

Assisted Reproductive Technology (ART) Program Reporting System

OMB Control Number 0920-0556

Extension Request

Supporting Statement: Part A

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- **Goal of the study:** To comply with Section 2(a) of the Federal Clinic Success Rate and Certification Act (FCSRCA) requiring that each Assisted Reproductive Technology (ART) clinic submits information to CDC and that CDC publishes pregnancy success rates; to provide consumers the information they need to make informed decisions about fertility treatments; and to conduct secondary epidemiologic analyses to address safety and efficacy issues related to ART treatment for improving maternal and child health outcomes.
- **Intended use of the resulting data:** Information collected is used to publish the mandated annual clinic-specific pregnancy success rates report for Congress and provide accurate ART information needed by consumers. Clinic-specific profile data provide consumers with general information about each ART program. 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 technology 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.
- **Methods:** 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. Secondary epidemiologic analyses are conducted to address safety and efficacy issues related to ART treatment for improving maternal and child health outcomes.
- **The subpopulation to be studied:** NASS includes information on all clinics that provide ART services in the U.S. and its territories. Clinics report both clinic-specific information and ART cycle-specific information.
- **How data will be analyzed:** Descriptive and multivariate analyses will be performed using SAS or STATA statistical software.

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. 7/31/2018). 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, 2017, and December 31, 2017, need to be reported by December 15, 2018. This schedule allows sufficient time for all ART pregnancies conceived in 2017 to have reached completion, and for clinic personnel to compile and report information about the ART cycles and outcomes.

CDC seeks OMB approval on a Revision request to continue information collection for an additional 3 years. Compared to the burden previously approved, the annualized burden requested is lower, due to the burden that was associated with a one-time system upgrade that is no longer needed. However, some of this reduction will be offset by an increase in the number of ART clinics and cycles reported, due to an increase in the utilization of ART in the United States.

a.

A. Justification

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.

Currently, ART clinics continue to report information to CDC through the electronic National ART Surveillance System (NASS) information management system. Screen shots of the current NASS are provided in **Attachment C1**; 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 first to submit ART cycle information to CDC annually by an established deadline and then 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 also 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.

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, a key publication available to Congress, individual clinics, consumers, the states, and the general public. This report provides clinic-specific profile data and provides consumers with general information about each ART program, by clinic name and location. In addition, for each ART program, the report provides a table showing pregnancy success rates for all reported ART procedures at individual clinics. 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 aggregation over years 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 where annual estimates would be unstable, or presentation of information could present a risk to patient privacy. 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**). Related to these activities, in addition to use for public health surveillance (**Attachment E1**), the CDC Institutional Review Board (IRB) has approved the use of the NASS information for epidemiological studies (**Attachment E2**). Findings from secondary analyses are typically disseminated through peer-reviewed 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 identifying factors that influence ART success rates.

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 C1**). In addition to direct data entry, NASS allows clinics to import data directly from compatible electronic medical record systems. CDC also accepts submissions from SART's Clinical Outcome Reporting System (CORS) from members of SART, as the information required under FCSRCA is also collected in SART CORS. This arrangement allows clinics to use one transmission to meet the requirements of the federal government and SART membership.

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.

A recently updated and improved electronic management and reporting system is available for deployment 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 C1**).

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. This information is collected through NASS and is the only source of population-based, and clinic level data on all ART procedures. Although some states include a small amount of information about the use of ART on birth certificates, this information is limited in scope (e.g., the birth certificate might address “Was this child conceived using ART? Yes/No”), uses non-standard variables and inconsistent definitions of ART, and does not capture the use of ART not resulting in live birth. Therefore, birth certificate data cannot be used to calculate success rates.

Additionally, while SART’s CORS does contain the information requested through NASS on ART procedures that do and do not result in livebirth, SART’s CORS does not collect data from non SART members, and therefore does not include information on all clinics. As a condition of membership, SART requires member clinics to report cycle-specific data to SART CORS. For the approximately 85% of reporting clinics that are members of SART, to prevent duplication of efforts and to reduce burden on providers, CDC accepts submissions from SART CORS from members of SART, as the information required under FCSRCA is also collected in SART CORS. This arrangement allows clinics to use one transmission to meet the requirements of the federal government and SART membership.

Collection of the FCSRCA-required ART data and the publication of the annual report are not conducted elsewhere within CDC or within the Department of Health and Human Services.

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 an intuitive web-based system that embeds logic and skip patterns to route users to the minimum number of applicable questions.

To further avoid duplication of efforts and minimize burden, ART programs also have the option of transmitting system-compatible files from the SART CORS to NASS, instead of entering data directly into the web-based NASS interface. ART programs that submit data through SART may be charged fees by SART to use their services.

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.

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) A 60-day notice was published in the Federal Register on May10, 2018 (83 FR 21779) to make the public aware of this proposed information collection (**Attachment B**). No public comments were received.
- b) The field of ART has seen rapid change with new developments in medical science. Therefore, professional and consumer groups and individuals have been consulted to confirm the validity of all ART data collection instruments, variables, and definitions, and will continue to be consulted on a periodic basis as new knowledge concerning ART methods and techniques becomes available.

