



**Collaborative**  
for Assisted Reproductive Technology  
**Epidemiologic Research**

**Collaborative for Assisted Reproductive  
Technology Epidemiologic Research (CARTER):  
Guide for Researchers**



## Contents

Overview of the National ART Surveillance System (NASS) .....	<a href="#">3</a>
Overview of CARTER .....	<a href="#">3</a>
Description of NASS Dataset.....	<a href="#">4</a>
Steps for Project Proposal Submission .....	<a href="#">5</a>
Authorship Guidelines .....	<a href="#">6</a>
CDC Review and Clearance .....	<a href="#">8</a>
Appendix A. Contents of NASS Dataset .....	<a href="#">9</a>
Appendix B. CARTER Proposal Approval Process.....	<a href="#">11</a>
Appendix C. CARTER Project Proposal Form .....	<a href="#">12</a>
Appendix D. CARTER Reviewer Evaluation Form .....	<a href="#">14</a>
Appendix E. Confidentiality Agreement Information & Forms.....	<a href="#">16</a>

## Overview of the National ART Surveillance System (NASS)

The Fertility Clinic Success Rate and Certification Act (FCSRCA) of 1992 requires that all fertility clinics in the US report standardized data for each assisted reproductive technology (ART) cycle initiated during a given reporting year (defined as January 1 through December 31) to CDC. For reporting years 1995-2003, CDC contracted with the Society for Assisted Reproductive Technology (SART) to maintain a population-based registry of ART cycles initiated annually in the US. Starting in reporting year 2004 through the present, CDC developed and maintains a web-based ART data reporting system

ART includes all treatments or procedures that involve the handling of human eggs or embryos for the purpose of establishing a pregnancy. This primarily includes in vitro fertilization (IVF) and such rare procedures as gamete intrafallopian transfer (GIFT) and zygote intrafallopian transfer (ZIFT). An ART cycle is defined as a process in which (1) a woman undergoes ovarian stimulation or monitoring with the intent of having an ART procedure (even if the cycle is subsequently canceled and no embryos are transferred) or (2) embryos are thawed with the intent of transferring them to a woman. Data collected in the National ART Surveillance System (NASS) include patient characteristics, characteristics of the treatment cycles, and treatment outcomes.

## Overview of CARTER

The Collaborative for ART Epidemiologic Research (CARTER) is a new research initiative of the CDC's ART Surveillance and Research Team of the Division of Reproductive Health (DRH) to promote and facilitate collaborative research using NASS data. The goal of CARTER is to establish a consortium of innovative research projects that aim to improve maternal, pregnancy, and infant health outcomes.

ART surveillance data are sensitive because they contain personal medical information about both the people undergoing ART and resultant infants and are protected by the [Assurance of Confidentiality](#) under the Public Health Service Act Section 308(d). Although the data do not contain any primary identifiers, such as names or social security numbers, other indirect identifiers are available in the dataset. As a result of confidentiality restrictions resulting from the sensitive and potentially identifying nature of the data, access to data files is currently limited to the ART team and approved guest researchers. External researchers interested in conducting research using NASS data are invited to

submit research proposals to CARTER following the process described in detail below. If approved, ART team statisticians and scientists will conduct analyses and provide outputs in tables and figures to support scientific publication. NASS data cannot be released to external collaborators.

## Description of NASS Dataset

In the United States, all ART cycles must be reported to NASS, which is currently estimated to include 98% of all ART cycles performed each year.<sup>1</sup> These data include all ART cycles with fresh, cryopreserved and/or donor embryos or oocytes and all ovarian stimulation or monitoring cycles with the intention of ART, including cycles canceled for any reason. The start of a cycle occurs when a woman begins taking fertility drugs, initiates ovarian monitoring, or when frozen eggs or embryos are thawed.

