



U.S. Department of  
Health and Human Services  
Centers for Disease  
Control and Prevention

Print Date: 5/13/24

**Title:** Assisted Reproductive Technology Program Reporting System

**Project Id:** 0900f3eb8224e08d

**Accession #:** NCCDPHP-ARTSRT-10/24/23-4e08d

**Project Contact:** Saswati Sunderam

**Organization:** NCCDPHP/DRH/WHF/ARTSRT

**Status:** **Project In Progress**

**Intended Use:** **Project Determination**

**Estimated Start Date:** 10/14/1995

**Estimated Completion Date:** 10/14/2050

**CDC/ATSDR HRPO/IRB Protocol #:** 2238

**OMB Control #:** 0920-0556

## Determinations

Determination	Justification	Completed	Entered By & Role
HSC: Does NOT Require HRPO Review	Not Research - Public Health Surveillance <i>45 CFR 46.102(l)(2)</i>	3/12/24	Redmond Leonard_Joan (jrl3) CIO HSC
PRA: PRA Applies		3/12/24	Still-LeMelle_Terri (cse6) OMB / PRA

ICRO:  
PRA Applies

OMB Approval date: 12/15/21  
OMB Expiration date: 12/31/24

3/13/24

Zirger\_Jeffrey (wtj5) ICRO Reviewer

## Description & Funding

### Description

**Priority:** Standard

**Determination Start Date:** 03/05/24

**Description:**

The proposed project aims to collect annual data from all practicing assisted reproductive technology (ART) clinic programs in the US and its territories via the National ART Surveillance System (NASS), a web-based management information system. 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. Information collected is used to publish the annual clinic-specific pregnancy success rates as required by FCSRCA and provide accurate ART information needed by consumers. Clinic-specific profile data provide consumers with general information about each ART program. Detailed cycle-specific 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 helps 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. Clinics report both clinic-specific information and ART cycle-specific information to CDC through NASS. The cycle-specific data are organized with one record per cycle. This project is a non-research, public health practice activity designed to support the ongoing public health surveillance project for data collection and quality control as required by the Fertility Clinic Success Rate and Certification Act (FCSRCA) of 1992 (Public Law 102-493). It is not intended to contribute to generalizable knowledge. OMB approval under the Paperwork Reduction Act has been received (OMB No. 0920-0556).

**IMS/CIO/Epi-Aid/Lab-Aid/Chemical Exposure Submission:** No

**IMS Activation Name:** Not selected

**Primary Priority of the Project:** Not selected

**Secondary Priority(s) of the Project:** Not selected

**Task Force Associated with the Response:** Not selected

**CIO Emergency Response Name:** Not selected

**Epi-Aid Name:** Not selected

**Lab-Aid Name:** Not selected

**Assessment of Chemical Exposure Name:** Not selected

**Goals/Purpose**

The primary goal of data collection is to comply with Section 2(a) of the Fertility Clinic Success Rate and Certification Act (FCSRCA) that requires each ART clinic to submit information to CDC and CDC to publish pregnancy success rates for each clinic. CDC's primary objective 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 will estimate and disseminate ART pregnancy success rates information by clinic and nationally for all ART cycles initiated from 1995 to 2050. CDC uses NASS data to publish annual ART Reports on-line, which contain a national summary, as well as information about the factors that contribute to success and trends of ART use. CDC will also publish on-line an annual ART Fertility Clinic and National Summary Report as well as a State-Specific ART Surveillance Data Brief 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 overall and by state.

