# **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

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|  | **PATIENT PROFILE** |

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| --- | --- |
| **Quex ID** | **LEAD QUESTION** |
| 1 | **Date of cycle reporting (mm/dd/yyyy):** |\_\_|\_\_| - |\_\_|\_\_| - |\_\_|\_\_|\_\_|\_\_| |
| 2 | **NASS Patient ID**: |\_\_|\_\_|\_\_|\_\_| - |\_\_|\_\_|\_\_|\_\_| - |\_\_|\_\_| |
| 3 | **Patient Optional Identifiers**  Optional Identifier 1 |\_\_|\_\_|\_\_|\_\_|\_\_|\_\_|\_\_|  maximum 7 digits or characters |
|  | Optional Identifier 2 |\_\_|\_\_|\_\_|\_\_|\_\_|\_\_|\_\_|  maximum 7 digits or characters |
| 4 | **Patient Date of Birth (mm/dd/yyyy):** |\_\_|\_\_| - |\_\_|\_\_| - |\_\_|\_\_|\_\_|\_\_| |
| 5 | **Sex of patient:** ⃝ Male ⃝ Female |

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:** ⃝ Male ⃝ Female |
| 5A | **Patient ethnicity**  ⃝ NOT Hispanic or Latino  ⃝ Hispanic or Latino  ⃝ Refused  ⃝ Unknown |
| 5B | **Patient race (select all that apply)**  White  Black or African American  Asian  Native Hawaiian or other Pacific Islander  American Indian or Alaska Native  Or |
| 5C | **Reason race not reported**  ⃝ Refused  ⃝ 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

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| --- | --- | --- | --- | --- |
| **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  Height unknown | | |
| Text, checkbox (SR) | 17 | **Weight at the start of this cycle**  |\_\_|\_\_|\_\_|\_\_| Pounds or |\_\_|\_\_|\_\_|\_\_| Kilograms  Or  Weight unknown | | |
| Radio | 18 | Did the patient smoke during the 3 months before the cycle started?  Yes  No  Unknown | | |
| Radio | 19 | **Any prior pregnancies?**  ⃝Yes  ⃝ 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 | **[SKIP IF NO PRIOR PREGNANCIES]** | | **Number of prior pregnancies |\_\_|\_\_|** |
| 19C | **Number of prior full term births (live and stillbirths) |\_\_|\_\_|** |
| 19D | **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? ⃝Yes ⃝ No** | |
| Text, checkbox (SR) | 22 | **Maximum FSH level (MIU/mls) |\_\_|\_\_|\_\_| . |\_\_|\_\_|**  Or  FSH level unknown | | |
| Text, checkbox (SR), date | 23 | **Most recent AMH level (ng/mL) |\_\_|\_\_|\_\_| . |\_\_|\_\_|**  Or  AMH level unknown  **Date of most recent AMH level (mm/dd/yyyy) |\_\_|\_\_| - |\_\_|\_\_| - |\_\_|\_\_|\_\_|\_\_|** | | |
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Change #2: Proposed Question format

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| --- | --- | --- | --- | --- |
| **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  Height unknown | | |
| Text, checkbox (SR) | 17 | **Weight at the start of this cycle**  |\_\_|\_\_|\_\_|\_\_| Pounds or |\_\_|\_\_|\_\_|\_\_| Kilograms  Or  Weight unknown | | |
| Radio | 18 | Did the patient smoke during the 3 months before the cycle started?  Yes  No  Unknown | | |
| Radio | 19 | **Any prior pregnancies?**  ⃝Yes  ⃝ 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 | **[SKIP IF NO PRIOR PREGNANCIES]** | | **Number of prior pregnancies |\_\_|\_\_|** |
| 19C | **Number of prior full term births (live and stillbirths) |\_\_|\_\_|** |
| 19D | **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 | **SKIP IF NO PRIOR ART CYCLES** | **Did any prior ART cycles result in a live birth? ⃝Yes ⃝ No** | |
| Text, checkbox (SR) | 22 | **Maximum FSH level (MIU/mls) |\_\_|\_\_|\_\_| . |\_\_|\_\_|**  Or  FSH level unknown | | |
| Text, checkbox (SR), date | 23 | **Most recent AMH level (ng/mL) |\_\_|\_\_|\_\_| . |\_\_|\_\_|**  Or  AMH level unknown  **Date of most recent AMH level (mm/dd/yyyy) |\_\_|\_\_| - |\_\_|\_\_| - |\_\_|\_\_|\_\_|\_\_|** | | |
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**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

