**ATTACHMENT H.**

**ART VALIDATION DESCRIPTION**

**2012 Validation Procedures**

The validation sample for Reporting Year (RY) 2012 will maintain the historical sample size of 35 ART clinics. Clinics will be stratified by number of cycles reported in NASS, with larger clinics having greater chance of selection. The purpose of sampling larger clinics at a higher rate is to provide better representation of the majority of cycles, most of which are found in larger clinics.

Clinics will be sampled with equal probability within strata. To avoid validating a program two years in a row, clinics that were selected for validation during the past two years will be removed from stratum for the current year.

The following procedures will be used to select clinics for the RY 2012 validation sample:

* Create an initial ART clinic sampling frame by including all clinics that submitted ART data in NASS for RY 2012.
* Delete those clinics that were validated for RY 2010 and RY 2011 from the sampling frame.
* Sort the sampling frame by (1) stratum and then by (2) annual number of ART cycles reported for RY 2012.
* Use systematic sampling to select 4 clinics from Stratum 1; 9 clinics from Stratum 2; and so forth. The probability of a cycle being selected for validation will vary by stratum, ranging from about 1.4% in Stratum 1 to 1.1% in Stratum 4.
* As noted earlier, two clinics have been pre-designated for validation and will be included in the sample, resulting in a total of 35 clinics.

Sorting the sampling frame by clinic size (within strata) and selecting systematic samples of clinics will have the effect of further stabilizing the size of clinics, in addition to the effect of stratification. That is, this approach eliminates the chance of selecting only the largest or smallest clinics within a given stratum. Moreover, the average number of annual ART cycles per clinics for the selected sample should be close to the average number of annual ART cycles per clinics for the entire sampling frame.

RY 2012 cycles at each clinic selected for validation will be reviewed as follows:

* Full validation of up to 10 donor cycles;
* Full validation of up to 20 non-gestation cycles (nondonor);
* Full validation of up to 40 single or multiple-gestation cycles (nondonor);
* Partial validation of up to 10 embryo-banking cycles; and
* Partial validation of up to 10 unreported cycles.

To calculate validation discrepancy rates, the collected validation data must be associated with the appropriate sample of cycles. There are four different samples of cycles:

* Sample of fully-validated donor cycles. This is a two-stage sample—a clinic is the first-stage sample unit, and sample of up to 10 donor cycles constitute the second-stage sample units.
* Sample of fully-validated nondonor cycles resulting in no gestation. This is a two-stage sample—a clinic is the first-stage sample unit, and an ART cycle is the second-stage sample unit.
* Sample of fully-validated nondonor cycles resulting in single or multiple gestation. This is a two-stage sample—a clinic is the first-stage sample unit, and an ART cycle is the second-stage sample unit.
* Sample of embryo banking cycles. This is a two-stage cluster sample, with the clinic as the first stage cluster, and the sample of up to 10 embryo banking cycles as the second stage.

**SELECTION OF ART PROGRAMS FOR VALIDATION OF 2012 DATA**

**Specifics of Selection Process**

There were 458 clinics that submitted RY 2012 data through NASS. Of those, 67 clinics were selected for validation of either their RY 2010 or RY 2011 NASS data, and therefore were excluded from consideration for the present validation. The remaining 391 ART programs were eligible for 2012 validation sampling, from which 35 were sampled.

**Clinics selected for RY 2012 validation, by sample stratum (n=35 clinics)**

(The names of the clinics have been concealed to protect their identity)

|  |  |  |  |
| --- | --- | --- | --- |
| Clinic | State | Clinic Cycle Counts | Validation Cycle Counts |
|  Nondonor  |  Donor3 |  Banking  | Total | Full Validation | Banking Validation |
| 1 | CA | 12 | 4 | 0 | 16 | 16 | 0 |
| 2 | CT | 47 | 2 | 0 | 49 | 49 | 0 |
| 3 | NY | 65 | 28 | 3 | 96 | 60 | 3 |
| 4 | AL | 121 | 6 | 1 | 128 | 60 | 1 |
|   |   |   |   |   |   |  |  |
| 5 | HI | 125 | 9 | 27 | 161 | 60 | 10 |
| 6 | KY | 155 | 19 | 2 | 176 | 60 | 2 |
| 7 | CA | 154 | 17 | 19 | 190 | 60 | 10 |
| 8 | CA | 197 | 19 | 0 | 216 | 60 | 0 |
| 9 | PA | 147 | 9 | 85 | 241 | 60 | 10 |
| 10 | GA | 252 | 15 | 11 | 278 | 60 | 10 |
| 11 | NM | 217 | 37 | 51 | 305 | 60 | 10 |
| 12 | CA | 297 | 29 | 14 | 340 | 60 | 10 |
| 13 | UT | 353 | 31 | 3 | 387 | 60 | 3 |
|   |   |   |   |   |   |  |  |
| 14 | NJ | 412 | 32 | 5 | 449 | 60 | 5 |
| 15 | AZ | 386 | 50 | 24 | 460 | 60 | 10 |
| 16 | HI | 300 | 176 | 0 | 476 | 60 | 0 |
| 17 | CA | 461 | 43 | 1 | 505 | 60 | 1 |
| 18 | OH | 465 | 46 | 6 | 517 | 60 | 6 |
| 19 | IN | 446 | 86 | 1 | 533 | 60 | 1 |
| 20 | FL | 502 | 94 | 1 | 597 | 60 | 1 |
| 21 | IL | 525 | 68 | 28 | 621 | 60 | 10 |
| 22 | NY | 433 | 39 | 215 | 687 | 60 | 10 |
|   |   |   |   |   |   |  |  |
| 23 | TX | 611 | 99 | 65 | 775 | 60 | 10 |
| 24 | FL | 639 | 78 | 85 | 802 | 60 | 10 |
| 25 | NJ | 717 | 50 | 67 | 834 | 60 | 10 |
| 26 | CA | 793 | 54 | 15 | 862 | 60 | 10 |
| 27 | TX | 760 | 137 | 41 | 938 | 60 | 10 |
| 28 | OH | 859 | 94 | 5 | 958 | 60 | 5 |
| 29 | FL | 945 | 105 | 12 | 1062 | 60 | 10 |
| 30 | CA | 912 | 216 | 11 | 1139 | 60 | 10 |
| 31 | NY | 1416 | 39 | 149 | 1604 | 60 | 10 |
| 32 | IL | 1837 | 349 | 347 | 2533 | 60 | 10 |
| 33 | NY | 1618 | 148 | 2675 | 4441 | 60 | 10 |
|   |   |   |   |   |   |  |  |
| 34 | CA | 124 | 40 | 21 | 185 | 60 | 10 |
| 35 | CA | 447 | 100 | 64 | 611 | 60 | 10 |

**List of Variables for Full and Partial Validation**

Patient date of birth

Cycle start date

* Cycle intention

Any additional ART cycles for this patient started in 2006

Patient diagnosis (i.e., reasons for ART)

Transfer type (e.g., IVF, GIFT)

Cancelled cycle notations if applicable

Total number of embryos or oocytes transferred

Outcome of treatment (e.g., biochemical only, clinical uterine gestation, ectopic)

Ultrasound with maximum number of fetal hearts detected

Outcome of pregnancy (e.g., live birth, spontaneous abortion)

Date of pregnancy outcome

Number of infants born

Donor date of birth or donor age