FRN Section III.B. Data to be Reported	Variable status (add, drop, modify, unchanged)	Current NASS Instructions and/or Definitions	Notes and justification	Proposed NASS instructions and/or definitions
Date of cycle reporting	Add	Not currently collected	New variable added for prospective data entry. The addition of the "date of cycle reporting" is necessary for the implementation of prospective data reporting. This type of reporting provides more accurate information on success rates because it reduces potential misclassification of cycles. The date is needed to ensure that initial reporting of cycle intent and selected patient information occurs within 4 days of cycle start, as outlined in the revised Federal Registry Notice.	Indicate the date when cycle is being reported. Always record the month first, using the two-digit equivalent (e.g., January = 01, February = 02). Record two digits for the day, and four digits for the year.
NASS Patient ID	Unchanged	This ID is generated by the NASS system. If you are using this worksheet to enter data for a *new* patient in NASS, the NASS Patient ID will be generated and displayed on the screen after you have selected to add a new patient.	No changes recommended.	This ID is generated by the NASS system. If you are using this worksheet to enter data for a *new* patient in NASS, the NASS Patient ID will be generated and displayed on the screen after you have selected to add a new patient.
Patient Optional Identifiers	Modify	Optional Identifier 1 [max 3 characters] Optional Identifier 2 [max 4 characters]	Revised to allow expanded number of characters — current number of characters may not be sufficient for clinics.	Optional Identifier 1 Optional Identifier 2 [expanded number of characters allowed]
Date of Birth (Patient)	Unchanged	Date of Birth: It is critical to enter the patient's month, day, and year of birth. Always record the month first, using the two-digit equivalent (e.g., January = 01, February = 02). Record two digits for the day, and four digits for the year.	No changes recommended.	Patient Date of Birth: It is critical to enter the patient's month, day, and year of birth. Always record the month first, using the two-digit equivalent (e.g., January = 01, February = 02). Record two digits for the day, and four digits for the year.

FRN Section III.B. Data to be Reported	Variable status (add, drop, modify, unchanged)	Current NASS Instructions and/or Definitions	Notes and justification	Proposed NASS instructions and/or definitions
Sex of patient seeking ART	Add	Not currently collected	New variable added to determine sex of patient seeking ART services. This variable allows for differentiation between male and female patients using ART services. This will also allow for appropriate skip patterns for male patients (e.g., questions on female patient history will not be shown).	Indicate the sex of the patient seeking ART (male or female)
Cycle start date	Modify	Date current cycle started: Enter the start date of the current cycle using NASS date reporting conventions as indicated on the screen. The cycle start date depends on the type of cycle as described below. **Fresh patient oocyte unstimulated cycles**: First day of natural menses or withdrawal bleeding. **Fresh patient oocyte stimulated cycles**: First day medication is given to stimulate follicular development. **Fresh donor oocyte cycles**: If exogenous sex steroids were used to prepare the endometrium, then first day the patient or gestational carrier receives exogenous sex steroids to prepare endometrium; or if no drugs were given to prepare the endometrium, then first day of natural menses or withdrawal bleeding. **Thawed embryo cycles:** If exogenous sex steroids were used to prepare the	The definitions were modified to include specific information on flare-gonadotropin cycles, which was a common reporting discrepancy due to clinic misinterpretationStimulated and unstimulated cycles were further clarified in the examples provided for the different definitions. This will facilitate more accurate calculation of cycle start date.	Indicate the cycle start date, determined as follows (dates should be entered as mm/dd/yyyy): **Fresh, non-donor cycles** 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 in a clomiphene / gonadotropin cycle or a clomiphene only cycle; d. The first day of natural menses or withdrawal bleeding in an unstimulated cycle. **Fresh, donor cycles (including gestational carrier cycles)** a. The first day the patient, donor, recipient or gestational carrier receives

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		endometrium, then first day the patient or gestational carrier receives exogenous sex steroids to prepare endometrium; or if no drugs were given to prepare the endometrium, then first day of natural menses or withdrawal bleeding.		exogenous sex steroids to prepare the endometrium; b. The first day of natural menses or withdrawal bleeding in an unstimulated cycle. **Frozen cycles (both donor and non-donor)** a. The first day the patient or recipient receives exogenous sex steroids to prepare the endometrium; b. The first day of natural menses or withdrawal bleeding in an unstimulated cycle.
Patient US Resident	Modify	Primary residence in U.S.: Use the drop-down list to indicate whether the patient's main residence is in the United States or its territories (regardless of legal residency status). Primary residence refers to the place where the person usually lives. U.S. territories that should be considered include Puerto Rico, Guam, U.S. Virgin Islands, American Samoa, Northern Mariana Islands, Wake Island, and Johnston Atoll. If primary residence of the patient is unknown, select "Not ascertained by clinic" from the drop-down menu.	Removed the "not ascertained by clinic" option to discourage non-report of residency.	Indicate whether the patient's primary residence during the current cycle is in the United States or its territories (regardless of legal residency status). Primary residence refers to the place where the person usually lives. U.S. territories that should be considered include Puerto Rico, Guam, U.S. Virgin Islands, American Samoa, Northern Mariana Islands, Wake Island, and Johnston Atoll. If patient refuses to answer, select "refused".
Patient Country of Residence (if not United States)	Unchanged	Country of primary residence: If you entered "Yes" for Primary residence in U.S., then "United States" will be	No changes recommended.	If you entered "Yes" for Primary residence in U.S., then "United States" will be automatically entered into the

FRN Section III.B. Data to be Reported	Variable status (add, drop, modify, unchanged)	Current NASS Instructions and/or Definitions	Notes and justification	Proposed NASS instructions and/or definitions
		automatically entered into the Country of primary residence field. If you entered "No" in the Primary residence in U.S. field, you must use the drop-down list to select the country where the patient resides. The drop down list of countries is arranged alphabetically. If unknown, leave the ---Select--- box as is. Tip: Select "United Kingdom" for patients whose primary residence is England or Great Britain.		Country of primary residence field. If you entered "No" in the Primary residence in U.S. field, you must select the country where the patient resides. Tip: Select "United Kingdom" for patients whose primary residence is England or Great Britain.
Patient State of Residence	Modify	U.S. state of primary residence: If the patient's primary residence is in the U.S., select the state of her primary or main residence using the drop down menu of states listed in alphabetical order. If unknown, leave the ---Select--- box as is	Change "state of her primary residence" to "state of his or her primary residence" for clarity.	If the patient's primary residence is in the U.S., select the state of his or her primary or main residence using the drop down menu of states listed in alphabetical order. If unknown, leave the ---Select--- box as is.
Patient city of residence	Modify	U.S. city of primary residence: If the patient's primary residence is in the U.S., enter the city of her primary or main residence. If unknown, leave blank.	Changed "city of her primary residence" to "city of his or her primary residence"	U.S. city of primary residence: If the patient's primary residence is in the U.S., enter the city of his or her primary or main residence. If unknown, leave blank.
Patient Zip Code of residence	Modify	U.S. zip code of primary residence: If the patient's primary residence is in the U.S., enter the US Postal Service zip code of her primary residence. You can enter either five digits or nine digits using a dash after the first five (e.g., 43420-1345). If unknown, leave blank.	Change "zip code of her primary residence" to "zip code of his or her primary residence" for clarity.	If the patient's primary residence is in the U.S., enter the US Postal Service zip code of his or her primary residence. You can enter either five digits or nine digits using a dash after the first five (e.g., 43420-1345). If unknown, leave blank.

FRN Section III.B. Data to be Reported	Variable status (add, drop, modify, unchanged)	Current NASS Instructions and/or Definitions	Notes and justification	Proposed NASS instructions and/or definitions
				US Postal Service Zip Code of the patient's residence.
Intended cycle type	Modify	Intended Transfer Method (Select all that apply): Check the box next to each intended transfer method for the current cycle. IVF: In vitro fertilization is a method of assisted reproduction that involves removing oocytes from a woman's ovaries, combining them with sperm in the laboratory, and after fertilization and culture, placing the resulting embryo(s) into the woman's uterus. GIFT: Gamete intrafallopian transfer involves removing oocytes from a woman's ovary, combining them with sperm, and immediately transferring the oocytes and sperm into the fallopian tube. Fertilization takes place inside the fallopian tube. ZIFT or TET: Zygote intrafallopian transfer is a procedure in which the oocytes are collected and fertilized, and the resulting zygotes are then transferred to the fallopian tube. Tubal embryo transfer (TET) is the transfer of early stage embryos to the fallopian tube.	Given the recent increases in oocyte and embryo banking and the potential for these cycles to be underreported (see justification for the next question), an option was added to indicate that the cycle was intended for oocyte or embryo banking. Reference: Kushnir VA, Vidali A, Barad DH, Gleicher N. The status of public reporting of clinical outcomes in assisted reproductive technology. Fertil Steril. 2013;100:736-41.	Intended Transfer Method (Select all that apply): Check the box next to each intended transfer method for the current cycle. IVF: In vitro fertilization is a method of assisted reproduction that involves removing oocytes from a woman's ovaries, combining them with sperm in the laboratory, and after fertilization and culture, placing the resulting embryo(s) into the woman's uterus. GIFT: Gamete intrafallopian transfer involves removing oocytes from a woman's ovary, combining them with sperm, and immediately transferring the oocytes and sperm into the fallopian tube. Fertilization takes place inside the fallopian tube. ZIFT or TET: Zygote intrafallopian transfer is a procedure in which the oocytes are collected and fertilized, and the resulting zygotes are then transferred to the fallopian tube. Tubal embryo transfer (TET) is the transfer of early stage embryos to the fallopian tube.

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				EMBRYO/OOCYTE BANKING: Indicate if the current cycle is intended to be an oocyte or embryo banking cycle initiated with the intent of cryopreserving all oocytes or fertilized 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 or oocyte banking type	Modify	Embryo or oocyte banking cycle: Click on either "Yes" or "No" to indicate if the current cycle is intended to be an embryo banking, oocyte banking, or donor oocyte banking cycle initiated with the intent of cryopreserving all oocytes or fertilized 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).	Question was revised to include a sub-question for indicating banking type (oocyte or embryo banking) and duration of banking (if banking was indicated). Collecting information on cycles intended for embryo/oocyte banking only allows more accurate calculation of clinic success rates by reducing misclassification of cycles intended only for banking oocytes or embryos. Oocyte banking is no longer considered experimental; thus increased use of oocyte banking is anticipated. Furthermore, long term banking (≥12 months) is indicative of fertility preservation, a practice that has become increasingly common and for which the long term health implications are not known. Short term banking often represents a preference to using frozen oocytes/embryos in the immediate future due to some evidence of better success rates with frozen embryos.	If cycle is for banking only, specify the banking type (select all that apply): embryo banking or oocyte banking. EMBRYO BANKING: An embryo banking cycle is defined as a cycle initiated with the intent of cryopreserving all fertilized 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 for use in future cycles. AUTOLOGOUS OOCYTE BANKING: An oocyte banking cycle is defined as a cycle initiated with the intent of cryopreserving all un-fertilized oocytes for later use. This does not apply to

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			Kushnir VA, Vidali A, Barad DH, Gleicher N. The status of public reporting of clinical outcomes in assisted reproductive technology. Fertil Steril. 2013, in press, Jun 8. The Practice Committees of the American Society for Reproductive Medicine and the Society for Assisted Reproductive Technology. Mature oocyte cryopreservation: a guideline. Fertil Steril 2013;99:37-43.	cycles initiated with the intent to transfer embryos. Autologous oocyte banking refers to cycles where the patient is banking her own oocytes for later use. DONOR OOCYTE BANKING: An oocyte banking cycle is defined as 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. Donor oocyte banking refers to cycles where a donor is banking oocytes for use by someone else at a later date.
Intended duration of oocyte banking	Add	Not currently collected	Long term banking (≥12 months) is indicative of fertility preservation, a practice that has become increasingly common and for which the long term health implications are not known. Furthermore, increasing numbers of women are choosing to freeze their oocytes or embryos prior to undergoing surgery, radiation or other gonadotoxic medical treatments for malignancies. Although the American Clinical Oncology Society and the American Society for Reproductive medicine both recommend that providers discuss fertility preservation options with patients treated for malignancy during their reproductive years, there are currently no surveillance data regarding the use of fertility preservation among this population.	Indicated the anticipated duration of oocyte banking - short term (less than 12 months) - long term (12 months or longer) banking for fertility preservation prior to gonadotoxic medical treatments - long term (12 months or longer) banking for other reasons

FRN Section III.B. Data to be Reported	Variable status (add, drop, modify, unchanged)	Current NASS Instructions and/or Definitions	Notes and justification	Proposed NASS instructions and/or definitions
			Short term banking often represents a preference for using frozen oocytes/embryos in the immediate future due to some evidence of better success rates with frozen embryos. References: Loren AW, Mangu PB, Beck LN, Brennan L, Magdalinski AJ, Partridge AH, Quinn G, Wallace WH, Oktay K; American Society of Clinical Oncology. Fertility preservation for patients with cancer: American Society of Clinical Oncology clinical practice guideline update. J Clin Oncol. 2013;31:2500-10 American Society for Reproductive Medicine. Fertility preservation and reproduction in patients facing gonadotoxic therapies: a committee opinion. Fertil Steril. 2013;100:1224–31	
Intended duration of embryo banking	Add	Not currently collected	Long term banking (≥12 months) is indicative of fertility preservation, a practice that has become increasingly common and for which the long term health implications are not known. Furthermore, increasing numbers of women are choosing to freeze their oocytes or embryos prior to undergoing surgery, radiation or other gonadotoxic medical treatments for malignancies. Although the American Clinical Oncology Society and the American Society for Reproductive medicine both recommend that providers discuss fertility preservation options with patients treated for malignancy during their reproductive years, there are currently no surveillance data regarding the use of fertility preservation among this population.	Indicated the anticipated duration of oocyte or embryo banking - short term (less than 12 months) o Short term delay of transfer to obtain genetic information (e.g. via PGD/PGS). o Short term delay of transfer for all other reasons (e.g., patient safety, pooling embryos, or other

