

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	
	Intended type of ART (select all that apply) <input type="checkbox"/> IVF: Transcervical <input type="checkbox"/> GIFT: Gametes to tubes <input type="checkbox"/> ZIFT: Zygotes to tubes or TET: tubal embryo transfer Or <input type="checkbox"/> Oocyte or embryo banking
	[SKIP IF NOT A BANKING ONLY CYCLE] Banking type (select all that apply) <input type="checkbox"/> Embryo banking <input type="checkbox"/> Autologous oocyte banking <input type="checkbox"/> Donor oocyte banking
	Intended duration of oocyte banking (select all that apply) <input type="checkbox"/> Short term (<12 months) <input type="checkbox"/> Long term (≥12 months) banking for fertility preservation prior to gonadotoxic medical treatments <input type="checkbox"/> Long term (≥12 months) banking for other reasons
	Intended duration of embryo banking (select all that apply)

	<input type="checkbox"/> Short term (<12 months) <ul style="list-style-type: none"> <input type="checkbox"/> Delay of transfer to obtain genetic information <input type="checkbox"/> Delay of transfer for other reasons <input type="checkbox"/> Long term (≥12 months) banking for fertility preservation prior to gonadotoxic medical treatments <input type="checkbox"/> Long term (≥12 months) banking for other reasons <p>[IF BANKING ONLY, SKIP TO #11 AFTER #9 IS COMPLETED]</p>
10	Intended embryo source (select all that apply) <input type="checkbox"/> Patient embryos <input type="checkbox"/> Donor embryos (donated from another patient's IVF cycle) <ul style="list-style-type: none"> <input type="checkbox"/> FRESH embryos <input type="checkbox"/> FROZEN embryos
10A	Intended oocyte source and state for FRESH embryos (select all that apply) <input type="checkbox"/> PATIENT oocytes <input type="checkbox"/> PATIENT frozen oocytes <input type="checkbox"/> DONOR fresh oocytes <input type="checkbox"/> DONOR frozen oocytes <p>Intended oocyte source and state for FROZEN embryos (select all that apply)</p> <input type="checkbox"/> PATIENT fresh oocytes <input type="checkbox"/> PATIENT frozen oocytes <input type="checkbox"/> DONOR fresh oocytes <input type="checkbox"/> DONOR frozen oocytes <input type="checkbox"/> DONOR Unknown (select only if oocyte source is unknown)
11	Intended sperm source (select all that apply) [SKIP IF DONOR EMBRYO IS INTENDED SOURCE] <input type="checkbox"/> Partner <input type="checkbox"/> Donor <input type="checkbox"/> Patient, if male <p>Or</p> <input type="checkbox"/> Unknown (select only if <u>all</u> sperm sources unknown)
12	Intended pregnancy carrier <input type="checkbox"/> Patient <input type="checkbox"/> Gestational carrier <input type="checkbox"/> None (oocyte or embryo banking cycle only)

Proposed Question Format

INTENT	
	Intended type of ART (select all that apply) <input type="checkbox"/> IVF: Transcervical <input type="checkbox"/> GIFT: Gametes to tubes <input type="checkbox"/> ZIFT: Zygotes to tubes or TET: tubal embryo transfer <p>Or</p> <input type="checkbox"/> Oocyte or embryo banking
	[SKIP IF NOT A BANKING ONLY CYCLE] Banking type (select all that apply) <input type="checkbox"/> Embryo banking from autologous oocytes <input type="checkbox"/> Embryo banking from donor oocytes <input type="checkbox"/> Autologous oocyte banking <input type="checkbox"/> Donor oocyte banking
	Intended duration of oocyte banking (select all that apply) <input type="checkbox"/> Short term (<12 months) <input type="checkbox"/> Long term (≥12 months) banking for fertility preservation prior to gonadotoxic medical treatments <input type="checkbox"/> Long term (≥12 months) banking for other reasons
	Intended duration of embryo banking (select all that apply) <input type="checkbox"/> Short term (<12 months) <ul style="list-style-type: none"> <input type="checkbox"/> Delay of transfer to obtain genetic information <input type="checkbox"/> Delay of transfer for other reasons <input type="checkbox"/> Long term (≥12 months) banking for fertility preservation prior to gonadotoxic medical treatments <input type="checkbox"/> Long term (≥12 months) banking for other reasons

[IF BANKING ONLY, SKIP TO #11 AFTER #9 IS COMPLETED]	
10	<p>Intended embryo source (select all that apply)</p> <p><input type="checkbox"/> Patient embryos</p> <p><input type="checkbox"/> Donor embryos (donated from another patient's IVF cycle)</p> <p style="padding-left: 40px;"><input type="checkbox"/> FRESH embryos <input type="checkbox"/> FROZEN embryos</p>
10A	<p>Intended oocyte source and state for FRESH embryos (select all that apply)</p> <p><input type="checkbox"/> PATIENT oocytes <input type="checkbox"/> PATIENT frozen oocytes</p> <p><input type="checkbox"/> DONOR fresh oocytes <input type="checkbox"/> DONOR frozen oocytes</p> <p>Intended oocyte source and state for FROZEN embryos (select all that apply)</p> <p><input type="checkbox"/> PATIENT fresh oocytes <input type="checkbox"/> PATIENT frozen oocytes</p> <p><input type="checkbox"/> DONOR fresh oocytes <input type="checkbox"/> DONOR frozen oocytes <input type="checkbox"/> DONOR Unknown (select only if oocyte source is unknown)</p>
11	<p>Intended sperm source (select all that apply) [SKIP IF DONOR EMBRYO IS INTENDED SOURCE]</p> <p><input type="checkbox"/> Partner</p> <p><input type="checkbox"/> Donor</p> <p><input type="checkbox"/> Patient, if male</p> <p>Or</p> <p><input type="checkbox"/> Unknown (select only if <u>all</u> sperm sources unknown)</p>
12	<p>Intended pregnancy carrier</p> <p><input type="checkbox"/> Patient</p> <p><input type="checkbox"/> Gestational carrier</p> <p><input type="checkbox"/> None (oocyte or embryo banking cycle only)</p>

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.