DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Centers for Disease Control
and Prevention (CDC)

Memorandum

Date February 5, 2024

To Dr. Karen Hacker, MD, MPH
Director, National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP)

From Joanne Cono MD, ScM
Acting Director, Office of Science, CDC

Subject **Authorization to Extend 308(d) Assurance of Confidentiality Protection for the "National Assisted Reproductive Technology (ART) Surveillance System (NASS)."**

This memo is to provide formal approval of the NCCDPHP request to extend the authorization to assure confidentiality under Section 308(d) of the Public Health Service Act for the "National Assisted Reproductive Technology (ART) Surveillance System (NASS)."

For ongoing projects, CDC practice is that every five years, the program must apply for a formal extension of the 308(d) authority. Please apply for the extension at least six months prior to March 31, 2029.

Please use 42 USC 242(k), and 42 USC 242(m) as the legal references for information collection and protection.

If you have any questions, please contact Joseph Rush Jr., Senior Privacy Analyst, at (404) 639-4772.

2/15/2024

X Joanne Cono

Joanne Cono MD, ScM
Acting Director, Office of Science, CDC
Signed by: Joanne Cono -S

Privacy and Confidentiality Unit:

Assurance of Confidentiality (AoC) Application

Cover Page

Project name:	**NATIONAL ASSISTED REPRODUCTIVE TECHNOLOGY SURVEILLANCE SYSTEM**

Contact information

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Original Application 3/19/2001
Application Amended 6/20/2005
Extension Requested 2/21/2006
Extended Application Finalized 4/16/2009 – 3/14/2014
Extended and Amendment Application Finalized 3/14/2014 – 3/14/2019
Application Amended 7/18/2017
Extended 3/14/2019 -3/14/2024
Extended 3/14/2024 – 3/31/2029

This document is an updated Assurance of Confidentiality for the National Assisted Reproductive Technology Surveillance System (NASS).

A) Purpose of Project

Describe the programmatic purpose(s) of the project including the type of data to be collected and the uses of the information collected. This section is a summary of the project and should be approximately two pages.

In 1992, Congress passed the Fertility Clinic Success Rate and Certification Act (FCSRCA), which requires that CDC collect data from all assisted reproductive technology (ART) clinics and report success rates, defined as all live births per ovarian stimulation procedures or ART procedures, for each ART clinic. ART is defined to include all treatments or procedures that involve the handling of human eggs and sperm for the purpose of establishing a pregnancy, including in vitro fertilization (IVF), gamete intrafallopian transfer (GIFT), zygote intrafallopian transfer (ZIFT), embryo cryopreservation, and surrogate birth.

The Society for Assisted Reproductive Technology (SART) has collected data covering ART outcomes

since 1986 and has been compiling and publishing clinic-specific reports since 1989. To avoid duplication of efforts, CDC purchased SART data on procedures performed between 1995 and 2003. During that period, ART programs that were not SART members were required to use the SART data entry software to submit data to the CDC. Beginning with ART procedures performed in 2004, CDC contracted with Westat for the development of a data collection system that allows clinics to submit data through an independent mechanism.

In collaboration with SART and the infertility consumer interest group RESOLVE, CDC has published annual ART Success Rates Reports for ART procedures performed in 1995 through 2021. In compliance with the FCSRCA requirements, each annual report includes a national summary report that uses information from all ART clinics as well as clinic-specific reports for each ART clinic. The annual report for 2010 and later is divided into two separate publications; the first consists of clinic-specific data and the second contains national summary data. Beginning with ART procedures performed in 2002, CDC has produced an annual Surveillance Summary that presents results grouped by state, and research articles that employ the data to address public health research questions on ART.[1]

CDC has held an Assurance of Confidentiality under section 308(d) of the Public Health Service (PHS) Act (42 USC 242m(d)) protecting the NASS data since 2001. The Assurance covers ART procedures performed 1995-present, and specifically protects data that would permit direct or indirect identification of women or infants, and could link assisted reproductive technology clinic identifiers with sensitive information. An amendment of the Assurance of Confidentiality was approved on June 20, 2005 to recognize the changes in the data acquisition mechanism, to expand 308(d) protection to include information collected through contract with Westat, and to clarify the detailed nature of information protected by 308(d). An additional amendment was approved on March 21, 2014 to further expand the 308(d) protection to future data acquisition mechanisms that CDC may require in order to fulfill the mandate set forth by Law, and to incorporate the availability of a de-identified, public use dataset available through the Research Data Center. The 2017 amendment expands the Assurance of Confidentiality to protect the identification of women, infants, or clinics that may result explicitly from previously conducted or future public health practice activities, in addition to surveillance and research activities, using the NASS data. This would include activities such as the recent quality assurance of practice project conducted under contract with SART. This amendment also updates the referenced IRB protocols.

B) Justification of Need

Describe why it is important to protect the individual or institution with an Assurance of Confidentiality.

1 Continuous production and dissemination of research findings is expected because ART is changing rapidly and its use is constantly expanding in the United States. The procedures in this Assurance are designed to allow research use of the data while maximizing protection of confidential data.

The NASS collects the following data for each ART procedure: 1) Patient demographic information such as date of birth and residence; 2) Patient history information such as prior full term and preterm births, months of infertility since the last birth, and number of prior ART procedures; 3) ART procedure information, such as the reasons for ART, the ART procedure start date, the type of ART procedures employed; and 4) Outcome information such as whether an ultrasound was performed and the date, the pregnancy outcome and date, the source of the pregnancy outcome information, the number of infants born, 5) Other applicable data as necessary and provided to CDC or its contractor.