FRN Section III.B. Data to be Reported	Variable status (add, drop, modify, unchanged)	Current NASS Instructions and/or Definitions	Notes and justification	Proposed NASS instructions and/or definitions
			Short term banking often represents a preference for using frozen oocytes/embryos in the immediate future due to some evidence of better success rates with frozen embryos. References: Loren AW, Mangu PB, Beck LN, Brennan L, Magdalinski AJ, Partridge AH, Quinn G, Wallace WH, Oktay K; American Society of Clinical Oncology. Fertility preservation for patients with cancer: American Society of Clinical Oncology clinical practice guideline update. J Clin Oncol. 2013;31:2500-10 American Society for Reproductive Medicine. Fertility preservation and reproduction in patients facing gonadotoxic therapies: a committee opinion. Fertil Steril. 2013;100:1224–31	reasons) - long term (12 months or longer) banking for fertility preservation prior to gonadotoxic medical treatments - long term (12 months or longer) banking for other reasons
Intended embryo source	Modify	Patient: Intent to use patient's oocytes/embryos, fertilized with partner or donor sperm Donor: Intent to use donor oocytes/embryos, fertilized with partner or donor sperm		Indicate the intended embryo source (select ALL that apply): - patient embryos - donor embryos PATIENT EMBRYOS: Intent to use patient's embryos, fertilized with partner or donor sperm DONOR EMBRYOS: Intent to use donor embryos, fertilized with donor sperm

FRN Section III.B. Data to be Reported	Variable status (add, drop, modify, unchanged)	Current NASS Instructions and/or Definitions	Notes and justification	Proposed NASS instructions and/or definitions
Intended Oocyte Source and state	Modify	Patient: Intent to use patient's oocytes/embryos, fertilized with partner or donor sperm Donor: Intent to use donor oocytes/embryos, fertilized with partner or donor sperm FRESH: Intent to transfer fresh oocytes/embryos retrieved during this cycle FRESH: Intent to transfer fresh oocytes/embryos retrieved during this cycle FROZEN: Intend to transfer thawed embryos retrieved during a previous cycle Note: The sperm source may be either the patient's partner or a sperm donor selected by the patient.	Two separate questions on oocyte/embryo source and type were combined into one question that distinguishes between patient oocytes and donor oocytes, fresh or frozen. Previous questions did not differentiate between use of patient oocyte versus use of donor oocyte (only donor embryo was collected). This change will eliminate misclassification of cycles and therefore improve methods for calculating success rates.	Check the box next to each intended oocyte/embryo source and state for the current cycle. (select all that apply): PATIENT OOCYTE: Intend to use patient's oocytes DONOR OOCYTE: Intend to use donor's oocytes. NOTE: the oocyte donor can include the female same sex partner in situations where one partner is donating the oocytes and the other is carrying the pregnancy. FRESH: intend to use fresh oocytes or embryos retrieved during this cycle FROZEN: intend to use thawed oocytes or embryos from a previous cycle UNKNOWN: Select only if oocyte source is not known when using donor embryos
Intended Sperm Source (Partner, Donor, Mixed)	Modify	Source of semen used for fertilization: Use the drop-down list to select the source of semen used for fertilization during this patient's ART cycle. Partner: Semen used to fertilize the oocytes is that of the patient's partner.	Question revised for prospective data collection to reflect intent and to change from "semen" to "sperm". An additional category for "patient" was added for those cycles where the patient is male. The "mixed" option was eliminated since the clinic can select all sources that are applicable.	Select the intended source of sperm for fertilization during this patient's ART cycle. (SELECT ALL THAT APPLY) PARTNER: Sperm used to fertilize the oocytes is that of the patient's partner. DONOR: Sperm used to fertilize the oocytes is that of a donor (whether known or anonymous).

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		Donor: Semen used to fertilize the oocytes is that of a donor (whether known or anonymous). Mixed (donor and partner): Semen from both the patient's partner and a donor are used to fertilize the oocytes. Unknown because embryos thawed from previous cycle: This response should only be selected for frozen cycles where the record does not provide the semen source. If the semen source is known in a frozen cycle, it should be recorded in the appropriate category above.		PATIENT (if male): Sperm used to fertilize the oocytes is that of the patient. UNKNOWN: Source is not known. This response should only be selected if all sperm sources are unknown for a frozen cycle. If at least one sperm source is known in a frozen cycle, it should be recorded in the appropriate category above.
Intended pregnancy carrier	Modify	Intended transfer method: Gestational carrier (yes/no). Gestational carrier is a woman who gestates an embryo that did not develop from her egg with the expectation of returning the infant to its intended parents.	Question was revised to include options for patient, gestational carrier, or none (e.g., an oocyte or embryo banking cycles). The instructions were revised to note that 2 cycles should be reported if both the patient and a gestational carrier are used.	Indicate whether the intended carrier for this cycle is the patient, a gestational carrier (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)), or none (in the case of cycles only intended for oocyte or embryo banking) NOTE: if the intended carrier is a patient and gestational carrier, 2 cycles should be reported. For female same sex couples, the woman who will carry the pregnancy should be identified as the patient.
Cycle type	Modify	Intended Transfer Method (Select all that apply): Check the box next to	Question revised slightly to remove intent for the purpose of collecting information on the procedures	Indicate cycle type (select all that apply)

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		each intended transfer method for the current cycle. IVF: In vitro fertilization is a method of assisted reproduction that involves removing oocytes from a woman's ovaries, combining them with sperm in the laboratory, and after fertilization and culture, placing the resulting embryo(s) into the woman's uterus. GIFT: Gamete intrafallopian transfer involves removing oocytes from a woman's ovary, combining them with sperm, and immediately transferring the oocytes and sperm into the fallopian tube. Fertilization takes place inside the fallopian tube. ZIFT or TET: Zygote intrafallopian transfer is a procedure in which the oocytes are collected and fertilized, and the resulting zygotes are then transferred to the fallopian tube. Tubal embryo transfer (TET) is the transfer of early stage embryos to the fallopian tube.	that were actually performed, which may differ from what was intended at the cycle start due to factors such as inadequate number of oocytes retrieved, detection of chromosomal abnormalities during PGD, or development of ovarian hyperstimulation syndrome. By requiring clinics to prospectively report intended cycle type followed by the actual cycle type, we will be better able to accurately calculate success rates and evaluate differences between intent and actual treatment methods. Most importantly, this will reduce inaccurate reporting of cancelled cycles. Also, given the recent increases in oocyte/embryo banking, an option for oocyte/embryo banking was added.	IVF: In vitro fertilization is a method of assisted reproduction that involves removing oocytes from a woman's ovaries, combining them with sperm in the laboratory, and after fertilization and culture, placing the resulting embryo(s) into the woman's uterus. GIFT: Gamete intrafallopian transfer involves removing oocytes from a woman's ovary, combining them with sperm, and immediately transferring the oocytes and sperm into the fallopian tube. Fertilization takes place inside the fallopian tube. ZIFT or TET: Zygote intrafallopian transfer is a procedure in which the oocytes are collected and fertilized, and the resulting zygotes are then transferred to the fallopian tube. Tubal embryo transfer (TET) is the transfer of early stage embryos to the fallopian tube. EMBRYO/OOCYTE BANKING: Indicate if the current cycle is an oocyte or embryo banking cycle initiated with the intent of cryopreserving all oocytes or fertilized embryos for later use. This does not apply to cycles initiated with the intent to transfer embryos, but for which all embryos were subsequently

FRN Section III.B. Data to be Reported	Variable status (add, drop, modify, unchanged)	Current NASS Instructions and/or Definitions	Notes and justification	Proposed NASS instructions and/or definitions
				cryopreserved (regardless of the reason).
Embryo source	Modify	Patient: Intent to use patient's oocytes/embryos, fertilized with partner or donor sperm Donor: Intent to use donor oocytes/embryos, fertilized with partner or donor sperm		Indicate the embryo source (select ALL that apply): - patient embryos - donor embryos PATIENT EMBRYOS: used patient's embryos, fertilized with partner or donor sperm DONOR EMBRYOS: used donor embryos, fertilized with donor sperm
Oocyte Source and state	Modify	Patient: Intent to use patient's oocytes/embryos, fertilized with partner or donor sperm Donor: Intent to use donor oocytes/embryos, fertilized with partner or donor sperm FRESH: Intent to transfer fresh oocytes/embryos retrieved during this cycle FRESH: Intent to transfer fresh oocytes/embryos retrieved during this cycle	Question revised to ask separate questions on intent for the purpose of collecting information on actual oocyte/embryo source and state. By requiring clinics to prospectively report oocyte/embryo source and state followed by the actual source and state, we will be better able to accurately calculate success rates and evaluate differences between intent and actual treatment methods. Two separate questions on oocyte/embryo source and type were combined into one question that distinguishes between patient oocytes/embryos and donor oocytes/embryos, fresh or frozen. Previous questions did not differentiate between patient oocyte and embryo. This change will eliminate misclassification of cycles and therefore improve	Indicate oocyte/embryo source for current cycle (select all that apply): PATIENT OOCYTE: Used patient's oocytes PATIENT EMBRYO: Used patient's embryos fertilized with patient, partner or donor sperm DONOR OOCYTE: Used donor's oocytes DONOR EMBRYO: Used donor's embryos fertilized with patient, partner or donor sperm NOTE: the oocyte donor can include the

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		FROZEN: Intend to transfer thawed embryos retrieved during a previous cycle Note: The sperm source may be either the patient's partner or a sperm donor selected by the patient.	methods for calculating success rates.	female same sex partner in situations where one partner is donating the oocytes and the other is carrying the pregnancy. FRESH: Used fresh oocytes or embryos retrieved during this cycle FROZEN: Used thawed oocytes or embryos from a previous cycle UNKNOWN: Select only if oocyte source is not known when using donor embryos
Reason for ART	Modify	Reason for ART: Check the box next to all reasons that apply that make the patient (and partner) a candidate for ART. For on-screen definitions, click on the reasons or question marks to show/hide the definitions. Male infertility: This is infertility due to abnormal semen parameters, abnormal sperm function, or surgical sterilization (vasectomy). If surgical sterilization of partner has been selected in the Patient History I section, the box for Male infertility should be checked. History of endometriosis: This is the presence of tissue resembling endometrium in locations outside the uterus such as the ovaries, fallopian	Reason for ART has consistently high discrepancy rates since the inception of NASS. About 20% of discrepancies are due to a single wrong diagnosis reported (usually other or unexplained). This question was revised to add additional options to increase the specificity of the question and to reduce the likelihood that clinics will select other/unexplained. Type of infertility is directly related to treatment success and has been shown to differentially impact perinatal outcomes; thus accurate information is needed to properly evaluate differences in treatment outcomes. References: Practice Committee of the American Society for Reproductive Medicine. Recommendations for practices utilizing gestational carriers: an ASRM Practice Committee guideline. Fertil Steril. 2012;97(6):1301-8.	Check the box next to all reasons that apply that make the patient (and/or partner) a candidate for ART. - Male infertility o Medical condition o Genetic or chromosomal abnormality (specify) o Abnormal sperm parameters - Azoospermia, obstructive - Azoospermia, non-obstructive - Oligospermia, severe - Oligospermia, moderate - Low motility - Low morphology

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		tubes, and abdominal cavity; a history of all stages of endometriosis (minimal to severe) whether treated or not, may be a reason for ART. Tubal ligation (not reversed): Sterilization of the female by constricting, severing, or crushing the uterine tubes; constriction may be with an encircling plastic ring or other ligature. Tubal disease (hydrosalpinx): An accumulation of watery fluid in a fallopian tube that usually results from damage to the tube. Other tubal disease (not hydrosalpinx): 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). Ovulatory disorders/PCO (polycystic ovaries): This includes one or more disorders causing reduced fecundity associated with structural, anatomic, or functional impairment of one or both ovaries; includes multiple ovarian cysts affecting fertility, oligo-ovulation (<6 cycles per year), anovulation (of hypothalamic or non-hypothalamic causes).	Practice Committee of American Society for Reproductive Medicine. Diagnostic evaluation of the infertile male: a committee opinion. Fertil Steril. 2012;98(2):294-301 Optimal Evaluation of the Infertile Male: AUA Best Practice Statement. Available at: https://www.auanet.org/common/pdf/education/clinical-guidance/Male-Infertility-d.pdf Practice Committee of American Society for Reproductive Medicine. Diagnostic evaluation of the infertile female: a committee opinion. Fertil Steril. 2012;98(2):302-7 Practice Committee of American Society for Reproductive Medicine. Definitions of infertility and recurrent pregnancy loss: a committee opinion. Fertil Steril. 2013;99(1):63. Johnston RC, Kovacs GT, Lording DH, Baker HW. Correlation of semen variables and pregnancy rates for donor insemination: a 15-year retrospective. Fertil Steril. 1994;61(2):355-9.	o Other male factor (specify) - History of endometriosis - Tubal ligation for contraception - Current or prior hydrosalpinx o Communicating o Occluded - Other tubal disease (not current or historic hydrosalpinx) - Ovulatory disorders o PCO o 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. o Absence of uterus o Significant uterine anomaly (irreparable Asherman syndrome, unicornate uterus associated with recurrent pregnancy loss) o Medical contraindication to pregnancy (pulmonary hypertension or other serious medical condition that could be exacerbated by pregnancy or cause significant risk to the fetus)

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		Diminished ovarian reserve: A condition of reduced fecundity related to diminished ovarian function; includes high FSH or high estradiol measured in the early follicular phase or during a clomiphene challenge test; reduced ovarian volume related to congenital, medical, surgical or other causes; or advanced maternal age. 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, or congenital anomalies. Other reason for infertility: Infertility due to other factors such as immunologic, chromosomal, cancer chemotherapy, or systemic disease. Note: If this category is selected, type in the other reason for infertility in the space provided. 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,		o Recurrent pregnancy loss o Unknown - Recurrent pregnancy loss - Other causes of infertility (specify) - Unexplained infertility Definitions: <u>Male infertility</u>: Medical condition: Significant medical conditions presenting as, or contributing to, male infertility (i.e., hormonal and oxidative dysfunction such as diabetes mellitus, thyroid disease, pituitary adenoma, hypopituitarism, cancer of prostate or testes, retroperitoneal and spinal cord tumors, polycycstic kidney disease, varicocele, retrograde ejaculation, infection, inflammation and autoimmunity involving the genitourinary system, etc.) Genetic or chromosomal abnormality: Presence of a laboratory documented genetic condition known to be associated with male infertility (Y chromosome microdeletion, Klinefelter syndrome, Cystic Fibrosis etc.) Specify abnormality type. Abnormal sperm parameters (indicate findings from semen analysis)

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		or systemic disease) has been identified.		- Azoospermia is defined as the complete absence of sperm from the ejaculate. Obstructive azoospermia may result from epididymal, vasal, or ejaculatory duct pathology. Vasectomy is the most common cause of vasal obstruction. Other causes include severe genitourinary infections, iatrogenic injury during scrotal or inguinal surgical procedures and congenital anomalies. Non-obstructive azoospermia refers to abnormal sperm production due to testicular failure, varicoceles, or chromosomal abnormalities such as Y-chromosome microdeletions or karyotypic abnormalities (e.g., Klinefelter syndrome). - Oligospermia refers to 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. - Low motility refers to sperm motility less than 40%. - Low morphology refers to sperm morphology less than 4% normal.