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| **SOURCES & CARRIERS PROFILES** |

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

Change #3: Proposed Question Format

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| **SOURCES & CARRIERS PROFILES** |

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

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| O1 | **Oocyte source height**  |\_\_| Feet and/or |\_\_|\_\_| Inches or |\_\_|\_\_|\_\_|\_\_| Centimeters  Or  Height unknown |
| O2 | **Oocyte source weight**  |\_\_|\_\_|\_\_|\_\_| Pounds or |\_\_|\_\_|\_\_|\_\_| Kilograms  Or  Weight unknown |

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| O3 | Did the oocyte source smoke during the 3 months before the cycle started?  Yes  No  Unknown |

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| O4 | **Any prior pregnancies?**  ⃝Yes  ⃝ No | |
| O5 | **[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** | |
|  | **[SKIP IF NO PRIOR PREGNANCIES]** | **Number of prior pregnancies |\_\_|\_\_|** |
| O6A | **Number of prior full term births (live and stillbirths) |\_\_|\_\_|** |
| O6B | **Number of prior preterm births (live and stillbirths) |\_\_|\_\_|** |
| O6C | **Number of prior stillbirths |\_\_|\_\_|** |
| O6D | **Number of prior spontaneous abortions |\_\_|\_\_|** |
| 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 |\_\_|\_\_|** | |

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| 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? ⃝Yes ⃝ No** |

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| O7 | **Maximum FSH level (MIU/mls) |\_\_|\_\_|\_\_|. |\_\_|\_\_|**  Or  FSH level unknown |
| O8 | **Most recent AMH level (ng/mL) |\_\_|\_\_|\_\_|. |\_\_|\_\_|**  Or  AMH level unknown  **Date of most recent AMH level (mm/dd/yyyy) |\_\_|\_\_| - |\_\_|\_\_| - |\_\_|\_\_|\_\_|\_\_|** |
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**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

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| **TRANSFER** | | |
|  | TRANSFER ATTEMPT | |
| 53 | **Was a transfer attempted?**  ⃝Yes ⃝ No | |
| 53A | **[SKIP IF TRANSFER ATTEMPTED]** | **Primary reason no transfer was attempted**  Low ovarian response  High ovarian response  Failure to survive oocyte thaw  Inadequate endometrial response  Concurrent illness  Withdrawal only for personal reasons  Unable to obtain sperm specimen  Insufficient embryos  Other (specify) **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
|  | **[IF TRANSFER NOT ATTEMPTED, STOP HERE]** | |
|  | GENERAL TRANSFER DETAILS | |
| 54 | **Date 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 one fresh embryo was transferred to the uterus, was this an elective single embryo transfer?**  ⃝Yes ⃝ No | |
| 58A-X | **Quality of embryo #1–X**  Good  Fair  Poor  Unknown | |
| 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 one thawed embryo was transferred to the uterus, was this an elective single embryo transfer?**  ⃝Yes ⃝ No | |
| 62A-X | **Quality of embryo #1–X**  Good  Fair  Poor  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

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| **TRANSFER** | | |
|  | TRANSFER ATTEMPT | |
| 53 | **Was a transfer attempted?**  ⃝Yes ⃝ No | |
| 53A | **[SKIP IF TRANSFER ATTEMPTED]** | **Primary reason no transfer was attempted**  Low ovarian response  High ovarian response  Failure to survive oocyte thaw  Inadequate endometrial response  Concurrent illness  Withdrawal only for personal reasons  Unable to obtain sperm specimen  Insufficient embryos  Other (specify) **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
|  | **[IF TRANSFER NOT ATTEMPTED, STOP HERE]** | |
|  | GENERAL TRANSFER DETAILS | |
| 54 | **Date 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 one fresh embryo was transferred to the uterus, was this an elective single embryo transfer?**  ⃝Yes ⃝ No | |
| 58A-X | **Quality of embryo #1–X**  Good  Fair  Poor  Unknown | |
| 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?**  ⃝Yes ⃝ 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 one thawed embryo was transferred to the uterus, was this an elective single embryo transfer?**  ⃝Yes ⃝ No | |
| 62A-X | **Quality of embryo #1–X**  Good  Fair  Poor  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?**  ⃝Yes ⃝ 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 |