National ART Surveillance System
NASS 2.0
(Proposed for 2016)

DRAFT

INITIAL REPORTING: PATIENT PROFILE (PROSPECTIVE)

Quex ID	LEAD QUESTION
1	**Date of cycle reporting (mm/dd/yyyy):** |__|__| - |__|__| - |__|__|__|__|
2	**NASS Patient ID:** |__|__|__|__| - |__|__|__|__| - |__|__|
3	**Patient Optional Identifiers** Optional Identifier 1 |__|__|__|__|__|__|__| maximum 7 digits or characters Optional Identifier 2 |__|__|__|__|__|__|__| maximum 7 digits or characters
4	**Patient Date of Birth (mm/dd/yyyy):** |__|__| - |__|__| - |__|__|__|__|
5	**Sex of patient:** ◯ Male ◯ Female
6	**Cycle Start Date** |__|__| - |__|__| - |__|__|__|__|
	RESIDENCY
7	**At the start of the cycle, is patient residency primarily in U.S.?** ◯ Yes ◯ No ◯ Refused
7A	**U.S. state of primary residence:** **City of primary residence** **U.S. zip code at primary residence** |__|__|__|__|__| **OR** **Country of primary residence:**
	INTENT
8	**Intended type of ART? Select all that apply:** ☐ IVF: Transcervical ☐ GIFT: Gametes to tubes ☐ ZIFT: Zygotes to tubes or TET: tubal embryo transfer ☐ Oocyte or embryo banking
9	**[SKIP IF NOT A BANKING ONLY CYCLE]** **If cycle is for banking only, specify banking type (select all that apply):** ☐ Embryo banking ☐ Autologous oocyte banking ☐ Donor oocyte banking
9A	**Indicate anticipated duration of oocyte banking SKIP IF EMBRYO BANKING ONLY** ☐ Short term (<12 months) ☐ Long term (≥12 months) banking for fertility preservation prior to gonadotoxic medical treatments ☐ Long term (≥12 months) banking for other reasons
9B	**Indicate anticipated duration of embryo banking SKIP IF OOCYTE BANKING ONLY** ☐ Short term (<12 months) ☐ Delay of transfer to obtain genetic information ☐ Delay of transfer for other reasons ☐ Long term (≥12 months) banking for fertility preservation prior to gonadotoxic medical treatments ☐ Long term (≥12 months) banking for other reasons
10	**Intended embryo source (select all that apply): [IF ONLY DONOR EMBRYOS SELECTED, SKIP TO #12]** ☐ **Patient embryos** ☐ **Donor embryos** ☐ **Fresh embryos** ☐ **Frozen embryos**
10A	**If intent is to use FRESH EMBRYOS, specify intended oocyte source. Select all that apply:** ☐ Fresh patient oocytes ☐ Frozen patient oocytes ☐ Fresh donor oocytes ☐ Frozen donor oocytes

	If intent is to use FROZEN EMBRYOS, specify intended oocyte source. Select all that apply: ☐ Fresh patient oocytes ☐ Frozen patient oocytes ☐ Fresh donor oocytes ☐ Frozen donor oocytes ☐ Unknown (select only if oocyte source is unknown)
10B	**If intend is to use donor embryos (select all that apply):** ☐ Fresh embryos ☐ Frozen embryos
11	**Specify intended sperm source. Select all that apply. [SKIP IF DONOR EMBRYO IS INTENDED SOURCE]** ☐ Partner ☐ Donor ☐ Patient, if male ☐ Unknown (select only if all sperm sources unknown for frozen)
12	**Pregnancy carrier** ☐ Patient ☐ Gestational carrier ☐ None (oocyte or embryo banking cycle only)

CYCLE INFORMATION (NOT PROSPECTIVE FROM HERE FORWARD)

Quex ID	LEAD QUESTION
13	**Type of ART performed? Select all that apply:** ☐ IVF: Transcervical ☐ GIFT: Gametes to tubes ☐ ZIFT: Zygotes to tubes or TET: tubal embryo transfer ☐ Oocyte or embryo banking
14	**Embryo source (select all that apply): [IF ONLY DONOR EMBRYOS SELECTED, SKIP TO #15]** ☐ Patient embryos ☐ Donor embryos ☐ Fresh embryos ☐ Frozen embryos
14A	**If FRESH EMBRYOS were used, specify intended oocyte source. Select all that apply:** ☐ Fresh patient oocytes ☐ Frozen patient oocytes ☐ Fresh donor oocytes ☐ Frozen donor oocytes **If FROZEN EMBRYOS were used, specify intended oocyte source. Select all that apply:** ☐ Fresh patient oocytes ☐ Frozen patient oocytes ☐ Fresh donor oocytes ☐ Frozen donor oocytes ☐ Unknown (select only if oocyte source is unknown)