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				History of endometriosis: This is 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. 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. Current or prior hydrosalpinx: An 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. - Unknown. Other Tubal Disease: Any other tubal disease, including, but not limited to, pelvic or peritubal adhesive disease,

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				prior tubal surgery, prior ectopic pregnancy, or tubal occlusion (partial or complete without current or prior hydrosalpinx) Ovulatory disorders: This includes one or more disorders causing reduced fecundity associated with structural, anatomic, or functional impairment of one or both ovaries;, - PCO (polycystic ovaries): multiple ovarian cysts affecting fertility - Other ovulatory disorders (not polycystic ovaries) such as oligo-ovulation (<6 cycles per year), anovulation (of hypothalamic or non-hypothalamic causes), or other endocrine abnormality. Diminished ovarian reserve: A condition of reduced fecundity related to diminished ovarian function based on clinical assessment; often indicated by FSH>10 or AMH<1.0 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, adenomyosis,

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				or congenital anomalies. PGD as primary reason for ART - Any cycle in which a patient undergoes IVF for the primary purpose of conducting preimplanatation genetic screening or diagnosis. This option should only be selected if the patient is trying to prevent transmission of inherited disease. Oocyte or embryo banking as reason for ART – cycles where oocyte or embryo banking is reason for ART Indication for use of gestational carrier. - Absence of uterus - Significant uterine anomaly (e.g. irreparable Asherman syndrome, unicornate uterus associated with recurrent pregnancy loss) - Medical contraindication to pregnancy (including pulmonary hypertension or other serious medical condition that could be exacerbated by pregnancy or cause significant risk to the fetus) - Recurrent pregnancy loss - a disease distinct from infertility, defined by two or more failed pregnancies. This should be selected if recurrent pregnancy loss

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				due to maternal causes is the primary indication for use of a gestational carrier. - Unknown reason <u>Recurrent pregnancy loss</u> (a disease distinct from infertility, defined by two or more failed pregnancies). This includes cycles in which IVF with PGD is performed to exclude oocytes/embryos with chromosomal abnormalities to reduce the likelihood of recurrent pregnancy loss. <u>Other causes</u> (please specify) <u>Unexplained Infertility</u>: Infertility in which no etiology has been identified.
Female Patient Height	Unchanged	Report height in units as recorded in medical chart. Do not convert measurements. (Report in Feet and/or Inches or Centimeters or Unknown)	No changes recommended.	Report height of female patient in units as recorded in medical chart. Do not convert measurements. (Report in Feet and/or Inches or Centimeters or Unknown)

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Female Patient Weight at the start of this cycle:	Unchanged	Report weight in units as recorded in medical chart. Do not convert measurements. (Report in Pounds or Kilograms or Unknown)	No changes recommended.	Report weight of female patient in units as recorded in medical chart. Do not convert measurements. (Report in Pounds or Kilograms or Unknown)
History of cigarette smoking	Modify	Has this patient smoked at least 100 cigarettes during entire life? ☐ Yes ☐ No ☐ Unknown During the 3 months before this cycle started, did the patient smoke <u>any</u> cigarettes? ☐ Yes ☐ No ☐ Unknown If patient smoked cigarettes during the 3 months before this cycle, on <u>average</u>, how many cigarettes per day did the patient <u>usually</u> smoke during those 3 months? |__|__| Number of cigarettes smoked per day during the 3 months before this cycle. or	The question was revised to eliminate the question on lifetime smoking and to focus on smoking during the 3 months prior to the cycle start. Accurate collection of this variable is needed due to the association between smoking and infertility as well as increased risk for spontaneous abortion and ectopic pregnancy among smokers. Reference: Smoking and infertility: a committee opinion. Fertil Steril. 2012 Sep 5.	Did the patient smoke during the 3 months before the cycle started? ☐ Yes ☐ No ☐ Unknown

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		☐ Patient smoked less than 1 cigarette per day on average, during the 3 months before this cycle. (For example, patient smoked less than 7 cigarettes per week, or smoked a couple cigarettes only on weekends) or ☐ Unknown how many cigarettes the patient smoked per day during the 3 months before this cycle		
Prior pregnancy	Add	Gravidity (as defined in another question): Gravidity is defined as the total number of prior pregnancies a patient has had. This includes ectopic pregnancies, and pregnancies that ended in therapeutic abortion, spontaneous abortion, stillbirth, or live birth.	This is a "top-level" question that determines whether all subsequent questions on pregnancy history are shown (i.e., except for duration of infertility, the subsequent questions on pregnancy history are not relevant). NASS currently collects information on number of previous pregnancies, but this new, "top-level" question allows for skip patterns for those with no previous pregnancies.	Click on either "Yes" or "No" to indicate if the female patient had any prior pregnancies. This includes ectopic pregnancies, biochemical pregnancies, and pregnancies that ended in therapeutic abortion, spontaneous abortion, stillbirth, or live birth.
Months attempting pregnancy (if couple is not surgically sterile)	Add	Not currently collected	New variable. Duration of infertility has been identified as a predictor of success rates. Studies have also shown that women with a long time to pregnancy have increased risk for preterm birth. Thus, collection of information on the duration of infertility can help distinguish the potential effect of underlying infertility on success rates and adverse perinatal outcomes following ART. NOTE: question will only be shown if answered "yes" to	If any prior pregnancy reported, enter the number of months attempting pregnancy (without fertility treatment) since the last pregnancy. (Question is not applicable if the couple is surgically sterile.) If no prior pregnancies reported, enter the number of months attempting

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			prior pregnancy. References: Messerlian C, Maclagan L, Basso O. Infertility and the risk of adverse pregnancy outcomes: a systematic review and meta-analysis. Hum Reprod. 2013 Jan;28(1):125-37 Cai QF, Wan F, Huang R, Zhang HW. Factors predicting the cumulative outcome of IVF/ICSI treatment: a multivariable analysis of 2450 patients. Hum Reprod. 2011 Sep;26(9):2532-40.	pregnancy (without fertility treatment). (Question is not applicable if the couple is surgically sterile.)
Female Patient Gravidity	Modify	Gravidity: Gravidity is defined as the total number of prior pregnancies a patient has had. This includes ectopic pregnancies, and pregnancies that ended in therapeutic abortion, spontaneous abortion, stillbirth, or live birth.	Question was revised to include biochemical pregnancies in the definition for completeness. This is consistent with NCHS definition for gravidity which includes the total number of times a woman has been pregnant, regardless of regardless of whether the pregnancy resulted in a live birth. NOTE: question will only be shown if answered “yes” to prior pregnancy.	If any prior pregnancies reported, enter the total number of prior pregnancies (gravidity) Gravidity is defined as the 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.
Prior Full-Term Births	Unchanged	Number of prior full term births (>=37 weeks): Enter the total number of prior live and stillbirths a patient has had that reached 37 completed weeks gestation. Births are counted by birth events (e.g., triplets would be counted as one	No changes recommended. NOTE: question will only be shown if answered “yes” to prior pregnancy.	Enter the total number of prior births a female patient has had which reached 37 completed weeks gestation. This includes both live births and stillbirths. Births are counted by birth events (e.g. a triplet birth is counted as one).

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		birth).		A birth (delivery) in which at least one fetus was live born (showed signs of life after the complete expulsion or extraction from its mother). Signs of life include breathing, beating of the heart, pulsation of umbilical cord, or definite movement of 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.
Prior Preterm Births	Unchanged	Number of prior preterm births (>=20 & <37 weeks): Enter the total number of prior live and still births a patient has had that were at least 20 but less than 37 completed weeks gestation. Births are counted by birth events (e.g., triplets would be counted as one birth).	No changes recommended. NOTE: question will only be shown if answered "yes" to prior pregnancy.	Enter the total number of prior births a female patient has had that were at least 20 but less than 37 completed weeks gestation. This includes both live births and stillbirths. Births are counted as birth events (e.g. a triplet birth is counted as one).
Number of Prior Stillbirths	Add	Instructions - N/A Stillbirth defined as 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.	New variable. Previous stillbirth is a risk factor for stillbirth in subsequent pregnancies. Therefore, previous stillbirth may explain variations in live birth rates following ART. The current stillbirth definition was revised to include a birth weight threshold when gestational age is not known (consistent with the NCHS definition of stillbirth).	Number of Prior Stillbirth: Enter the total number of prior stillbirths. Stillbirth is a birth (delivery) after completion of 20 weeks of gestation (if the gestational age is known), or a weight greater than or equal to 350 grams (if the gestational age is not known) in which the fetus showed no

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			NOTE: question will only be shown if answered "yes" to prior pregnancy. Reference: Flenady V, Koopmans L, Middleton P, Frøen JF, Smith GC, Gibbons K, Coory M, Gordon A, Ellwood D, McIntyre HD, Fretts R, Ezzati M. Major risk factors for stillbirth in high-income countries: a systematic review and meta-analysis. Lancet. 2011;377(9774):1331-40.	signs of life after the complete expulsion or extraction from the mother. Stillbirths should be counted as infant-level events (e.g. a twin pregnancy with one stillbirth and one live birth would be reported as one and a twin pregnancy with two stillbirths would be reported as two).
Prior Spontaneous Abortions (miscarriage)	Unchanged	Number of prior spontaneous abortions (<20 weeks): This is the total number of prior clinical pregnancies 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). These are also known as miscarriages.	No changes recommended. NOTE: question will only be shown if answered "yes" to prior pregnancy.	Number of prior spontaneous abortions (<20 weeks): Enter the total number of prior clinical pregnancies ending in spontaneous loss of the entire pregnancy prior to completion of 20 weeks of gestation. These are also known as miscarriages.
Prior ectopic pregnancies	Add	Not currently collected	Ectopic pregnancy was added to fully account for all outcomes of prior pregnancies. Prior ectopic pregnancy is also a risk factor for repeated ectopic pregnancy and may therefore impact success rates and live birth rates following ART. NOTE: question will only be shown if answered "yes" to prior pregnancy. Weigert M, Gruber D, Pernicka E, et al. Previous tubal ectopic pregnancy raises the incidence of repeated ectopic pregnancies in in vitro fertilization-embryo	Enter the total number of prior ectopic pregnancies. An ectopic pregnancy is defined as the presence of an extrauterine gestation documented by ultrasound or salpingectomy,

FRN Section III.B. Data to be Reported	Variable status (add, drop, modify, unchanged)	Current NASS Instructions and/or Definitions	Notes and justification	Proposed NASS instructions and/or definitions
			transfer patients. J Assist Reprod Genet 2009; 26:13–17.	
Prior stimulations for ART	Modify	Number of prior fresh ART cycles: Enter the number of fresh ART cycles started before the initiation of this cycle. ART is defined as all treatments or procedures that include the handling of sperm or embryos for the purpose of establishing a pregnancy. This includes but is not limited to IVF, transcervical embryo transfer, GIFT, ZIFT, and TET. ART does not include assisted insemination. A prior ART cycle is defined as any cycle in which: ◊ The patient has undergone ovarian stimulation or monitoring (i.e. performance of sonogram, serum estradiol, or LH measurements) with the intent of undergoing ART; or ◊ ART has been used; ◊ In the case of donor oocytes, a patient began medication for endometrial preparation with the intent of undergoing ART. Note: Include ALL previous fresh ART cycles, even those started at other clinics.	Question was reworded to "prior stimulations for ART" (instead of prior ART cycles) for clarity. Definition was revised to include definition of stimulation and to add note that stimulations for prior cancelled cycles should also be included.	Number of prior stimulations for ART: Enter the number of prior stimulations for ART. Stimulation refers to the use of drugs to stimulate the ovary to develop follicles and oocytes. ART is defined as all treatments or procedures that include the handling of sperm or embryos for the purpose of establishing a pregnancy. This includes but is not limited to IVF, transcervical embryo transfer, GIFT, ZIFT, and TET. ART does not include assisted insemination. Note: Include ALL previous stimulations, even those started at other clinics, regardless of whether the cycle was cancelled.
Prior Frozen ART Cycles	Unchanged	Number of prior frozen ART cycles: Enter the number of frozen embryo transfer procedures a patient underwent prior to the initiation of	No changes recommended.	Enter the total number of frozen embryo transfer procedures a patient has undergone prior to the initiation of this cycle. This should include cycles

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		this cycle. √ Note: Include ALL previous frozen ART cycles, even those started at other clinics.		performed at the reporting clinic, plus all other clinics. Frozen embryo transfer cycles (cancelled cycles) that did not proceed to transfer (regardless of reason) are not included in this definition.
Prior ART cycles resulted in pregnancy	Add	Not currently collected	New variable. For younger women, prior successful cycles are associated with increased likelihood of success in current cycle. In addition, previous successful IVF is one of the criteria for the use of elective single embryo transfer, which is the best approach for reducing multiple births associated with ART. NOTE: this question will only be shown if 1 or more prior stimulations or frozen cycles are reported. Kalu E, Thum MY, Abdalla H. Prognostic value of first IVF cycle on success of a subsequent cycle. J Assist Reprod Genet. 2011 Apr;28(4):379-82. Practice Committee of the Society for Assisted Reproductive Technology and Practice Committee of the American Society for Reproductive Medicine. Elective single embryo transfer. Fertil Steril 2012; 97:835–42.	Indicate whether any of the prior ART cycles resulted in a live birth (yes/no).
Female Patient Maximum Follicle Stimulating Hormone (FSH) Level	Modify	Patient maximum FSH: If laboratory reports are available, review them to determine the maximum FSH level observed on Day 2, 3, or 4 of the patient's menstrual cycle or Day 10 of a clomiphene challenge test.	Question revised to add more specificity about minimum values to report. References: Weghofer et al. Age-specific FSH levels as a tool for appropriate patient counselling in assisted	Report the maximum FSH level (in mIU/ml) observed on cycle day 2, 3, or 4 OR on day 10 of a clomiphene challenge test. Results must be evidenced by a laboratory report (from your clinic, another clinic or a third

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		√ Note: You must have documentation of the FSH test results.	reproduction Hum Reprod. 2005 Sep;20(9):2448-52 Barad et al. Age-Specific Levels for Basal Follicle-Stimulating Hormone Assessment of Ovarian Function Obstet Gynecol. 2007 Jun;109(6):1404-10.	party laboratory). If FSH testing for this patient has never been performed, select unknown. Please note that if the patient's highest FSH level was less than the minimum the lab reports as a value for follicular phase females (e.g. the lab reports all values less than 2 mIU/ml as <2), then enter that minimum (e.g. 2)
Anti-Mullerian Hormone (AMH) level (ng/mL)	Add	Not currently collected	New variable. Anti-mullerian hormone (AMH) level is a measure of diminished ovarian reserve which predicts pregnancy chances. AMH levels are associated with likelihood of live birth, independent of age. Information on AMH level can therefore provide important information relative to success rates and IVF outcomes in patients with diminished ovarian reserve. Because AMH levels decrease with increasing age, it is necessary to collect the date of the most recent level. References: Gleicher N, Kim A, Kushnir V, Weghofer A, Shohat-Tal A, Lazzaroni E, Lee HJ, Barad DH. Clinical Relevance of Combined FSH and AMH Observations in Infertile Women. J Clin Endocrinol Metab. 2013, in press. Gleicher et al. Anti-Müllerian hormone (AMH) defines, independent of age, low versus good live-birth chances in women with severely diminished ovarian reserve. Fertil Steril. 2010 Dec;94(7):2824-7	Enter the female patient's most recent Anti-Mullerian Hormone (AMH) level in ng/mL, if performed within one year of the current ART cycle. Results must be evidenced by a laboratory report (from your clinic, another clinic or a third party laboratory). Please note that if the patient's AMH level was less than the minimum the lab reports as a value (e.g. the lab reports all values less than 0.16 ng/mL as <0.16), then enter that minimum (e.g. 0.16) If AMH testing for this patient has never been performed, select unknown. Enter the date of the most recent AMH level.