**Objective:**

**Does your project measure health disparities among populations/groups experiencing social, economic, geographic, and/or environmental disadvantages?:** Yes

**Does your project investigate underlying contributors to health inequities among populations /groups experiencing social, economic, geographic, and/or environmental disadvantages?:** Yes

**Does your project propose, implement, or evaluate an action to move towards eliminating health inequities?:** No

**Activities or Tasks:** New Collection of Information, Data, or Biospecimens ; Secondary Data or Specimen Analysis

**Target Populations to be Included/Represented:** General US Population ; Pregnant Women ; Female ; Male ; Patient

**Tags/Keywords:** Reproduction ; assisted reproduction ; infertility treatments

**CDC's Role:** Activity originated and designed by CDC staff, or conducted at the specific request of CDC, or CDC staff will approve study design and data collection as a condition of any funding provided ; CDC employees or agents will obtain or use identifiable (including coded) private data or biological specimens ; CDC employees will participate as co-authors in presentation(s) or publication(s) ; CDC employees will provide substantial technical assistance or oversight ; CDC is providing funding ; CDC is the sole institution conducting activity

**Method Categories:** Surveillance Support

**Methods:** The Fertility Clinic Success Rate and Certification Act mandates that all ART clinics report pregnancy success rate data to the CDC in a standardized manner. The details of reporting requirements are outlined in the Federal Register Notices, which describe: (1) who shall report to HHS/CDC, (2) the reporting system (National ART Surveillance System or NASS) and process for reporting by each ART program, (3) the data items and definition to be included in the reporting database, and (4) how pregnancy success rates will be defined and reported using the NASS data. Currently, ART clinics are operating under the Federal Register Notice published August 26, 2015, using NASS 2.0. In addition, a Federal Register Notice announcing clarifications and modifications of certain definitions used for reporting of ART success rates was released on December 15, 2016. Clinics report both clinic-specific information and ART cycle-specific information to CDC through NASS. The cycle-specific data are organized with one record per cycle. To ensure data quality, validation procedures are undertaken using a stratified sampling approach, with higher sampling rates among larger clinics. Clinics will be sampled with equal probability within strata. Each ART program selected for validation will be reviewed as follows: validation of all up to 50 embryo-banking cycles; full validation of up to 25 non-gestation cycles; and full validation of up to 50 single or multiple-gestation cycles.

Clinic-specific information and ART cycle-specific information will be collected from ART clinics through NASS, a web-based

**Collection of Info, Data or Biospecimen:**

management information system. Protected information including indirectly identifiable information such as zip code, state of residence, and birth date of the women and resultant infants are collected for surveillance activities. Cycle-specific data for the following patients must be reported: (A) All patients undergoing ART, (B) all patients undergoing ovarian stimulation or monitoring with the intent of undergoing ART but who did not proceed to oocyte retrieval or transfer of embryos for any reason, including patients whose cycles were canceled for any reason, (C) all patients providing donor oocytes, and (D) all patients undergoing monitoring and/or embryo (or oocyte) thawing with the intention of transferring cryopreserved embryos. Only cycles performed in the U.S. may be reported to CDC. The following data is collected for each patient cycle: patient demographics; intended and actual cycle information; patient medical history and evaluation; oocyte, sperm, and carrier source; pharmacological use; medical complications; laboratory information; embryo transfers; procedure types; and outcome information.

**Expected Use of Findings/Results and their impact:**

Information collected are used to publish the mandated annual clinic-specific pregnancy success rates as required by the Fertility Clinic Success Rate and Certification Act and provide accurate ART information needed by consumers. Clinic-specific profile data provide consumers with general information about each ART program. Detailed cycle-specific 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 helps 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.

**Could Individuals potentially be identified based on Information Collected?** Yes

**Will PII be captured (including coded data)?** Yes

**Does CDC have access to the identifiers (including coded data)?:** Yes

**Is this project covered by an Assurance of Confidentiality?** Yes

**Assurances of Confidentiality associated with this project:** NCCDPHP - Assisted Reproductive Technology (ART)

**Does this activity meet the criteria for a Certificate of Confidentiality (CoC)?** No

**Is there a formal written agreement prohibiting the release of identifiers?** No

**Funding**

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award	Budget Amount
CDC Contract	National Assisted Reproductive Technology (ART) Surveillance System (NASS) and ART Data Collection Support Services	75D30123C15764	2023	5	2150725.00

## **HSC Review**

---

## **Regulation and Policy**

---

Do you anticipate this project will need IRB review by the CDC IRB, NIOSH IRB, or through reliance on an external IRB? No