Some of the data in the NASS are sensitive because they a) may be used to identify an individual woman or child, a clinic location, or clinic personnel and b) relate to issues about which people may have strong ethical, religious, and/or cultural concerns. In compliance with the FCSRCA, ART clinics and key personnel are fully identified in the annual report, which provides aggregate information on procedures and outcomes. This Assurance seeks to restrict further linkage of clinic identifiers with detailed, cycle-specific information. Potential patient-identifying information includes place of residence and birth date of both the women undergoing ART and resultant infants. The confidentiality assurance is also necessary to protect data on details of the ART procedure, of the pregnancy, or of the pregnancy outcome which, if released, might lead to identifying the patient or cause harm to the clinic personnel. Depending on the type of data released together with identifiable information, women who elect to undergo ART treatment and the clinic personnel who may be involved in administering the treatment may face possible embarrassment, persecution and potentially legal and physical harm. An Assurance also helps ensure continual clinic participation and encourage more complete sharing of clinic information with CDC. Some clinics could choose not to submit their data to CDC if they did not believe that confidentiality of data was protected. Such behavior would threaten CDC's ability to serve the public and fulfill the requirements set forth by FCSRCA. Thus, we are requesting an extension of the Assurance that protects all of the ART data that have been collected and are maintained by the CDC or other entity acting under contract with the CDC.

Describe why the individual or institution will not furnish or permit access to the information unless an Assurance of Confidentiality is issued.

Without an Assurance of Confidentiality, obtaining clinic reporting of individually sensitive information could become difficult. Clinic management may fear potential persecution by activist groups and potential harm to property, personnel and patients and may hesitate in reporting sensitive data if it is not protected by the Assurance.

Describe whether or not the information could be obtained with the same degree of reliability from sources that do not require an assurance.

FCSRCA requires that CDC collect data from all ART clinics and report success rates. The only reasonable way for CDC to obtain such population-based procedure-level assisted reproductive technology data is through a contract. Whereas some states are putting a small amount of information about the use of ART on birth certificates, such information is limited (e.g., was this child conceived using ART? yes/no), uses inconsistent definitions of ART, and is not nationwide. Thus, there is no suitable alternative source of information.

Describe how the information is essential to the success of the particular statistical or epidemiological project and is not duplicative of other information gathering activities of the Department of Health and Human Services.

Collecting ART information and publishing clinic success rates is required of CDC under FCSRCA. The ART Surveillance and Research Team in the Women's Health and Fertility Branch of the Division of Reproductive Health, NCCDPHP, was created to promote the health of women and men who receive infertility services, the health of pregnancies achieved through these services and the health of infants conceived through these services by conducting surveillance and research, creating and maintaining strategic partnerships, and moving science to practice. The Team has obtained OMB approval for the ART data collection system (OMB No. 0920-0556). The Team also has obtained IRB approval (Protocol No. 2238) to conduct epidemiologic analyses using the ART data. The ART information is essential to fulfilling the federal mandate as well as to answering important assisted reproductive technology research questions. These activities are not done elsewhere at CDC or elsewhere within the Department.

Describe how the issuance of the Assurance of Confidentiality might restrain CDC from carrying out any of its responsibilities.

It is not expected that the Assurance of Confidentiality will restrain CDC from carrying out any of its responsibility of surveillance and reporting of ART success rates and conduct of epidemiological studies using the NASS. However, we anticipate collaborating with researchers inside and outside the CDC, and these situations will require specific precautions to ensure 308(d) confidentiality. The ART Surveillance and Research Team staff will be involved in all collaborations in which the ART data are used; this will help ensure protection of the ART data. Researchers from other CDC components requesting use of NASS data will be required to obtain specific approval of the Technical and Business Stewards of the NASS, and sign the special 308(d) pledge (Attachment F).

Occasionally, guest researchers, visiting fellows, and other non-CDC employees may have access to NASS data. Such an arrangement will be time-limited, and will take place under the direct supervision of the ART Surveillance and Research Team Leader. All guest researchers, visiting fellows, and non-CDC employees will be required to sign a special 308(d) confidentiality pledge (Attachment G).

Scientists outside the federal government have requested access to the NASS data for legitimate research purposes. For data collected on ART procedures performed in 1995 through 2003 (collected under contract with SART), in accordance with the Assurance, CDC will continue to be responsible for review and approval of data release requests submitted by third parties to SART. Beginning with data collected on ART procedures performed in 2004 (collected under contract with Westat), the CDC intends to release limited, de-identified information to outside parties. CDC has developed a policy for releasing post-2003 data by creating a public-use dataset which will respect the constraints imposed by the Assurance. Thus, the Assurance will not unduly affect the ability of CDC to release data of public health significance. Whereas the intent and scope of data protected by the Assurance is the same as initially approved, we are taking the opportunity of this extension to clarify the nature of protected information more in detail. In particular, data items that will not be released or disclosed without consent of the parties given this Assurance include but are not limited to cycle identification number, patient identification number, patient date of birth, infant date of birth or date of pregnancy outcome, gestational carrier date of birth, donor date of birth, patient country of residence, patient state of residence, patient city of residence, patient zip code, clinic name, laboratory name, clinic address, clinic

city, clinic state, clinic zip code, clinic identification number maintained by SART and Westat, names of laboratory and clinic personnel, and details of the ART procedure, of the pregnancy, or of the pregnancy outcome which, if released, might lead to identifying the patient or cause harm to the clinic personnel. Other data items have been altered to reduce the disclosure risk (e.g. categorizing variables, top or bottom coding variables). Users of the public use, de-identified dataset will be required to sign a special 308(d) confidentiality pledge (Attachment H).

Describe the advantages of assuring confidentiality and how they outweigh the disadvantages.

The advantages of assuring confidentiality include 1) protection of clinics and patients from unwarranted access to sensitive information by parties that may subject them to embarrassment or harm, 2) increased confidence of clinics and patients in CDC's intention and ability to protect the information that is submitted to the government, and as a consequence, 3) higher participation and better quality of information provided by CDC to the public. These advantages greatly outweigh the limited disadvantages of restricting access to identifiable information in the NASS.