NASS includes the following data for each ART cycle:

- 1) Patient and/or donor demographic information (e.g., race/ethnicity, date of birth, residence)
- 2) Patient medical and obstetrical history (e.g., prior full term and preterm births, months of infertility since last birth, reasons for ART, number of prior ART procedures)
- 3) Clinical parameters of the ART treatment cycle (e.g., ART procedure start date, type of ART procedure)
- 4) Outcomes (e.g., whether an ultrasound was performed and date, pregnancy outcome and date, source of pregnancy outcome information, number of infants born)

A summarized list of the variables currently collected by NASS is provided in Appendix A. Information collected by NASS has been modified and expanded over time to reflect ongoing advances in the field of ART, and an updated version of NASS, NASS 2.0, was introduced in 2016. As a result, not all variables are available for all years of data. In addition, some NASS variables (e.g., patient race/ethnicity) have a high level of missing information. CDC is currently working to create an imputed dataset to address this limitation. Note: when drawing conclusions from NASS data, it is important to consider that data are cycle-specific; linking multiple cycles for the same patient can be challenging and is limited to data from 2016 onward.

---

<sup>1</sup> Centers for Disease Control and Prevention, *2018 Assisted Reproductive Technology Fertility Clinic Success Rates Report*. 2020, US Dept of Health and Human Services: Atlanta, GA.

## Steps for Project Proposal Submission

Steps for project proposal submission and approval process are described below and are summarized in the flowchart in Appendix B.

### Step 1

The Principal Investigator completes and submits an application to the CARTER Coordinator at [ARTinfo@cdc.gov](mailto:ARTinfo@cdc.gov) for initial review. The CARTER application includes:

- Project Proposal Form (Appendix C)
- Biographical sketch or C.V. for each co-author

Submissions will be initially screened for completeness, consistency with available data, and potential overlap with planned or ongoing projects. The initial screening will take approximately 2 weeks. Proposals not passing the initial screen will be returned for revision. A list of approved NASS projects can be requested via [ARTinfo@cdc.gov](mailto:ARTinfo@cdc.gov) prior to submitting the Project Proposal Form to ensure that a project is not duplicative of ongoing analyses.

### Step 2

Proposals that meet the screening criteria will be forwarded to the CARTER Review Committee to be evaluated during their monthly call. To promote the principles of scientific integrity and to ensure objectivity, clarity and reproducibility of results, proposals will be evaluated by the Committee for scientific merit, appropriateness of analytic approach, and public health importance or clinical relevance. See Appendix D for the Project Evaluation Form. Proposals determined to be deficient in any of these categories will be rejected.

The Review Committee is composed of individuals with extensive knowledge of ART, NASS data, and experience in scientific research. The Committee review will take approximately 4 weeks. The Principal Investigator will be informed whether a proposal is rejected, requires major revision, is approved pending minor revisions, or is approved without revision. If the Committee requires revisions (major or minor), the researcher has 4 weeks to submit a revised proposal. If the revisions are not submitted within this timeframe, the proposal will be rejected. Revised proposals submitted after the 4-week deadline, will be considered “new” and the approval process will start over.

### Step 3

Once a proposal receives Committee approval, the Primary Investigator and all collaborators should complete and return the 2 required confidentiality forms (see Appendix E) and, if needed by CDC or their organization, seek IRB approval. Although CDC has granted ongoing IRB approval for epidemiologic research using NASS data, some projects, such as those that involve data linkages, may require a separate IRB protocol.

### Step 4

Upon receipt of all required confidentiality forms, and IRB approval (if needed) has been obtained, the research project will begin. CDC staff will work with the Principal Investigator to conduct analyses and provide outputs in tables and figures. Only pre-approved analyses with minor adjustments will be conducted. If a researcher desires to conduct additional analyses, a separate proposal may be required.

### Step 5

The Principal Investigator will be asked to provide an update on the status of the project 6 months after analyses are completed. Researchers are highly encouraged to share at least the first draft of the manuscript within this time period. Projects that have not been submitted for publication within 1 year from the completion of analyses will be re-evaluated by the CARTER Review Committee. At that time, the Committee may recommend replacement of authors or the research topic may be made available to other interested researchers.

