

GENERAL SERVICES ADMINISTRATION

[Notice—CECANF—2015—07; Docket No. 2015—0004; Sequence No. 8]

Commission To Eliminate Child Abuse and Neglect Fatalities; Announcement of Meeting

AGENCY: Commission to Eliminate Child Abuse and Neglect Fatalities, GSA.

ACTION: Meeting Notice.

SUMMARY: The Commission to Eliminate Child Abuse and Neglect Fatalities (CECANF), a Federal Advisory Committee established by the Protect Our Kids Act of 2012, will hold conference calls open to the public on the following dates: Wednesday, August 26, 2015; Thursday, September 24, 2015; Friday, October 30, 2015; Thursday, November 12, 2015; and December 3, 2015.

DATES: The meetings will be held on the noted dates from 1:00 p.m. to 3:00 p.m., Eastern Daylight Time (EDT).

ADDRESSES: CECANF will convene these meetings via conference call.

Submit comments identified by “Notice—CECANF—2015—08,” by either of the following methods:

- *Regulations.gov:* <http://www.regulations.gov>.

Submit comments via the Federal eRulemaking portal by searching for “Notice—CECANF—2015—08.” Select the link “Comment Now” that corresponds with “Notice—CECANF—2015—08.” Follow the instructions provided on the screen. Please include your name, organization name (if any), and “Notice—CECANF—2015—08” on your attached document.

- *Mail:* U.S. General Services Administration, 1800 F Street NW., Room 7003D, Washington DC 20405, Attention: Tom Hodnett (CD) for CECANF.

Instructions: Please submit comments only and cite “Notice—CECANF—2015—08, Announcement of Meeting” in all correspondence related to this notice. Comments received generally will be posted without change to <http://www.regulations.gov>, including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check <http://www.regulations.gov>, approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Visit the CECANF Web site at <https://eliminatechildabusefatalities.sites.usa.gov/> or contact Patricia Brincefield,

Communications Director, at 202–818–9596, General Services Administration, 1800 F Street NW., Room 7003D, Washington DC 20405, Attention: Tom Hodnett (CD) for CECANF.

SUPPLEMENTARY INFORMATION:

Background: CECANF was established to develop a national strategy and recommendations for reducing fatalities resulting from child abuse and neglect.

Agenda: Commission members will continue discussing the work plans of the Commission subcommittees, the information that they have obtained to date, and emerging recommendations.

Attendance at the Meetings: Individuals interested in participating by teleconference should dial 1–800–870–9004 and then enter *3676137#. Detailed meeting minutes will be posted within 90 days of the meeting. Members of the public will not have the opportunity to ask questions or otherwise participate in the meeting.

However, members of the public wishing to comment should follow the steps detailed under the heading **ADDRESSES** in this publication or contact us via the CECANF Web site at <https://eliminatechildabusefatalities.sites.usa.gov/contact-us/>.

Dated: August 20, 2015.

Karen White,

Executive Assistant.

[FR Doc. 2015–21189 Filed 8–25–15; 8:45 am]

BILLING CODE 6820–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Reporting of Pregnancy Success Rates From Assisted Reproductive Technology (ART) Programs

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS).

ACTION: Final notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) announces the requirements for reporting of pregnancy success rates from assisted reproductive technology (ART) programs as required by the Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA). This notice describes who shall report to HHS/CDC, the reporting system (National ART Surveillance System (NASS)); the process for reporting by each ART program; the data to be

reported; and the contents of the published reports. The proposed changes to reporting requirements were published in the **Federal Register** on July 21, 2014 (79 FR. 42328) and February 18, 2015 (80 FR. 8659) in accordance with requirements under the Paperwork Reduction Act; public comments and recommendations were requested. This notice incorporates the comments received from those notices and supersedes the previous notice published in the **Federal Register**, September 1, 2000 (65 FR. 53310).

FOR FURTHER INFORMATION CONTACT: Jeani Chang, Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Highway, MS–74, Atlanta, Georgia 30341. Phone: (770) 488–6370. Email: artinfo@cdc.gov.

SUPPLEMENTARY INFORMATION: Section 2(a) of Public Law 102–493 (42 U.S.C.263a–1(a)), the Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA) requires that each ART program report annually to the Secretary of the Department of Health and Human Services through the Centers for Disease Control and Prevention (1) pregnancy success rates achieved by such ART program and (2) the identity of each embryo laboratory used by such ART program and whether the laboratory is certified or has applied for such certification under the act.

FCSRCA defines “assisted reproductive technology” (ART) as “all treatments or procedures which include the handling of human oocytes or embryos, including in vitro fertilization, gamete intrafallopian transfer, zygote intrafallopian transfer, and such other specific technologies as the Secretary may include in this definition, after making public any proposed definition in such manner as to facilitate comment from any person (including any federal or other public agency).”

The Secretary is directed in FCSRCA to define pregnancy success rates and “make public any proposed definition in such a manner as to facilitate comment from any person during its development.”

Section 2(c) (42 U.S.C. 263a–1(c)) states “the Secretary shall consult with appropriate consumer and professional organizations with expertise in using, providing, and evaluating professional services and embryo laboratories associated with assisted reproductive technologies.”

Since 1995, HHS/CDC has reported pregnancy success rates of United States ART programs as required by FCSRCA. Changes in ART practice require

periodic revision of the National ART Surveillance System in order to maintain accurate reporting of ART success rates. In updating the definitions of success rates, as well as various factors and characteristics required for calculating the success rates or that might influence the success rates, HHS/CDC consulted with representatives of the Society for Assisted Reproductive Technology (SART, a national professional association of ART clinical programs), the American Society for Reproductive Medicine (ASRM, a national society dedicated to the advancement of the science and practice of reproductive medicine), RESOLVE (the National Infertility Association, a national, nonprofit consumer organization), Path2Parenthood (P2P, a national, nonprofit consumer organization), and the American Urological Association (AUA, a national professional association of urologic community) as well as a variety of individuals with expertise and interest in infertility and/or ART.

Public Comment Summary and Responses

Seven comments were received in response to the July 21, 2014 (79 FR. 42328) notice that outlined the reporting requirements, changes to NASS data elements, and the associated burden. Comments are summarized by the following topics: burden estimates, proposed NASS data elements, duplicative data collection, and request for additional data elements. Some commenters provide comments on multiple topics. Summaries of these comments, as well as HHS/CDC's responses, are provided below.

1. Burden estimates: Four commenters expressed concern that implementation of the new NASS system was not included in the total burden estimates, thus the burden to clinics for data reporting was underestimated.

Response: The estimated annual burden to clinics is calculated using the average time required to answer the number of questions and possible responses to each question when applicable. We acknowledge that there is an additional burden for the first year of this transition associated with making the appropriate software modifications that was not represented in the notice published on July 21, 2014. In order to minimize the impact of this burden on clinic operations, projected implementation of the new data collection system was changed from January 1, 2015 to January 1, 2016. We have also recalculated the burden for the first year to include the fixed burden

associated with changes to the data collection systems in each clinic. The following changes were made to the burden estimate: a) increased the average burden to 43 minutes per response and b) added a one-time system implementation for each clinic (40 hours per each response) to update their data collection systems to reflect the new platform and interface of the NASS web-application over a 3-year clearance period.

