

Change Request

May 1, 2017

Information Collection Request: “Assisted Reproductive Technology (ART) Program Reporting System”
(OMB no. 0920-0556, exp. date 7/31/2018)

Background and Justification

CDC is currently approved to collect information needed to determine the annual pregnancy success rates of each clinic that provides assisted reproductive technology (ART) services. This information includes clinical information pertaining to the ART procedure, outcome information on resultant pregnancies and births, and information on factors that may affect outcomes, such as de-identified patient demographics, medical history, and infertility diagnosis.

CDC obtained the current approval for ART information collection in July 2015 with minor modifications approved through the change mechanism in August 2016; screen shots of the approved NASS questionnaire can be found in Att C1b_v3_NASS screens.

During the implementation of the new data collection system, it became apparent that some information was not collected consistently for all types of ART cycles, and was inadvertently omitted in some rare situations. The purpose of this change request is to explicitly incorporate these data elements into the approved screen shots, allowing for the most efficient capture of the previously approved information in relation to pregnancy success rates with minimal additional time burden. The proposed revision to the NASS questionnaire (Att C1b_v4_NASS screens) contains the following four change requests:

Requested Change 1:

CDC is approved to collect information on race/ethnicity of male and female patients, oocyte source, pregnancy carrier, and sperm source. This information is captured in the current questionnaire with questions #25-26A of Att C1b_v3 (race/ethnicity of oocyte source), questions #29-30A of Att C1b_v3 (race/ethnicity of pregnancy carrier), and questions #33-34A of Att C1b_v3 (race/ethnicity of sperm source). However, in the rare situation when a patient uses donor eggs, donor sperms, and a gestational carrier, these existing questions will not capture patient race/ethnicity. We propose adding questions #5A-5C (highlighted) of Att C1b v4 (race/ethnicity of patient). In adding these questions to the patient profile in the beginning of the questionnaire, the system will pre-fill race/ethnicity of oocyte source (questions #25-26A; Att C1b_v3) if it is indicated in question #24A that the patient is the oocyte source, it will prefill race/ethnicity of the pregnancy carrier (questions #29-30A; Att C1b_v3) if it is indicated in question #27 that the patient is the pregnancy carrier, and it will prefill race/ethnicity of the sperm source (questions #33-34A; Att C1b_v3) if it is indicated in question #31 that the patient is the sperm source. Thus, because these fields will be pre-populated upon completion of question #5A-C there will be no overall impact on burden.

Change #1: Currently Approved Question Format

PATIENT PROFILE	
Quex ID	LEAD QUESTION
1	Date of cycle reporting (mm/dd/yyyy): _ _ - _ _ - _ _ _ _ _
2	NASS Patient ID: _ _ _ _ _ - _ _ _ _ _ - _ _ _
3	Patient Optional Identifiers Optional Identifier 1 _ _ _ _ _ _ _ _ _ maximum 7 digits or characters Optional Identifier 2 _ _ _ _ _ _ _ _ _ maximum 7 digits or characters
4	Patient Date of Birth (mm/dd/yyyy): _ _ - _ _ - _ _ _ _ _
5	Sex of patient: <input type="radio"/> Male <input type="radio"/> Female

Change #1: Proposed Question Format

PATIENT PROFILE	
Quex ID	LEAD QUESTION
1	Date of cycle reporting (mm/dd/yyyy): _ _ - _ _ - _ _ _ _ _
2	NASS Patient ID: _ _ _ _ _ - _ _ _ _ _ - _ _ _
3	Patient Optional Identifiers Optional Identifier 1 _ _ _ _ _ _ _ _ _ maximum 7 digits or characters Optional Identifier 2 _ _ _ _ _ _ _ _ _ maximum 7 digits or characters
4	Patient Date of Birth (mm/dd/yyyy): _ _ - _ _ - _ _ _ _ _
5	Sex of patient: <input type="radio"/> Male <input type="radio"/> Female
5A	Patient ethnicity <input type="radio"/> NOT Hispanic or Latino <input type="radio"/> Hispanic or Latino <input type="radio"/> Refused <input type="radio"/> Unknown
5B	Patient race (select all that apply) <input type="checkbox"/> White <input type="checkbox"/> Black or African American <input type="checkbox"/> Asian <input type="checkbox"/> Native Hawaiian or other Pacific Islander <input type="checkbox"/> American Indian or Alaska Native Or
5C	Reason race not reported <input type="radio"/> Refused <input type="radio"/> Unknown