PATIENT MEDICAL EVALUATION

REASON FOR ART

Quex ID	LEAD QUESTION	
15	**Reason for ART (Select all that apply):** ☐ Male infertility (select all that apply)	
	[SKIP IF MALE INFERTILITY NOT SELECTED]	☐ 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_____

	☐ History of endometriosis ☐ Tubal ligation for contraception ☐ Current or prior hydrosalpinx	
	[SKIP IF HYDROSALPINX NOT SELECTED]	☐ Communicating ☐ Occluded ☐ Unknown
	☐ Other tubal disease (not current or historic hydrosalpinx) ☐ Ovulatory disorders	
	[SKIP IF OVULATORY DISORDER NOT SELECTED]	☐ PCO ☐ Other ovulatory disorders
	☐ 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	
	[SKIP IF GESTATIONAL CARRIER NOT INDICATED]	☐ 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	
	FEMALE PATIENT HISTORY AND PHYSICAL	
16	**[IF SEX OF PATIENT = MALE (FROM QUESTION #5) THEN SKIP #16-23]** **Height:** |__| Feet and/or |__|__| Inches or |__|__|__|__| Centimeters or ☐ Height unknown	
17	**Weight at the start of this cycle** |__|__|__|__| Pounds or |__|__|__|__| Kilograms or ☐ Weight unknown	
18	**History of cigarette smoking:** Did the patient smoke during the 3 months before the cycle started? ☐ Yes ☐ No ☐ Unknown	
19	**Any prior pregnancies?** ◯ Yes ◯ No	
19A	**[SKIP IF NO PRIOR PREGNANCIES]** **If prior pregnancies reported and couple is not surgically sterile, enter months or years attempting pregnancy since last clinical pregnancy |__|__|__| months and/or |__|__| years** **[SKIP IF ANY PRIOR PREGNANCIES]** **If no prior pregnancies reported and couple is not surgically sterile, enter months attempting pregnancy |__|__|__| months and/or |__|__| years**	
19B	**SKIP IF NO PRIOR**	**If prior pregnancies reported, how many |__|__|**

19C	PREGNANCIES	**Number of prior full term births** |__|__|
19D		**Number of prior preterm births** |__|__|
19E		**Number of prior stillbirths** |__|__|
19F		**Number of prior spontaneous abortions** |__|__|
19G		**Number of ectopic pregnancies** |__|__|
20	**Number of prior stimulations for ART:** |__|__|	
21	**Number of prior frozen ART cycles:** |__|__|	
21A	**SKIP IF NO PRIOR ART CYCLES**	**Did any of the prior ART cycles result in a live birth?** ◯**Yes** ◯ **No**
22	**Patient maximum FSH level (MIU/mls):** |__|__|__| . |__|__| Or FSH unknown: ☐	
23	**Most recent AMH level (ng/mL):** |__|__|__| . |__|__| Or AMH unknown: ☐ **Date of most recent AMH level** |__|__| - |__|__| - |__|__|__|__|	

SOURCE AND CARRIER PROFILES

OOCYTE SOURCE PROFILE

Quex ID	LEAD QUESTION
24A	**[IF OOCYTE SOURCE = PATIENT AND DONOR, ANSWER THIS QUESTION]** **Youngest oocyte source** ☐ Patient **[SKIP TO Q25]** ☐ Donor **[CONTINUE TO Q24)**
24B	**OOCYTE SOURCE Date of Birth (mm/dd/yyyy): [FIELD PRE-FILLED IF OOCYTE SOURCE=PATIENT]** |__|__| - |__|__| - |__|__|__|__| **OR age at earliest time oocytes were retrieved ____**
25	**OOCYTE SOURCE Ethnicity:** **Select one:** ☐ NOT Hispanic or Latino ☐ Hispanic or Latino ☐ Refused ☐ Unknown
26	**OOCYTE SOURCE Race (based on oocyte source self-report)** **Select all that apply:** ☐ White ☐ Black or African American ☐ Asian ☐ Native Hawaiian or other Pacific Islander ☐ American Indian or Alaska Native
26A	**Select reason race not reported:** ◯ Refused ◯ Unknown

PREGNANCY CARRIER PROFILE

27	**Pregnancy carrier** ☐ Patient ☐ Gestational carrier ☐ None (oocyte or embryo banking cycle only)