2. Proposed NASS data elements: There was concern from one commenter that the proposed data elements went beyond the mandate established by FCSRCA and its implementing regulations. Commenter cited the information related to the quality of any embryo considered for transfer and prior ART cycles that resulted in pregnancy as two examples that appear to go beyond the mandate.

Response: HHS/CDC thanks the commenter for this comment, but notes that changes to the NASS data elements are essential to keep pace with changes in medical practice, ensure that reported success rates reflect standardized definitions, and provide additional insight into factors that may affect success rates. Regarding the addition of variables such as embryo quality and the number of prior ART cycles, the NASS system collects information on ART outcomes as well as other patient and procedure characteristics that may affect treatment outcomes. The reporting of success rates by patient and procedural factors allows consumers to see success rates for patients similar to themselves and undergoing procedures with similar characteristics. Presenting success rates without taking patient and procedural characteristics into account could produce inaccurate rates.

3. Duplicative data collection: There was concern from one commenter that the collection of ART outcomes by HHS/CDC duplicates the work SART already does and the resulting cost of a duplicative data collection to the government and taxpayers is not warranted.

Response: HHS/CDC notes the commenter's concern and reminds the commenter that this data collection is mandated by statute while data collection by a private entity is not required by law. FCSRCA requires that each assisted reproductive technology (ART) program annually report pregnancy success rates achieved by such ART program to the Secretary through HHS/CDC. Changes in ART practice require periodic revision of the National ART Surveillance System in order to maintain accurate reporting of ART success rates.

4. Request for additional data elements: Three commenters suggested the addition of data elements.

Commenter 1 suggested that it would be important for the NASS and Assisted Reproductive Technology Team to consider adding variables relating to infant outcomes (as listed below).

(1) Use of traditional or gestational surrogate carriers: Surrogate age, number of prior pregnancies, number of previous live born infants, and number of prior surrogacy (either gestational carrier or traditional surrogate).

(2) Maternal variables: occurrence of pregnancy induced hypertension, maternal diabetes and stage, hyperemesis gravidarium, fetal ultrasound results with special focus on fetal echocardiogram at 20–24 weeks.

(3) Placental examination: placental abnormalities, evidence of single umbilical artery, histologic chorioamnionitis, in twins or multiple gestations presence of twin to twin transfusion syndrome associated with artery-venous shunting in the placenta, placentation (diamniotic-dichorionic, monochorionic-diamniotic, and placentation of greater than twin).

(4) Neonatal Variables Suggested to be added:

A. Infant Weight, Length, and Head Circumference

B. Infant Gestational age as determined by Ballard Physical and Neurodevelopment examination

C. Admission to Neonatal Intensive Care Unit

D. Specific Neonatal Variables:

1. Apgar Scores as 1 and 5 minutes, requirement for resuscitation,
2. NICU admission,
3. Length of Hospital Stay,
4. Time (in days) to regain birth weight,

5. Specific Neonatal Morbidities:

a. Occurrence of Respiratory Distress Syndrome,
b. Presence of patent ductus arterioles,
c. Hyperbilirubinemia requiring A) phototherapy and/or B) exchange transfusion and maximum total serum bilirubin,
d. Occurrence of intraventricular hemorrhages by grade (Papille)*i.e.* Grade I to IV,
e. Occurrence of periventricular leukomalacia,
f. Occurrence of necrotizing enterocolitis using the Bell scoring system,
g. Occurrence of electrographic seizures,
h. Did the infant pass the newborn hearing screen,
i. Abnormalities on the Newborn Metabolic Screen,

- j. Results of the screen for congenital heart disease (Upper and Lower SpO2 after 24 hours),
- k. Occurrence of minor and major phenotypic anomalies, occurrence of specific syndromes including imprinting disorders,
- l. Karyotype results (if performed), results of chromosomal arrays (if performed).

Response: FCSRCA requires that each assisted reproductive technology (ART) program annually report pregnancy success rates achieved by such ART program to the Secretary through HHS/CDC. Many of the suggested data elements are only available through vital records (*i.e.* birth certificates, fetal death certificates) and NASS does not collect information from birth certificates. Collection of the additional variables suggested is not feasible as part of this effort. No changes to the data collection were made as a result of this comment.

Commenter 2 requested clarification if the following male infertility data points are included in the new planned data collection:

- Medical condition
- Genetic or chromosomal abnormality, Specify _____
- Abnormal sperm parameters (select all that apply)
 - Azoospermia, obstructive
 - Azoospermia, non-obstructive
 - Oligospermia, severe (<5 million/mL)
 - Oligospermia, moderate (5–15 million/mL)
 - Low motility (<40%)
 - Low morphology (4%)
- Other male factor (not included above), Specify _____

Response: The suggested male infertility data points are already in the proposed NASS data elements; thus, no changes were made to the data collection as a result of this comment.

Commenter 3 recommended adding the method of delivery (Vaginal or C-section): Indication for c-section (if c-section used) (Prior c-section, Overdue delivery, Medical complication, Non-medical indication/Patient preference). This will take less than two additional minutes per cycle with live birth (zero for cycles without birth), as this information is almost always in the documents we routinely obtain.

Rationale for inclusion of this information includes: Some reports indicate c-section delivery is more common with frozen-thawed embryo transfer. It is also reported that frozen-thawed embryo transfer is associated with larger birthweights. These two variables might be causally related, or might be confounded in assessments of

perinatal outcomes. Consider that large infants can motivate a c-section, FET cycles often follow a fresh delivery that might have used a c-section and thus create an indication for c-section, and c-sections abbreviate a pregnancy so that birth by c-section occurs some hours or days earlier than otherwise would have.

Response: HHS/CDC appreciates the suggestion to add 'Method of Delivery' to the data collection and agrees that this information could be reliably reported by the patient. 'Method of Delivery (Vaginal or C-section)' was added as a proposed data element. However, 'Indication for C-Section' is usually only available through either the birth certificate or from the obstetrical care providers. Collecting information directly from the obstetrician/gynecologists is not feasible as part of this effort.

Appendix—Notice for the Reporting of Pregnancy Success Rates From Assisted Reproductive Technology Programs

Introduction

This notice includes four sections:

- I. Who Reports: describes who shall report to HHS/CDC.
- II. When and How to Report: describes the reporting system and process for reporting by each ART program.
- III. What to Report: describes the data items and definitions to be included in the reporting database.
- IV. Published Reports and Data Usage: outlines the topics that will be included in the annual published reports and describes how data are collected in the reporting database.

I. Who Reports

The Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA) requires that each assisted reproductive technology (ART) program shall annually report pregnancy success rates to the Secretary of the Department of Health and Human Services through HHS/CDC. HHS/CDC began collecting data from ART programs starting with ART cycles performed in 1995. Between 1997 and 2003, HHS/CDC contracted with the Society for Assisted Reproductive Technology (SART) to annually obtain a copy of their clinic-specific database. Since 2004, HHS/CDC has maintained the National ART Surveillance System (NASS), a web-based ART data reporting system.

The following guidelines have been established to define an ART program and the reporting responsibilities of an ART program, including the responsibilities of each ART program's Medical Director.

A. Criteria to be Considered an ART Program

An ART program is defined as a practice, program, or clinic if it meets the following criteria:

- (1) It is a legal business entity that practices under State law;
- (2) It is recognizable to the consumer as a stand-alone ART program or clinic, separate

and apart from another ART program or clinic with whom that program may share some or all resources or liability;

(3) It provides ART services to patients who have experienced infertility or are undergoing ART for other reasons.