Requested Change 2:

One of the previously approved pregnancy history questions in the female patient history regarding the number of prior frozen ART cycles (question #21; Att C1b_v3) needs to be clarified to more completely capture ART treatment history. We propose changing the question from “number of prior frozen ART cycles” to “number of prior ART cycles started with the intent to transfer oocytes or embryos” (highlighted). This change should not affect burden, as we are proposing to clarify one question with a comparable question.

Change #2: Currently Approved Question Format

FEMALE PATIENT HISTORY & PHYSICAL		
FEMALE PATIENT HISTORY & PHYSICAL		
Text, checkbox (SR)	16	[IF SEX OF PATIENT = MALE (FROM QUESTION #5) THEN SKIP #16-23] Height _ _ Feet and/or _ _ Inches or _ _ _ _ Centimeters Or <input type="checkbox"/> Height unknown
Text, checkbox (SR)		Weight at the start of this cycle _ _ _ Pounds or _ _ _ Kilograms Or <input type="checkbox"/> Weight unknown
Radio	18	Did the patient smoke during the 3 months before the cycle started? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Radio	19	Any prior pregnancies? <input type="radio"/> Yes <input type="radio"/> No
Text	19A	[SKIP IF NO PRIOR PREGNANCIES] If prior pregnancies reported and couple is not surgically sterile, enter months and/or years attempting pregnancy since last clinical pregnancy _ _ _ months and/or _ _ years [SKIP IF ANY PRIOR PREGNANCIES] If no prior pregnancies reported and couple is not surgically sterile, enter months and/or years attempting pregnancy _ _ _ months and/or _ _ years
Text	19B	Number of prior pregnancies _ _
	19C	Number of prior full term births (live and stillbirths) _ _
		Number of prior preterm births (live and stillbirths) _ _
	19E	Number of prior stillbirths _ _
	19F	Number of prior spontaneous abortions _ _
	19G	Number of prior ectopic pregnancies _ _
	20	Number of prior stimulations for fresh ART cycles _ _
	21	Number of prior frozen ART cycles _ _
Radio	21A	SKIP IF NO PRIOR ART CYCLES Did any prior ART cycles result in a live birth? <input type="radio"/> Yes <input type="radio"/> No
Text, checkbox (SR)	22	Maximum FSH level (MIU/mls) _ _ _ . _ _ Or <input type="checkbox"/> FSH level unknown

Text, checkbox (SR), date	23	<p>Most recent AMH level (ng/mL) _ _ _ . _ _ </p> <p>Or</p> <p><input type="checkbox"/> AMH level unknown</p> <p>Date of most recent AMH level (mm/dd/yyyy) _ _ - _ _ - _ _ _ _ </p>
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Change #2: Proposed Question format