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

American Society for Reproductive Medicine (ASRM):

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Society of Assisted Reproductive Technology (SART):

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9. Explanation of Any Payment or Gift to Respondents

No payment or gifts will be provided to respondents.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

CDC's Information Systems Security Officer has determined that the Privacy Act does apply (**Attachment E3**). The SORN is 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems."

Three types of information are reported to CDC:

- 1) Clinic information needed to identify the reporting clinic. Clinics submit clinic-specific profile data such as clinic name and address, name of embryo laboratory used, and services provided.
- 2) Patient information needed to produce and interpret ART success rates. No direct patient identifiers (e.g., patient name, street address, or SSN) are collected, although sensitive information that could be used to indirectly identify patients is obtained, including demographics, medical history, patient date of birth, infant date of birth, diagnosis of infertility, clinical information pertaining to the ART procedure, outcome information on resultant pregnancies and births, and information on factors that may affect outcomes. Cycle-specific profile data are organized with one record per cycle (**Attachment C1**).
- 3) 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.

The Fertility Clinic Success Rate and Certification Act (FCSRCA) of 1992 requires the medical director of each clinic, or a designee, to submit ART cycle 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. In addition, clinics are required to update the clinic profile information, including embryo laboratory accreditation annually.

No information is collected directly from the patients who utilize the clinics. ART clinic staff extract the clinical data from patient medical records and the clinics have the option to upload ART data directly into a secure, web-based data collection system (the National ART Surveillance System, NASS), or to transmit NASS-compatible files that have been extracted from other medical record systems. CDC also accepts submissions from SART's Clinical Outcome Reporting System (CORS) from members of SART as the information required under FCSRCA is also collected in SART CORS. This arrangement allows clinics to use one transmission to meet the requirements of the federal government and SART membership.

CDC employs a contractor to operate and maintain NASS. Administrator controls in place include regular backups, security training, completion of a security C&A, security plans, and policies. Technical controls include firewalls, encryption, and an intrusion detection system. Physical access controls include guards, identification badges, key cards, and other security measures.

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 ensure that all data is

encrypted following the Data Encryption Standard (DES) or triple-DES encryption standard. The contractor either provides for the encryption of the data files as a whole, or programmatically encrypts 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.

Directly identifiable data remain with each individual clinic and are not shared or disclosed to public entities, external agencies, or other people or organizations outside the agency. Nonetheless, because some information contained in the database could indirectly identify the patients or link sensitive information with individually indefinable clinics, an Assurance of Confidentiality has been granted to safeguard the confidentiality of the information collected in NASS and the information maintained by the clinics (see **Attachment E4**). NASS does not involve any content directed to children of any age.

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**). Clinic directors and data entry personnel who are authorized to submit information to NASS are required to enter a unique and valid user ID and password to gain access. 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. 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.

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.

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. The collected information could not practicably be ascertained without the waiver

or alteration. CDC’s Institutional Review Board oversees certain types of data analysis conducted with this information collection (see IRB approval letter, **Attachment E2**) and the PII collected in NASS is protected by an Assurance of Confidentiality under Section 308(d) of the Public Health Service Act (see **Attachment E4**).

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

CDC's IRB has approval to conduct epidemiological analyses with NASS data under protocol #2238 “Assisted Reproductive Technology Database-Protocol for Epidemiologic Research” (**Attachment E2**).

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.

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 C1**).
- II. The burden of preparing ART data for data validation and quality control process (required; annual; see **Attachment H**).
- III. The burden of participating in a voluntary annual feedback survey (optional; annual; see **Attachment C4**).

Burden of Reporting ART Cycle Data

To calculate the burden of reporting information required by the FCSRCA, each ART cycle is considered one response (**Attachment C1** for reporting data elements). We estimated the average burden per response is 42 minutes. The burden is averaged across cycles and 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, upload data for each record into the software system, and verify the clinic-specific summary report as required for submission to CDC. Because not all ART cycles result in egg retrieval,

embryo transfer, or pregnancy, NASS embeds logic and skip patterns to minimize the number of questions asked to those which are applicable. This results in an estimated average completion of 42 minutes, which is shorter than would be the case if the full form were completed for each cycle.

The estimated number of respondents (clinics) is 464, based on the number of clinics that provided information in 2015. The average number of responses per respondent (i.e., the average number of ART cycles reported by each clinic) is 350, which was calculated by dividing the total number of ART cycles reported to CDC by the total number of clinics.

In addition to reporting for each cycle, every year approximately 5-10% of the reporting clinics are randomly selected for data validation (35 ART clinics were selected for validation in 2015). In each selected clinic, the validated sample included up to 60 ART cycles resulting in pregnancy for full validation and up to 10 embryo banking cycles and 10 additional cycles for partial validation. A description of the full and abbreviated validation is included (**Attachment H**). The average burden for preparation of validation procedures was estimated at 23 minutes per cycle validated. This burden includes pulling the medical records together and flagging the validated variables for the validators.