Estimated number of study participants

Population - Children

Protocol Page #:

Population - Minors

Protocol Page #:

Population - Prisoners

Protocol Page #:

Population - Pregnant Women

Protocol Page #:

Population - Emancipated Minors

Protocol Page #:

Suggested level of risk to subjects

Do you anticipate this project will be exempt research or non-exempt research

### **Requested consent process wavers**

Informed consent for adults No Selection

Children capable of providing assent No Selection

Parental permission No Selection

Alteration of authorization under HIPAA Privacy Rule No Selection

### **Requested Waivers of Documentation of Informed Consent**

<b>Informed consent for adults</b>	No Selection
<b>Children capable of providing assent</b>	No Selection
<b>Parental permission</b>	No Selection

### **Consent process shown in an understandable language**

<b>Reading level has been estimated</b>	No Selection
<b>Comprehension tool is provided</b>	No Selection
<b>Short form is provided</b>	No Selection
<b>Translation planned or performed</b>	No Selection
<b>Certified translation / translator</b>	No Selection
<b>Translation and back-translation to/from target language(s)</b>	No Selection
<b>Other method</b>	No Selection

### **Clinical Trial**

<b>Involves human participants</b>	No Selection
<b>Assigned to an intervention</b>	No Selection
<b>Evaluate the effect of the intervention</b>	No Selection
<b>Evaluation of a health related biomedical or behavioral outcome</b>	No Selection
<b>Registerable clinical trial</b>	No Selection

### **Other Considerations**

<b>Exception is requested to PHS informing those bested about HIV serostatus</b>	No Selection
<b>Human genetic testing is planned now or in the future</b>	No Selection
<b>Involves long-term storage of identifiable biological specimens</b>	No Selection
<b>Involves a drug, biologic, or device</b>	No Selection
<b>Conducted under an Investigational New Drug exemption or Investigational Device Exemption</b>	No Selection

## Institutions & Staff

---

### Institutions

Will you be working with an outside Organization or Institution? No

Institutions yet to be added .....

### Staff

Staff Member	SIQT Exp. Date	CITI Biomedical Exp. Date	CITI Social & Behavioral Exp. Date	CITI Good Clinical Practice Exp. Date	Staff Role	Email	Phone	Organization
Amelia Jewett	07/19 /2026		01/02/2027		Co-Investigator	iu3@cdc.gov	770-488-3470	ASSISTED REPRODUCTIVE TECHNOLOGY SURVEILLANCE & RESEARCH TEAM
Dmitry Kissin	02/10 /2026	12/01/2026	11/13/2022		Principal Investigator	dtk3@cdc.gov	770-488-6408	WOMEN'S HEALTH & FERTILITY BRANCH
Sarah Mardovich	08/07 /2026		03/04/2027		Project Officer	nfr8@cdc.gov	404-498-0967	ASSISTED REPRODUCTIVE TECHNOLOGY SURVEILLANCE & RESEARCH TEAM
Saswati Sunderam	02/07 /2026		11/17/2026		Co-Investigator	zga0@cdc.gov	770-488-6356	ASSISTED REPRODUCTIVE TECHNOLOGY SURVEILLANCE & RESEARCH TEAM
Yujia Zhang	07/06 /2026	11/17/2026			Statistician	coi8@cdc.gov	770-488-6342	ASSISTED REPRODUCTIVE TECHNOLOGY SURVEILLANCE & RESEARCH TEAM

## Data

---

### DMP

**Proposed Data Collection Start Date:** 10/14/95  
**Proposed Data Collection End Date:** 10/14/50  
**Proposed Public Access Level:** Restricted

*Restricted Details:*

**Data Use Type:** Data Sharing Agreement  
**Data Use Type URL:** <https://www.cdc.gov/art/index.html>  
**Data Use Contact:** Amelia Jewett iuj3@cdc.gov

**Public Access Justification:** The National ART Surveillance System (NASS) database is protected by an Assurance of Confidentiality, which is a formal statute protecting the confidentiality of highly sensitive data used primarily for surveillance systems, under section 308(d) of the Public Health Service Act. All ART data collected since 1995 by CDC are protected by this Assurance of Confidentiality.