C) Confidentiality Assurance Statement

CDC ASSURANCE OF CONFIDENTIALITY

ASSURANCE OF CONFIDENTIALITY FOR THE NATIONAL ASSISTED REPRODUCTIVE TECHNOLOGY SURVEILLANCE SYSTEM

Surveillance of assisted reproductive technology (ART) procedures performed in the United States is being conducted by the Division of Reproductive Health (DRH), National Center for Chronic Disease Prevention and Health Promotion of the Centers for Disease Control and Prevention (CDC), an agency of the United States Department of Health and Human Services. The information compiled by CDC has been collected by the Society for Assisted Reproductive Technology (SART) for the years 1995-2003, and will be collected by Westat for the years 2004-2025. Other contractors may collect this information on behalf of CDC in future years. The information on each ART procedure is gathered from Assisted Reproductive Technology clinics. This information includes in part clinic information such as its address and services offered, patient demographic information such as dates of birth of the mothers and city and state of residence, patient history information such as gravidity and parity, and details of the ART procedure, of the pregnancy, or of the pregnancy outcome which, if released, might lead to identifying the patient or cause harm to the clinic personnel. The data are used by CDC scientists to publish an annual Assisted Reproductive Technology Success Rates Report as mandated by law as well as to study the risks associated with the use of assisted reproductive technology for both the women and the resulting infants.

Information collected as part of this surveillance both in the past under contract with SART (ART procedures performed in 1995 through 2003), under contract with Westat (ART procedures performed in 2004 through 2025), and potentially under contract with other organizations in the future, as well as information related to this surveillance used for previously conducted or future public health practice activities, such as for the quality assurance of ART practice project, that would permit direct or indirect identification of women or infants (including but not limited to cycle identification number, patient identification number, patient date of birth, infant date of birth, patient place of residence) and/or could link assisted reproductive technology clinic identifiers (including but not limited to clinic name, laboratory name, clinic address, clinic identification number, and key personnel) with details of the ART procedure, of the pregnancy, or of the pregnancy outcome which, if released, might lead to identifying the patient or cause harm to the clinic personnel, and collected by CDC and/or its contractor under Section 306 of the Public Health Service (PHS) Act (42 USC 242k) is protected with an assurance that it will be held in strict confidence in accordance with Section 308(d) of the PHS Act (42 USC 242m(d)). It will be used only for purposes stated in this Assurance, and it will not otherwise be disclosed or released without the consent of the parties given this Assurance. This protection will continue, even following the death of the women and infants in this surveillance system or the closing or reorganization of the ART clinics.

Information collected by the CDC will be used without personal identifiers for publication in statistical and analytic summaries and epidemiologic studies. Institutional identifiers will be used as required for publication of the annual Success Rates Report but will not be used for publication of other statistical and analytic summaries and epidemiologic studies and in no way will institutional identifiers be linked with further details that might compromise the confidentiality of the information provided by the patients.

Information that contains identifiers will not be shared with researchers outside of DRH except for very rare occasions. These rare occasions may occur if a guest researcher, expert consultant, or other similar non-employee, is invited to work on-site at the Division of Reproductive Health using the NASS database. Such an arrangement will be time-limited, and will take place under the direct supervision of the Technical

Steward of this Assurance. These individuals will be required to sign a special 308(d) confidentiality pledge containing language approved by the CDC OGC.

Information within this surveillance program will be kept confidential and, aside from authorized personnel, no one will be allowed to see or have access to the information. Such individuals will be required to handle the information in accordance with procedures outlined in the CDC Staff Manual on Confidentiality and to follow the specific procedures documented in the Confidentiality Security Statement for this project.

No identifying information will be made available for any purpose other than those outlined in this Assurance Statement. For example, such information will not be disclosed to insurance companies; any party involved in civil, criminal, or administrative litigation; family members; or any member of a public or private organization.

"*CDC is in compliance with applicable federal law requiring the protection of federal computer networks from cybersecurity risks like hacking, internet attacks, and other security weakness; computer network experts working for, or on behalf, of the government, may intercept and review information sent through government networks for cyber threats if the information is sent through the government network triggers a cyber threat indicator*."

D) Confidentiality Security Statement

CONFIDENTIALITY SECURITY STATEMENT FOR
DRH NATIONAL ART SURVEILLANCE SYSTEM

The Division of Reproductive Health (DRH), National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) has applied for a 308(d) Assurance of Confidentiality for the surveillance activity entitled National ART Surveillance System (NASS). Because of this Assurance, all study files will be considered confidential materials and will be safeguarded to the greatest extent possible. Because the data are highly sensitive, and have 308(d) protection, the security requirement is rated as high. It is the moral and legal responsibility of each DRH and contractor staff member working on the NASS to protect the right to confidentiality. This document describes the procedures and practices that DRH intends to use to protect the confidentiality of the data collected as part of this surveillance activity.

DRH and contractor staff are required to maintain and protect at all times the confidential data that may come under their control. To assure that they are aware of this responsibility and of the penalties for failing to comply, each DRH staff member who will have access to the NASS data must read and sign a Nondisclosure Agreement (CDC 0.979), assuring that all identifying information will be kept confidential and will be used only for epidemiologic or statistical purposes. When confidentiality authorization is obtained, DRH and contractor staff working on this project will be required to attend an annual training session at which the confidentiality procedures for the study will be discussed in greater detail by a member of the ART team.

The Technical Steward for this project is the person holding the position of team leader, ART Surveillance and Research Team. The Business Steward is the person holding the position of Chief, Women's Health and Fertility Branch, Division of Reproductive Health, NCCDPHP.

In Attachment C is the Nondisclosure Agreement that all DRH staff on the project will sign. The originals will be retained by DRH, with copies at the Office of Scientific Regulatory Services (OSRS). 308(d) clauses will be added to the contract securing data acquisition. All data acquisition contractor employees with access to the data will be required to sign the contractor pledge. In Attachment D is the Contractor's Pledge of Confidentiality signed by SART, the ART data collection contractor for 1995–2003 data reporting years. Attachment E includes the 308(d) Contract Clause signed by Westat, the ART data collection contractor for 2004–2025 data reporting years. Originals of these documents will be retained by PGO with copies on file at DRH and OSRS. The same procedures and appropriately modified forms will be used by future data acquisition contractors.