B. Reporting Responsibilities of the Medical Director

The current Medical Director of the ART program at the time of the reporting is responsible for verifying and reporting all ART cycle data for that reporting year. If the Medical Director is not available to verify and approve the reported cycle data due to unforeseen circumstances, the Laboratory Director may assume the reporting responsibilities for the Medical Director. If there is a change in personnel, including the Medical Director's position, between the time the ART cycles occurred and the time the reporting year data are due, the current Medical Director in position at the time of the final reporting deadline is responsible for reporting and verifying all ART cycles performed by that program in that reporting year.

C. Reporting Responsibilities of ART Program

There are a variety of ways in which ART programs might be structured. Reporting is based upon ART cycles performed within a program not by an individual physician. Therefore, one or more individual physicians within a single ART program may not report their data separately from the remainder of the physician group. Individual physicians who practice independently may not pool their data and report together as one program.

The following sections provide guidance on the reporting responsibilities for programs:

(1) One practice, one site—An ART program with one or more physicians who share resources and/or liability, but not necessarily patients, at one location. In a practice with several physicians, the Medical Director is required to report every ART cycle performed at the ART program under one NASS ID, even when other practitioners in the ART program may have performed most or all of the work for the cycle(s). An ART program cannot report cycles from another program for which one of their current or former practice physicians are responsible except in the case of reorganization. Reorganization of an ART program is defined as a change in ownership or affiliation, or when at least two of the three key staff positions (Practice Director, Medical Director, or Laboratory Director) change because the person(s) in those positions is/are no longer employed with the practice. In the case of reorganization, the clinic Medical Director in position at the time of the final reporting deadline is responsible for reporting and verifying all ART cycles performed by that program in that reporting year.

(2) One practice, multiple sites—An ART program with one or more physicians who share resources and/or liability, but not necessarily patients, at multiple locations. If any site satisfies the definition of an individual ART program as described above (Section I, A), that site should report

separately under a unique NASS ID. Contact the NASS Help Desk at 1-888-650-0822 to discuss other multiple site scenarios. A reporting determination will be made based on the definitions and guidance provided here.

(3) Multiple ART programs involved in one cycle—Different ART programs responsible for ovarian stimulation, oocyte retrieval, and/or embryo transfer.

The following guidelines should be used:

a. The requirement to report cycles lies with the ART program that accepts responsibility for the embryo culture. The ART programs involved must have a method in place to ensure that these cycles can be prospectively reported by the ART program required to report them. In addition, all canceled cycles must be reported by the ART program accepting responsibility for the embryo culture.

b. Cycles involving previously cryopreserved oocytes/embryos are to be reported by the ART program that accepts responsibility for thawing the oocytes/embryos.

(4) Multiple ART programs sharing one ART laboratory—Independent ART programs that share an embryology laboratory or use another program's laboratory must report their cycles independently under their own unique NASS IDs.

II. When and How To Report

A. Reporting Activities

The deadline for reporting ART cycle and pregnancy outcome data to HHS/CDC is December 15 of the year after which cycles were conducted. For example, the deadline to report data on cycles initiated between January 1, 2013 and December 31, 2013 was December 15, 2014. HHS/CDC will send a letter to all qualifying ART programs to announce each reporting year deadline 90 days before cycle data are due. An ART program is considered to be non-compliant with the federal reporting requirements of the FCSRCA if the program was in operation at any time during the reporting year and performed any ART cycles and (a) fails to submit ART cycle data to HHS/CDC by the reporting deadline, or (b) the program's Medical Director fails to verify the clinic success rates table by the reporting deadline. These programs will be identified as non-reporters in HHS/CDC's annual Assisted Reproductive Technology Fertility Clinic Success Rates Report. ART programs that were in operation at any time during the reporting year but did not perform any ART cycles will not be included in HHS/CDC's annual ART report (either as a reporting or as a non-reporting clinic).

ART programs that are submitting data to HHS/CDC via the NASS or through an approved alternative (*i.e.*, SART member clinics may report their data to NASS through SART) will be considered to be in compliance with federal reporting requirements of the FCSRCA. Regardless of the method chosen for submitting data to NASS, each clinic must complete the annual submission steps as detailed in the NASS Annual Submission Guide posted on the NASS Web site (www.artreporting.org). A NASS account can be set up by calling the

NASS Help Desk at 1-888-650-0822 or by sending an email to NASS@artreporting.org. NASS accounts established previously can be used for data submission by the same clinic, although user passwords may need to be re-established if they have expired since last using NASS. ART programs should also notify the NASS Help Desk of any changes in clinic location, ownership, or key staff (*i.e.*, Practice, Medical, or Laboratory Director) and provide NASS with a list of all practicing physicians in the program.

All cycle data must be reported prospectively, *i.e.*, reporting of initial cycle intent and select patient details is required within four days of cycle initiation. Each ART patient will be assigned a unique, system-generated patient ID when the program first enters the patient in NASS. The program is responsible for linking each patient's ID to the patient's medical records for reporting any future ART cycles. Each ART cycle for each patient is also assigned a unique cycle code. In NASS, the patient is identified by the NASS ID and the patient ID; the cycle code (cycle IDs) allows identification of all cycles performed on a single patient. Since the patient's name and social security number are not included in the reporting database, each program should maintain personal identifiers in the program's database on site in order to link every cycle reported to CDC to a specific patient.

B. Updating of Reporting Requirements

ART is a rapidly developing medical science. To keep current as practices evolve, ART reporting requirements, including data collection instruments, variables, and definitions, will be periodically reviewed and updated as new knowledge concerning ART methods and techniques becomes available. During such a review, professional and consumer groups and individuals will be consulted to confirm the validity of the new or revised reporting requirements and data elements. Clinics will be notified in writing at least 120 days in advance of January 1st of the reporting year of all changes to the reporting requirements.

ART programs are ultimately responsible for ensuring that their data are mapped accurately into the required NASS format if using third-party electronic medical records or reporting systems to submit their ART data through NASS to HHS/CDC. ART programs must ensure their clinic data can be correctly transmitted to NASS for pre-import NASS quality control reviews and imported into NASS in time for the required NASS annual submission steps by the HHS/CDC deadline. HHS/CDC will continue to inform clinics of all necessary requirements for importing data from other electronic medical record systems into NASS and for checking imported data to ensure that it retains the accuracy and compatibility of the data entry system from which it was extracted.

Each ART program should be aware that the Paperwork Reduction Act is applicable to this data collection. Under the Paperwork Reduction Act of 1995, a Federal agency shall not conduct or sponsor a collection of information from ten or more persons other than Federal employees, unless the agency

has obtained approval from the Office of Management and Budget (OMB) for the collection of information. A person is not required to respond to a collection of information unless it displays a currently valid OMB control number. In compliance with the Paperwork Reduction Act, HHS/CDC has obtained OMB approval to collect this data under OMB control No. 0920-0556, expiration 07/31/2018.

C. External Validation of Clinic Data

As part of the annual routine activities of this surveillance program, all ART programs are subject to external validation of their reporting activities, which will include review by appropriate professionals from CDC staff and CDC contractors. This review may include but is not limited to examination of medical and laboratory records and comparison with data reported in NASS.