28	**[IF CARRIER=NONE THEN SKIP 28-31] or** **[IF CARRIER=PATIENT AND OOCYTE SOURCE=PATIENT THEN SKIP 28-31]** **Pregnancy carrier** **Date of Birth (mm/dd/yyyy):** |__|__| - |__|__| - |__|__|__|__| **OR age at time of transfer** ____
29	**Pregnancy carrier Ethnicity:** **Select one:** ○◯ NOT Hispanic or Latino ○◯ Hispanic or Latino ○◯ Refused ○◯ Unknown
30	**Pregnancy carrier Race (based on gestational carrier self report)** **Select all that apply:** ☐ White ☐ Black or African American ☐ Asian ☐ Native Hawaiian or other Pacific Islander ☐ American Indian or Alaska Native
30A	Yes **Select reason race not reported:** ○◯ Refused ○◯ Unknown

Quex ID	LEAD QUESTION
	SPERM SOURCE PROFILE
31	**Specify sperm source. Select all that apply.** ☐ Partner ☐ Donor ☐ Patient, if male ☐ Unknown (select only if all sperm sources unknown for frozen)
32	**SPERM source Date of Birth (mm/dd/yyyy):** |__|__| - |__|__| - |__|__|__|__| **[FIELD PRE-FILLED IF SPERM SOURCE=MALE PATIENT]** Or ☐ Unknown
33	**SPERM source Ethnicity:** **Select one:** ○◯ NOT Hispanic or Latino ○◯ Hispanic or Latino ○◯ Refused ○◯ Unknown
34	**SPERM source Race (based on patient self report)** **Select all that apply:** ☐ White ☐ Black or African American ☐ Asian ☐ Native Hawaiian or other Pacific Islander ☐ American Indian or Alaska Native
34A	**Select reason race not reported:** ○◯ Refused ○◯ Unknown
	STIMULATION AND RETRIEVAL
Quex ID	LEAD QUESTION
	OVARIAN STIMULATION AND MEDICATIONS
35	**Was there stimulation for follicular development? [IF NO STIMULATION OR FROZEN CYCLE, SKIP #36-39]** ◯Yes ◯ No

	Was this a minimal stimulation cycle? ◯Yes ◯ No	
36	**Oral medication such as aromatase inhibitor or selective estrogen receptor modulator?** ◯Yes ◯ No	
36A	**[SKIP IF NO ORAL MEDS]**	**Clomiphene dosage (Total mgs):** |__|__|__|__|__|__| . |__|__| **Letrozole dosage (Total mgs)** |__|__|__|__|__|__| . |__|__| **Other (specify)_____ dosage** |__|__|__|__|__|__| . |__|__|
37	**Medication(s) containing FSH?** ◯**Yes** ◯ **No**	
37A	**[SKIP IF NO FSH MEDS]**	**Short-acting FSH (Total IUs):** |__|__|__|__|__|__| . |__|__|
37B		**Long-acting FSH (Total mgs):** |__|__|__|__|__|__| . |__|__|
38	**Medication(s) with LH/HCG activity?** ◯**Yes** ◯ **No**	
Quex ID	**LEAD QUESTION**	
39	**GnRH Protocol** **Select the one primary protocol:** ◯ No GnRH protocol ◯ GnRH Agonist Suppression ◯ GnRH Agonist Flare ◯ GnRH Antagonist Suppression	
	CANCELLATION-I (open only for fresh cycles)	
40	**[IF OOCYTE/EMBRYO SOURCE = FROZEN THEN SKIP 40-45]** **Was this ART cycle canceled prior to retrieval?** ◯Yes ◯ No	
40A	**[SKIP IF CYCLE NOT CANCELLED]**	**Date cycle canceled (mm/dd/yyyy):** |__|__| - |__|__| - |__|__|__|__|
40B		**Select one primary reason cycle was canceled:** ☐ **Low ovarian response** ☐ **High ovarian response** ☐ **Inadequate endometrial response** ☐ **Concurrent illness** ☐ **Withdrawal only for personal reasons** ☐ **OTHER – specify _____**
	[IF CYCLE CANCELLED, STOP HERE]	
	FRESH OOCYTE RETRIEVAL	
41	**Date retrieval performed (mm/dd/yyyy):** |__|__| - |__|__| - |__|__|__|__|	
42	**Total number of patient oocytes retrieved:** |__|__|	
43	**Total number of donor oocytes retrieved:** |__|__|	
44	**Use of retrieved oocytes Select all that apply:** ☐ Used for this cycle ☐ Oocytes frozen for future use ☐ Oocytes shared with other patients ☐ Embryos frozen for future use	
44A	**[SKIP IF NO OOCYTES FROZEN]**	**Number of FRESH oocytes frozen for future use:** |__|__|
	COMPLICATIONS OF OVARIAN STIMULATION OR OOCYTE RETRIEVAL	
45	**Were there any complications of ovarian stimulation or oocyte retrieval?** ◯Yes ◯ No	