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			Seifer et al. Age-specific serum anti-Müllerian hormone values for 17,120 women presenting to fertility centers within the United States Fertil Steril. 2011 Feb;95(2):747-50	
Date of Birth (Oocyte source)	Modify	**Answer if oocyte/embryo source is DONOR:** Enter donor date of birth (mm/dd/yyyy): Note: If multiple donors, enter birth date of **youngest** donor. or If donor date of birth cannot be reported, provide donor age at earliest time donor oocytes were retrieved: Note: If multiple donors, enter age of **youngest** donor. **or** Unknown birth date and age of donor	Question was revised to collect information on the oocyte "source" (e.g., either the patient or a donor). Revised to remove "unknown" option since patient or donor DOB or age will always be known.	Enter date of birth (month, day, and year of birth) for oocyte source (either patient or oocyte donor). Always record the month first, using the two-digit equivalent (e.g., January = 01, February = 02). Record two digits for the day, and four digits for the year. Note: If multiple sources, enter birth date of youngest source. or If source date of birth cannot be reported, provide oocyte source age at earliest retrieval
Oocyte source ethnicity	Modify	Ethnicity (patient): Using the drop-down list, select one of the following: NOT Hispanic or Latino; Hispanic or Latino; Refused; Patient doesn't know; or Not ascertained by clinic. Hispanic or Latino ethnicity should be self-reported by the patient, and	Previously, only information on patient race/ethnicity was collected, even if donor oocytes were used. The question was thus revised to collect information on oocyte source (either patient or donor) since that information is most relevant for success rates and infant outcomes.	Oocyte source Ethnicity: Using the drop-down list, select one of the following: NOT Hispanic or Latino; Hispanic or Latino; Refused; or Unknown. Hispanic or Latino ethnicity should be self-reported, and refers to anyone born in or having ancestors

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		refers to anyone born in or having ancestors from Spain or one of the western hemisphere countries or territories where Spanish is the primary language (e.g., Mexico, Puerto Rico, Nicaragua, El Salvador, Dominican Republic, Columbia, Peru, Chile).	Wellons et al. Race matters: a systematic review of racial/ethnic disparity in Society for Assisted Reproductive Technology reported outcomes. Fertil Steril 2012;98:406-9.	from Spain or one of the western hemisphere countries or territories where Spanish is the primary language (e.g., Mexico, Puerto Rico, Nicaragua, El Salvador, Dominican Republic, Columbia, Peru, Chile).
Oocyte source race	Modify	Race (based on Patient self-report) Select ALL that apply: American Indian or Alaska Native, Asian , Black or African American , , Native Hawaiian or Other Pacific Islander, White, Refused, Unknown, Not ascertained by clinic	Previously, only information on patient race/ethnicity was collected, even if donor oocytes were used. The question was thus revised to collect information on oocyte source (either patient or donor) since that information is most relevant for success rates and infant outcomes. Wellons et al. Race matters: a systematic review of racial/ethnic disparity in Society for Assisted Reproductive Technology reported outcomes. Fertil Steril 2012;98:406-9.	Oocyte source race (based on self-report): Select ALL that apply: American Indian or Alaska Native, Asian , Black or African American , Native Hawaiian or Other Pacific Islander, White, Refused, or Unknown.
Pregnancy carrier	Modify	Intended transfer method: Gestational carrier (yes/no). Gestational carrier is a woman who gestates an embryo that did not develop from her egg with the expectation of returning the infant to its intended parents.	Question was revised slightly to include options for patient, gestational carrier or none (e.g., oocyte or embryo banking cycle). The instructions were revised to note that 2 cycles should be reported if both the patient and a gestational carrier are used. This is similar to question #9 which collects information on intended pregnancy carrier. This question collects information on actual pregnancy carrier, which could change during the course of treatment.	Indicate whether the intended carrier for this cycle is the patient, a gestational carrier (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)), or none (in the case of cycles only intended for oocyte or embryo banking). NOTE: if the intended carrier is a patient and gestational carrier, 2 cycles should be

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				reported . For female same sex couples, the woman who will carry the pregnancy should be identified as the patient.
Pregnancy carrier date of birth	Modify	Enter gestational carrier date of birth (mm/dd/yyyy): Or, if DOB unknown, enter age of gestational carrier at time of transfer Or Unknown gestational carrier date of birth	Question was revised to include all options for pregnancy carrier (e.g., patient or gestational carrier). Added option for entering age of pregnancy carrier when date of birth is not known.	Enter pregnancy carrier date of birth (mm/dd/yyyy): or Unknown pregnancy carrier date of birth
Pregnancy carrier Ethnicity	Modify	Ethnicity (patient): Using the drop-down list, select one of the following: NOT Hispanic or Latino; Hispanic or Latino; Refused; Patient doesn't know; or Not ascertained by clinic. Hispanic or Latino ethnicity should be self-reported by the patient, and refers to anyone born in or having ancestors from Spain or one of the western hemisphere countries or territories where Spanish is the primary language (e.g., Mexico, Puerto Rico, Nicaragua, El Salvador, Dominican Republic, Columbia, Peru, Chile).	Question was revised to include all options for pregnancy carrier (e.g., patient or gestational carrier). The collection of information on race/ethnicity of pregnancy carriers is important for the following reasons: (1) Response to treatment and corresponding success rates may differ among racial/ ethnic groups. (2) There is relatively little valid data on racial/ethnic trends and disparities in ART use and outcomes.(3) Recent studies have indicated racial and ethnic disparities in preterm birth among pregnancies conceived by ART. We also eliminated the "not ascertained by clinic" option since it was redundant with the "unknown" option. NOTE: if pregnancy carrier is patient and the patient's oocytes were used, this question will not be shown (race/ethnicity are collected in previous question on oocyte source)	Ethnicity (carrier): Using the drop-down list, select one of the following: NOT Hispanic or Latino; Hispanic or Latino; Refused; or Unknown. Hispanic or Latino ethnicity should be self-reported by the patient, and refers to anyone born in or having ancestors from the Iberian Peninsula (Spain and Portugal) or one of the western hemisphere countries or territories where Spanish or Portuguese is the primary language (e.g., Mexico, Puerto Rico, Nicaragua, El Salvador, Dominican Republic, Columbia, Peru, Chile, Brazil).

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			Wellons et al. Race matters: a systematic review of racial/ethnic disparity in Society for Assisted Reproductive Technology reported outcomes. Fertil Steril 2012;98:406-9. Xiong X,Pridjian G, Dickey RP. Racial and ethnic disparities in preterm births in infants conceived by in vitro fertilization in the U.S. Am Journ Obset Gynecol 2013; in press.	
Pregnancy carrier Race	Modify	Race (based on Patient self-report) Select ALL that apply: American Indian or Alaska Native, Asian , Black or African American , , Native Hawaiian or Other Pacific Islander, White, Refused, Unknown, Not ascertained by clinic	Question was revised to include all options for pregnancy carrier (e.g., patient or gestational carrier) and to eliminate the "not ascertained" option. NOTE: if pregnancy carrier is patient and the patient's oocytes were used, this question will not be shown (race/ethnicity are collected in previous question on oocyte source)	Race (based on carrier self-report) Select ALL that apply: American Indian or Alaska Native, Asian , Black or African American , Hispanic or Latino, Native Hawaiian or Other Pacific Islander White, Refused ,Unknown
Sperm source	Modify	Source of semen used for fertilization: Use the drop-down list to select the source of semen used for fertilization during this patient's ART cycle. Partner: Semen used to fertilize the oocytes is that of the patient's partner. Donor: Semen used to fertilize the oocytes is that of a donor (whether known or anonymous). Mixed (donor and partner): Semen	Question revised to change "semen" to "sperm". An additional category for "patient" was added for those cycles where the patient is male. The "mixed" option was eliminated since the clinic can select all sources that are applicable.	Select the intended source of sperm for fertilization during this patient's ART cycle. (SELECT ALL THAT APPLY) PARTNER: Sperm used to fertilize the oocytes is that of the patient's partner. DONOR: Sperm used to fertilize the oocytes is that of a donor (whether known or anonymous). PATIENT (if male): Sperm used to fertilize the oocytes is that of the patient. UNKNOWN: Source is not known. This

FRN Section III.B. Data to be Reported	Variable status (add, drop, modify, unchanged)	Current NASS Instructions and/or Definitions	Notes and justification	Proposed NASS instructions and/or definitions
		from both the patient's partner and a donor are used to fertilize the oocytes. Unknown because embryos thawed from previous cycle: This response should only be selected for frozen cycles where the record does not provide the semen source. If the semen source is known in a frozen cycle, it should be recorded in the appropriate category above.		response should only be selected if all sperm sources are unknown for a frozen cycle. If at least one sperm source is known in a frozen cycle, it should be recorded in the appropriate category above.
Sperm source date of birth	Add	Not currently collected	New variable. Sperm source age was added in light of growing recognition of the importance of paternal age on neurodevelopmental outcomes. Also, sperm quality and pregnancy rates naturally decline with age. References: Frattarelli JL, Miller KA, Miller BT, Elkind-Hirsch K, Scott RT. Male age negatively impacts embryo development and reproductive outcome in donor oocyte assisted reproductive technology cycles. Fertil Steril 2008;90:97–103. Levitas E., Lunenfeld E., Weisz N., Friger M., and Potashnik G. "Relationship between age and semen parameters in men with normal sperm concentration: analysis of 6,022 semen samples." Andrologia. April 2007. 39(2):45-50. Kong, A. et al. Rate of de novo mutations and the importance of father's age to disease risk. Nature 488, 471–475 (2012).	Enter sperm source date of birth (mm/dd/yyyy): Note: If multiple sources, enter birth date of youngest source. or If source date of birth cannot be reported, provide source age at earliest time of sperm collection: Note: If multiple donors, enter age of youngest donor.

FRN Section III.B. Data to be Reported	Variable status (add, drop, modify, unchanged)	Current NASS Instructions and/or Definitions	Notes and justification	Proposed NASS instructions and/or definitions
			Kidd SA, Eskenazi B, Wyrobek AJ (2001). Effects of male age on semen quality and fertility: a review of the literature. Fertil. Steril., 75: 237-248.	
Sperm source Ethnicity	Add	Not currently collected	New variable. The reason for collecting information on sperm source race/ethnicity is evaluate potential disparities s in ART use and success rates.	Sperm source ethnicity: Using the drop-down list, select one of the following: NOT Hispanic or Latino; Hispanic or Latino; Refused; or Unknown. Hispanic or Latino ethnicity should be self-reported by the patient, and refers to anyone born in or having ancestors from Spain or one of the western hemisphere countries or territories where Spanish is the primary language (e.g., Mexico, Puerto Rico, Nicaragua, El Salvador, Dominican Republic, Columbia, Peru, Chile).
Sperm source Race	Add	Not currently collected	New variable. The reason for collecting information on sperm source race/ethnicity is evaluate potential disparities s in ART use and success rates.	Sperm source race : Select ALL that apply: American Indian or Alaska Native, Asian , Black or African American , , Native Hawaiian or Other Pacific Islander, White, Refused, or Unknown.
Medications given to	Unchanged	**Patient medicated to stimulate**		**Complete this section for the source of**

FRN Section III.B. Data to be Reported	Variable status (add, drop, modify, unchanged)	Current NASS Instructions and/or Definitions	Notes and justification	Proposed NASS instructions and/or definitions
stimulate follicular development		**follicular development:** Click on either "Yes" or "No" to indicate if the patient received medication to stimulate follicular development.		**oocytes.** **Patient medicated to stimulate follicular development:** Indicate whether medications (and dosage) were given to stimulate follicular development. If none were given, select "no"
Oral medications given	Modify	Medications containing clomiphene: Click on either "Yes" or "No" to report clomiphene administration in this cycle. Clomiphene citrate is an ovulation induction medication with trade names such as Clomid®, Serophene®, and Milophene®. Clomiphene dosage: Report total clomiphene dosage in mgs that patient received in this cycle.Tip: You can enter the Clomiphe dosage with up to two decimal places to the right of the decimal point, instead of rounding up.	Question was revised to reflect recent changes in types of medications used for ovarian stimulation. An "other medication" category was added to the oral medication question to allow for the reporting of new medications. We also added information on LSH dosage. Information on the use and dosage of these are highly correlated with cycle outcome and risk for ovarian hyperstimulation syndrome.	Oral medications such as aromatase inhibitors or selective estrogen receptors (e.g., clomiphene or letrozole)? (yes/no) Clomiphene dosage: Clomiphene citrate is an ovulation induction medication with trade names such as Clomid®, Serophene®, and Milophene®. Report total clomiphene dosage in mgs that patient received in this cycle. Letrozole dosage: Report total Letrozole dosage in mgs that patient received in this cycle.Tip: You can enter the Clomiphine dosage with up to two decimal places to the right of the decimal point, instead of rounding up. Other oral medications (specify): Indicate the name or type of other oral medication and report total dosage in

