**Change Request**

**Assisted Reproductive Technology (ART) Program Reporting System**

(OMB Control No. 0920-0556; Exp. date 08/31/2021)

April 24, 2019

**Summary**

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.

We request OMB approval to add oocyte source for embryo banking cycles (question #9).

**Background and Justification**

CDC is approved to collect information on intended type of ART, including oocyte or embryo banking cycles (questions #8-9; Att C1b\_v4). However, for embryo banking cycles, oocyte source was not included in the approved collection tool (question #9; AttC1b\_v4). Per the Federal Register Notice for “Assisted Reproductive Technology (ART) Success Rates Reporting and Data Validation Procedures” (October 22, 2018; 83 FR (53253-53255)), success rates are calculated by oocyte source (autologous oocytes vs. donor oocytes), including for embryo banking cycles; thus, we must collect information on the oocyte source for embryo banking cycles.

**Explanation of Changes**

We propose adding responses for oocyte source to embryo banking cycles (question #9; Att C1b\_v5).

CDC plans to begin administering the revised instrument in 2020. The proposed change is illustrated below.

*Currently Approved Question Format*

|  |  |
| --- | --- |
|  | **INTENT**  |
|  8 | **Intended type of ART (select all that apply)**[ ]  IVF: Transcervical[ ]  GIFT: Gametes to tubes [ ]  ZIFT: Zygotes to tubes or TET: tubal embryo transferOr [ ]  Oocyte or embryo banking |
|  9 | **[SKIP IF NOT A BANKING ONLY CYCLE]** | **Banking type (select all that apply)**[ ]  Embryo banking [ ]  Autologous oocyte banking [ ]  Donor oocyte banking |
|  9A | **Intended duration of oocyte banking (select all that apply)**[ ]  Short term (<12 months) [ ]  Long term (≥12 months) banking for fertility preservation prior to gonadotoxic medical treatments[ ]  Long term (≥12 months) banking for other reasons |
| 9B | **Intended duration of embryo banking (select all that apply)**[ ]  Short term (<12 months) * Delay of transfer to obtain genetic information
* Delay of transfer for other reasons

[ ]  Long term (≥12 months) banking for fertility preservation prior to gonadotoxic medical treatments[ ]  Long term (≥12 months) banking for other reasons**[IF BANKING ONLY, SKIP TO #11 AFTER #9 IS COMPLETED]** |
| 10 | **Intended embryo source (select all that apply)**[ ]  Patient embryos [ ]  Donor embryos (donated from another patient’s IVF cycle) [ ]  FRESH embryos [ ]  FROZEN embryos |
| 10A | **Intended oocyte source and state for FRESH embryos (select all that apply)**  [ ]  PATIENT oocytes [ ]  PATIENT frozen oocytes  [ ]  DONOR fresh oocytes [ ]  DONOR frozen oocytes **Intended oocyte source and state for FROZEN embryos (select all that apply)**  [ ]  PATIENT fresh oocytes [ ]  PATIENT frozen oocytes  [ ]  DONOR fresh oocytes [ ]  DONOR frozen oocytes [ ]  DONOR Unknown (select only if oocyte source is unknown) |
| 11 | **Intended sperm source (select all that apply) [SKIP IF DONOR EMBRYO IS INTENDED SOURCE]**[ ]  Partner[ ]  Donor[ ]  Patient, if maleOr [ ]  Unknown (select only if all sperm sources unknown) |
| 12 | **Intended pregnancy carrier** [ ]  Patient [ ]  Gestational carrier [ ]  None (oocyte or embryo banking cycle only) |

*Proposed Question Format*

|  |  |
| --- | --- |
|  | **INTENT**  |
|  8 | **Intended type of ART (select all that apply)**[ ]  IVF: Transcervical[ ]  GIFT: Gametes to tubes [ ]  ZIFT: Zygotes to tubes or TET: tubal embryo transferOr [ ]  Oocyte or embryo banking |
|  9 | **[SKIP IF NOT A BANKING ONLY CYCLE]** | **Banking type (select all that apply)**[ ]  Embryo banking from autologous oocytes [ ]  Embryo banking from donor oocytes [ ]  Autologous oocyte banking [ ]  Donor oocyte banking |
|  9A | **Intended duration of oocyte banking (select all that apply)**[ ]  Short term (<12 months) [ ]  Long term (≥12 months) banking for fertility preservation prior to gonadotoxic medical treatments[ ]  Long term (≥12 months) banking for other reasons |
| 9B | **Intended duration of embryo banking (select all that apply)**[ ]  Short term (<12 months) * Delay of transfer to obtain genetic information
* Delay of transfer for other reasons

[ ]  Long term (≥12 months) banking for fertility preservation prior to gonadotoxic medical treatments[ ]  Long term (≥12 months) banking for other reasons**[IF BANKING ONLY, SKIP TO #11 AFTER #9 IS COMPLETED]** |
| 10 | **Intended embryo source (select all that apply)**[ ]  Patient embryos [ ]  Donor embryos (donated from another patient’s IVF cycle) [ ]  FRESH embryos [ ]  FROZEN embryos |
| 10A | **Intended oocyte source and state for FRESH embryos (select all that apply)**  [ ]  PATIENT oocytes [ ]  PATIENT frozen oocytes  [ ]  DONOR fresh oocytes [ ]  DONOR frozen oocytes **Intended oocyte source and state for FROZEN embryos (select all that apply)**  [ ]  PATIENT fresh oocytes [ ]  PATIENT frozen oocytes  [ ]  DONOR fresh oocytes [ ]  DONOR frozen oocytes [ ]  DONOR Unknown (select only if oocyte source is unknown) |
| 11 | **Intended sperm source (select all that apply) [SKIP IF DONOR EMBRYO IS INTENDED SOURCE]**[ ]  Partner[ ]  Donor[ ]  Patient, if maleOr [ ]  Unknown (select only if all sperm sources unknown) |
| 12 | **Intended pregnancy carrier** [ ]  Patient [ ]  Gestational carrier [ ]  None (oocyte or embryo banking cycle only) |

**Burden Estimate**

No change to the burden estimate is requested.

**Effect of Proposed Changes on Currently Approved Instruments and Attachments**

Non-substantive change to question #9 of data collection instrument.

**Request for Approval**

OMB approval is requested, effective immediately.