FEMALE PATIENT HISTORY & PHYSICAL		
FEMALE PATIENT HISTORY & PHYSICAL		
Text, checkbox (SR)	16	<p>[IF SEX OF PATIENT = MALE (FROM QUESTION #5) THEN SKIP #16-23]</p> <p>Height</p> <p> _ Feet and/or _ _ Inches or _ _ _ _ Centimeters</p> <p>Or</p> <p><input type="checkbox"/> Height unknown</p>
Text, checkbox (SR)		<p>Weight at the start of this cycle</p> <p> _ _ _ Pounds or _ _ _ _ Kilograms</p> <p>Or</p> <p><input type="checkbox"/> Weight unknown</p>
Radio	18	<p>Did the patient smoke during the 3 months before the cycle started?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Unknown</p>
Radio	19	<p>Any prior pregnancies?</p> <p><input type="radio"/> Yes</p> <p><input type="radio"/> No</p>
Text	19A	<p>[SKIP IF NO PRIOR PREGNANCIES]</p> <p>If prior pregnancies reported and couple is not surgically sterile, enter months and/or years attempting pregnancy since last clinical pregnancy _ _ _ months and/or _ _ years</p> <p>[SKIP IF ANY PRIOR PREGNANCIES]</p> <p>If no prior pregnancies reported and couple is not surgically sterile, enter months and/or years attempting pregnancy _ _ _ months and/or _ _ years</p>
Text	19B	Number of prior pregnancies _ _
	19C	Number of prior full term births (live and stillbirths) _ _
		Number of prior preterm births (live and stillbirths) _ _
	19E	Number of prior stillbirths _ _
	19F	Number of prior spontaneous abortions _ _
	19G	Number of prior ectopic pregnancies _ _
	20	Number of prior stimulations for fresh ART cycles _ _
	21	Number of prior ART cycles started with the intent to transfer oocytes or embryos _ _
Radio	21A	<p>SKIP IF NO PRIOR ART CYCLES</p> <p>Did any prior ART cycles result in a live birth? <input type="radio"/> Yes <input type="radio"/> No</p>
Text, checkbox (SR)	22	<p>Maximum FSH level (MIU/mls) _ _ _ . _ _ </p> <p>Or</p> <p><input type="checkbox"/> FSH level unknown</p>
Text, checkbox (SR), date	23	<p>Most recent AMH level (ng/mL) _ _ _ . _ _ </p> <p>Or</p> <p><input type="checkbox"/> AMH level unknown</p> <p>Date of most recent AMH level (mm/dd/yyyy) _ _ - _ _ - _ _ _ _ </p>

Requested Change 3

CDC is approved to collect information on height, weight and pregnancy history for patients seeking ART treatment (questions #16-23; Att C1b_v3). However, for oocyte donors, height, weight, and pregnancy history was inadvertently omitted from the approved collection tool. Because this information is important regardless of oocyte source, we therefore propose adding questions #O1-#O8; Att C1b_v4 (highlighted) to the oocyte source profile, if the oocyte source is a donor (i.e. not the patient). The estimated additional time burden, on average will be minimal (0.3 min) given that a small overall proportion of cycles use donated oocytes. If the oocyte source is the patient, questions #O1-O8 will be prefilled using information from questions #16-23, to avoid any impact on overall burden.

Change #3: Currently Approved Question Format

SOURCES & CARRIERS PROFILES	
OOCYTE SOURCE PROFILE	
24A	<p>[IF OOCYTE SOURCE = PATIENT AND DONOR, ANSWER THIS QUESTION]</p> <p>Youngest oocyte source</p> <p><input type="checkbox"/> Patient [SKIP TO Q25]</p> <p><input type="checkbox"/> Donor [CONTINUE TO Q24B]</p>
24B	<p>Oocyte source date of birth (mm/dd/yyyy) [FIELD PRE-FILLED IF OOCYTE SOURCE=PATIENT]</p> <p> _ _ - _ _ - _ _ _ _ </p> <p>Or</p> <p>Age at earliest time oocytes were retrieved _____</p>
25	<p>Oocyte source ethnicity</p> <p><input type="radio"/> NOT Hispanic or Latino</p> <p><input type="radio"/> Hispanic or Latino</p> <p><input type="radio"/> Refused</p> <p><input type="radio"/> Unknown</p>
26	<p>Oocyte source race (select all that apply)</p> <p><input type="checkbox"/> White</p> <p><input type="checkbox"/> Black or African American</p> <p><input type="checkbox"/> Asian</p> <p><input type="checkbox"/> Native Hawaiian or other Pacific Islander</p> <p><input type="checkbox"/> American Indian or Alaska Native</p> <p>Or</p>
26A	<p>Reason race not reported</p> <p><input type="radio"/> Refused</p> <p><input type="radio"/> Unknown</p>