## Authorship Guidelines

1. All co-authors must participate in the writing and make substantive contributions to the conception of the work, design of the analysis, interpretation and content.
  - a) A minimum basis for authorship requires active participation in all of the following:
    - I. Study conception and design and/or analysis and interpretation of data.
    - II. Drafting the manuscript or making significant revisions for important intellectual content.
    - III. Approval of the final version of the manuscript to be published.

- b) All qualified collaborators should be included as co-authors according to their contributions.
2. Because CARTER is a collaborative effort between CDC staff and external collaborators, CARTER should also be included as a corporate author, named as the final author after the name of the senior author, and/or CARTER should appear in the acknowledgment section of the paper with a listing of the group members. An acknowledgement statement should also be included for projects supported by grant funding.
  3. The lead author has primary responsibility for timely completion of the manuscript and preparation of the publication. An individual cannot be assigned as a lead author on a second CARTER publication until the first manuscript has been submitted for publication.
  4. It is highly encouraged that the first draft of the manuscript be shared within 6 months of the completion of analyses. Projects that have not been submitted for clearance within 1 year from the completion of analyses will be re-evaluated by the CARTER Review Committee. At that time, the Committee may recommend replacement of authors or the research topic may be made available to other interested researchers.
  5. All manuscripts and presentations with CDC co-authors must go through CDC Review and Clearance and include the following disclaimer: *The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.*
  6. The use of NASS data in publications or presentations must be appropriately noted in the methods section of the manuscript or elsewhere, as appropriate. For example, “data were collected using the National ART Surveillance System (NASS, Division of Reproductive Health, Centers for Disease Control and Prevention [CDC]).”

## CDC Review and Clearance

All manuscripts, abstracts, presentations, posters, etc. that include a CDC author must successfully complete the CDC clearance process. This process helps ensure that CDC co-author(s), as employees and representatives of a federal agency, are held to a high standard of scientific rigor. It also ensures that CDC co-authors adhere to applicable federal laws and current policies and do not present individual opinion in a manner that could be interpreted as the position of the agency. Clearance is not for editing or peer review, but authors may receive suggestions, and sometimes changes are required for clarity and scientific accuracy before final clearance approval. Please note that manuscripts should be carefully reviewed for clarity and accuracy by all co-authors and be journal submission ready before being submitted for CDC clearance.

Lead authors are required to submit CARTER manuscripts to the Coordinator to initiate CDC clearance 6-8 weeks prior to intended submission to a peer-reviewed journal. Manuscripts submitted for review should also include information on the intended journal and the submission deadline, if any. Similarly, conference abstracts and presentations should be submitted for CDC clearance 4 weeks prior to the submission deadline. Abstract and presentation submissions should include information on the intended meeting/conference and the deadline. Manuscripts, abstracts, and presentations cannot be submitted before CDC clearance.

## Appendix A. Contents of the NASS Dataset

Below is a list of the information available in the NASS dataset since 2016. Information collected by NASS has been modified and expanded over time to reflect ongoing advances in the field of ART. As a result, not all variables are available for all years of data.

### Patient and Partner Information

- Patient/partner race and ethnicity
- Patient zip code, city, state, country of residence
- Patient/partner (if sperm source) age at cycle start
- Patient height, weight, BMI at cycle start
- Patient smoking status (any smoking 3 months prior to cycle start)
- Gravidity (total number of previous pregnancies)
- Number of prior pre-term and full-term births (live and stillborn)
- Number of prior spontaneous abortions, ectopic pregnancies
- Parity (total number of previous births)
- Number of prior fresh/frozen ART cycles
- Surgical sterilization (patient or partner)
- Months attempting pregnancy
- Reason for ART: diminished ovarian reserve, endometriosis, male infertility (includes subcategories), ovulation disorders, polycystic ovaries, tubal factor, hydrosalpinx (in place), tubal ligation not reversed, other tubal disease, uterine factor, PGD, other, unexplained
- Reason for use of gestational carrier: absence of uterus, significant uterine anomaly, medical contraindication to pregnancy, recurrent pregnancy loss, unknown
- Patient maximum FSH level
- Most recent patient AMH level and date

