified reporting requirements.

- In 2015, we estimate that 440 clinics will submit an average of 339 responses each and approximately 8-10% of the reporting clinics are randomly selected for data validation (35 ART clinics were selected for validation in 2013). The average burden for validation procedures was estimated at 23 minutes per cycle validated (see Attachment H for validation description). 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 based on current NASS reporting standards and procedures. Since July 2005, respondents have the option of entering information directly into the web-based NASS (**Attachment C1a**), or of transmitting NASS-compatible files that can be uploaded into the database. Each clinic receives submission instructions in an annual letter (**Attachment C2**). Instructions to respondents are provided in the NASS User's Manual

(Attachment C3).

- In 2016 and 2017, we estimate that 450 clinics will report on an average of 360 responses each year. These responses will be based on modified reporting standards (see **Attachment C5 and Attachment C6**; upon OMB approval of this Revision, the interface will be finalized and revised screen shots will be uploaded as outlined in **Attachment C1b**). The average burden per response is 43 minutes. Although the modified reporting requirements include additional data elements, pre-testing with a prototype of the new interface indicates that burden per response will increase only slightly, due to improved organization of the data entry screens and more efficient conditional logic including the capacity to auto-fill responses when applicable.

To reflect changes in the factors used to estimate burden, Table A.12-1 is based on adjusted averages over the three-year period of this Revision request.

The adjusted annualized number of responding clinics [by year] was calculated as follows: $(440 [2015] + 450 [2016] + 450 [2017]) / 3 = 447$.

The adjusted annualized number of responses per respondent [by year] was calculated as follows: $(339 [2015] + 360 [2016] + 360 [2017]) / 3 = 353$.

The adjusted annualized burden per response [by year] was calculated as follows: $(39/60 [2015] + 43/60 [2016] + 43/60 [2017]) / 3 = 42/60$. **The adjusted annualized burden per response includes an allocation for data validation (Attachment H).** Each year, 8-10% of clinics are selected to participate in a data validation process.

II. Burden of Annual Feedback Survey

In 2012, CDC implemented a brief, optional feedback survey to clinics (**Attachment C4**). CDC estimates that approximately 335 clinics (75% of 447, the adjusted average number of reporting clinics) will participate in the voluntary feedback survey. The estimated burden per response is 2 minutes.

III. Burden of Implementing Revised Reporting Requirements

CDC anticipates that the revised reporting requirements will entail an additional burden of 40 hours for each responding clinic. This estimate includes system deployment and preparatory activities such as staff training, which will occur primarily in 2015. In the burden table, 149 respondents $(447 / 3)$ are used to represent annualization of this activity over the 3-year clearance period.

The total estimated annualized burden for all information collection is 116,425 hours.

A. 12 – 1 Estimated Annualized Burden Hours

Respondents	Form Name	No. of Respondents	Average No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
ART Clinics	NASS	447	353	42/60	110,454
	2015 Feedback Survey	335	1	2/60	11
	One-time System Deployment	149	1	40	5,960
Total					116,425

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 85% 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 \$43.00 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 2011 General Schedule: Data entry clerks, \$18 per hour; Nurses, \$33 per hour; Lab Technicians, \$18 per hour; Physicians, \$101 per hour. The total annualized cost to respondents for both data entry and data validation is estimated to be \$5,006,275.

A. 12 – 2 Annualized Cost to Respondents

Respondents	Total Burden (in hours)	Average Hourly Wage Rate	Respondent Cost
ART Programs (data entry, data validation, and feedback survey)	116,425	\$43.00	\$5,006,275

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

There are no additional costs to respondents or record keepers.

A.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 Surveillance Program	
Contract	Annualized Cost
1. Total labor	\$229,078
2. Total other direct costs	\$151,744
3. Total overhead	\$216,846
4. General and administrative expense	\$96,634
5. Fee @ 8%	\$55,544
Subtotal	\$749,846
CDC/NCCDPHP/DRH/WHFB FTEs	Salary
1. Epidemiologist, GS-601-14	\$101,035
2. Epidemiologist, GS-601-13	\$99,749
3. Health Scientist, GS-601-13	\$99,749
4. Statistician, GS-1529-13	\$91,200

Subtotal	\$391,733
Total Federal Government Cost	\$1,141,579

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 FCSRCA, 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.

A.15. Explanation for Program Changes or Adjustments

The ART Program Reporting System clearance was previously approved with 96,960 annualized burden hours. The current estimate is 116,425 annualized burden hours, an increase of 19,465 hours. Increases reflect an estimated increase in the number of reporting clinics, an estimated increase in the number of ART cycles reported by each clinic, and a one-time allocation of burden associated with training on revised reporting requirements and implementation of an updated user interface for NASS.

A.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 ART clinics in the U.S. and its territories. All U.S. clinics that perform ART are now required to submit data to this contractor via NASS. 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 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-May 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.