FRN Section III.B. Data to be Reported	Variable status (add, drop, modify, unchanged)	Current NASS Instructions and/or Definitions	Notes and justification	Proposed NASS instructions and/or definitions
				appropriate units that patient received in this cycle .
Medications containing FSH	Modify	Medications containing FSH: Click on "Yes" or "No" to report FSH administration in this cycle. FSH is available in several types of preparations, some of which also include luteinizing hormone (LH). Trade names include Gonal-f®, Metrodin®, Fertinex™, Bravelle™, Repronex®, Pergonal®, Humegon®, and Follistim™. FSH medication dosage: Report total FSH dosage in IUs the patient received in this cycle. Note: If the FSH preparation included luteinizing hormone, report only the FSH dosage. Tip: You can enter the FSH dosage with up to two decimal places to the right of the decimal point, instead of rounding up.	Question was revised to reflect recent changes in types of medications used for ovarian stimulation and to account for differences between short and long acting formulations. Platteau P, Nyboe Andersen A, Loft A, Smitz J, Danglas P, Devroey P. Highly purified HMG versus recombinant FSH for ovarian stimulation in IVF cycles. Reprod Biomed Online. 2008 Aug;17(2):190-8. Andersen AN, Devroey P, Arce JC. Clinical outcome following stimulation with highly purified hMG or recombinant FSH in patients undergoing IVF: a randomized assessor-blind controlled trial.Hum Reprod. 2006 Dec;21(12):3217-27.	Medications containing FSH: Indicate (yes/no) whether medications (and dosage) containing FSH were given. 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™. Short and long-acting FSH medication dosage: Report total FSH dosage in IUs (short-acting) or mgs (long-acting) that the patient received in this cycle. Note: If the FSH preparation included luteinizing hormone, report only the FSH dosage. Tip: You can enter the FSH dosage with up to two decimal places to the right of the decimal point, instead of rounding up.
Medications with LH/HCG activity	Add	Not currently collected.	Question was added in light of new types of stimulation medication given during an IVF cycle. Dosage not collected because this information was considered unnecessary for these particular	Medications with LH/HCG activity: Report if patient received medications with LH/HCG activity during this cycle (yes/no)

FRN Section III.B. Data to be Reported	Variable status (add, drop, modify, unchanged)	Current NASS Instructions and/or Definitions	Notes and justification	Proposed NASS instructions and/or definitions
			medications.	
GnRH Protocol	Modify	GnRH Protocol: This should be answered if the patient was administered a GnRH analog to control follicular development. Check the box next to the one protocol that applies as described below. GnRH Agonist Suppression: Select this box if a GnRH agonist was used. GnRH Agonist Flare: Select this box if a GnRH agonist was used. GnRH Antagonist Suppression: Check this box if a GnRH antagonist was used.	The question was revised to collect information on the "primary" protocol used. Also, an option for no GnRH protocol was added.	GnRH Protocol: This should be answered if the patient was administered a GnRH analog to control follicular development. Check the box next to the primary protocol that applies as described below. No GnRH protocol used GnRH Agonist Suppression: Select this box if a GnRH agonist was used. GnRH Agonist Flare: Select this box if a GnRH agonist was used for a GnRH agonist flare up protocol. GnRH Antagonist Suppression: Check this box if a GnRH antagonist was used.
Cycle cancelled before retrieval	Unchanged	Cycle cancelled before oocyte retrieval (y/n)?	No changes	Indicate whether cycle was cancelled before retrieval (yes/no). A canceled cycle is considered one in which ovarian stimulation or monitoring has been carried out with the intent of undergoing ART but which did not proceed to oocyte retrieval
Date of Cancellation	Unchanged	Cycle Cancel Date Enter the date the cycle was canceled (mm/dd/yyyy).	No changes recommended	Cycle Cancel Date Enter the date the cycle was canceled (mm/dd/yyyy).

FRN Section III.B. Data to be Reported	Variable status (add, drop, modify, unchanged)	Current NASS Instructions and/or Definitions	Notes and justification	Proposed NASS instructions and/or definitions
Reason for Cancel	Modify	Select reason cycle was cancelled: (Low Ovarian Response, High Ovarian Response, Failure to Survive Thaw, Inadequate Endometrial Response, Concurrent Illness, Patient Withdrawal from Treatment, Unable to Obtain Sperm Specimen)	The responses were modified slightly (to remove those that were not relevant) and an option for 'other' was added.	Select reason for ART cycle cancellation prior to oocyte retrieval or thaw: - Low Ovarian Response - High Ovarian Response - Inadequate Endometrial Response - Concurrent Illness - Withdrawal from Treatment only for personal reasons - Other (specify)
Date of Oocyte Retrieval	Unchanged	Date patient oocyte retrieval performed: Record the date that oocytes were retrieved from the patient, or when retrieval was attempted, whether successful or not, using NASS date reporting conventions as indicated on the screen. Oocyte retrieval is defined as a procedure to collect the eggs contained within the ovarian follicles.	No changes Note: this question will not be shown for frozen cycles.	Date patient oocyte retrieval performed: Record the date that oocytes were retrieved from the patient, or when retrieval was attempted, whether successful or not, using NASS date reporting conventions as indicated on the screen. Oocyte retrieval is defined as a procedure to collect the eggs contained within the ovarian follicles. Note: if the source of the oocytes is the patient and donor(s) complete this section for the female patient. If source is donor only and >1 donor was used, complete information for youngest donor.
Number of Patient Oocytes Retrieved	Unchanged	Number of patient oocytes retrieved: Record the number of oocytes retrieved from the patient. If retrieval	No changes Note: this question will not be shown for frozen cycles	Number of patient oocytes retrieved: Record the number of oocytes retrieved from the patient. If retrieval was

FRN Section III.B. Data to be Reported	Variable status (add, drop, modify, unchanged)	Current NASS Instructions and/or Definitions	Notes and justification	Proposed NASS instructions and/or definitions
		was attempted but not successful, record “0”.		attempted but not successful, record “0”. Note: if the source of the oocytes is the patient complete this section for the female patient.
Number of Donor Oocytes Retrieved	Unchanged	Number of donor oocytes retrieved: Record the number of oocytes retrieved from the patient. If retrieval was attempted but not successful, record “0”.	No changes Note: this question will not be shown for frozen cycles	Number of donor oocytes retrieved: Record the number of donor oocytes retrieved from the patient. If retrieval was attempted but not successful, record “0”. Note: if the source of the oocytes is the patient complete this section for the female patient. If source is donor only and >1 donor was used, complete information for youngest donor.
Use of retrieved oocytes	Modify	Were donor oocytes shared with multiple patients?: Click on “Yes” or “No” to indicate if oocytes collected from the donor for use in this cycle were also shared with other patients.	The original question (were donor oocytes shared with multiple patients) was included as an option for a broader question on the use of the retrieved oocytes. This will allow for better tracking of oocytes following retrieval.	Indicate how the retrieved oocytes were used (select all that apply): - Used for this cycle - Oocytes frozen for future use - Oocytes shared with other patients
Number of Fresh Oocytes Cryopreserved	Unchanged	Number of FRESH embryos cryopreserved: Enter the number of fresh embryos that were cryopreserved (frozen), or “0” to indicate none.	No changes. Note: this question will only be shown if answer to previous question (use of retrieved oocytes) is “oocytes frozen for future use”	Number of FRESH oocytes cryopreserved: Enter the number of fresh oocytes that were cryopreserved (frozen), or “0” to indicate none.

FRN Section III.B. Data to be Reported	Variable status (add, drop, modify, unchanged)	Current NASS Instructions and/or Definitions	Notes and justification	Proposed NASS instructions and/or definitions
Complications of stimulation or retrieval	Add	Not currently collected.	Question added as a top-level question for complications. If 'no' is selected, the subsequent question on complication type will not be shown.	Indicate (yes/no) whether there were any complications of ovarian stimulation or oocyte retrieval.
Type of complications related to ovarian stimulation or oocyte retrieval	Modify	Select if the patient developed a complication directly related to ART within 12 weeks of cycle initiation: (Infection, Hemorrhage, Moderate Ovarian Hyperstimulation Syndrome, Severe Ovarian Hyperstimulation Syndrome, Medication Side Effect, Anesthetic Complication, Psychological Stress, Death, Other Complication, None)	The question was revised to add thrombosis to list of complications due to reports of elevated risk for first trimester venous thromboembolism among IVF pregnancies. In addition, moderate/severe ovarian hyperstimulation was replaced with ovarian hyperstimulation requiring intervention of hospitalization. Psychological stress was removed as an option. Reference: Rova et al. Venous thromboembolism in relation to in vitro fertilization: an approach to determining the incidence and increase in risk in successful cycles. Fertil Steril. 2012 Jan;97(1):95-100	Select if the patient developed a complication directly related to ART within 12 weeks of cycle initiation: - Infection - Hemorrhage requiring transfusion - Ovarian hyperstimulation requiring hospitalization - Medication side effect - Anesthetic complication - Thrombosis - Death of patient - Other (specify) <u>Infection :</u> Temperature greater than or equal to 100.5 degrees Fahrenheit attributed to pelvic infection; <u>Hemorrhage :</u> Requiring blood transfusion; <u>Ovarian hyperstimulation requiring intervention or hospitalization:</u> hyperstimulation may be evidenced by abdominal distension and discomfort; features of grade 1 plus 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,

FRN Section III.B. Data to be Reported	Variable status (add, drop, modify, unchanged)	Current NASS Instructions and/or Definitions	Notes and justification	Proposed NASS instructions and/or definitions
				increased blood viscosity due to hemoconcentration, coagulation abnormalities, and diminished renal perfusion and function - Hct > 50%; and requiring intervention or hospitalization; Medication side effect: Requiring change in intended treatment; Anesthetic complication: complication of anesthesia Thrombosis: formation of a blood clot in a vessel obstructing the flow of blood through the circulatory system. Psychological stress: Requiring acute mental health professional Intervention Death: death related to ART treatment or a complication associated with ART treatment Other
Hospitalization for Complication	Modify	Hospitalization related to complication	Question was revised to indicate timing of the hospitalization in relation to cycle initiation (within 12 weeks). The 12-week timeframe was included to better capture complications directly related to ART vs. those related to an early pregnancy resulting from ART	Report if the patient was hospitalized due to a complication of ovarian stimulation or oocyte retrieval within 12 weeks of cycle initiation. Hospitalization related to the above complication.
Sperm State	Add	Not currently collected	Question was added in light of evidence that the cryopreservation and subsequent thawing of human sperm may lead to reductions in sperm viability or motility and increases in DNA fragmentation and oxidative damage.	Indicate if sperm used was - Fresh - Thawed - Mix of fresh and thawed Note: if the source of the semen is the

FRN Section III.B. Data to be Reported	Variable status (add, drop, modify, unchanged)	Current NASS Instructions and/or Definitions	Notes and justification	Proposed NASS instructions and/or definitions
			References: Punyatanasakchai P, et al. Comparison of cryopreserved human sperm in vapor and liquid phases of liquid nitrogen: effect on motility parameters, morphology and sperm function. Fertil Steril. 2008;90:1978-82. Donnelly ET, Steele EK, McClure N, Lewis SE. Assessment of DNA integrity and morphology of ejaculated spermatozoa from fertile and infertile men before and after cryopreservation. Hum Reprod 2001;16:1191–9. Zribi N,et al. Effects of cryopreservation on human sperm deoxyribonucleic acid integrity. Fertil Steril. 2010;93:159-66.	female patient's male partner and donor(s) complete this section for the female patient's partner. If source is donor only and >1 donor was used, complete information for youngest donor.
Sperm Collection Method (Ejaculation, Epididymal Aspiration, Testicular Biopsy, Electroejaculation, Retrograde Ejaculation)	Modify	Choose the method for obtaining semen: Use the drop-down list to choose the method for obtaining semen. Ejaculation: Sperm is collected from a semen sample obtained by ejaculation. Ejaculation is the release of semen from the penis during orgasm. Epididymal aspiration: This is a technique in which sperm is aspirated and sampled percutaneously from the epididymis. Testicular biopsy: Sperm are obtained from a biopsy of seminiferous tubules.	Changed "semen" to "sperm" and added a separate unknown category	Choose the method for obtaining sperm: Ejaculation: Sperm is collected from a semen sample obtained by ejaculation. Ejaculation is the release of semen from the penis during orgasm. Epididymal aspiration: This is a technique in which sperm is aspirated and sampled percutaneously from the epididymis. Testicular biopsy: Sperm are obtained from a biopsy of seminiferous tubules.