### Oocyte Donor/Sperm Donor/Gestational Carrier Information

- Age
- Race/ethnicity

### Cycle Information

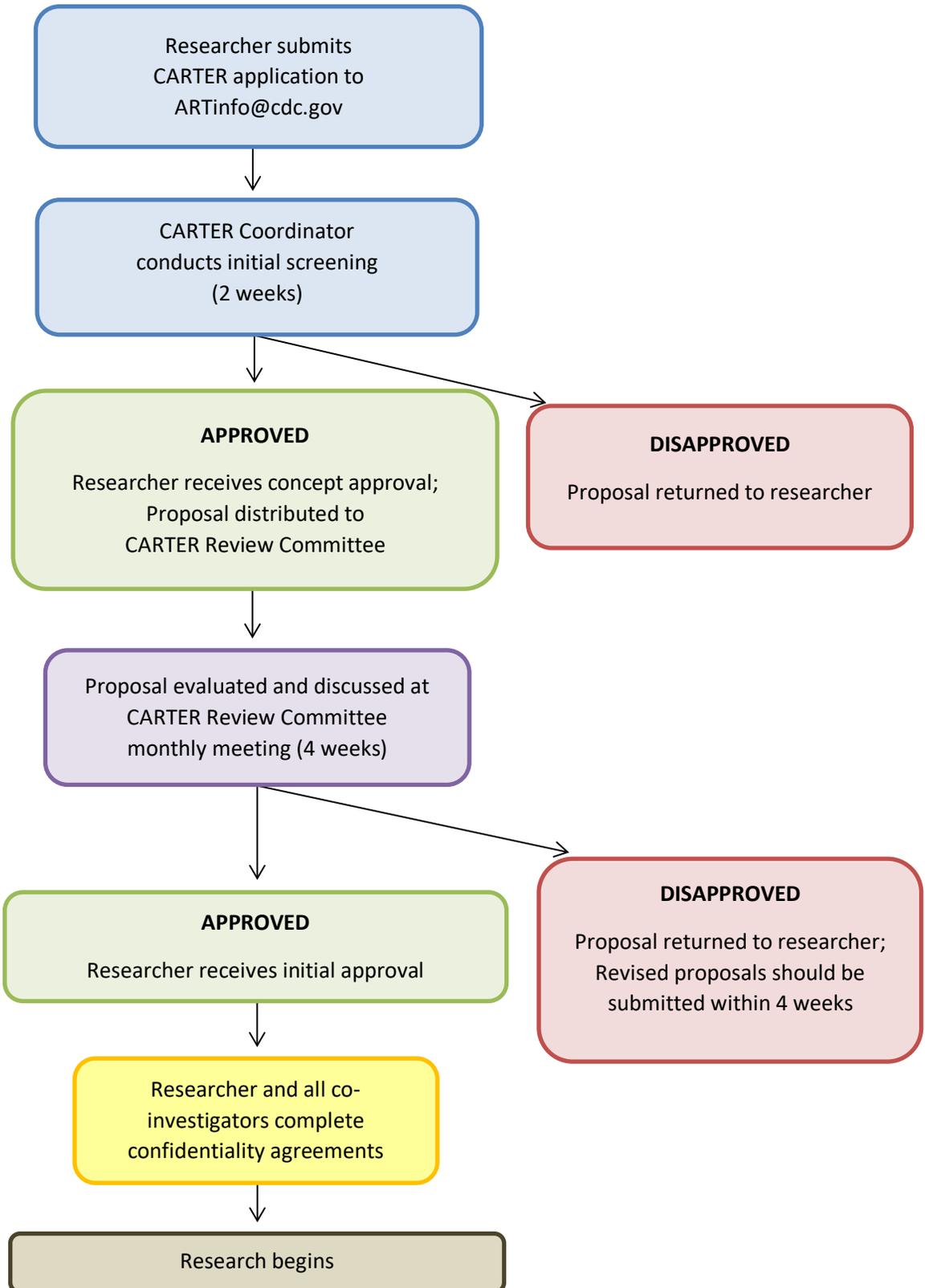
- Dates of cycle start, retrieval, transfer
- Cycle intention: IVF, GIFT, ZIFT/TET, banking
- Intended duration for oocyte or embryo banking: < 12 months or ≥ 12 months
- Intended purpose for oocyte or embryo banking < 12 months: PGD/PGT, other, both
- Intended purpose for oocyte or embryo banking ≥ 12 months: fertility preservation, other, both
- Cycle cancellation and reason
- Stimulation protocol: minimal stimulation, oral med, short- or long-acting FSH, medications with LH/HCG activity, GnRHa (Agonist Flare, Agonist Suppression, Antagonist Suppression)
- Oocyte source: donor embryo, donor oocyte, patient
- Oocytes/embryos state: fresh, thawed
- Number of oocytes retrieved (patient/donor)
- Semen source: patient, partner, donor
- Semen status: fresh, thawed, mix
- Sperm source: ejaculation, epididymal, testis, electroejaculation, retrograde urine, donor