Change #3: Proposed Question Format

SOURCES & CARRIERS PROFILES	
OOCYTE SOURCE PROFILE	
24A	<p>[IF OOCYTE SOURCE = PATIENT AND DONOR, ANSWER THIS QUESTION]</p> <p>Youngest oocyte source</p> <p><input type="checkbox"/> Patient [SKIP TO Q25]</p> <p><input type="checkbox"/> Donor [CONTINUE TO Q24B]</p>
24B	<p>Oocyte source date of birth (mm/dd/yyyy) [FIELD PRE-FILLED IF OOCYTE SOURCE=PATIENT]</p> <p> _ _ - _ _ - _ _ _ _ </p> <p>Or</p> <p>Age at earliest time oocytes were retrieved ____</p>
25	<p>Oocyte source ethnicity</p> <p><input type="radio"/> NOT Hispanic or Latino</p> <p><input type="radio"/> Hispanic or Latino</p> <p><input type="radio"/> Refused</p> <p><input type="radio"/> Unknown</p>
26	<p>Oocyte source race (select all that apply)</p> <p><input type="checkbox"/> White</p> <p><input type="checkbox"/> Black or African American</p> <p><input type="checkbox"/> Asian</p> <p><input type="checkbox"/> Native Hawaiian or other Pacific Islander</p> <p><input type="checkbox"/> American Indian or Alaska Native</p> <p>Or</p>
26A	<p>Reason race not reported</p> <p><input type="radio"/> Refused</p> <p><input type="radio"/> Unknown</p>
O1	<p>Oocyte source height</p> <p> _ Feet and/or _ _ Inches or _ _ _ _ Centimeters</p> <p>Or</p> <p><input type="checkbox"/> Height unknown</p>
	<p>Oocyte source weight</p> <p> _ _ _ Pounds or _ _ _ Kilograms</p> <p>Or</p> <p><input type="checkbox"/> Weight unknown</p>
O3	<p>Did the oocyte source smoke during the 3 months before the cycle started?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Unknown</p>
O4	<p>Any prior pregnancies?</p> <p><input type="radio"/> Yes</p> <p><input type="radio"/> No</p>
O5	<p>[SKIP IF NO PRIOR PREGNANCIES]</p> <p>If prior pregnancies reported and couple is not surgically sterile, enter months and/or years attempting pregnancy since last clinical pregnancy _ _ _ months and/or _ _ years</p> <p>[SKIP IF ANY PRIOR PREGNANCIES]</p> <p>If no prior pregnancies reported and couple is not surgically sterile, enter months and/or years attempting pregnancy _ _ _ months and/or _ _ years</p>
O6A	<p>[SKIP IF NO PRIOR PREGNANCIES]</p> <p>Number of prior pregnancies _ _ </p>
O6C	<p>Number of prior full term births (live and stillbirths) _ _ </p>
O6D	<p>Number of prior preterm births (live and stillbirths) _ _ </p>
	<p>Number of prior stillbirths _ _ </p>
	<p>Number of prior spontaneous abortions _ _ </p>

O6E		Number of prior ectopic pregnancies __ __
O6F		Number of prior stimulations for ART treatment __ __
O6G		Number of prior ART cycles started with the intent to transfer oocytes or embryos __ __
O6H	SKIP IF NO PRIOR ART CYCLES started with intent to transfer	Did any prior ART cycles started with the intent to transfer oocytes or embryos result in a live birth? <input type="radio"/> Yes <input type="radio"/> No
O7		Maximum FSH level (MIU/mls) __ __ __ . __ __ Or <input type="checkbox"/> FSH level unknown
O8		Most recent AMH level (ng/mL) __ __ __ . __ __ Or <input type="checkbox"/> AMH level unknown Date of most recent AMH level (mm/dd/yyyy) __ __ - __ __ - __ __ __ __

Requested Change #4:

CDC is approved to collect the date of any previous oocyte retrieval that contributed to a reported embryo transfer cycle to allow for details of previous retrievals to be linked to current transfers. However, this information only allows for the linkage of retrievals and transfers if the retrieval and transfer occurred in the same clinic; it does not capture the situation in which oocytes were retrieved in an ART clinic that is different from the ART clinic where the current transfer is taking place. Collection of the date of any previous retrieval, along with the clinic in which the previous retrieval took place (if different from the clinic performing the transfer) will allow for more complete linkage of embryo transfers to egg retrievals. This information will allow for a better understanding of the cumulative success rates over multiple ART treatment cycles.

We therefore propose adding questions #58C and #62C (highlighted; Att C1b_v4) to capture information on previous oocyte retrievals for current fresh embryo transfers or thawed embryo transfers if the retrieval and transfer did not occur in the same clinic. It is estimated that this change will add an average burden of 0.2 minutes.