FRN Section III.B. Data to be Reported	Variable status (add, drop, modify, unchanged)	Current NASS Instructions and/or Definitions	Notes and justification	Proposed NASS instructions and/or definitions
		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. 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. Unknown because embryos thawed from previous cycle: This response should only be selected for frozen cycles where the record does not show how the semen was collected. If the method of semen collection is known in a frozen cycle, it should be recorded in the appropriate category above.		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. 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. Unknown – method not known. This response should only be selected if the method of sperm collection is not known (e.g., frozen cycles where the record does not show how the semen was collected). If the method of semen collection is known in a frozen cycle, it should be recorded in the appropriate category above Note: if the source of the semen is the female patient's male partner and donor(s) complete this section for the female patient's partner. If source is donor only and >1 donor was used,

FRN Section III.B. Data to be Reported	Variable status (add, drop, modify, unchanged)	Current NASS Instructions and/or Definitions	Notes and justification	Proposed NASS instructions and/or definitions
				complete information for youngest donor.
Use of Intracytoplasmic Sperm Injection	Modify	Intracytoplasmic sperm injection (ICSI) performed on oocytes: ICSI is the placement of a single sperm into the cytoplasm of an oocyte by micro-operative techniques. Yes: ICSI was performed on some or all of the oocytes in this cycle. No: ICSI was not performed on any oocytes in this cycle. Unknown because embryos thawed from previous cycle: This response should only be selected for frozen cycles where the record does not show whether ICSI was performed on the oocytes. If you are able to look up this information, it should be recorded in the appropriate category above.	Revised to include options for use of ICSI on all, some, or no oocytes since situations can occur in which not all oocytes are fertilized using ICSI.	Intracytoplasmic sperm injection (ICSI) performed on oocytes: ICSI is the placement of a single sperm into the cytoplasm of an oocyte by micro-operative techniques. All oocytes: ICSI was performed on all of the oocytes in this cycle. Some oocytes: ICSI was performed on some of the oocytes in this cycle. No oocytes: ICSI was not performed on any oocytes in this cycle. Unknown because embryos thawed from previous cycle: This response should only be selected for frozen cycles where the record does not show whether ICSI was performed on the oocytes. If you are able to look up this information, it should be recorded in the appropriate category above.
Indication for ICSI	Add	Not currently collected	ICSI has been shown to be safe and effective for overcoming male factor infertility. However, there is evidence of increasing rates of ICSI use for other indications, despite a lack of evidence of improved clinical outcomes. Furthermore, the safety of ICSI in these situations has not been established. Thus it is important to collect information on the indication for use of ICSI in ART cycles.	If ICSI was used, indicate the reason (select all that apply): - Prior failed fertilization (prior total failed fertilization with normal semen analysis in a prior IVF cycle) - Poor fertilization - PGD - Abnormal semen parameters on

FRN Section III.B. Data to be Reported	Variable status (add, drop, modify, unchanged)	Current NASS Instructions and/or Definitions	Notes and justification	Proposed NASS instructions and/or definitions
			The Practice Committees of the American Society for Reproductive Medicine and Society for Assisted Reproductive Technology. Intracytoplasmic sperm injection (ICSI) for non-male factor infertility: a committee opinion. Fertil Steril. 2012;98:1395-9 W. Kuczynski, M. Dhont, C. Grygoruk, P. Pietrewicz, S. Redzko, M. Szamatowicz. Rescue ICSI of unfertilized oocytes after IVF Hum Reprod 2002;17: 2423–2427.	the day of fertilization - Low oocyte yield (6 or fewer oocytes) - Laboratory routine (routine use of ICSI for all cycles) - Frozen cycle - Rescue ICSI - Other (e.g. patient preference): Specify_____ Rescue ICSI – ICSI performed immediately after observation of failed fertilization of oocyte in an effort to salvage the cycle
In vitro maturation used?	Modify	Special Techniques: Check the box next to all of the techniques that apply. IMMATURE oocyte retrieval & fertilization OR thawing IMMATURE fertilized oocytes, with intent to transfer in current cycle: Immature oocyte retrieval with the intent to fertilize and transfer during the current treatment cycle OR thawing previously fertilized immature oocytes for transfer during the current treatment cycle. Note: Do NOT check the box for immature oocyte research if the intent was to cryopreserve all retrieved oocytes for use in a later cycle—instead, select "Yes" to embryo or oocyte banking.	This question was previously a choice in another question on study types in research cycles (currently #53A). Although still experimental, use of in vitro maturation (IVM) is becoming increasingly common particularly among women with polycystic ovary syndrome; however, there is controversy regarding which IVM methods produce the best fertilization and pregnancy rates. To better monitor the use of this developing technology, we opted to include this as a separate question. Reinblatt SL, Son WY, Shalom-Paz E, Holzer H. Controversies in IVM. J Assist Reprod Genet. 2011 Jun;28(6):525-30	Indicate whether immature oocyte retrieval with the intent to fertilize and transfer during the current treatment cycle OR thawing previously fertilized immature oocytes for transfer during the current treatment cycle. 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..

FRN Section III.B. Data to be Reported	Variable status (add, drop, modify, unchanged)	Current NASS Instructions and/or Definitions	Notes and justification	Proposed NASS instructions and/or definitions
PGD or PGS performed on embryos	Unchanged	Preimplantation genetic diagnosis or screening performed on embryos (yes, no, unknown because embryos thawed from previous cycle)	No changes recommended.	Indicate whether PGD or PGS was performed on embryos. - Yes - No - Unknown because embryos thawed from previous cycle
Total 2PN	Add	Not currently collected	2PN refers to the stage of embryo development that typically occurs 1 day after sperm is added to the egg. The total number of 2PN embryos can be used to calculate fertilization rates, compare the effectiveness of IVF procedures, and evaluate oocyte and sperm factors contributing to infertility. In addition, some clinics use a threshold based on total 2PN as a selection criteria for good prognosis patients. References: Robertson AD, Missmer SA, Ginsburg ES. Embryo yield after in vitro fertilization in women undergoing embryo banking for fertility preservation before chemotherapy. Fertil Steril. 2011 Feb;95(2):588-91 Younis JS, Radin O, Mirsky N, Izhaki I, Majara T, Bar-ami S, Ben-ami M. First polar body and nucleolar precursor body morphology is related to the ovarian reserve of infertile women. Reprod Biomed Online. 2008 Jun;16:851-8.	Total 2PN On Any Day Embryos Are In Culture For all fresh retrievals the maximum number of two pronuclei embryos that were observed during fertilization.
Pre-implantation genetic diagnosis (PGD) or screening (PGS) reason	Modify	Please indicate the reason for PGD or PGS (Select all that apply): ☐ Either genetic parent is a known carrier of a gene mutation or a chromosomal abnormality	Question was revised to add a category for elective gender determination and remove unknown option. Gender determination via PGS can be conducted for medical (avoid disease transmission) and non-medical	Please indicate the reason for PGD or PGS (Select all that apply): ☐ Not performed ☐ Either genetic parent is a known

FRN Section III.B. Data to be Reported	Variable status (add, drop, modify, unchanged)	Current NASS Instructions and/or Definitions	Notes and justification	Proposed NASS instructions and/or definitions
		☐ Aneuploidy screening of the embryos ☐ Other screening of the embryos ☐ Unknown	(sex preference of parents) reasons. In 2008, approximately 4% of ART cycles in the U.S. used PGS and there was a 5% increase in the use of PGS for elective sex selection from 2007-2008. Thus, surveillance of utilization and trends of elective gender determination is warranted. Reference: Ginsburg ES, Baker VL, Racowsky C, Wantman E, Goldfarb J, Stern JE. Use of preimplantation genetic diagnosis and preimplantation genetic screening in the United States: a Society for Assisted Reproductive Technology Writing Group paper. Fertil Steril. 2011;96:865-8 Dondorp W, De Wert G, Pennings G, Shenfield F, Deyroey P, Tarlatzis B, Barri P, Diedrich K. ESHRE Task Force on ethics and Law 20: sex selection for non-medical reasons. Hum. Reprod. 2013; 28: 1448-1454	carrier of a gene mutation or a chromosomal abnormality ☐ Aneuploidy screening of the embryos ☐ Elective Gender Determination ☐ Other screening of the embryos
Pre-implantation genetic diagnosis or screening technique	Add	Not currently collected	New question. PGD/PGS results can be affected by misdiagnosis due to the genetic testing processes employed. Embryo misdiagnosis can occur due to possible discordance of chromosomal composition of biopsied cell and remainder of embryo or may occur with mosaicism of aneuploid and euploid cell lines in the same embryo. Given the risks of misdiagnosis and that PGD/PGD is being increasingly incorporated into routine IVF treatments, it is important to collect information pertaining to the types of techniques used for PGD/PGS.	Indicate the PGD or PGS screening technique. ☐ Polar Body Biopsy ☐ Blastomere Biopsy ☐ Blastocyst Biopsy ☐ Unknown 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

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			Gleicher N, Barad DH. A review of, and commentary on, the ongoing second clinical introduction of preimplantation genetic screening (PGS) to routine IVF practice. J Assist Reprod Genet. 2012;29:1159-66 Brezina PR, Brezina DS, Kearns WG. Preimplantation genetic testing. BMJ. 2012; 18;345:e5908	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. Blastomere biopsy: Blastomeres are cells from the Day 3 cleavage stage embryo, when approximately 6-8 cells are present. Each blastomere contains both maternal and paternal genetic information. Blastomere biopsy is the most common method of PGD testing, and involves the removal of one of these cells at the Day 3 stage. Since chromosomal mosaicism is highest at the Day 3 stage, blastomere testing may not always be representative of the genetic content of the embryo. Blastocyst/Trophectoderm biopsy: 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 “extra-embryonic” tissues. Blastocyst biopsy involves the

FRN Section III.B. Data to be Reported	Variable status (add, drop, modify, unchanged)	Current NASS Instructions and/or Definitions	Notes and justification	Proposed NASS instructions and/or definitions
				removal of a small number of trophectoderm cells for genetic testing. Testing the embryo at this stage has the advantage of reduced chromosomal mosaicism as well as improved DNA amplification, and therefore, improved test accuracy.
Use of Assisted Hatching	Modify	Assisted hatching performed on embryos: Assisted hatching is a micromanipulation technique that involves making a small opening in the zona wall of the embryo in an effort to enhance implantation. Yes: Assisted hatching was performed on some or all embryos transferred in this cycle. No: Assisted hatching was not performed on any embryos transferred in this cycle.	Question revised to add categories for all, some, or no embryos.	Indicate whether assisted hatching was performed on embryos: - All embryos: Assisted hatching was performed all embryos transferred in this cycle. - Some embryos: Assisted hatching was performed on some embryos transferred in this cycle. - No embryos: Assisted hatching was not performed on any embryos transferred in this cycle. - Unknown Assisted hatching is a micromanipulation technique that involves making a small opening in the zona wall of the embryo in an effort to enhance implantation. -

FRN Section III.B. Data to be Reported	Variable status (add, drop, modify, unchanged)	Current NASS Instructions and/or Definitions	Notes and justification	Proposed NASS instructions and/or definitions
Research cycle	Add	Not currently collected	This top-level question was added to determine whether the cycle was a research cycle. If respondent answers 'no' subsequent questions on study type will not be shown.	Indicate whether this was a research cycle: -yes - no - unknown If yes, enter approval code _____
Study type	Modify	NASS does not ask about SART approved research, although it does ask about special techniques and research/studies. as follows: Special Techniques: Check the box next to all of the techniques that apply. If none of them apply to this cycle, then skip the Special Techniques section. Round spermatid nucleic injection (ROSNI): A method of assisted fertilization in which precursors of mature spermatozoa are injected into oocytes. Cytoplasmic transfer: Cytoplasmic transfer involves the injection of a small amount of cytoplasm (the viscous semifluid inside an oocyte), taken from a donor oocyte, directly into the patient's oocytes. The transferred cytoplasm is thought to contain components missing or abnormally functioning in the	Question was revised to remove round spermatid nucleic injection, cytoplasmic transfer, immature oocyte retrieval and fertilization as a response. Also, laboratory technique was added as an option and a field for specifying the type of study was added for the "other" response. Note: this question will only be shown if it was indicated in the previous question that the cycle was identified as research.	Check the box next to all of the study types that apply. - Device study: An investigational device is a medical device that is the subject of a clinical study designed to evaluate the effectiveness and/or safety of the device. - Protocol study: A study involving the evaluation of a new procedure. - Pharmaceutical study: A study involving the evaluation of a new drug or a new application of an existing drug - Laboratory technique: a study involving the evaluation of new laboratory method or technique. - Other research: Check this box if the cycle is being performed under an approved research protocol that does not fit into any of the above categories.

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		recipient oocytes. IMMATURE oocyte retrieval & fertilization OR thawing IMMATURE fertilized oocytes, with intent to transfer in current cycle: Immature oocyte retrieval with the intent to fertilize and transfer during the current treatment cycle OR thawing previously fertilized immature oocytes for transfer during the current treatment cycle. Note: Do NOT check the box for immature oocyte research if the intent was to cryopreserve all retrieved oocytes for use in a later cycle—instead, select "Yes" to embryo or oocyte banking. Device study: An investigational device is a medical device that is the subject of a clinical study designed to evaluate the effectiveness and/or safety of the device. Protocol study: A study involving the evaluation of a new procedure. Pharmacological study: A study involving the evaluation of a new drug or a new application of an existing drug. Other research: Check this box if the cycle is being performed under an approved research protocol that does not fit into any of the above categories.		- If other, please specify

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Transfer attempted	Add	Not currently collected	This top-level question was added to screen for those cycles where a transfer took place. If the respondent selects 'no' other question in this section will not be shown. A cycle can be canceled before retrieval of between the retrieval and transfer. Thus we added this question and the following question to further evaluate the timing of the cancellation and the implications for patient safety.	Indicate whether embryo transfer was attempted (yes/no)
Reason transfer not attempted	Add	Select reason cycle was cancelled: (Low Ovarian Response, High Ovarian Response, Failure to Survive Thaw, Inadequate Endometrial Response, Concurrent Illness, Patient Withdrawal from Treatment, Unable to Obtain Sperm Specimen)	The responses were modified slightly: - 'Failure to survive thaw' was changed to 'failure to survive oocyte thaw' - Options for 'insufficient embryos' and 'unable to obtain sperm specimen' was added based on feedback from clinics. - An option for 'other' was added Note: question will only be shown if answers "no" to transfer attempted	Select reason for ART cycle cancellation prior to transfer: - Low Ovarian Response - High Ovarian Response - Failure to Survive Oocyte Thaw - Inadequate Endometrial Response - Concurrent Illness - Patient Withdrawal from Treatment - Unable to Obtain Sperm Specimen - Insufficient embryos - Other (specify)
Transfer Date	Unchanged	Date of transfer: Enter the date of transfer or attempted transfer using the NASS date reporting convention as shown on the screen.	No changes recommended. Note: question will only be shown if answers "yes" to transfer attempted	Date of transfer: Enter the date of transfer or attempted transfer using the NASS date reporting convention as shown on the screen.
Endometrial Thickness	Add	Not currently collected	This question was added because endometrial thickness reflects uterine receptivity to embryos and therefore can affect success rates.	Enter the most recent endometrial thickness in mm (on day of embryo transfer or HCG trigger)

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			Casper RF. It's time to pay attention to the endometrium. Fertil Steril. 2011 Sep;96(3):519-21.	
Number of Fresh Embryos Transferred to Uterus	Unchanged	Number of FRESH embryos transferred to uterus: Enter the number of fresh embryos transferred to the uterus via transcervical transfer (IVF), or "0" to indicate that none were successfully transferred. Leave this variable blank ONLY if the transfer of fresh embryos to the uterus was not attempted.	No changes recommended.	Number of FRESH embryos transferred to uterus: Enter the number of fresh embryos transferred to the uterus via transcervical transfer (IVF), or "0" to indicate that none were successfully transferred. Leave this variable blank ONLY if the transfer of fresh embryos to the uterus was not attempted.
Elective single embryo transfer (fresh transfers)	Unchanged	Answer the following question if a total of only one embryo was transferred to the uterus during this cycle (regardless if ultrasound guidance was used): If only <u>one</u> embryo was transferred to the uterus, was this an <u>elective</u> single embryo transfer?	No changes recommended.	Answer the following question if a total of only one embryo was transferred to the uterus during this cycle (regardless if ultrasound guidance was used): If only one embryo was transferred to the uterus, was this an elective single embryo transfer?
Quality of embryo (fresh transfers)	Add	Not currently collected	This question was added because embryo selection is one of the most important steps in determining IVF outcome. Embryo quality (as determined by morphology) is highly correlated with implantation rates and pregnancy outcome. Furthermore, clinicians routinely use this information when determining the number of embryos to transfer; therefore there is an association between embryo quality and multiple pregnancy rates. References:	For each embryo that was transferred to the uterus, report the overall grade of 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.