**How Access Will Be Provided for Data:** Public access to national and clinic-specific success rates data is provided through an interactive on-line application. CDC also publishes on-line an annual ART Fertility Clinic and National Summary Report and a State-Specific ART Surveillance Data Brief 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 and by State. According to NASS's Assurance of Confidentiality, NASS data are strictly protected and are only accessible to on-site signatories of the Assurance of Confidentiality. Researchers who require more granular data than mentioned above have additional mechanisms through which to access data: (a) Analyzing aggregate data using the Assisted Reproductive Technology Fertility Clinic Success Rates Dataset in Excel spreadsheets (available on the CDC Data Website), (b) Submitting data requests through ARTinfo@cdc.gov, (c) Working with DRH statisticians/scientists on collaborative projects, (d) Accessing NASS data on-site at DRH as guest researchers, (e) Analyzing NASS data (without identifiable information about any individual patient or clinic) at one of the Research Data Centers (RDC). The RDC facilitates the hosting of restricted data within the Department of Health and Human Services. This mechanism allows researchers to access restricted data in a secure environment while protecting the privacy and confidentiality of the data. Primary identifiers such as names or social security numbers and indirect identifiers such as date of birth and zip code are not included. To access data through the RDC, researchers submit proposals to the RDC, and, if the proposed analysis is approved, the researcher may access NASS data to conduct their own analyses in a secure environment. Approaches for accessing NASS data require signing confidentiality forms as follows: 1) 308(d) Assurance of Confidentiality, Non-CDC Employees (must be signed by guest researchers, visiting fellows, students, trainees, or employees of a Federal Agency other than CDC); 2) 308(d) Assurance of Confidentiality for Research Data Center Users (must be signed by Research Data Center users); and 3) Confidentiality Pledge (must be signed by everyone working with NASS data). Based on the legal requirements of the Fertility Clinic Success Rate and Certification Act, 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 sensitive information such as number of pregnancies lost, use of donor eggs, sperm, or donated embryos. Therefore, the Privacy Act applies, and precautions are taken to protect privacy. Unauthorized disclosure of the information in identifiable form (IIF) data captured in the NASS could have adverse effects such as embarrassment to the patients utilizing ART and public relations problems for clinic directors. 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. Identifiable information about any individual patient or clinic will not be disclosed in any reports (except for clinic specific ART Fertility Clinic Success Rates on the public web domain [www.cdc.gov/art/artdata/index.html](http://www.cdc.gov/art/artdata/index.html) required by FCSRCA), statistical summaries, or other publications.

**Plans for Archival and Long Term Preservation:** All ART reports are archived here: <https://www.cdc.gov/art/index.html>. ART records are filed by reporting year (record series) and are kept on a secure CDC server. ART records are considered official public records and are preserved according to The Federal Records Act of 1950 (amended to 44 U.S.C. Chapter 31). Retention of such records will follow the Scientific and Research Project Retention Schedule available at: <http://intranet.cdc.gov/ocoo/docs/sbiu/records-management/bb-scientific-research.docx>.

## Spatiality

Country	State/Province	County/Region
United States		

## Dataset

Dataset Title	Dataset Description	Data Publisher /Owner	Public Access Level	Public Access Justification	External Access URL	Download URL	Type of Data Released	Collection Start Date	Collection End Date
Dataset yet to be added...									

## Supporting Info

Current	CDC Staff Member and Role	Date Added	Description	Supporting Info Type	Supporting Info
	Zirger_Jeffrey (wtj5) ICRO Reviewer	03/13/2024	NOA 0920-0556 (2021)	Notice of Action	<a href="#">NOA 0920-0556_2021.pdf</a>
	Cox_Shanna (cio8) Division ADS	03/06/2024	DMP approved in 2019	Other	<a href="#">NASS Data Management Plan 11 18 2019.docx</a>



U.S. Department of Health and Human Services  
Centers for Disease Control and Prevention