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 Cycle Counts				Validation Cycle Counts	
Clinic	State	Nondonor	Donor[3]	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