Assisted Reproductive Technology (ART) Program Reporting System

OMB Control Number 0920-0556

Revision Request

Supporting Statement: Part B

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B.1. Respondent Universe and Sampling Methods

Information is collected from all clinics that provide assisted reproductive technology (ART) services within the U.S. and its territories as required by the 1992 Fertility Clinic Success Rate and Certification Act (FCSRCA). CDC's data collection contractor maintains an index of ART clinics known to be in operation each year and tracks clinic reorganizations and closings. It is the responsibility of the clinic's practice director to notify the contractor of the clinic's existence and any changes in address, location, or key staff. The contractor also follows up reports of ART physicians or clinics that are not on its list. These reports generally originate from consumers looking for a particular clinic in the annual ART report. Frequently, follow-up reveals that the clinic opened during the reporting year, and thus was not eligible for inclusion in the previous ART report.

In 2012, 486 clinics provided ART services and were subject to FCSRCA reporting requirements. Four hundred fifty-six (456) clinics submitted the required information to CDC through the National ART Surveillance System (NASS). Thirty clinics (6.2%) did not report data, despite the federal mandate, and were listed in CDC's required report to Congress as non-reporters (the only consequence allowed under the law). Based on the response rates during previous years of data collection, we have estimated that an annualized average of 447 clinics will serve as respondents during the three-year period of this Revision request.

Although sampling methods are not used to select respondents for the primary data collection, sampling methods are used to identify a limited number of respondents (8-10% of clinics) for data validation. Once all the data is reported and quality control measures implemented, a random sample of reporting clinics are chosen for data validation site visits. In consultation with the contractor, CDC decides upon the criteria for clinic selection each year in advance of data collection (thus ensuring that the criteria are not influenced by review of any clinic's data). In general, most of the clinics are chosen using a simple random sampling scheme with weighting to reduce the likelihood that a clinic previously validated will be chosen again. For each clinic selected for data validation in 2012, the validated sample included up to 60 ART cycles for full validation. In addition, up to 10 embryo banking cycles and up to 10 additional cycles for partial validation.

B.2. Procedures for the Collection of Information

The current deadline for data submission is in December, approximately one year after the year in which the ART treatment was initiated. For example, ART cycles initiated between January 1, 2013, and December 31, 2013, would be reported by December 15, 2014. This schedule allows sufficient time for all pregnancies conceived subsequent to ART services in 2013 to have reached completion, and for clinic personnel to compile information on both the ART procedures and the outcomes of these procedures. The medical director of each clinic is required to submit

the clinic data to SART by the established deadline and to verify by signature that the data reported are accurate.

Clinics abstract data from clinic records and either enter their data into the web-based NASS interface, or extract data from other electronic medical record systems and transmit NASS-compatible electronic files that can be imported into NASS. **Attachment C1a** provides screen shots of the NASS interface to be used for information collection through December 31, 2015. Beginning January 1, 2016, revised data elements will be collected through an updated and enhanced NASS interface. Screen shots of this interface are provided in **Attachment C1b**.

Each year before ART data collection begins, the contractor sends reporting instructions **(Attachment C2)** to all qualifying clinics. Each clinic also receives a NASS users' manual **(Attachment C3)** that contains information about how to use the NASS system and how to set up the user IDs, passwords, and other security information. The NASS users' manual will be updated after CDC receives OMB approval of revised data elements pertaining to ART cycles initiated on or after January 1, 2016 (see **Attachment 5** and **Attachment 6**).

After the reporting deadline, the contractor compiles the individual clinic data files and submits the national data file to CDC. CDC and the data collection contractor work together to review the data and identify inconsistencies and logic errors. Clinics with errors for key data elements are asked to reconcile the discrepancies and submit updates to the contractor. Then, the contractor compiles and submits the final national data set to CDC. In addition to data entry for each ART cycle, NASS includes programming that uses the cycle-level data to calculate key ART statistics for each clinic. The contractor develops this programming in conjunction with CDC to ensure that these clinic-level statistics meet the needs of the fertility clinic tables section of the annual ART report. Once the national data set of individual ART cycles is finalized, the contractor additionally compiles an *aggregate*-level data set of clinic statistics (clinic table data set) and submits this file to CDC.

Clinics that do not submit the required information receive notification from both CDC and the data collection contractor in a letter outlining the reporting process. Clinics that do not submit their data by the deadline are informed that they will be listed in the ART Success Rates, National Summary and Fertility Clinic Report as non-reporters.

Upon completion of ART cycle reporting, as required by FCSRCA, responding clinics are also offered the opportunity to participate in a brief, optional feedback survey (**Attachment C4**).

<u>Data Validation for a Subset of Clinics</u>

The data-validation process for ART cycle information is meant to be primarily educational and to identify particular problem areas in the data collection process so that they may be corrected in subsequent data collections. Contractor validation teams conduct the data validation site visits. A CDC representative attends a portion of the visits to observe the process. During the visits, the

validation teams will compare data that were reported to the data collection contractor with clinic records **(Attachment H)**. Discrepancies will be noted on paper data validation forms; these forms will be forwarded to the contractor for data entry and analysis. The contractor calculates error rates within and across clinics and for each data item validated. CDC and the contractor review these findings.

Within this context, CDC and the contractor may institute global changes to NASS on the basis of the validation findings and/or may contact individual clinics after validation to review specific problems. In nearly all instances, validation results are not expected to affect a clinic's status in the annual ART report. However, in rare instances, validation may reveal an unacceptable error rate. The prevailing consideration in deciding if a clinic's data are unacceptable is: do the validation findings suggest that publication of the clinic's data as reported present a misleading account of that clinics true success rate? If such a situation arises, the contractor and CDC may work with the clinic and allow for corrections in time for the publication of the annual report. If timely corrections are not possible, the clinic may opt to remove its data from the annual report and be listed as a non-reporter. To date, error rates for all clinics validated have been within acceptable limits. Moreover, the majority of errors identified have been minor, e.g., date mis-recorded by one or two days, and the impact of errors on the success rates reported has been estimated to be minimal.

B.3. Methods to Maximize Response Rates and Deal with Non-response

Efforts are made to maximize the response rate. Clinics receive a letter outlining the reporting requirements, data submission timelines, and outcomes if data are not reported. All clinics known to be in operation throughout a given reporting year that fail to submit the required materials to the contractor by the required deadline are considered to *not* be in compliance with the federal reporting requirements of FCSRCA. These clinics are notified that they will be listed as non-reporting clinics in the annual ART report if the data are not submitted by the deadline.

B.4. Tests of Procedures or Methods to be Undertaken

The ART program reporting system has been in operation since 1989 and has been revised based on the needs of CDC and input from ART provider organizations such as the American Society for Reproductive Medicine's affiliate, the Society for Assisted Reproductive Technology, and national consumer organizations such as RESOLVE and The American Fertility Association.

B.5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

National ART Surveillance System designed by:

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