45A	**SKIP IF NO COMPLICATIONS**	**Select all complications that apply:** ☐ Infection ☐ Hemorrhage requiring transfusion ☐ Ovarian hyperstimulation requiring intervention or hospitalization ☐ Medication side effect ☐ Anesthetic complication ☐ Thrombosis ☐ Death of patient ☐ Other – specify _____
45B	**SKIP IF NO COMPLICATIONS**	**Did the complication(s) require hospitalization?** ◯Yes ◯ No
	[IF OOCYTE BANKING CYCLE <u>ONLY</u>, STOP HERE]	

	SPERM RETRIEVAL	
46	**Sperm status:** ☐ Fresh ☐ Thawed ☐ Mix of fresh and thawed	
47	**Sperm source utilized:** ○◯ Ejaculated ○◯ Epididymal ○◯ Testis ○◯ Electroejaculation ○◯ Retrograde urine ○◯ Donor ○◯ Unknown	
	LABORATORY INFORMATION	
Quex ID	**LEAD QUESTION**	
	MANIPULATION	
48	**Intracytoplasmic sperm injection (ICSI) performed on oocytes?** ○◯ All oocytes ○◯ Some oocytes ○◯ No oocytes ○◯ Unknown	
48A	**SKIP IF NO ICSI**	**Indication for ICSI (select all that apply)** ○◯ Prior failed fertilization ○◯ Poor fertilization ○◯ PGD ○◯ Abnormal semen parameters on day of fertilization ○◯ Low oocyte yield ○◯ Laboratory routine ○◯ Frozen cycle ○◯ Rescue ICSI ○◯ Other – specify _____
49	**In vitro maturation (IVM) performed on oocytes?** ○◯ All oocytes ○◯ Some oocytes ○◯ No oocytes ○◯ Unknown	
50	**Pre-implantation genetic diagnosis or screening performed on embryos?** ○◯ Yes ○◯ No ○◯ Unknown	
50A	**SKIP IF PGD/PGS NOT PERFORMED OR UNKNOWN**	**Total number of 2PN:** |__|__|
50B		**Reason(s) for pre-implantation genetic diagnosis or screening (Select all that apply):** ☐ Either genetic parent is a known carrier of a gene mutation or a chromosomal abnormality ☐ Aneuploidy screening of the embryos ☐ Elective Gender Determination ☐ Other screening of the embryos
50C		**Technique(s) used for pre-implantation genetic diagnosis or screening (Select all that apply):** ☐ Polar Body Biopsy ☐ Blastomere Biopsy ☐ Blastocyst Biopsy ☐ Unknown
51	**Assisted hatching performed on embryos?** ○◯ All embryos ○◯ Some embryos ○◯ No embryos ○◯ Unknown	

52	**Was this a research cycle?** ○◯ Yes Enter SART approval code_____ ○◯ No	
52A	**SKIP IF NOT RESEARCH CYCLE**	**Study type:** ☐ Device study ☐ Protocol study ☐ Pharmaceutical study ☐ Laboratory technique ☐ Other research
		If 'Other', please specify _____
	[IF EMBRYO BANKING CYCLE ONLY, SKIP TO #59, THEN STOP]	