- Number of embryos thawed (with the intent to transfer)
- Number of fresh/thawed embryos transferred to the uterus or fallopian tubes
- Quality of embryo(s) transferred: good, fair, poor, unknown
- Elective single embryo transfer (as reported and calculated)
- Number of fresh embryos cryopreserved
- Number of thawed embryos cryopreserved (refrozen)
- Embryo stage at transfer (fresh cycles only, derived from number of days between retrieval and transfer)
- Endometrial thickness at trigger
- IVF cycle used ultrasound guidance
- In vitro maturation performed on oocytes
- Assisted hatching performed
- ICSI performed and indication
- PGD performed, indication and technique
- Complications related to ART: hemorrhage, ovarian hyperstimulation, infection, medication side effect, anesthetic complication, thrombosis, death, other
- Hospitalization related to a complication occurred

#### Outcomes Information

- Treatment outcome: not pregnant, clinical, ectopic, heterotopic, intrauterine pregnancy
- Whether an ultrasound was performed
- Number of fetal heartbeats (ultrasound result)
- Implantation rate
- Type of gestation (singleton, twin, higher order)
- Pregnancy outcome: live birth, stillbirth, therapeutic abortion, spontaneous abortion
- Number of live born/still born infants
- Delivery method
- Gestational age, weeks
- Infant(s) birth weight
- Infant(s) gender
- Birth defects: cleft lip/palate, genetic/chromosomal abnormality, neural tube, cardiac, limb abnormality

## Appendix B. CARTER Proposal Approval Process



## Appendix C. CARTER Project Proposal Form

For easier editing, please email [ARTinfo@cdc.gov](mailto:ARTinfo@cdc.gov) for a Word document version of the Proposal Form.

PROJECT INFORMATION	
Date	
Title of Project	
Funding Source (if applicable)	

PRINCIPAL INVESTIGATOR	
Name	
Email	
Phone	
Institution	
Mailing Address	

**A. Rationale for the analysis and hypothesis to be tested (maximum 2 pages):** Include a short literature review with references, focusing on papers that discuss your topic and address the methodology that you plan to use.

**B. Research questions:** Include study purpose, hypotheses, goals, or research questions.

**C. Study design and methods:**

1. Analysis plan: Please provide an overall analysis plan that specifies what analytic procedures or models you will use.
2. Unit or level of analysis and denominators: There can be many levels of analysis; provide as much detail as possible.

**D. Data requirements:**

1. Years to be included: List ART reporting years (calendar years during which ART cycles were initiated) to be included in the analyses.
2. Variables: List requested variables and how they will be used.



## Appendix D: CARTER Reviewer Evaluation Form

Reviewer name \_\_\_\_\_ Review date \_\_\_\_\_

Title of proposal \_\_\_\_\_

Scientific Merit	Yes	No	Don't know	N/A	Comments
1. The proposed topic has public health importance or clinical relevancy.					
2. The proposal includes appropriate justification of the need for the study (with corresponding scientific references) and evidence that the study provides <u>new</u> information.					
3. The hypothesis is objective, clear and concise.					
4. The topic is a priority or represents a novel concept.					
5. The research question(s) overlap with other submitted or approved proposals.					