Each year, HHS/CDC selects a random sample of 5–10% of all reporting ART programs, after taking into consideration some clinic characteristics, *e.g.*, size of clinics, number of cancelled cycles, or number of multiple births for an on-site validation visit. The purpose of validation is to evaluate the overall accuracy of data reported in NASS. It also serves to identify any systematic problems that could cause data collection to be inconsistent or incomplete. During validation visits, data submitted to NASS are compared with data recorded in the patient medical records, which allows for the calculation of discrepancy rates. All potential data discrepancies identified during the on-site visit will be discussed with staff of the ART program. If major data discrepancies are identified during data validation (*e.g.*, lack of supporting information for pregnancy outcomes, underreporting cycles, etc.), HHS/CDC may re-select these ART programs for data validation during the following reporting year(s) to assess corrections of identified data errors. Aggregate findings for validated data fields from all ART programs participating in validation will be reported in HHS/CDC's Fertility Clinic Success Rates Report. The HHS/CDC validation process is not an assessment of clinical practice or overall record keeping; however, the results of the validation may be helpful to ART programs.

Each clinic is responsible for maintaining appropriate medical and laboratory records that contain information reported in NASS. This information must be able to link each patient, cycle, oocyte retrieved, transfer, and pregnancy outcome for the purpose of external validation.

III. What To Report

Cycle-specific data for the following patients must be reported: (1) All patients undergoing ART, (2) 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, (3) all patients providing donor oocytes, and (4) 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. ART programs must report the following data items:

A. Patient Demographic Information

Date of Cycle Reporting
NASS ID
Optional Identifier (as needed)
Date of Birth
Gender
U.S. Residency
City of Residence
State of Residence
Country of Residence (if not United States)

B. Cycle Information

1. Intended Cycle Information

Intended Type of Cycle (IVF, GIFT, ZIFT, Oocyte or embryo banking)
Intended Embryo Source (Patient, Donor)
Intended Embryo State (Fresh, Frozen)
Intended Oocyte Source (Patient, Donor)
Intended Oocyte State (Fresh, Frozen)
Intended Sperm Source (Partner, Donor, Patient, Unknown)
Pregnancy Carrier (Patient, gestational carrier, none-for oocyte/embryo banking only)

2. Cycle Information

Type of Cycle (IVF, GIFT, ZIFT, Oocyte or embryo banking)
Embryo Source (Patient, Donor)
Embryo State (Fresh, Frozen)
Oocyte Source (Patient, Donor)
Oocyte State (Fresh, Frozen)

3. Patient Medical Evaluation

Reason(s) for ART

Male Infertility (Medical condition, Genetic or chromosomal abnormality, abnormal sperm parameters, Obstructive azoospermia, Non-obstructive azoospermia, Severe oligospermia, Moderate oligospermia, Low motility, Low morphology, other)

History of Endometriosis

Tubal Ligation for Contraception
Current or Prior Hydrosalpinx
Other Tubal Disease (Not Current or Historic Hydrosalpinx)
Ovulatory Disorders (PCO, Other)
Diminished Ovarian Reserve

Uterine Factor

Preimplantation Genetic Diagnosis as Primary Reason for ART

Oocyte or Embryo Banking As Reason for ART

Indication for Use of Gestational Carrier (Absence of uterus, Significant uterine anomaly, Medical contraindication to pregnancy, Recurrent pregnancy loss, Unknown)

Recurrent Pregnancy Loss

Other Reasons Related to Infertility (Specify)

Other Reasons Not Related to Infertility (Specify)

Unexplained Infertility

C. Patient History

Height
Weight
History of Smoking
History of Prior Pregnancy (Number of prior full term, preterm, stillbirth,

spontaneous, ectopic pregnancies)

Months attempting pregnancy

History of Prior ART (Fresh & Frozen)

Maximum FSH Level (mIU/mL)

Recent AMH Level (ng/mL)

Date of Most recent AMH Level

D. Oocyte Source and Carrier Information

Date of Birth

Race (White, Black, Asian, Native Hawaiian/
Pacific Islander, American Indian or
Alaska Native)

Ethnicity (Hispanic, non-Hispanic, Refused, Unknown)

E. Sperm Source Information

Date of Birth

Race (White, Black, Asian, Native Hawaiian/
Pacific Islander, American Indian or
Alaska Native)

Ethnicity (Hispanic, non-Hispanic, Refused, Unknown)

F. Stimulation and Retrieval

Stimulation

Aromatase Inhibitor/Estrogen Receptor
Medication (Clomiphene and Letrozole dosage)

FSH Medication

LH/HCG Medication

GnRH (Gonadotropin-releasing hormone)(None, GnRH agonist suppression, GnRH agonist flare, GnRH Antagonist suppression)

Canceled Cycle

Date of Canceled Cycle

Reason for Canceled Cycle (Low ovarian response, High ovarian response, Inadequate endometrial response, Concurrent illness, Withdrawal for personal reasons, Other)

Date of Retrieval

Number of Patient Oocytes Retrieved

Number of Donor Oocytes Retrieved

Use of Oocytes (For this cycle, Oocytes frozen for future use, Oocytes shared with other patients, Embryos frozen for future use)

Complications of Stimulation and Retrieval

(Infection, Hemorrhage, Ovarian Hyperstimulation requiring intervention or hospitalization, Medication Side Effect, Anesthetic Complication, Thrombosis, Death, Other) Sperm Status (Fresh, Thawed, Mix of fresh and thawed) Sperm Source Utilized (Ejaculated, Epididymal, Testis, Electroejaculation, Retrograde urine, Donor, Unknown)

G. Laboratory Information

ICSI (Intracytoplasmic sperm injection) (All oocytes, Some oocytes, No oocytes, Unknown)

Indication for ICSI (Prior failed fertilization, Poor fertilization, PGD, Abnormal semen parameters, Low oocyte yield, Laboratory routine, Frozen cycle, Rescue ICSI, Other)

IVM (In vitro maturation)

PGD (Pre-implantation genetic diagnosis)

PGS (Pre-implantation genetic screening)

Reasons for PGD/PGS

Technique(s) Used for PGD/PGS

Assisted Hatching

2 Pronuclei

Research Cycle

SART Approval Code for Research Cycle

H. Transfer Information

Attempted Transfer

Reason for No Transfer (Low Ovarian

Response, High Ovarian Response,

Failure to Survive Thaw, Inadequate

Endometrial Response, Concurrent

Illness, Patient Withdrawal from

Treatment, Unable to Obtain Sperm

Specimen, Insufficient Embryos, Other)

Date of Transfer

Endometrial Thickness

1. Fresh Embryo Transfer

Number of Fresh Embryos Available for Transfer

Number of Fresh Embryos Transferred

eSET

Quality of Embryo (Good, Fair, Poor, Unknown)

Number of Fresh Embryos Cryopreserved

2. Thawed Embryo Transfer

Number of Thawed Embryos Available for Transfer

Number of Thawed Embryos Transferred

Quality of Embryo

Date of Oocyte retrieved for the Thawed Embryos

Number of Thawed Embryos Cryopreserved

3. GIFT/ZIFT/TET Transfer (for Non-IVF Cycle)

Number of Oocytes/Embryos Transferred to Fallopian Tube

I. Outcome Information

Outcome of Treatment (Not Pregnant, Biochemical Pregnancy, Ectopic Pregnancy, Clinical Intrauterine Gestation, Heterotopic Pregnancy, Unknown)