Attachment F is a Confidentiality Pledge to be signed by CDC employees within other CDC components who request Assisted Reproductive Technology data to conduct an IRB approved study. In Attachment G is the Pledge of Confidentiality to be signed by CDC guest researchers and others who are not CDC employees or CDC data acquisition contractors but work in collaboration with the Division of Reproductive Health and have access to identifiable information included in NASS. Attachment H is a Confidentiality Pledge to be signed by approved researchers that will be accessing a de-identified version of the NASS data remotely via the Research Data Center. The originals of these documents will

be retained by DRH, with copies at the OSRS.

Restrictions on Use of Information and Safeguarding Measures:

- Division of Reproductive Health staff are responsible for protecting all confidential records from eye observation, from theft, or from accidental loss or misplacement due to carelessness. All reasonable precautions will be taken to protect confidential study data.

- All data acquisition contractor personnel are to receive additional training in confidentiality procedures. Training has been and will be conducted immediately prior to their assignment to the project. No data (or copies of data) shall be retained by the contractor after the period of performance of the contract. SART maintains a copy of data collected from its member clinics, which includes the data elements submitted by SART clinics to fulfill the FCSRCA requirements, and additional data elements required by SART but not by the CDC. SART transmits the required data elements to Westat.

- Both DRH and contractor staff are not to divulge any personal or institutional identifying information to anyone other than authorized project staff on a "need to know" basis appropriate to conduct official business. In general conversation outside the workplace, neither the identifying information, the nature of the data collected, nor the means by which they are collected should be discussed in any detail.

- When not in use by authorized project staff, all hard copy material and physical media containing confidential data will be stored in locked containers, file cabinets, or rooms. Access to locked storage areas will be limited to authorized project staff. This procedure will apply to all physical media containing confidential data, including data collection forms, printouts, diskettes, and magnetic data tapes. Staff working with confidential materials during forms processing and data handling will have access only to the materials that they are currently processing. When confidential records are in use, they must be kept out of sight of persons not authorized to work with these records.

- Except as needed for operational purposes, photocopies of confidential records are not to be made. If photocopies are necessary, care should be taken that all copies and originals are recovered from the copy machines and work areas. Records containing names or other information identifying a single individual, institution, city, or state will not be faxed or E-mailed. All confidential paper records will be destroyed as soon as operational requirements permit by shredding the documents.

- Any correspondence containing NASS records will be sent via first class certified mail in sealed envelopes marked “CONFIDENTIAL”. Upon receipt, these records will be stored in locked files. After information from these records is coded, the records will be kept in secured storage.

Enhanced Protection of Computerized Files:

All data will be protected in confidential computer files. The following safeguards are implemented to

protect the NASS files so that the accuracy and the confidentiality of the data can be maintained:

- Computer files containing programs, documents, or confidential data will be stored in computer systems that are protected from accidental alteration and unauthorized access. Computer files, whether they are stored on the CDC mainframe computer, or DRH local area network (LAN), will be protected by password systems, controlled sharing, and routine daily backup procedures.

- The CDC Data Center, the NCCDPHP LAN, and the DRH LAN comply with several Federal policies, statutes, regulations, and other directives for the collection, maintenance, use, and dissemination of data, including the Department of Health and Human Services Automated Information Systems Security Program and the Computer Security Act of 1987 (Public Law 100-235). Additionally, both centers are in compliance with CDC's IRMO ADP Security Policy. The CDC Data Center is a limited access, secured physical environment. The NCCDPHP LAN currently implements security features including user ID and password protection; mandatory password changes; limited logins; virus protection; variance detection; and user rights/file attribute restrictions.

- At DRH, password protection will impose user name and password log-in requirements to prevent unauthorized access. Each user name will be assigned limited access rights to files and directories at varying levels to control file sharing. Computer facilities at all sites are protected from potential fire or water damage.

- Whenever practical, electronic data files will not contain any personal identifiers other than the NASS procedure identification number.

- CDC is in compliance with applicable federal law requiring the protection of federal computer networks from cybersecurity risks like hacking, internet attacks, and other security weakness; computer network experts working for, or on behalf, of the government, may intercept and review information sent through government networks for cyber threats if the information is sent through the government network triggers a cyber threat indicator.

Dissemination of Study Results

Whereas Congress requires that ART clinics be identified in the annual ART Success Rates Reports published by the CDC, all other reports and publications of collected data will be presented in a manner that will not allow the identification of individual clinics. In addition, no individual patient identifiers will be presented in any publication. Reports will be written so that no person may be individually identified, even indirectly. Statistical data will be presented in accordance with the CDC Staff Manual on Confidentiality.

Data Sharing with Other CDC Components

Individually identified data on individuals or establishments generally will not be shared with other CDC components. Access to identifiable information may be obtained for reason (e.g., use of the date of birth is a necessary preliminary step for generating the desired de-identified datasets) and upon specific approval of the Technical and Business Stewards. Such an arrangement will be time-limited, and will take place under the direct supervision of the ART Surveillance and Research Team Leader. The study must be an IRB approved study and the request for data sharing must be for a study clearly in

line with the original purpose for which the data have been collected. The Office of General Counsel and/or the CDC Confidentiality Officer should be consulted if there are requests that present unusual circumstances or appear problematic.

The Project Officer making the request must sign a special 308(d) pledge (Attachment F) and provide to the Business Steward or Technical Steward copies of similarly signed pledges from each employee within the new component who will have access to the individually identified data. This pledge is different from the Nondisclosure Oath employees generally sign so that the component would pay closer attention to safeguarding the data. It clearly states their understanding of the fact that the data are protected by 308(d), the Confidentiality Security Statement elements will be followed, and data obtained will be returned to the Business Steward upon completion of the study.