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			Vernon M, Stern JE, Ball GD, Wininger D, Mayer J, Racowsky C. Utility of the national embryo morphology data collection by the Society for Assisted Reproductive Technologies (SART): correlation between day-3 morphology grade and live-birth outcome. Fertil Steril. 2011;95:2761-3. Racowsky C, Vernon M, Mayer J, Ball GD, Behr B, Pomeroy KO, Wininger D, Gibbons W, Conaghan J, Stern JE. Standardization of grading embryo morphology. J Assist Reprod Genet. 2010;27:437-9.	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.
Number of Fresh Embryos Cryopreserved	Unchanged	Number of FRESH embryos cryopreserved: Enter the number of fresh embryos that were cryopreserved (frozen), or “0” to indicate none.	No changes recommended.	Number of FRESH embryos cryopreserved: Enter the number of fresh embryos that were cryopreserved (frozen), or “0” to indicate none.
Number of Thawed Embryos Transferred to Uterus	Unchanged	Number of THAWED embryos transferred to uterus: Enter the number of thawed embryos transferred to the uterus via transcervical transfer, or “0” to indicate that none were successfully transferred. Leave this variable blank ONLY if the transfer of thawed embryos to the uterus was not attempted. This number should include both thawed patient and thawed donor embryos.	No changes recommended	Number of THAWED embryos transferred to uterus: Enter the number of thawed embryos transferred to the uterus via transcervical transfer, or “0” to indicate that none were successfully transferred. Leave this variable blank ONLY if the transfer of thawed embryos to the uterus was not attempted. This number should include both thawed patient and thawed donor embryos.
Elective single embryo	Modify	Answer the following question if a	This question was added to collect information on	Answer the following question if a total

FRN Section III.B. Data to be Reported	Variable status (add, drop, modify, unchanged)	Current NASS Instructions and/or Definitions	Notes and justification	Proposed NASS instructions and/or definitions
transfer (frozen transfers)		total of only one embryo was transferred to the uterus during this cycle (regardless if ultrasound guidance was used): If only one embryo was transferred to the uterus, was this an elective single embryo transfer?	elective single embryo transfers for frozen transfers. While this information was previously collected for all transfers using one question, the new format of the worksheet requires that the question be asked separately for fresh and frozen transfers to preserve the logical flow of information.	of only one embryo was transferred to the uterus during this cycle (regardless if ultrasound guidance was used): If only one embryo was transferred to the uterus, was this an elective single embryo transfer?
Quality of embryo (frozen transfers)	Add	Not currently collected	This question was added because embryo selection is one of the most important steps in determining IVF outcome. Embryo quality (as determined by morphology) is highly correlated with implantation rates and pregnancy outcome. Furthermore, clinicians routinely use this information when determining the number of embryos to transfer; therefore there is an association between embryo quality and multiple pregnancy rates. References: Vernon M, Stern JE, Ball GD, Wininger D, Mayer J, Racowsky C. Utility of the national embryo morphology data collection by the Society for Assisted Reproductive Technologies (SART): correlation between day-3 morphology grade and live-birth outcome. Fertil Steril. 2011;95:2761-3. Racowsky C, Vernon M, Mayer J, Ball GD, Behr B, Pomeroy KO, Wininger D, Gibbons W, Conaghan J, Stern JE. Standardization of grading embryo morphology. J Assist Reprod Genet. 2010;27:437-9.	For each embryo that was transferred to the uterus, report the overall grade of 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 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.

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Date of oocyte retrieval (thawed embryos)	Add	Not currently collected	This question was added in order to facilitate the linking of oocyte or embryo banking cycles with outcomes for more accurate calculation of success rates. Recently, there has been an increasing trend of short-term embryo banking (cycles in which all embryos are created with the intent of cryopreservation for subsequent transfer in frozen/thawed cycle(s) in the next few months). Because these cycles do not result in an outcome, they are not included in the overall success rates for ART. There is some evidence that clinics may be encouraging poor prognosis patients to undergo multiple banking cycles in an effort to accumulate embryos and to facilitate the selection of the best embryos for transfer. A result of this trend is that clinics using this practice have inflated success rates because the "accumulation" cycles are not reported. In an effort to address this issue, CDC hopes to link oocyte or embryo banking cycles with subsequent frozen/thawed cycles to more accurately calculate success rates. Thus collection of information on oocyte retrieval date is needed to enable this linkage to occur. Kushnir VA, Vidali A, Barad DH, Gleicher N. The status of public reporting of clinical outcomes in assisted reproductive technology. Fertil Steril. 2013, in press, Jun 8.	For each thawed embryo, enter the date of oocyte retrieval. Always record the month first, using the two-digit equivalent (e.g., January = 01, February = 02). Record two digits for the day, and four digits for the year.
Number of Thawed Embryos	Unchanged	Number of THAWED oocytes cryopreserved: Enter the number of	No changes recommended.	Number of THAWED oocytes cryopreserved: Enter the number of

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Cryopreserved (re-frozen)		thawed embryos that were cryopreserved (re-frozen) during this cycle, or "0" to indicate none.		thawed embryos that were cryopreserved (re-frozen) during this cycle, or "0" to indicate none.
Number of Oocytes or embryos Transferred to Fallopian Tubes	Modify	Number of OOCYTES: FRESH Transfers to Fallopian Tubes: Fresh oocytes are transferred to fallopian tubes when GIFT is chosen as the transfer method. Enter the number of fresh oocytes transferred, or "0" to indicate that none were successfully transferred. Do not leave this variable blank if the transfer of fresh oocytes to the fallopian tubes was attempted. Number of EMBRYOS: FRESH Transfers to Fallopian Tubes: Enter the number of fresh embryos transferred to the fallopian tubes, or "0" to indicate that none were successfully transferred. Do not leave this variable blank if the transfer of fresh embryos to the fallopian tubes was attempted. Include the number of zygotes transferred to fallopian tubes if zygote intrafallopian transfer (ZIFT) was the method of transfer for this cycle. Record the number of	Because the use of GIFT, ZIFT and TET is rare, 3 previous questions on oocyte and embryo transfers to fallopian tubes were combined into one question.	Total number of oocytes/embryos transferred to Fallopian Tubes: Enter the number of fresh oocytes transferred, fresh embryos transferred, or frozen embryos transferred, or "0" to indicate that none were successfully transferred. Do not leave this variable blank if the transfer of fresh oocytes or embryos to the fallopian tubes was attempted. Fresh oocytes are transferred to fallopian tubes when GIFT is chosen as the transfer method. Include the number of fresh or thawed zygotes transferred to fallopian tubes if zygote intrafallopian transfer (ZIFT) was the method of transfer for this cycle. Record the number of fresh or thawed early stage embryos transferred if tubal embryo transfer (TET) was used in this cycle.

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		early stage embryos transferred if tubal embryo transfer (TET) was used in this cycle. Number of EMBRYOS: THAWED Transfers to Fallopian Tubes: Enter the number of thawed embryos transferred to the fallopian tubes, or "0" to indicate that none were successfully transferred. Include the number of thawed zygotes transferred to fallopian tubes if zygote intrafallopian transfer (ZIFT) was the method of transfer for this cycle. Also, include any zygotes that were produced from thawed oocytes and sperm. Record the number of thawed early stage embryos transferred if tubal embryo transfer (TET) was used in this cycle		
Outcome of Treatment (Not Pregnant, Biochemical Pregnancy, Ectopic Pregnancy, Clinical Intrauterine Gestation, Heterotopic Pregnancy, Unknown)	Unchanged	Outcome of treatment cycle: From the drop-down list, select the one appropriate outcome of this treatment cycle. Not pregnant: No indication of pregnancy from either Beta-hCG or ultrasound. Biochemical only: Select this	No changes recommended. Note: question will only be shown for those cycles where a transfer occurred.	Outcome of treatment cycle: Select the one appropriate outcome of this treatment cycle. - Not pregnant: No indication of pregnancy from either Beta-hCG or ultrasound. - Biochemical only: Select this response if the patient's serum

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		response if the patient's serum pregnancy test (Beta- hCG) result was positive without ultrasound confirmation of a gestational sac within the uterus, and without diagnosis of an ectopic pregnancy. Ectopic: Select this response if a pregnancy was confirmed in which the fertilized oocyte implanted outside the uterine cavity. Ectopic pregnancies can be diagnosed either through an ultrasound that confirmed the gestational sac(s) outside the uterus, or by high serial serum Beta-hCG values in the absence of intrauterine gestation (i.e. Beta-hCG levels are indicative of ectopic pregnancy rather than early biochemical pregnancy). Clinical intrauterine gestation: Select this response when an ultrasound confirms the presence of a gestational sac within the uterus. In the case of missing ultrasound data, this may be confirmed by documented occurrence of a birth, spontaneous abortion, or induced abortion. Ectopic pregnancies should not be counted here. Clinical pregnancies include all gestational sacs regardless of whether or not a heartbeat is observed or a fetal pole		pregnancy test (Beta- hCG) result was positive without ultrasound confirmation of a gestational sac within the uterus, and without diagnosis of an ectopic pregnancy. - Ectopic: Select this response if a pregnancy was confirmed in which the fertilized oocyte implanted outside the uterine cavity. Ectopic pregnancies can be diagnosed either through an ultrasound that confirmed the gestational sac(s) outside the uterus, or by high serial serum Beta-hCG values in the absence of intrauterine gestation (i.e. Beta-hCG levels are indicative of ectopic pregnancy rather than early biochemical pregnancy). - Clinical intrauterine gestation: Select this response when an ultrasound confirms the presence of a gestational sac within the uterus. In the case of missing ultrasound data, this may be confirmed by documented occurrence of a birth, spontaneous abortion, or induced abortion. Ectopic pregnancies should not be counted here. Clinical pregnancies include all gestational sacs regardless of whether or not a heartbeat is observed or a fetal

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		is established. Heterotopic: This response should be selected in cases of a clinical intrauterine gestation in combination with an ectopic pregnancy. Unknown: Select this response only if the patient was lost to followup.		pole is established. - Heterotopic: This response should be selected in cases of a clinical intrauterine gestation in combination with an ectopic pregnancy. - Unknown: Select this response only if the patient was lost to followup.
Maximum Number of Fetal Hearts Observed on Ultrasound	Modify	Maximum fetal hearts on ultrasound prior to reduction, if any: Record the highest number of fetal hearts noted during ultrasounds after the date of transfer. If the number of fetuses was reduced, record the highest number of fetal hearts observed on ultrasound before the number of fetuses was reduced.	Question was revised to remove the "if any" statement. Instructions were accordingly revised to indicate that '0' should be reported in the event that no fetal hearts were detected. Note: data entry for this field will only be allowed if there is indication that an ultrasound was performed.	Maximum fetal hearts on ultrasound prior to reduction: Record the highest number of fetal hearts noted during ultrasounds after the date of transfer. If the number of fetuses was reduced, record the highest number of fetal hearts observed on ultrasound before the number of fetuses was reduced. If no fetal hearts were noted, enter '0'. If no ultrasound was performed before 7 weeks, check the "no ultrasound performed" box.
Ultrasound Date	Modify	Date ultrasound with max. number of fetal hearts observed: Enter the earliest date that the maximum number of fetal hearts were detected on ultrasound using NASS date reporting conventions as indicated on the screen.	Revised to indicate that results should be reported for U/S before 7 weeks. Note: data entry for this field will only be allowed if there is indication that an ultrasound was performed.	Date of ultrasound with maximum number of fetal hearts observed before 7 weeks: Enter the earliest <u>date</u> that the maximum number of fetal hearts were detected on ultrasound before 7 weeks gestation using NASS date reporting conventions as indicated on the screen. The date should be within 7 weeks gestation.
Monochorionicity	Add	Not currently collected	Monochorionic twins are at increased risk for stillbirth and increased perinatal mortality and morbidity. IVF is	If 2 or more fetal hearts were found on ultrasound, indicate if there were any

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			associated with higher rates of monozygotic twinning than spontaneously conceived infants. Thus information on chorionicity can be used to evaluate risks for adverse perinatal outcomes among ART-conceived infants. Danon D, Sekar R, Hack KE, Fisk NM. Increased Stillbirth in Uncomplicated Monochorionic Twin Pregnancies: A Systematic Review and Meta-analysis. Obstet Gynecol. 2013;121:1318-26 Smith NA, Wilkins-Haug L, Santolaya-Forgas J, Acker D, Economy KE, Benson CB, Robinson JN. Contemporary management of monochorionic diamniotic twins: outcomes and delivery recommendations revisited. Am J Obstet Gynecol. 2010;203:133.e1-6. Knopman J, Krey LC, Lee J, Fino ME, Novetsky AP, Noyes N. Monozygotic twinning: an eight-year experience at a large IVF center. Fertil Steril. 2010;94:502-10	monochorionic twins or multiples? -Yes - No - Unknown
Outcome of Pregnancy (Live birth, Stillbirth, Spontaneous Abortion, Induced Abortion, Maternal Death Prior to Birth, Unknown)	Unchanged	Outcome of pregnancy: Select the appropriate outcome from the drop-down list. In the case of a multiple birth event with a combination of live born with any other outcome (e.g., one twin stillborn, one twin live born) select “Live birth”. Live birth: A live birth includes a birth (delivery) in which at least one fetus showed signs of life after the	No changes recommended.	Outcome of pregnancy: Select the appropriate outcome from the drop-down list. In the case of a multiple birth event with a combination of live born with any other outcome (e.g., one twin stillborn, one twin live born) select “Live birth”. Live birth: A live birth includes a birth (delivery) in which at least one fetus showed signs of life after the complete