TRANSFER

Quex ID	LEAD QUESTION	
	CANCELLATION-II	
53	**Was a transfer attempted?** ◯Yes ◯ No	
53A		**Select one primary reason no transfer was attempted:** ☐ Low ovarian response ☐ High ovarian response ☐ Failure to survive oocyte thaw ☐ Inadequate endometrial response ☐ Concurrent illness ☐ Withdrawal only for personal reasons ☐ Unable to obtain sperm specimen ☐ Insufficient embryos ☐ OTHER – specify _____
	[IF TRANSFER NOT ATTEMPTED, STOP HERE]	
	GENERAL TRANSFER DETAILS	
54	**Date of embryo transfer (mm/dd/yyyy): |__|__| - |__|__| - |__|__|__|__|**	
55	**Endometrial thickness at trigger: |__|__|mm**	
	FRESH EMBRYO TRANSFER DETAILS	
56	**[IF NO FRESH EMBRYOS TRANSFERRED, SKIP #57-58]** **Number of FRESH embryos transferred to uterus: |__|__|**	
57	**[SKIP #57 FOR MIXED CYCLE]** **If only one fresh embryo was transferred to the uterus, was this an elective single embryo transfer?** ◯Yes ◯ No	
58A-X	**Quality of embryo #1–X** ☐ Good ☐ Fair ☐ Poor ☐ Unknown	
		Date of oocyte retrieval for embryo #1-X |__|__| - |__|__| - |__|__|__|__|
59	**Number of FRESH embryos cryopreserved: |__|__| [STOP HERE FOR EMBRYO BANKING ONLY CYCLE]**	
	THAWED EMBRYO TRANSFER DETAILS	
60	**Number of FROZEN or THAWED embryos available on day of transfer: |__|__|**	
61	**Number of THAWED embryos transferred to uterus: |__|__| [IF NO THAWED EMBRYOS TRANSFERRED, SKIP #62]**	

62	**[SKIP #63 FOR MIXED CYCLE]** **If only <u>one</u> thawed embryo was transferred to the uterus, was this an <u>elective</u> single embryo transfer?** ○◯Yes ◯ No	
62A-X	**Quality of embryo #1–X** ☐ Good ☐ Fair ☐ Poor ☐ Unknown	
		Date of oocyte retrieval for embryo #1-X |__|__| - |__|__| - |__|__|__|__|
63	**Number of THAWED embryos cryopreserved (re-frozen):** |__|__|	
	GIFT/ZIFT/TET TRANSFER DETAILS	
64	**[SKIP IF IVF CYCLE]** **Number of oocytes or embryos transferred to the FALLOPIAN TUBE:** |__|__|	
	TREATMENT OUTCOME (only opens if transfer >0)	
Quex ID	**LEAD QUESTION**	
	OUTCOME OF TRANSFER	
65	**Outcome of treatment cycle:** ☐ Not pregnant ☐ Biochemical only ☐ Clinical intrauterine gestation ☐ Ectopic ☐ Heterotopic ☐ Unknown **[IF NOT PREGNANT, BIOCHEMICAL ONLY, ECTOPIC, OR HETEROTOPIC, STOP HERE]**	
66		**Maximum fetal hearts on ultrasound performed before 7 weeks or prior to reduction:** |__|__| ☐ **No ultrasound performed before 7 weeks gestation**
66A	**[SKIP IF NO U/S]**	**Date ultrasound with max. number of fetal hearts observed before 7 weeks (mm/dd/yyyy):** |__|__| - |__|__| - |__|__|__|__|
66B	**[SKIP IF NO U/S]**	**If 2 or more fetal hearts, any monochorionic twins or multiples? ◯Yes ◯ No ◯Unknown**
	PREGNANCY OUTCOME (only opens if pregnancy = yes)	
Quex ID	**LEAD QUESTION**	
	OUTCOME OF PREGNANCY	
67	**Outcome of pregnancy:** ☐ Live birth ☐ Spontaneous abortion ☐ Stillbirth ☐ Induced abortion ☐ Maternal death prior to birth ☐ Outcome unknown	
68	**Date of pregnancy outcome (mm/dd/yyyy):** |__|__| - |__|__| - |__|__|__|__| **NOTE: If multiple births cover more than one date, enter date of first born.**	
68A	**Method of delivery** ☐ **Vaginal** ☐ **Cesarean section**	
69	**Source of information confirming pregnancy outcome:** **(Select all that apply)** ☐ Verbal confirmation from patient ☐ Written confirmation from patient ☐ Verbal confirmation from physician or hospital	

	☐ Written confirmation from physician or hospital
	BIRTH INFORMATION
70	**Number of infants born: |__|__|**
71A-X	**Birth Status infant #1-X** ☐ Live birth ☐ Stillbirth ☐ Unknown
72A-X	**Gender infant #1-X** ☐ Male ☐ Female ☐ Unknown
73A-X	**Weight in pounds and ounces, or grams infant #1-X** **|__|__| lbs and |__|__| oz. OR |__|__|__|__| g** **OR** ☐ **Weight unknown**
74A-X	**Birth defects (select all that apply) infant #1-X** ☐ None ☐ Cleft lip/palate ☐ Genetic defect/chromosomal abnormality ☐ Neural tube defect ☐ Cardiac defect ☐ Limb defect ☐ Other (specify) OR ☐ Unknown