Data Sharing/Release to Outside Parties

Data collected on ART procedures performed in 2004-2025 are considered the property of the federal government. As such, CDC will allow the release of limited information to outside researchers via the Research Data Center (RDC). The RDC facilitates the hosting of restricted data for groups 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. The ART Surveillance and Research Team will provide the RDC with copies of the NASS data containing approved data elements. Primary identifiers such as names or social security numbers will not be included. If approved, researchers will be able to submit data analysis requests and receive output electronically, without directly accessing the data. At no time will researchers be able to see individual data records or link data files.

Records Disposition for the National Archives and Records Administration

After analyses of the project are complete, if the records are determined to be permanently valuable, a public use data tape is sent to the National Archive and Records Administration (NARA). This transfer will be done in accordance with the May 1996 agreement stating that CDC will transfer to NARA all permanent data sets in accordance with approved schedules contained in part IV of the CDC Records Control Schedule B-321, with the exception of identifying information collected under an assurance of confidentiality agreement as specified under the Public Health Service Act, Sections 301(d) and 308(d).

E) Research/ Non-Research Determination

Non-Research Determination

This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy. See e.g., 45 C.F.R. part 46.102(l)(2), 21 C.F.R. part 56; 42 U.S.C. §241(d); 5 U.S.C. §552a; 44 U.S.C. §3501 et seq. It has been determined that the project is non-research.

PRA Determination

The activity was reviewed by CDC and it has been determined that the Paperwork Reduction Act (PRA) applies to this project. The OMB control # is 0920-0556.

Privacy Act Applicability

The activity was reviewed by CDC and it has been determined that the Privacy Act applies to this project. The SORN is 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems."

Attachments

List all attachments associated with your project or application (Please note some attachments will vary based on the project):
Attachment A: Confidentiality pledge to be signed by all CDC employees in the Division of Reproductive Health, NCCDPHP, who have access to the NASS data Attachment B: Confidentiality pledge signed by SART, the ART data collection contractor for 1995–2003 data reporting years Attachment C: 308(d) Contract clause added to the ART data collection contract with Westat. This clause has been signed by all Westat employees with access to the data Attachment D: 308(d) Assurance Pledge for CDC Components Using Identifiable Assisted Reproductive Technology (ART) Data Protected by 308(d) Confidentiality Attachment E: 308(d) Assurance Pledge for non-CDC employees (guest researchers, visiting fellows, students, trainees, employees of a federal agency other than CDC, etc.) Attachment F: 308(d) Assurance Pledge for non-CDC employees that will be accessing the NASS data remotely via the Research Data Center Attachment G: Research projects carried out under the Assurance of Confidentiality for NASS Attachment H: Non-Research Determination for NASS Attachment I: Privacy Impact Assessment Attachment J: OMB Notice of Action

ATTACHMENT A.

This attachment includes the confidentiality pledge to be signed by all CDC employees in the Division of Reproductive Health, NCCDPHP, who have access to the NASS data.

NONDISCLOSURE AGREEMENT

ACCESS TO THE NATIONAL ART SURVEILLANCE SYSTEM
(*308(d) Assurance of Confidentiality for CDC Employees*)

The success of CDC's operations depends upon the voluntary cooperation of States, of establishments, and of individuals who provide the information required by CDC programs under an assurance that such information will be kept confidential and be used only for epidemiological or statistical purposes.

When confidentiality is authorized, CDC operates under the restrictions of Section 308(d) of the Public Health Service Act which provides in summary that no information obtained in the course of its activities may be used for any purpose other than the purpose for which it was supplied, and that such information may not be published or released in a manner in which the establishment or person supplying the information or described in it is identifiable unless such establishment or person has consented.

I am aware that unauthorized disclosure of confidential information is punishable under Title 18, Section 1905 of the U.S. Code, which reads: "Whoever, being an officer or employee of the United States or of any department or agency thereof, publishes, divulges, discloses, or makes known in any manner or to any extent not authorized by law any information coming to him in the course of his employment or official duties or by reason of any examination or investigation made by, or return, report or record made to or filed with, such department or agency or officer or employee thereof, which information concerns or relates to the trade secrets, processes, operations, style of work, or apparatus, or to the identity, confidential statistical data, amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation, or association; or permits any income return or copy thereof or any book containing any abstract or particulars thereof to be seen or examined by any person except as provided by law; shall be fined not more than $1,000, or imprisoned not more than one year, or both; and shall be removed from office or employment."

I understand that unauthorized disclosure of confidential information is also punishable under the Privacy Act of 1974, Subsection 552a (i) (1), which reads: "Any officer or employee of an agency, who by virtue of his employment or official position, has possession of, or access to, agency records which contain individually identifiable information the disclosure of which is prohibited by this section or by rules or regulations established thereunder, and who knowing that disclosure of the specific material is so prohibited, willfully discloses the material in any manner to any person or agency not entitled to receive it, shall be guilty of a misdemeanor and fined not more than $5,000."
My signature below indicates that I have read, understood, and agreed to comply with the above statements.

_____	_____	_____
Typed/Printed Name	Signature	Date

_____
NCCDPHP/DRH

CDC 0.979 (E), Revised September 2001

ATTACHMENT B.

This attachment includes the confidentiality pledge signed by SART, the ART data collection contractor for 1995–2003 data reporting years.

Safeguards for Individuals and Establishments
Against Invasions of Privacy
(*308(d) Assurance of Confidentiality for Contractors*)

In accordance with Section 308(d) of the Public Health Service Act (42 U.S.C. 242m), the contractor is required to give an assurance of confidentiality and to provide for safeguards to assure that confidentiality is maintained.