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		complete expulsion or extraction from its mother. Signs of life include breathing (not fleeting gasps), beating of the heart (not transient cardiac contractions), 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. Stillbirth: For pregnancies achieved by using ART, stillbirth is defined as occurring at 18 weeks or later from the date of transfer, in which no fetus showed signs of life after the complete expulsion or extraction from the mother. Spontaneous abortion (Miscarriage): For pregnancies achieved by using ART, a spontaneous abortion is defined as a clinical pregnancy ending in spontaneous loss of the entire pregnancy prior to completion of 18 weeks from the date of transfer. Induced abortion: This is defined as an operative procedure to electively terminate the entire pregnancy (no gestational age limit). Maternal death prior to birth: If one or more infants can be classified as a		expulsion or extraction from its mother. Signs of life include breathing (not fleeting gasps), beating of the heart (not transient cardiac contractions), 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. Stillbirth: For pregnancies achieved by using ART, stillbirth is defined as occurring at 18 weeks or later from the date of transfer, in which no fetus showed signs of life after the complete expulsion or extraction from the mother. Spontaneous abortion (Miscarriage): For pregnancies achieved by using ART, a spontaneous abortion is defined as a clinical pregnancy ending in spontaneous loss of the entire pregnancy prior to completion of 18 weeks from the date of transfer. Induced abortion: This is defined as an operative procedure to electively terminate the entire pregnancy (no gestational age limit). Maternal death prior to birth: If one or more infants can be classified as a live birth (i.e. the physician was able to extract a live infant from the deceased

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		live birth (i.e. the physician was able to extract a live infant from the deceased mother), then record the outcome as Live birth. Outcome unknown: Select this choice if the patient was lost to follow-up before the pregnancy outcome was reported.		mother), then record the outcome as Live birth. Outcome unknown: Select this choice if the patient was lost to follow-up before the pregnancy outcome was reported.
Date of Pregnancy Outcome	Unchanged	Date of pregnancy outcome: Enter the date of the pregnancy outcome using NASS date reporting conventions as indicated on the screen. In cases of more than one birth during a single pregnancy that spans more than one date, enter the birth for the first live-born infant.	No changes recommended.	Date of pregnancy outcome: Enter the date of the pregnancy outcome using NASS date reporting conventions as indicated on the screen. In cases of more than one birth during a single pregnancy that spans more than one date, enter the birth for the first live-born infant
Method of delivery	Add	Not currently collected	This question was added because some reports indicated c-section delivery is more common with frozen-thawed embryo transfer. It is also reported that frozen-thawed embryo transfer is associated with larger birth weights. These two variables might be causally related, or might be confounded in assessments of perinatal outcomes.	If applicable, enter the method of delivery - Vaginal - Cesarean section
Source of information on pregnancy outcome	Unchanged	Source of information confirming pregnancy outcome: From the drop-down list, choose the source of information for outcome of	No changes recommended.	Indicate the source of information used to confirm pregnancy outcome - Verbal confirmation from patient - Written confirmation from patient

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		pregnancy. A birth certificate, birth announcement, or letter from the patient, physician, or the hospital in which the outcome occurred would be classified as valid written documents. For each birth reported to the surveillance system, the clinic should retain evidence of the birth in the patient's medical record. If the reporting of a birth and supplemental data pertaining to that birth is based on an oral communication from either the patient or her obstetric provider, that information should be recorded in ink in the patient's medical record and signed by a licensed medical provider. Clinics that use electronic medical records or clinics that have records that are stored offsite should also record information in an onsite patient medical record with a notation of where they obtained the information. Verbal confirmation, patient: The patient only reported the pregnancy outcome verbally. Written confirmation, patient: The patient submitted a written document confirming the pregnancy outcome. Verbal confirmation, physician or hospital: The pregnancy outcome		- Verbal confirmation from physician or hospital - Written confirmation from physician or hospital. - A birth certificate, birth announcement, or letter from the patient, physician, or the hospital in which the outcome occurred would be classified as valid written documents. For each birth reported to the surveillance system, the clinic should retain evidence of the birth in the patient's medical record. If the reporting of a birth and supplemental data pertaining to that birth is based on an oral communication from either the patient or her obstetric provider, that information should be recorded in ink in the patient's medical record and signed by a licensed medical provider. Clinics that use electronic medical records or clinics that have records that are stored offsite should also record information in an onsite patient medical record with a notation of where they obtained the information. <u>Verbal confirmation, patient</u>: The patient only reported the pregnancy outcome verbally. <u>Written confirmation, patient</u>: The

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		was reported verbally by the patient's attending physician or the hospital in which the outcome occurred. Written confirmation, physician or hospital: The attending physician or hospital submitted a written document confirming the pregnancy outcome.		patient submitted a written document confirming the pregnancy outcome. Verbal confirmation, physician or hospital: The pregnancy outcome was reported verbally by the patient's attending physician or the hospital in which the outcome occurred. Written confirmation, physician or hospital: The attending physician or hospital submitted a written document confirming the pregnancy outcome.
Number of Infants Born	Unchanged	Number of infants born: The number of infants born should include the total number of live born and stillborn infants.	No changes recommended.	Number of infants born: The number of infants born should include the total number of live born and stillborn infants.
Birth outcome for Each Infant	Unchanged	Indicate whether infant was live birth, stillbirth, neonatal death or unknown	Added definition of live birth for clarity.	Indicate whether infant was live birth, stillbirth, neonatal death or unknown A fetus is considered liveborn if it showed signs of life after the complete expulsion or extraction from its mother. Signs of life include breathing, beating of the heart, pulsation of the umbilical cord, or definite movement of the voluntary muscles. Heartbeats are to be distinguished from transient cardiac contractions; respirations are to be distinguished from fleeting respiratory efforts or gasps. The above definition for livebirth is currently used by all 50 states in the US . For practical purposes, a live birth is a birth for which a

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				certificate of live birth was filed.
Gender for each liveborn or stillborn infant	Unchanged	Indicate gender for each liveborn or stillborn infant (male, female, unknown)	No changes recommended Note: questions on births will only be shown for cycles where birth outcome reported as liveborn or stillborn infant(s)	Indicate gender for each liveborn or stillborn infant (male, female, unknown)
Birth weight for Each Live-born and Stillborn Infant	Unchanged	Birth Weight: If unknown, check "Weight unknown" for each infant born. If known, enter either pounds and ounces, or only grams for each infant born. Do not attempt to convert weight measurements to other units (e.g., grams to ounces; ounces to pounds). In the case of a multiple birth event, do not attempt to convert the weights of infants to the same unit(s). For example, if the weight for one twin was reported as grams, and the other twin's weight was reported in pounds and ounces, enter the respective weight measurements as is, for each infant.	No changes recommended. Note: questions on births will only be shown for cycles where birth outcome reported as liveborn or stillborn infant(s)	Birth Weight: If unknown, check "Weight unknown" for each infant born. If known, enter either pounds and ounces, or only grams for each infant born. Do not attempt to convert weight measurements to other units (e.g., grams to ounces; ounces to pounds). In the case of a multiple birth event, do not attempt to convert the weights of infants to the same unit(s). For example, if the weight for one twin was reported as grams, and the other twin's weight was reported in pounds and ounces, enter the respective weight measurements as is, for each infant.
Birth Defects Diagnosed for Each Live-born and Stillborn Infant (Genetic Defect/Chromosomal Abnormality, Cleft Lip or Palate, Neural Tube Defect, Cardiac Defect,	Modify	Birth Defects Diagnosed for Each Live-born and Stillborn Infant (Genetic Defect/Chromosomal Abnormality, Cleft Lip or Palate, Neural Tube Defect, Cardiac Defect, Limb Defect, Other Defect). Anomalies diagnosed within the first	This question was included in 2000 Federal Register notice but was subsequently dropped from data collection after 2003. Given growing attention to the potential association between ART and birth defects, we elected to include this information once again. The only change is to add a field for specifying the birth defect when "other" is selected.	For each live-born or stillborn infant, indicate any birth defects diagnosed (Genetic Defect/Chromosomal Abnormality, Cleft Lip or Palate, Neural Tube Defect, Cardiac Defect, Limb Defect, Other Defect, unknown) Birth defect - Anomalies diagnosed

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Limb Defect, Other Defect)		two weeks of life that result in death or cause 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.	Reference: Pinborg A, Henningsen AK, Malchau SS, Loft A. Congenital anomalies after assisted reproductive technology. Fertil Steril. 2013;99:327-32 Note: questions on births will only be shown for cycles where birth outcome reported as liveborn or stillborn infant(s)	within the first two weeks of life that result in death or cause 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.
Neonatal death (liveborn infants)	Add	Not currently collected	New question added to evaluate potential intrinsic perinatal risks associated with ART procedures. Note: questions on births will only be shown for cycles where birth outcome reported as liveborn or stillborn infant(s)	For each liveborn infant, indicate if neonatal death occurred. Neonatal death is the death of a liveborn infant before completion of the 28th day of life. If infant survival is unknown, select Unknown.
Lab Upper Normal Limit for that FSH level	Drop	Lab upper normal FSH (IUs): Enter the upper limit of the laboratory's normal range if known.	Question deleted. Information is not relevant due to discrepancies in how upper limits may be defined. Specifically, the upper range of normal should be based on age of the patient; in addition, most lab assays are accurate to very high numbers. (FSH of 9 is normal in a 42 year old but represents DOR in a 22 year old)	N/A
Lab upper normal FSH unknown	Drop	Lab upper normal FSH unknown: Check this box if the laboratory upper normal FSH level is unknown.	Question deleted since lab upper limit was also deleted.	N/A
FSH Unknown	Drop	FSH unknown: FSH (follicle stimulating hormone) is a	Question deleted and “unknown” added as an option to the patient maximum FSH question.	N/A

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		gonadotropin hormone produced and released from the pituitary that stimulates the ovary to ripen a follicle for ovulation. Check this box if FSH testing for this patient was never performed, or if the FSH level is not known		
Patient Maximum Estradiol Level	Drop	Estradiol (E2) – the predominant estrogen hormone produced by the ovary that has several activities important for reproduction. An elevated serum estradiol level in the early follicular phase of a woman's menstrual cycle may indicate diminished ovarian reserve.	Question deleted due to due to potential variations in estradiol (E2) levels. For example, patients often receive exogenous E2 priming leading up to gonadotropin initiation, thus E2 may be falsely elevated at baseline. E2 also varies widely through the menstrual cycle.	N/A
Lab Upper Normal Limit for that Estradiol Level	Drop		Question removed because it is not a useful variable. Labs can measure E2 to very high levels by diluting. An elevated E2 during early follicular phase can suggest DOR due to early follicular recruitment and be associated with a falsely suppressed FSH when measured simultaneously in individual patients. It does not make sense to use it for national surveillance since much better markers of ovarian reserve are available – AMH, antral follicle counts, etc.	N/A
Number of Fresh Embryos Transferred to Fallopian Tubes	Drop	Number of EMBRYOS: FRESH Transfers to Fallopian Tubes: Enter the number of fresh embryos transferred to the fallopian tubes, or "0" to indicate that none were successfully transferred. Do not leave this variable blank if the transfer of fresh embryos to the	This question was deleted. All questions on transfers to fallopian tubes (oocytes and fresh or frozen embryos) were combined into one question. GIFT, ZIFT and TET are rare; thus it was determined that this information could be combined.	N/A

FRN Section III.B. Data to be Reported	Variable status (add, drop, modify, unchanged)	Current NASS Instructions and/or Definitions	Notes and justification	Proposed NASS instructions and/or definitions
		fallopian tubes was attempted. Include the number of zygotes transferred to fallopian tubes if zygote intrafallopian transfer (ZIFT) was the method of transfer for this cycle. Record the number of early stage embryos transferred if tubal embryo transfer (TET) was used in this cycle.		
Number of Thawed Embryos Transferred to Fallopian Tubes	Drop	Number of EMBRYOS: THAWED Transfers to Fallopian Tubes: Enter the number of thawed embryos transferred to the fallopian tubes, or "0" to indicate that none were successfully transferred. Include the number of thawed zygotes transferred to fallopian tubes if zygote intrafallopian transfer (ZIFT) was the method of transfer for this cycle. Also, include any zygotes that were produced from thawed oocytes and sperm. Record the number of thawed early stage embryos transferred if tubal embryo transfer (TET) was used in this cycle	This question was deleted. All questions on transfers to fallopian tubes (oocytes and fresh or frozen embryos) were combined itno one question. GIFT, ZIFT and TET are rare; thus it was determined that this information could be combined.	N/A
Surgical Sterilization—Patient or Partner	Drop	Surgical Sterilization – patient or partner: Select the appropriate response from the drop- down list based on the guidelines below. Neither patient nor partner: Neither the patient nor the partner has undergone an operative procedure	This question was removed and surgical sterilization was added as an option for "reason for ART"	

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		for the purpose of termination of fertility without reversal. Yes, patient: The patient has undergone an operative procedure for the purpose of termination of fertility without reversal. Surgical sterilization includes tubal ligation or hysterectomy, for the purpose of termination of fertility, without reversal. Yes, partner: The partner has undergone an operative procedure, such as a vasectomy, for the purpose of termination of fertility, without reversal. Both patient and partner: Both the patient and partner have undergone operative procedures for the purpose of termination of fertility without reversal (described above). Patient does not know: The patient cannot recall the reason for undergoing a procedure resulting in termination of fertility, and/or does not know if her partner has undergone a procedure described above.		
Was an Ultrasound Performed?	Drop	If pregnant, was ultrasound performed: Click on either "Yes" or "No" to indicate if an ultrasound was performed.	The option of "no ultrasound performed" was added to the question on the number of fetal hearts on first ultrasound. Therefore there was no need for this question.	

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Donor medicated to stimulate follicular development	Drop		Current worksheet collects patient or donor medications in one question (instead of requiring separate questions on patient and donor medications)	
Donor medications containing clomiphene	Drop			
Donor clomiphene dosage	Drop		See above	
Donor medications containing FSH	Drop		See above	
Donor GnRH protocol	Drop		See above	
Patient smoked 100 cigarettes during life	Drop		Not necessary.	
Average daily cigarettes smoked	Drop		Not necessary.	

1