Change #4: Currently Approved Question Format

TRANSFER															
TRANSFER ATTEMPT															
53	Was a transfer attempted? <input type="radio"/> Yes <input type="radio"/> No														
53A	[SKIP IF TRANSFER ATTEMPTED] <table border="0"> <tr> <td>Primary reason no transfer was attempted</td> <td></td> </tr> <tr> <td><input type="checkbox"/> Low ovarian response</td> <td></td> </tr> <tr> <td><input type="checkbox"/> High ovarian response</td> <td></td> </tr> <tr> <td><input type="checkbox"/> Failure to survive oocyte thaw</td> <td></td> </tr> <tr> <td><input type="checkbox"/> Inadequate endometrial response</td> <td></td> </tr> <tr> <td><input type="checkbox"/> Concurrent illness</td> <td></td> </tr> <tr> <td><input type="checkbox"/> Withdrawal only for personal reasons</td> <td></td> </tr> </table>	Primary reason no transfer was attempted		<input type="checkbox"/> Low ovarian response		<input type="checkbox"/> High ovarian response		<input type="checkbox"/> Failure to survive oocyte thaw		<input type="checkbox"/> Inadequate endometrial response		<input type="checkbox"/> Concurrent illness		<input type="checkbox"/> Withdrawal only for personal reasons	
Primary reason no transfer was attempted															
<input type="checkbox"/> Low ovarian response															
<input type="checkbox"/> High ovarian response															
<input type="checkbox"/> Failure to survive oocyte thaw															
<input type="checkbox"/> Inadequate endometrial response															
<input type="checkbox"/> Concurrent illness															
<input type="checkbox"/> Withdrawal only for personal reasons															

		<input type="checkbox"/> Unable to obtain sperm specimen <input type="checkbox"/> Insufficient embryos <input type="checkbox"/> Other (specify) _____
[IF TRANSFER NOT ATTEMPTED, STOP HERE]		
GENERAL TRANSFER DETAILS		
54	Date transfer performed (mm/dd/yyyy) __ __ - __ __ - __ __ __ __	
55	Endometrial thickness at trigger __ __ mm	
FRESH EMBRYO TRANSFER DETAILS		
55N	Number of fresh embryos available on day of transfer __ __	
56	[IF NO FRESH EMBRYOS TRANSFERRED, SKIP #57-58] Number of fresh embryos transferred to uterus __ __	
57	[SKIP #57 FOR MIXED CYCLE] If only <u>one</u> fresh embryo was transferred to the uterus, was this an <u>elective</u> single embryo transfer? <input type="radio"/> Yes <input type="radio"/> No	
58A-X	Quality of embryo #1-X <input type="checkbox"/> Good <input type="checkbox"/> Fair <input type="checkbox"/> Poor <input type="checkbox"/> Unknown	
58B	Date of oocyte retrieval for embryo #1-X (mm/dd/yyyy) [DROPDOWN] Or __ __ - __ __ - __ __ __ __	
59	Number of fresh embryos cryopreserved __ __ [STOP HERE FOR EMBRYO BANKING ONLY CYCLE]	
FROZEN EMBRYO TRANSFER DETAILS		
60	Number of frozen or thawed embryos available on day of transfer __ __	
61	Number of thawed embryos transferred to uterus __ __ [IF NO THAWED EMBRYOS TRANSFERRED, SKIP #62]	
62	[SKIP #63 FOR MIXED CYCLE] If only <u>one</u> thawed embryo was transferred to the uterus, was this an <u>elective</u> single embryo transfer? <input type="radio"/> Yes <input type="radio"/> No	
62A-X	Quality of embryo #1-X <input type="checkbox"/> Good <input type="checkbox"/> Fair <input type="checkbox"/> Poor <input type="checkbox"/> Unknown	
62B	Date of oocyte retrieval for embryo #1-X (mm/dd/yyyy) [DROPDOWN] Or __ __ - __ __ - __ __ __ __	
63	Number of thawed embryos cryopreserved (re-frozen) __ __	
GIFT/ZIFT/TET TRANSFER DETAILS		
64	[SKIP IF IVF CYCLE] Number of oocytes or embryos transferred to the fallopian tube __ __	