To provide this assurance and these safeguards in performance of the contract, the contractor shall:

1. Be bound by the following assurance:

   Assurance of Confidentiality

   In accordance with Section 308(d) of the Public Health Service Act (42 U.S.C. 242m), the contractor assures all participating establishments or individuals that the confidentiality of the ART records they release will be maintained by the contractor and CDC and that no information obtained in the course of this activity may be disclosed in a manner in which the particular establishment or individual supplying the information or described in it is identifiable, unless such establishment or individual has consented to such disclosure, to anyone other than authorized staff of CDC.

2. Maintain the following safeguards to assure that this confidentiality is protected by the contractor's employees and to provide for the physical security of the records:

   a. After having read the above assurance of confidentiality, each employee of the contractor participating in this project is to sign the following pledge of confidentiality:

      I have carefully read and understand the CDC assurance which pertains to the confidential nature of all records to be handled in regard to this project. As an employee of the contractor I understand that I am prohibited by law from disclosing any such confidential information which has been obtained under the terms of this contract to anyone other than authorized staff of CDC.

   b. To preclude observation of confidential information by persons not employed on the project, the contractor shall maintain all confidential records that identify individuals or establishments or from which individuals or establishments could be identified under lock and key.

      Specifically, at each site where these items are processed or maintained, all confidential records that will permit identification of individuals or establishments are to be kept in locked containers when not in use by the contractor's employees. The keys or means of access to these containers are to be held by a limited number of the contractor's staff at each site. When confidential records are being used in a room, admittance to the room is to be restricted to employees pledged to confidentiality and employed on this project. If at any time the contractor's employees are absent from the room, it is to be locked.

   c. The contractor and his professional staff will take steps to insure that the intent of the pledge of confidentiality is enforced at all times through appropriate qualifications standards for all personnel working on this project and through adequate training and periodic follow-up procedures.

3. In a statement sent to the establishments or individuals asked to supply information, inform in clear and simple terms:

    a. That the collection of the information by CDC and its contractor is authorized by Section 306 of the Public Health Service Act (42 U.S.C. 242k);

    b. Of the purpose or purposes for which the information is intended to be used, any plans for disclosures of information in a form that would permit the identification of an establishment or individual, and a statement that the records will be used solely for epidemiological or statistical research and reporting purposes;
    c. That there are no penalties for declining to participate in whole or in part; and

    d. That no information collected under the authority of Section 306 of the Public Health Service Act (42 U.S.C. 242k) may be used for any purpose other than the purpose for which it was supplied, and such information may not be published or released in other form if the particular individual or establishment supplying the information or described in it is identifiable to anyone other than authorized staff of CDC, unless such establishment or individual has consented to such release.

4. Release no information from the data obtained or used under this contract to any person except authorized staff of CDC.

5. By a specified date, which may be no later than the date of completion of the contract, return all study data or copies of data to CDC or destroy all such data, as specified by the contract.

(Typed/printed Name)

(Signature)

(Date)

ATTACHMENT C.

This attachment includes the 308(d) contract clause added to the ART data collection contract with Westat. This clause has been signed by all Westat employees with access to the data.

308(d) CONTRACT CLAUSE for ART Surveillance Records
Safeguards for Individuals and Establishments Against Invasions of Privacy

In accordance with Subsection (m) of the Privacy Act of 1974 (5 U.S.C. 552a) and Section 308(d) of the Public Health Service Act (42 U.S.C. 242m), the contractor/subcontractor is required to comply with the applicable provisions of the Privacy Act and to undertake other safeguards for individuals and establishments against invasions of privacy.

To provide these safeguards in performance of the contract, the contractor/subcontractor shall:

(a) Be bound by the following assurance:

Assurance of Confidentiality

In accordance with Section 308(d) of the Public Health Service Act (42 U.S.C. 242m), the Director, CDC, assures all participating establishments or individuals that the confidentiality of the Assisted Reproductive Technology (ART) records that are collected and will be released to CDC will be maintained by the contractor/subcontractor and CDC and that no information obtained in the course of this activity may be disclosed in a manner in which the specific individual or establishment supplying the information or described in it is identifiable, unless such establishment or individual has consented to such disclosure, to anyone other than authorized staff of CDC.

(b) Maintain the following safeguards to assure that this confidentiality is protected by the contractor/subcontractor's employees and to provide for the physical security of the records:

(i) To preclude observation of confidential information by persons not employed on the project, the contractor/subcontractor shall maintain all confidential records that identify individuals or establishments or from which individuals or establishments could be identified under lock and key.

Specifically, at each site where these items are processed or maintained, all confidential records that will permit identification of individuals or establishments are to be kept in locked containers when not in use by the contractor's employees. The keys or means of access to these containers are to be held by a limited number of the contractor/subcontractor's staff at each site. When confidential records are being used in a room, admittance to the room is to be restricted to employees pledged to confidentiality and employed on this project. If at any time the contractor/subcontractor's employees are absent from the room, it is to be locked.

(ii) The contractor/subcontractor and his professional staff will take steps to insure that the intent of the pledge of confidentiality is enforced at all times through appropriate qualifications standards for all personnel working on this project and through adequate training and periodic follow-up procedures.

(c) (If applicable) Print on the questionnaire in a clearly visible location and in clearly visible letters the following notice of the confidential treatment to be accorded the information on the questionnaire by any individual who may see it:

Confidential Information

Information contained in this data collection system which would permit identification of any individual or establishment has been collected with a guarantee that it will be held in strict confidence by the contractor and CDC, will be used only for purposes stated in this surveillance activity, and will not be disclosed or released to anyone other than authorized staff of CDC without the consent of the individual or establishment in accordance with Section 308(d) of the Public Health Service Act (42 U.S.C. 242m).