Methodology/Feasibility	Yes	No	Don't know	N/A	Comments
6. Study design is appropriate and the study population is clearly defined, including inclusion and exclusion criteria.					
7. Predictor and outcome variables are relevant and well described.					
8. The table shells and requested variables are consistent with the study aims and hypothesis.					
9. The statistical methods are sufficiently described and consistent with the research questions.					
10. Methods for addressing confounding are included.					
11. A description of potential subgroup analyses and interactions is included, if appropriate.					

**Reviewer recommendation:**

- Approve without revision
- Approve pending minor revisions
- Revise and resubmit
- Reject

## Appendix E. Confidentiality Agreement Information and Forms

The Principal Investigator and all project collaborators must have signed confidentiality forms on file before work on a project can commence. The required forms are:

308D Assurance of Confidentiality, Non-CDC

Confidentiality Pledge

Signed agreements should be emailed to [ARTinfo@cdc.gov](mailto:ARTinfo@cdc.gov).

Note: If within the last year anyone involved in the project completed and submitted the confidentiality forms for a previous approved project, they do not need to resubmit these forms at this time. However, the form(s) must be completed at least annually. Please indicate any previous submission of these forms for the list of individuals involved in the project.

**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 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.

---

(Typed/Printed Name)

(Signature)

(Date)

## CONFIDENTIALITY PLEDGE

The undersigned gives the following assurances with respect to the National Assisted Reproductive Technology Surveillance System (NASS) database:

For **all** persons with direct or remote access to any version of the NASS data, as well as collaborators with access only to aggregate data:

1. I will not use these data in any way except for statistical reporting and analysis.
2. I will not attempt to use the data set nor permit others to use it to learn the identity of any person or establishment.
3. If I should inadvertently discover the identity of any person or establishment, then I will make no use of this knowledge, I will advise CDC of the incident immediately, I will destroy the information that would identify an individual or establishment, and I will inform no one else of the discovered identity.
4. I will not fax, email, or electronically transmit in any way records or data containing personally identifying information.
5. If I must send records or data containing personally identifying information to another location, I will send them via first-class, certified, return-receipt mail in a sealed envelope stamped "CONFIDENTIAL".
6. I will take reasonable measures to protect all confidential data in my possession from eye observation, theft, and/or accidental loss or misplacement. These measures shall include storing electronic output (printout, tables, etc.) that may contain potentially identifying information in password protected files, storing hard copies in locked file cabinets, and shredding hard copies at the end of use.
7. In all oral or written presentations of the results of the analyses of data from 1995-2003, I will acknowledge that the Assisted Reproductive Technology Database was developed by SART in conjunction with the CDC.

For persons with **direct** access to the NASS data:

8. I will take all reasonable measures to protect all confidential datasets in my possession from eye observation, theft, accidental loss, or misplacement. These measures shall include storing electronic datasets that may contain potentially identifying information in password protected files, and storing back-up files on diskette or other storage devices in a locked file cabinet.

For persons on the **CDC ART Team**:

9. If I have access to medical record data during a clinic visit, I will not remove or copy any personally identifying information from the clinic.

For persons with **remote** access for work on a specific project:

10. I will not release the data analysis output or any part of it to any person other than those listed as collaborators my approved proposal. I will assure that all approved collaborators understand that they may not share the output or any part of it.
11. I will not attempt to deduce the content of small or complementary cells that have been suppressed. If I should inadvertently deduce the content of small or complementary cells, I will make no use of, share, or permit others to use this knowledge. I will advise CDC staff of the incident immediately, and I will destroy the contents of the small and complementary cells.
12. When the proposed analyses are completed, all copies of output will be destroyed (confirmed in writing) or returned to CDC within 2 years of manuscript preparation.

My signature indicates my agreement to comply with the above-stated requirements.

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Organization: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_