Maximum Number of Fetal Hearts

Ultrasound Date

If >2 Fetal Hearts, any Monochorionic Twins/Multiples

Outcome of Pregnancy (Live Birth, Stillbirth, Spontaneous Abortion, Induced Abortion, Maternal Death Prior to Birth, Unknown)

Date of Pregnancy Outcome

Method of delivery (Vaginal, Cesarean section)

Source for Outcome of Pregnancy (Verbal Confirmation Patient, Written Confirmation Patient, Verbal Confirmation Physician or Hospital, Written Confirmation Physician or Hospital)

Method of Delivery (Vaginal, Cesarean section)

Number of Infants Born

Birth Status (Live Birth, Stillbirth, Unknown)

Gender of Infant (Each Live-born and Stillborn Infant)

Birth Weight (Each Live-born and Stillborn Infant)

Birth Defect (Each Live-born and Stillborn Infant) (Genetic Defect/Chromosomal Abnormality, Cleft Lip or Palate, Neural Tube Defect, Cardiac Defect, Limb Defect, Other Defect)

J. Definitions

The following definitions provide clarification for the required data items:

Assisted reproductive technology (ART)—All treatments or procedures that include the handling of human oocytes or embryos for the purpose of establishing a pregnancy. This includes, but is not limited to in vitro fertilization and transcervical embryo transfer, gamete intrafallopian transfer, zygote intrafallopian transfer, tubal embryo transfer, oocyte or embryo cryopreservation, oocyte or embryo donation, and gestational surrogacy. ART does not include assisted insemination using sperm from either a woman's partner or sperm donor.

ART cycle—ART cycles can be stimulated (use of ovulation induction) or unstimulated (natural cycle). An ART cycle is considered any cycle in which (1) ART has been used, (2) the woman has undergone ovarian stimulation or monitoring (*i.e.*, performance of sonogram, serum estradiol or LH measurements) with the intent of undergoing ART, (3) in the case of donor oocytes, a woman began medication for endometrial preparation with the intent of undergoing ART, or (4) in the case of cryopreserved embryos or oocytes, a woman began medication for endometrial preparation with the intent of undergoing ART and/or embryos were thawed with the intent of transfer.

Anti-mullerian hormone (AMH) level—A measure of diminished ovarian reserve that predicts the ovaries' response to ovarian stimulation during ART.

Assisted hatching—A micromanipulation technique that involves making a small opening in the zona wall of the embryo in an effort to enhance implantation.

Azoospermia, obstructive—Complete absence of sperm from the ejaculate. Obstructive azoospermia may result from epididymal, vasal, or ejaculatory duct pathology.

Azoospermia, non-obstructive—Complete absence of sperm in the ejaculate due to testicular failure, varicoceles, or chromosomal abnormalities such as Y-chromosome microdeletions or karyotypic abnormalities (*e.g.*, Klinefelter syndrome).

Birth defect—Anomaly diagnosed prior to or at birth that results in death or causes a serious disability requiring surgical and/or medical therapy. Specific anomalies to be identified include genetic defect/chromosomal abnormality, cleft lip or palate, neural tube defect, cardiac defect, limb defect, or other defect.

Biochemical pregnancy—A positive serum pregnancy test (Beta-hCG) without ultrasound confirmation of a gestational sac within the uterus, and without diagnosis of an ectopic pregnancy.

Blastocyst/trophectoderm biopsy—Procedure involving the removal of a small number of trophectoderm cells from a blastocyst stage embryo for genetic testing. A blastocyst is a day 5/6 embryo which contains two cell types—the inner cell mass, which eventually develops into fetal tissues, and the trophectoderm, which gives rise to the developing placenta and other tissues.

Blastomere biopsy—Procedure involving the removal of one blastomere from a cleavage stage embryo for genetic testing. A cleavage stage embryo is a day 3 embryo when approximately 6–8 cells are present.

Cancelled cycle—An ART cycle in which ovarian stimulation or monitoring or

endometrial preparation has been carried out with the intent of undergoing ART but which did not proceed to oocyte retrieval or to the transfer of embryos. Reasons for cancellation include low ovarian response, high ovarian response, inadequate endometrial response, concurrent illness, patient withdrawal from treatment, failure of oocytes to survive thaw, an inability to obtain sperm specimen, or insufficient embryos.

Clinical pregnancy/Clinical intrauterine gestation—An ultrasound-confirmed gestational sac within the uterus or the documented occurrence of a birth, spontaneous abortion, or induced abortion in cases of missing ultrasound data. Clinical pregnancies include all gestational sacs regardless of whether or not a heartbeat is observed or a fetal pole is established. This definition excludes ectopic pregnancy but includes pregnancies which end in live birth, stillbirth, spontaneous abortions, and induced abortions.

Clomiphene citrate—An ovulation induction medication with trade names such as Clomid®, Serophene®, or Milophene®.

Complication—A medical complication for the woman related to ART procedures. Specific complications to be identified include infection, hemorrhage requiring transfusion, ovarian hyperstimulation syndrome requiring intervention or hospitalization, medication side effect, anesthetic complication, thrombosis, death of patient, or other specified complication.

Cryopreservation—A technique used in ART to preserve sperm, oocytes, and embryos through freezing.

Cycle start date (cycle initiation date)—

(1) For fresh embryo, (both donor and non-donor): The first day that medication to stimulate follicular development is given in a stimulated cycle or the first day of menses in an unstimulated cycle. For example:

- a. The first day of gonadotropins in a gonadotropin only cycle or in a long suppression GnRH agonist-gonadotropin cycle;
- b. The first day of GnRH agonist in a GnRH agonist flare-gonadotropin cycle;
- c. The first day of clomiphene or letrozole in a clomiphene/gonadotropin cycle or a clomiphene only cycle;
- d. The first day of natural menses or withdrawal bleeding in an unstimulated cycle.

(2) For fresh embryo donor cycles:

- a. The first day exogenous sex steroids are given to patient to prepare the endometrium;
- b. The first day of natural menses or withdrawal bleeding in an unstimulated cycle.

(3) For frozen embryo cycles (both donor and non-donor):

- a. The first day exogenous sex steroids are given to prepare the endometrium;
- b. The first day of natural menses or withdrawal bleeding in an unstimulated cycle.

(4) For oocyte/embryo banking cycles:

- a. The first day of gonadotropins in a gonadotropin only cycle or in a long suppression GnRH agonist-gonadotropin cycle;
- b. The first day of GnRH agonist in a GnRH agonist flare-gonadotropin cycle;

c. The first day of clomiphene or letrozole in a clomiphene/gonadotropin cycle or a clomiphene only cycle;

d. The first day of natural menses or withdrawal bleeding in an unstimulated cycle.

Diminished ovarian reserve—A condition of reduced fecundity related to diminished ovarian function based on clinical assessment; often indicated by FSH \leq 10 mIU/mL or AMH $<$ 1.0 ng/mL.

Donor embryo cycle—A cycle initiated with the intent to transfer donated embryos, that is, embryos derived from oocytes previously fertilized for another couple's ART therapy that were subsequently donated.

Donor oocyte cycle—A cycle initiated with the intent to transfer oocytes, or embryos derived from oocytes that were retrieved from a woman serving as an oocyte donor (sperm source may be either the patient's partner or a sperm donor selected by the patient).