(d) On a letter or other form that can be retained by the individual or the establishment, or on the questionnaire form itself if it is a self-administered questionnaire, inform in clear and simple terms each individual or establishment asked to supply information:

(i) That the collection of the information by CDC and its contractor is authorized by Section 306 of the Public Health Service Act (42 U.S.C. 242k);

(ii) Of the purpose or purposes for which the information is intended to be used, any plans for disclosures of information in a form that would permit the identification of an establishment or individual, and a statement that the records will be used solely for epidemiological or statistical research and reporting purposes;

(iii) That, in accordance with the federal reporting requirements of the Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA), Section 2[a] of Public Law 102–493 [42 U.S.C. 263a–1], the penalty for declining to participate or submitting inadequate information is to be listed as a non-reporter in the annual Assisted Reproductive Technology Success Rates Report; and

(iv) That no information collected under the authority of Section 306 of the Public Health Service Act (42 U.S.C. 242k) may be used for any purpose other than the purpose for which it was supplied, and such information may not be published or released in other form if the particular individual or establishment supplying the information or described in it is identifiable to anyone other than authorized staff of CDC, unless the individual or establishment has consented to such release.

(e) Release no information from the data obtained or used under this contract to any person except authorized staff of CDC.

(f) By a specified date, which may be no later than the date of completion of the contract, return all study data to CDC or destroy all such data, as specified by the contract.

After having read the above assurance of confidentiality, each employee of the contractor participating in this project is to sign the following statement of understanding:

I have carefully read and understand the CDC assurance, which pertains to the confidential nature of all records to be handled in regard to this survey. As an employee of the contractor/subcontractor I understand that I am prohibited by law from disclosing any such confidential information, which has been obtained under the terms of this contract to anyone other than authorized staff of CDC. I understand that any willful and knowing disclosure in violation of the Privacy Act of 1974 is a misdemeanor and would subject the violator to a fine of up to $5,000.

_____
Typed/Printed Name

_____
Signature

_____
Date

ATTACHMENT D.

This attachment includes the 308(d) Assurance Pledge for CDC Components Using Identifiable Assisted Reproductive Technology (ART) Data Protected by 308(d) Confidentiality.

Safeguards for Individuals and Establishments Against Invasions of Privacy

In accordance with Section 308(d) of the Public Health Service Act (42 U.S.C. 242m(d)), as a condition of being granted access to identifiable ART data, each employee of the CDC component using identifiable ART data is required to undertake safeguards for individuals and establishments against invasions of privacy.

To provide these safeguards, the employees of the CDC component shall:

1. Be bound by the following assurance:

Assurance of Confidentiality

In accordance with Section 308(d) of the Public Health Service Act (42 U.S.C. 242m(d)), the employees of the CDC component assure all respondents that the confidentiality of their records within the NASS will be appropriately safeguarded by the CDC component and that no information obtained in the course of this activity will be disclosed in a manner in which the individual or establishment is identifiable, to anyone other than authorized staff of CDC.

2. Maintain the following safeguards (and those outlined in the Confidentiality Security Statement for NASS) to assure that confidentiality is protected by the CDC component's employees and to provide for the physical security of the records:

After having read the above assurance of confidentiality and the NASS Confidentiality Security Statement, each employee of the CDC component using identifiable ART data is to sign the following statement of understanding:

I have carefully read and understand the assurance which pertains to the confidential nature of all records to be handled in regard to the NASS data. I understand that I am prohibited from disclosing any such confidential information which has been obtained to anyone other than authorized staff of this CDC component.

To preclude observation of confidential information by persons not working on the project using ART data, the CDC component employees shall maintain all confidential records that identify individuals or establishments or from which individuals or establishments could be identified under lock and key.

Specifically, at each site where these items are processed or maintained, all confidential records that will permit identification of individuals or establishments are to be kept in locked containers or in encrypted computer files kept under password protected computer accounts when not in use by the CDC component. The keys or means of access to these containers or files are to be held by a limited number of the CDC component employees at each site. When confidential records are being used in a room, admittance to the room is to be restricted to employees pledged to confidentiality and working on this project. If at any time the CDC component employees are absent from the room, it is to be locked.

The Project Officer within the CDC component requesting ART data will take steps to insure compliance with this assurance pledge through adequate training and periodic follow up procedures.

Upon completion of the study, all identifiable ART data (and copies) will be returned to the ART Technical Steward.

_____	_____	_____
Typed/Printed Name	Signature	Date

_____
CDC Component

_____
Project Officer

ATTACHMENT E.

This attachment includes the 308(d) Assurance Pledge for non-CDC employees (guest researchers, visiting fellows, students, trainees, employees of a federal agency other than CDC, etc.).

Safeguards for Individuals and Establishments
Against Invasions of Privacy
(308(d) Assurance of Confidentiality for Non - CDC Employees)

I, as a non-CDC Employee (Guest Researcher, Visiting Fellow, Student, Trainee, Employee of a Federal Agency other than CDC, etc.) may be given access to directly or indirectly identifiable data on individuals and institutions that is covered by Section 308(d) of the Public Health Service Act (42 U.S.C. 242m). As a condition of this access, I am required to comply with the following safeguards for individuals and establishments against invasions of privacy.

1. I agree to be bound by the following assurance:
In accordance with Section 308(d) of the Public Health Service Act (42 U.S.C. 242m), all participating establishments and/or individuals supplying information are assured that this information will be kept confidential. No information obtained in the course of this activity will be disclosed in a manner in which the individual or establishment supplying the information or described in it is identifiable, unless the individual or establishment has consented to such disclosure, to anyone other than authorized staff of CDC.

2. I agree to maintain the following safeguards to assure that confidentiality is protected and to provide for the physical security of the records:
To preclude observation of confidential information by persons not authorized to have access to the information on the project, I shall maintain all records that directly or indirectly identify individuals or establishments or from which individuals or establishments could be identified in locked containers or protected computer files when not under immediate supervision by me or another authorized member of the project. The keys or means of access to these containers or files are not to be given to anyone other than CDC authorized staff. I further agree to abide by any additional requirements imposed by CDC for safeguarding the identity of individuals and establishments.