The average estimated burden for reporting information related to each cycle has not increased from the time burden previously approved. However, given the increasing number of cycles at each clinic and the increasing number of clinics, the total annual burden is higher than approved in previous years.

Burden of Annual Feedback Survey

Since 2012, CDC has been implementing a brief, optional feedback survey to clinics (**Attachment C4**). CDC estimates that approximately 348 clinics (75% of 464, the adjusted average number of reporting clinics) will participate in the voluntary feedback survey. The estimated burden per response is 2 minutes.

The total estimated annualized burden for all information collection is 114,631 hours.

A. 12 – 1 Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
ART Clinics	NASS Reporting Form (Attachment C1)	464	350	42/60	113,680
	Data Validation (Attachment H)	35	70	23/60	939
	Feedback Survey (Attachment C4)	348	1	2/60	12

	Total	114,631
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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, such as SART membership, the total burden estimate in this Information Collection Request reflects the total time commitment for collecting, validating, and reporting ART cycle information.

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 \$45.00 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 2014 General Schedule: Data entry clerks, \$19 per hour; Nurses, \$35 per hour; Lab Technicians, \$19 per hour; Physicians, \$106 per hour. The total annualized cost to respondents for both data entry and data validation is estimated to be \$5,158,395.

A. 12 – 2 Annualized Cost to Respondents

Respondents	Form Name	Total Burden (in hours)	Average Hourly Wage Rate	Respondent Cost
ART Programs (data entry, data validation, and feedback survey)	NASS	113,680	\$45.00	\$5,115,600
	Data Validation	939	\$45.00	\$42,255
	Feedback Survey	12	\$45.00	\$540
		114,631	\$45.00	\$5,158,395

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
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Assisted Reproductive Technology Surveillance Program	
Contract	Annualized Cost
1. Total labor	\$240,532
2. Total other direct costs	\$159,331
3. Total overhead	\$227,688
4. General and administrative expense	\$101,466
5. Fee @ 8%	\$58,321
Subtotal	\$787,338
CDC/NCCDPHP/DRH/WHFB FTEs	Salary
1. Epidemiologist, GS-601-14	\$106,086
2. Epidemiologist, GS-601-13	\$104,736
3. Health Scientist, GS-601-13	\$104,736
4. Statistician, GS-1529-13	\$104,736
Subtotal	\$420,294
Total Federal Government Cost	\$1,207,632

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.

15. Explanation for Program Changes or Adjustments

The ART Program Reporting System was last approved for a total annualized burden of 111,769 hours for collection of cycle data (**Attachment C1**); an additional annualized burden of 11 hours was approved for the feedback survey (**Attachment H**), and 5,960 hours for a one-time system update (completed and not included in the current request). The total previously approved annualized burden totaled 117,740 hours. The current information request is for a total of 114,631 hours, a reduction of 3,109 hours in the annualized burden. This decrease was primarily related to the exclusion of hours for implementing the one-time system update. This one-time update was completed in 2015 under the prior approval and is no longer needed. The decrease in burden related to the completion of this update is partially offset by an increase in the number of respondents (clinics) and therefore number of cycles (responses) related solely to the increased utilization of ART procedures in the United States. Changes in the distribution of burden hours are summarized below.

Form Name	Change in number of respondents	Change in number of responses per respondents	Change in time per response	Net change in burden
NASS Reporting Form (Attachment C1)	The number of clinics has increased by 17 (from 447 to 464) based on the number of clinics reporting in 2015.	The estimated number of cycles per clinic has decreased by 3 (from 353 to 350) based on the number of reported cycles per clinic in 2015.	The total time to complete the information requested for each cycle was most recently updated in a change request approved on 05/17/2017 to 42.5 minutes. This estimate included the data validation, completed by a 5%-10% sample, averaged over all clinics. The time for validation has now be separated (see Attachment H), reducing the burden estimate for the NASS reporting form from 42.5 to 42 minutes. The total annual burden for reporting cycle data is now estimated at 113,680	Increase of 1,991 hours

			hours.	
Data Validation (Attachment H)	This package contains a separate estimate for the validation, for an increase from 0 to 35 clinics	The estimated number of responses has increased from 0 to 70	The response time is now measured separately from the cycle data and is 23 minutes	Increase of 939 hours
Feedback Survey (Attachment C4)	The estimated number of clinics participating in the feedback survey has increased from 335 to 348, due to the increasing use of ART and thus number of participating clinics	The number of responses per clinic remains at 1	The response time is unchanged at 2 minutes per response	Increase of 1 hour
System update	The estimated number of respondents has decreased from 149 to 0, as the system update has been completed	The number of respondents has decreased from 149 to 0 as the system update has been completed	The response time has decreased from 40 to 0 hours as the system update has been completed	Decrease of 5,960 hours

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.