Ectopic pregnancy—A pregnancy in which the fertilized egg implants outside the uterine cavity.

Elective single embryo transfer—A procedure in which one embryo, selected from a larger number of available embryos, is placed in the uterus or fallopian tube. The embryo selected for eSET might be from a previous IVF cycle (*i.e.*, cryopreserved [frozen] embryos) or from a current fresh IVF cycle that yielded more than one embryo. The remaining embryos may be set aside for future use through cryopreservation.

Embryo—The normally (2 pronuclei) fertilized egg that has undergone one or more divisions.

Embryo banking cycle—A cycle initiated with the intent of cryopreserving all embryos for later use. (This does not apply to cycles initiated with the intent to transfer embryos but for which all embryos were subsequently cryopreserved regardless of the reason.) Embryo banking can be short term (<12 months) or long term (\geq 12 months).

Embryo quality—Refers to the quality of the embryo as determined by its morphology. Embryo morphology assessment includes two parts: an overall grade and the stage. Overall grading is a subjective assessment of the overall quality of the embryo as good, fair or poor, and is based on assessment of certain characteristics of the embryo, such as fragmentation, symmetry, inner cell mass (ICM) quality or trophectoderm quality. Stage dependent grading involves determining the developmental stage of the embryo.

—Good: Embryo free of imperfections or with only minor imperfections.

—Fair: Embryo lacking exceptional quality but not excessively imperfect either.

—Poor: Embryo with numerous imperfections.

Embryo transfer—Attempt to introduce embryo(s) into a woman's uterus or attempt to introduce embryos or gametes (oocytes and sperm) into a woman's fallopian tubes; a transfer procedure is considered to have been carried out, if attempted, even if no embryos or gametes were successfully transferred.

Endometriosis—The presence of tissue resembling endometrium in locations outside the uterus such as the ovaries, fallopian

tubes, and abdominal cavity; a history of all stages of endometriosis (minimal to severe) whether treated or not may be a reason for ART.

Endometrium—The lining of the uterus that is shed each month as the menstrual period. As the monthly cycle progresses, the endometrium thickens and thus provides a nourishing site for the implantation of a fertilized egg.

Fertilization—The penetration of the egg by the sperm and fusion of genetic materials to result in the development of a fertilized egg (or zygote).

Fetus—The developmental stage during pregnancy from the completion of embryonic development at eight weeks of gestation until delivery.

Flare protocol—A stimulation protocol in which a GnRH agonist is started on day 2 of the same menstrual cycle during which the eggs will be retrieved.

Follicle—A fluid-filled sac located just beneath the surface of the ovary that contains an oocyte and cells that produce hormones.

Fresh embryo—An embryo created during the current cycle (either from the patient or donor), *i.e.*, not a thawed embryo created during a previous cycle. Fresh embryos can be created from either fresh or frozen eggs or sperm.

Fresh oocyte—An oocyte retrieved during the current cycle (either from the patient or donor), *i.e.*, not a thawed oocyte retrieved during a previous cycle.

Follicle stimulating hormone (FSH)—A gonadotropin hormone produced and released from the pituitary that stimulates the ovary to ripen a follicle for ovulation. FSH is available in several types of preparations including: Urofollitropin, Follitropin alfa and Follitropin beta, some of which also include luteinizing hormone (LH). Trade names include Gonal-f®, Metrodin®, Fertinex™, Bravelle™, Repronex®, Pergonal®, Humegon®, and Follistim™.

Full-term birth—A birth that reached 37 completed weeks of gestation. This includes both live births and stillbirths. For the purpose of reporting prior full-term births, births are counted as birth events (*e.g.*, a triplet birth is counted as one).

Gamete intrafallopian transfer (GIFT)—An ART procedure that involves removing oocytes from a woman's ovary, combining them with sperm, and immediately transferring (via a catheter) the eggs and sperm into the fallopian tube. Fertilization takes place inside the fallopian tube.

Gestational carrier (sometimes referred to as a gestational surrogate)—A woman who gestates an embryo that did not develop from her oocyte, with the expectation of returning the infant to its intended parent(s). NOTE: For female same sex couples, the woman who will carry the pregnancy should be identified as the patient and a separate cycle should be reported if donor oocytes are used, even if the patient's partner is the source of the oocytes. If a gestational carrier is used, one cycle is reported for fresh embryo cycle; two cycles should be reported for frozen embryo cycle (one for the oocyte retrieval and one for the embryo transfer).

Gonadotropin—Hormones having a stimulating effect on the gonads (ovaries and

testes). Two such hormones are secreted by the anterior pituitary: follicle stimulating hormone (FSH) and luteinizing hormone (LH). Gonadotropins (FSH, either alone or with LH) are also included in drug preparations used to stimulate follicular development during an ART cycle.

Gonadotropin-releasing hormone (GnRH)—A hormone secreted by the hypothalamus which induces the pituitary gland to release follicle stimulating hormone (FSH) and luteinizing hormone (LH) into the bloodstream.

—GnRH agonists—synthetic hormones that stimulate and then suppress the secretion of FSH and LH

—GnRH antagonists—synthetic hormones that suppress the secretion of FSH and LH

Gravidity—Total number of prior pregnancies a patient has had. This includes ectopic pregnancies, biochemical pregnancies, and pregnancies that ended in therapeutic abortion, spontaneous abortion, stillbirth, or live birth.

Heterotopic pregnancy—A clinical intrauterine gestation in combination with an ectopic pregnancy.

Human chorionic gonadotropin (HCG)—A hormone produced by the placenta after implantation. It is used during ART to cause ovulation.

Hydrosalpinx (current and prior)—Accumulation of watery fluid in a fallopian tube that usually results from damage to the tube.

—Communicating: Patent fallopian tube. Non-occluded.

—Occluded: Non-communicating fallopian tube. Occlusion may be by means of salpingectomy, tubal ligation, or hysteroscopic occlusion.

Induced abortion—Operative or medical intervention to electively terminate the entire pregnancy (no gestational age limit).

Intracytoplasmic sperm injection (ICSI)—The placement of a single sperm into the ooplasm of an oocyte by micro-operative techniques.

In vitro fertilization (IVF)—A method of assisted reproduction that involves removing oocytes from a woman's ovaries, combining them with sperm in the laboratory, and after fertilization is confirmed, replacing the resulting embryo into the woman's uterus.

In vitro maturation (IVM)—Procedure in which eggs are removed from the ovaries and are collected when they are still immature. They are then matured in the laboratory before being fertilized.

Letrozole—An ovulation induction medication, such as the medication with the trade name Femara®.

Live birth—A birth (delivery) in which at least one fetus was live born, *i.e.*, showed signs of life after the complete expulsion or extraction from its mother or gestational carrier. Signs of life include breathing, beating of the heart, pulsation of the umbilical cord, or definite movement of the voluntary muscles. Any birth event in which an infant shows signs of life should be counted as a live birth, regardless of gestational age at birth. Live births are counted as birth events (*e.g.*, a triplet live birth is counted as one).

Low sperm motility—Sperm motility less than laboratory norm (varies by method used).

Low sperm morphology—Sperm morphology less than laboratory norm (varies by method used).

Luteinizing hormone (LH)—A gonadotropin hormone produced and released from the pituitary that stimulates the ovary to ripen a follicle for ovulation.

Male infertility—Infertility due to abnormal semen parameters or abnormal sperm function.