My signature below indicates that I have carefully read and understand this agreement and the assurance which pertains to the confidential nature of these records. As a(n) (_____)(employee of a Federal agency other than CDC, visiting scientist, guest researcher, fellow, trainee, etc.), I understand that I am prohibited from disclosing any such confidential information that has been obtained under this project to anyone other than authorized staff of CDC. I understand that any disclosure in violation of this Confidentiality Pledge is likely to lead to termination of my employment, fellowship or training experience with CDC as well as other penalties.

_____ _____
(Signature) (Date) (Typed/Printed Name)

ATTACHMENT F.

This attachment includes the 308(d) Assurance Pledge for non-CDC employees that will be accessing the NASS data remotely via the Research Data Center.

Safeguards for Individuals and Establishments
Against Invasions of Privacy
(308(d) Assurance of Confidentiality for Remote Access Users)

I, as user of the Research Data Center (RDC), will be given remote access to a de-identified version of the National Assisted Reproductive Technology Surveillance System (NASS) data, which contains data on individuals and institutions that are covered by Section 308(d) of the Public Health Service Act (42 U.S.C. 242m). As a condition of this access, I am required to comply with the following safeguards for individuals and establishments against invasions of privacy.

1. I agree to be bound by the following assurance:
In accordance with Section 308(d) of the Public Health Service Act (42 U.S.C. 242m), all participating establishments and/or individuals supplying information are assured that this information will be kept confidential. I will not attempt to learn the identity of any establishment or individual. If I inadvertently identify an establishment or individual, I will immediately bring it to the attention of authorized CDC staff, and I will not disclose any information in a manner in which the individual or establishment supplying the information or described in it is identifiable to anyone other than authorized staff of CDC.

2. I agree to maintain the following safeguards to assure that confidentiality is protected and to provide for the physical security of the records:
I will only conduct analyses related to the research questions for which I have received approval. I will not attempt to learn the identity of any establishment or individual in the de-identified files, and I will not attempt to deduce the content of small cells that have been suppressed in output returned to me from the RDC. If I inadvertently learn the identity of an establishment or individual, or deduce the contents of a small cell, I will not disclose this information to anyone other than authorized CDC staff, and I will immediately alert authorized CDC staff of the discovery. Also, I will destroy and/or delete any output inadvertently discovered to have identifying information or small cells with a count between one and four. I further agree to abide by any additional requirements imposed by CDC for safeguarding the identity of individuals and establishments.

My signature below indicates that I have carefully read and understand this agreement and the assurance which pertains to the confidential nature of these records. As a remote access user of the NASS database, I understand that I am prohibited from disclosing any such confidential information that has been obtained under this project to anyone other than authorized staff of CDC.

_____ (Typed/Printed Name)

_____ (Signature) (Date)

ATTACHMENT G.

Research projects carried out under the Assurance of Confidentiality for NASS.

EPIDEMIOLOGIC RESEARCH WITH NATIONAL ASSISTED REPRODUCTIVE TECHNOLOGY SURVEILLANCE SYSTEM DATA (CDC IRB PROTOCOL NO. 2238)

LINKAGE OF NATIONAL ASSISTED REPRODUCTIVE TECHNOLOGY SURVEILLANCE SYSTEM DATA WITH NATIONAL CENTER FOR HEALTH STATISTICS BIRTH-INFANT DATA FILES (CDC IRB PROTOCOL NO. 6975)

LINKAGE OF ASSISTED REPRODUCTIVE TECHNOLOGY DATA WITH STATE VITAL RECORDS AND DISEASE REGISTRIES (CDC IRB PROTOCOL NO. 6798)

LINKAGE OF ASSISTED REPRODUCTIVE TECHNOLOGY (ART) DATA WITH VITAL RECORDS FROM THE STATE OF CALIFORNIA (CDC IRB PROTOCOL NO. 6108)

ATTACHMENT H.

Non-Research Determination for NASS.

ATTACHMENT I.

Privacy Impact Assessment.

ATTACHMENT J.

OMB Notice of Action.

Request for Authorization to Give Assurance of Confidentiality

Control No:

UNDER SECTION 308(d) OF THE PUBLIC HEALTH SERVICE ACT

NOTE: *Do not obtain signature on this form until OS and the Project Officer have agreed on final versions of the 308(d) Justification, Assurance, and Security Statement.*

1. REQUESTED BY:

Name of Project Officer/Principal Investigator:	Bldg:	Rm No.:	MailStop:	Phone No.:
Dmitry Kissin	Chamblee		F-741	(770) 488-6408

Center/Institute/Office: NCCDPHP

Division: Division of Reproductive Health

Request Status:
☐ New ☐ Amended Request ☑ Extension Request

Period of time authorization needed for data collection:
(For OS use only)
From: 03/01/2024 To: 03/31/2029

2. TITLE OF PROJECT:

National Assisted Reproductive Technology (ART) Surveillance System (NASS)

3. JUSTIFICATION STATEMENT

Please attach the justification statement. (See "Assurance of Confidentiality Application Procedure" for further details.

4. APPROVAL OF REQUEST BY CENTER/INSTITUTE/OFFICE DIRECTOR OR DESIGNEE:

Name and Organizational Title:

Signature: Karen A. Hacker -S Digitally signed by Karen A. Hacker -S Date: 2023.12.13 12:01:59 -05'00' **Date:**

5. FOR OS USE ONLY:

Transmitted to Confidentiality Review Group
Date:

Confidentiality Review Group recommends:
◯ Approval ◯ Disapproval **Date:**

PCU Review Only:

Signature: Joseph Rush Jr -S Digitally signed by Joseph Rush Jr -S Date: 2024.02.05 12:17:45 -05'00' **Date:**

ASSURANCE OF CONFIDENTIALITY IS AUTHORIZED

Signature: Joanne Cono -S Digitally signed by Joanne Cono -S Date: 2024.02.15 16:28:57 -05'00' **Date:**

DIRECTOR, OFFICE OF SCIENCE OR
DEPUTY DIRECTOR OF SCIENCE

SAVE EMAIL PRINT