Change #4: Proposed Question Format

TRANSFER		
TRANSFER ATTEMPT		
53	Was a transfer attempted? <input type="radio"/> Yes <input type="radio"/> No	
53A	[SKIP IF TRANSFER ATTEMPTED]	Primary reason no transfer was attempted <input type="checkbox"/> Low ovarian response <input type="checkbox"/> High ovarian response <input type="checkbox"/> Failure to survive oocyte thaw <input type="checkbox"/> Inadequate endometrial response <input type="checkbox"/> Concurrent illness

		<input type="checkbox"/> Withdrawal only for personal reasons <input type="checkbox"/> Unable to obtain sperm specimen <input type="checkbox"/> Insufficient embryos <input type="checkbox"/> Other (specify) _____
[IF TRANSFER NOT ATTEMPTED, STOP HERE]		
GENERAL TRANSFER DETAILS		
54	Date transfer performed (mm/dd/yyyy) __ __ - __ __ - __ __ __ __	
55	Endometrial thickness at trigger __ __ mm	
FRESH EMBRYO TRANSFER DETAILS		
55N	Number of fresh embryos available on day of transfer __ __	
56	[IF NO FRESH EMBRYOS TRANSFERRED, SKIP #57-58] Number of fresh embryos transferred to uterus __ __	
57	[SKIP #57 FOR MIXED CYCLE] If only <u>one</u> fresh embryo was transferred to the uterus, was this an <u>elective</u> single embryo transfer? <input type="radio"/> Yes <input type="radio"/> No	
58A-X	Quality of embryo #1-X <input type="checkbox"/> Good <input type="checkbox"/> Fair <input type="checkbox"/> Poor <input type="checkbox"/> Unknown	
58B	Date of oocyte retrieval for embryo #1-X (mm/dd/yyyy) [DROPDOWN] Or __ __ - __ __ - __ __ __ __	
58C	Was the oocyte used to create the fresh embryo #1-X retrieved in a different clinic? <input type="radio"/> Yes <input type="radio"/> No If Yes, state [dropdown], city [dropdown], name of clinic [dropdown] or _____ [text], if not found in the dropdown menu	
59	Number of fresh embryos cryopreserved __ __ [STOP HERE FOR EMBRYO BANKING ONLY CYCLE]	
FROZEN EMBRYO TRANSFER DETAILS		
60	Number of frozen or thawed embryos available on day of transfer __ __	
61	Number of thawed embryos transferred to uterus __ __ [IF NO THAWED EMBRYOS TRANSFERRED, SKIP #62]	
62	[SKIP #63 FOR MIXED CYCLE] If only <u>one</u> thawed embryo was transferred to the uterus, was this an <u>elective</u> single embryo transfer? <input type="radio"/> Yes <input type="radio"/> No	
62A-X	Quality of embryo #1-X <input type="checkbox"/> Good <input type="checkbox"/> Fair <input type="checkbox"/> Poor <input type="checkbox"/> Unknown	
62B	Date of oocyte retrieval for embryo #1-X (mm/dd/yyyy) [DROPDOWN] Or __ __ - __ __ - __ __ __ __	
62C	Was the oocyte used to create the thawed embryo #1-X retrieved in a different clinic? <input type="radio"/> Yes <input type="radio"/> No If Yes, state [dropdown], city [dropdown], name of clinic [dropdown] or _____ [text], if not found in the dropdown menu	
63	Number of thawed embryos cryopreserved (re-frozen) __ __	
GIFT/ZIFT/TET TRANSFER DETAILS		
64	[SKIP IF IVF CYCLE] Number of oocytes or embryos transferred to the fallopian tube __ __	

Timeline and impact on Burden

CDC plans to begin administering the revised instruments in 2018. OMB approval is requested, effective immediately. Due to the rare occurrence of the situations described above, additional burden is minimal. The estimated average burden per response will increase from 42 minutes to 42.5 minutes with an increase of 1,315 total burden hours.

Estimated Annualized Burden Hours

Form Name	Respondents	No. of Respondents	Average No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Current NASS 2.0	ART clinics	447	353	42/60	110,454
Proposed NASS 2.0	ART clinics	447	353	42.5/60	111,769