Method of delivery—Method used to deliver infant(s), vaginal or Cesarean section.

Monochorionic—When two or more embryos or fetuses share the same chorion and the same placenta.

NASS ID—An identification number assigned to each ART clinical program by the reporting database operator.

Oligospermia—Semen with a low concentration of sperm. Severe oligospermia is defined by <5 million spermatozoa per mL; moderate is defined by 5–15 million spermatozoa per mL.

Oocyte—The female reproductive cell, also called an egg.

Oocyte banking—A cycle initiated with the intent of cryopreserving all un-fertilized oocytes for later use. This does not apply to cycles initiated with the intent to transfer embryos. Oocyte banking can be short term (<12 months) or long term (≥12 months).

—Autologous oocyte banking—refers to cycles where the patient is banking her own oocytes for later use.

—Donor oocyte banking—refers to cycles where a donor is banking oocytes for use by someone else at a later date.

Oocyte donor—A woman who undergoes an oocyte retrieval procedure with the intent of donating the oocytes retrieved to a couple(s) undergoing an ART donor oocyte cycle (see donor oocyte cycle).

Oocyte retrieval—A procedure to collect the eggs contained within the ovarian follicles. This definition includes procedures in which oocyte recovery was attempted but not successful.

Oocyte transfer—In GIFT (see definition), transfer of retrieved eggs into a woman's fallopian tubes. Includes attempted transfers, whether or not the transfer was successful.

Ovarian monitoring—Monitoring the development of ovarian follicles by ultrasound and/or blood or urine tests.

Ovarian stimulation—Use of one or more follicle stimulation medications to stimulate the ovary to develop follicles and oocytes.

Ovarian hyperstimulation requiring intervention or hospitalization—Hyperstimulation may be evidenced by abdominal distension and discomfort; nausea, vomiting, and/or diarrhea; ovaries enlarged 5–12 cm; ultrasonic evidence of ascites; clinical evidence of ascites and/or hydrothorax or breathing difficulties; change in blood volume; increased blood viscosity due to hemoconcentration; coagulation abnormalities; diminished renal perfusion and function, -hematocrit >50%; and requiring intervention such as paracentesis or hospitalization.

Ovulatory disorder—One or more disorders causing reduced fecundity that is associated

with structural, anatomic, or functional impairment of one or both ovaries; includes polycystic ovary syndrome (PCOS), oligo-ovulation (≤ 6 cycles per year), and anovulation (of hypothalamic or non-hypothalamic causes) such as functional hypothalamic amenorrhea (FHA).

Ovulation induction—See stimulated cycle.

Patient—Generally defined as the female undergoing treatment. More specifically:

—For heterosexual couples, the patient is always the female partner.

—For male same-sex couples, the male providing sperm is the patient. If both male partners or neither male partner is providing sperm, select one male to identify as the patient.

—For female same-sex couples, the patient is the female intending to carry the pregnancy. If neither female intends to carry the pregnancy (*i.e.* a gestational carrier will be used) the patient is the female providing the oocyte. If both females are providing oocytes, the patient is the youngest female providing oocytes. If neither female intends to carry the pregnancy or provide oocytes (*i.e.* donor oocytes are used with a gestational carrier), select one female to identify as the patient.

Pituitary—A small gland just beneath the hypothalamus in the brain which controls other hormone producing glands such as the ovaries, thyroid, and adrenal glands. Ovarian function is controlled through the secretion of follicle stimulating hormone (FSH) and luteinizing hormone (LH) from the pituitary.

Polar body biopsy—Polar bodies are the by-products of egg division. These cells do not serve any role for the egg or embryo and will naturally degrade; however, they can be removed and tested to determine the genetic status of the egg. Polar body testing only tests for the maternal genetic contribution to the embryo. Polar body biopsy occurs at the day 0 and/or day 1 stage. Both polar bodies must be removed and tested in order to make an accurate diagnosis.

Pregnancy test—A blood test that determines the level of human chorionic gonadotropin (hCG), a hormone produced by the placenta; if it is elevated, this confirms a pregnancy, which may be biochemical only, ectopic, or clinical intrauterine gestation (normally developing pregnancy).

Preimplantation genetic diagnosis (PGD)—Characterization of a cell or cells from pre-implanted embryos from IVF cycles to determine the presence or absence of a specific genetic defect.

Preimplantation genetic screening (PGS)—Characterization of a cell or cells from pre-implanted embryos from IVF cycles to identify genetic abnormalities.

Preterm birth—Birth at least 20 but less than 37 completed weeks of gestation. This includes both live births and stillbirths. For the purposes of reporting prior preterm births, births are counted as birth events (*e.g.* a triplet birth is counted as one).

Recipient—In an ART cycle, the woman in whom embryos or oocytes are transferred; includes the female patient or a gestational carrier for the patient.

Recurrent pregnancy loss—A disease distinct from infertility, defined by two or more failed pregnancies.

Semen—Fluid discharged at ejaculation in male.

Sperm—The male reproductive cell that has completed the process of meiosis and morphological differentiation. Sperm used for ART can be obtained using different methods:

—Ejaculation—Sperm is collected from a semen sample obtained by ejaculation, the release of semen from the penis during orgasm.

—Electroejaculation—This procedure is used in men who have a neurologic ejaculatory disorder, such as spinal cord injury or psychogenic anejaculation, without mechanical obstruction of the excurrent ductal system. This procedure involves the use of electricity to directly stimulate the ejaculatory organs.

—Epididymal aspiration—A technique in which sperm is aspirated and sampled percutaneously from the epididymis.

—Retrograde ejaculation—Ejaculation in which semen travels up the urethra towards the bladder instead of to the outside of the body. Sperm can be collected directly from the bladder or from voided urine.

—Testicular biopsy—Sperm are obtained from a biopsy of seminiferous tubules.

Sperm donor—A man providing sperm for the fertilization of oocytes of a woman other than his sexual partner.

Spontaneous abortion (miscarriage)—A clinical pregnancy ending in spontaneous loss of the entire pregnancy prior to completion of 20 weeks of gestation (or 18 weeks from the date of transfer if the pregnancy was achieved using ART).

Stillbirth—Birth (delivery) at 20 weeks of gestation or later (or 18 weeks or later from the date of transfer if the pregnancy was achieved using ART) in which no fetus showed signs of life after the complete expulsion or extraction from the mother. Stillbirths are counted as birth events (*e.g.* a triplet stillbirth is counted as one).

Stimulated cycle—An ART cycle in which a woman receives medication to stimulate follicular development including the use of clomiphene citrate, follicle stimulating hormone (FSH), or follicle stimulating hormone and luteinizing hormone (FSH and LH).

Surgical sterilization—An operative procedure for the purpose of termination of fertility. Surgical sterilization includes tubal ligation, salpingectomy, vasectomy and hysterectomy.

Thawed oocyte—Oocyte retrieved during a previous cycle, cryopreserved, and then thawed for use during the current cycle (either from the patient or donor), *i.e.*, not a fresh oocyte retrieved during the current cycle.

Thawed embryo—Embryo created during a previous cycle, cryopreserved, and then thawed for use during the current cycle (either from the patient or donor), *i.e.*, not a fresh embryo created during the current cycle. Frozen embryos can be created from either fresh or frozen eggs and sperm.

Thrombosis—Formation of a blood clot in a vessel obstructing the flow of blood through the circulatory system.

Tubal embryo transfer (TET)—Transfer of an early stage embryo to the fallopian tube.

Tubal factor—A factor causing reduced fecundity that is associated with structural, anatomic, or functional injury of one or both fallopian tubes; the following are included: (1) Tubal ligation, not reversed, (2) hydrosalpinx (in place), (3) History of hydrosalpinx (treated—by either surgical removal or hysteroscopic occlusion) and (4) any other tubal disease including but not limited to pelvic or peritubal adhesive disease, prior tubal surgery, prior ectopic pregnancy, or tubal occlusion (partial or complete without hydrosalpinx).

Tubal ligation for contraception—Sterilization of the female by constricting, severing, or crushing the fallopian tubes; constriction may be with an encircling plastic ring or other ligature.

Ultrasound—A technique for visualizing the follicles in the ovaries and the gestational sac or fetus in the uterus, allowing the estimation of size.

Unexplained infertility—Infertility in which no etiology (male infertility, endometriosis, tubal factor, ovulatory disorders/PCO, diminished ovarian reserve, uterine factor, or other factors (such as immunologic, chromosomal, cancer chemotherapy or other systemic disease) has been identified.

Unstimulated cycle—An ART cycle in which the woman does not receive medication to stimulate follicular development such as clomiphene or follicle stimulating hormone. Instead, natural follicular development occurs.

Uterine factor—A factor causing reduced fecundity that is associated with structural, anatomic, or functional injury to the uterus whether repaired or not; includes septum, myoma, Diethylstilbestrol (DES) exposure, intrauterine adhesions, congenital anomalies.

Zygote—A normal (2 pronuclei) fertilized egg before cell division begins.

Zygote intra fallopian transfer (ZIFT)—Eggs are collected and fertilized, and the resulting zygote is then transferred to the fallopian tube.

2 Pronuclei (2PN)—The earliest stage of embryonic development that occurs just after fertilization but before the nucleus from the sperm and the egg have fused (thus, 2 pronuclei are present). The appearance of two pronuclei indicates normal fertilization and is usually detected 16–20 hours after fertilization or insemination.

IV. Published Reports and Data Usage

A. Annual ART Reports

ART data are used to produce the annual Assisted Reproductive Technology Fertility Clinic Success Rates Report, a key publication available to Congress, individual clinics, consumers, the states, and the general public. This report has 3 major sections:

(a) Commonly asked questions—provides background information and an explanation of the data reporting process.

(b) Fertility clinic table—displays tabulated results of success rates for all reported ART procedures at individual U.S. fertility clinics.

(c) Appendices—contains summary of data validation; a glossary of technical and medical terms used in the report; the names, addresses, and telephone numbers of all reporting and non-reporting clinics; and a list

of national consumer organizations offering support to people experiencing infertility.

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

B. Data Usage and Data Access

HHS/CDC retains a copy of each reporting ART program's annual data files. In addition to the annual ART reports, the NASS database is used to evaluate emerging ART research questions and to monitor safety and efficacy issues related to ART treatment for improving maternal and child health outcomes. ART data files are protected under an Assurance of Confidentiality pursuant to Section 308(d) of the Public Health Service Act (42 U.S.C. 242[m]). This assurance allows HHS/CDC programs to assure that certain identifiable data collected on individuals and institutions involved in research or non-research projects remain confidential. Starting in 2013, researchers may analyze ART surveillance data using the National Center for Health Statistics' (NCHS) Research Data Center (RDC) under authorization of Sections 304 and 306 of the Public Health Service Act, 42 U.S.C.242(k) (See <http://www.cdc.gov/art/AccessData.html>). Researchers requesting access to the NASS data files are subject to all RDC procedures and protocols.

Dated: August 19, 2015.

Pamela J. Cox,

Director, Division of the Executive Secretariat, Office of the Chief of Staff, Centers for Disease Control and Prevention.

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BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Fees for Sanitation Inspections of Cruise Ships

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: General Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS) announces fees for vessel sanitation inspections for Fiscal Year (FY) 2016. These inspections are conducted by HHS/CDC's Vessel Sanitation Program (VSP). VSP helps the cruise line industry fulfill its responsibility for developing and implementing comprehensive sanitation programs to minimize the risk for acute gastroenteritis. Every vessel that has a foreign itinerary and carries 13 or more passengers is subject to twice-yearly unannounced inspections and, when necessary, reinspections.

DATES: These fees are effective October 1, 2015, through September 30, 2016.

FOR FURTHER INFORMATION CONTACT: CAPT Jaret T. Ames, Chief, Vessel Sanitation Program, National Center for Environmental Health, Centers for

Disease Control and Prevention, 4770 Buford Highway NE., MS F-59, Atlanta, Georgia 30341-3717; phone: 800-323-2132, 770-488-3141, or 954-356-6650; email: vsp@cdc.gov.

SUPPLEMENTARY INFORMATION:

Purpose and Background

HHS/CDC established the Vessel Sanitation Program (VSP) in the 1970s as a cooperative activity with the cruise ship industry. VSP helps the cruise ship industry prevent and control the introduction, transmission, and spread of gastrointestinal illnesses on cruise ships. VSP operates under the authority of the Public Health Service Act (Section 361 of the Public Health Service Act; 42 U.S.C. 264, "Control of Communicable Diseases"). Regulations found at 42 CFR 71.41 (Foreign Quarantine—Requirements Upon Arrival at U.S. Ports: Sanitary Inspection; General Provisions) state that carriers arriving at U.S. ports from foreign areas are subject to sanitary inspections to determine whether rodent, insect, or other vermin infestations exist, contaminated food or water, or other sanitary conditions requiring measures for the prevention of the introduction, transmission, or spread of communicable diseases are present.

The fee schedule for sanitation inspections of passenger cruise ships by VSP was first published in the **Federal Register** on November 24, 1987 (52 FR 45019). HHS/CDC began collecting fees on March 1, 1988. This notice announces fees that are effective for FY 2016, beginning on October 1, 2015, through September 30, 2016.

The following formula will be used to determine the fees:

$$\text{Average cost per inspection} = \frac{\text{Total cost of VSP}}{\text{Weighted number of annual inspections}}$$

The average cost per inspection is multiplied by size and cost factors to determine the fee for vessels in each size category. The size and cost factors were established in the fee schedule published in the **Federal Register** on July 17, 1987 (52 FR 27060). The fee schedule was most recently published in the **Federal Register** on July 31, 2014 (79 FR 44454). The size and cost factors for FY 2016 are presented in Appendix A.

Fee

The fee schedule (Appendix A) will be effective October 1, 2015, through September 30, 2016.

Applicability

The fees will apply to all passenger cruise vessels for which inspections are conducted as part of HHS/CDC's VSP. Inspections and reinspections involve the same procedures, require the same amount of time, and are therefore charged at the same rates.

Appendix A

SIZE/COST FACTORS USED TO DETERMINE INSPECTION FEES

Vessel size (GRT ¹)	Approximate cost per GRT ¹
Extra Small (<3,001 GRT)	US\$0.25
Small (3,001–15,000 GRT) ..	0.50
Medium (15,001–30,000 GRT)	1.00
Large (30,001–60,000 GRT)	1.50
Extra Large (60,001–120,000 GRT)	2.00
Mega (>120,001 GRT)	3.00