

Change Request
September 16, 2015

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 rate 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, diagnosis of infertility, etc.

In July 2015, CDC obtained OMB approval to revise the ART information collection. The revision ICR contained a detailed list of variables that were to be added, dropped, modified, or left unchanged (Attachment C6) and screen shots of the information collection system (Attachment C1b). This list indicated the intent was to collect whether the embryo was fresh or frozen (see Attachment C6, item 16, page 9; item 21, page 13). However, this distinction was inadvertently omitted from the screen shot (Attachment C1b). It is included in the revised version of Attachment C1b_V2 (p.5), attached to this request.

The purpose of the change request is to explicitly incorporate these data elements into the approved screen shots, allowing for the most efficient capture of embryo source without additional time burden. This specification will eliminate the misclassification of cycle characteristics and therefore improve methods for calculating success rates and reduce information collection burden accordingly. Screenshots are attached with this change request application and show how we propose these new data elements be added (Attachment C1b_v2). This includes the addition of a response option (highlighted below) on the state of donor embryos as to fresh or frozen for both intended and actual use of embryo source to two existing questions. It also includes the addition of a new question asking if multiple oocyte sources (e.g. patient oocyte and donor oocyte) were used, and whether the youngest oocyte was from the patient or donor based on the date of birth.

Itemized Changes in NASS screens

The three changes requested are illustrated bellow. For the two existing questions, the additional data element has been highlighted.

Currently Approved:

10	Intended embryo source (select all that apply): <input type="checkbox"/> Patient embryos <input type="checkbox"/> Donor embryos [IF ONLY DONOR EMBRYOS SELECTED, SKIP TO #12]
10A	If intent is to use FRESH EMBRYOS, specify intended oocyte source. Select all that apply: <input type="checkbox"/> Patient oocytes <input type="checkbox"/> Fresh oocytes <input type="checkbox"/> Frozen oocytes <input type="checkbox"/> Donor oocytes <input type="checkbox"/> Fresh oocytes <input type="checkbox"/> Frozen oocytes

	<p>If intent is to use FROZEN EMBRYOS, specify intended oocyte source. Select all that apply:</p> <p><input type="checkbox"/> Patient oocytes</p> <p><input type="checkbox"/> Fresh oocytes <input type="checkbox"/> Frozen oocytes</p> <p><input type="checkbox"/> Donor oocytes</p> <p><input type="checkbox"/> Fresh oocytes <input type="checkbox"/> Frozen oocytes <input type="checkbox"/> Unknown (select only if oocyte source is unknown)</p>
--	---

Proposed:

10	<p>Intended embryo source (select all that apply): [IF ONLY DONOR EMBRYOS SELECTED, SKIP TO #12]</p> <p><input type="checkbox"/> Patient embryos</p> <p><input type="checkbox"/> Donor embryos</p> <p><input type="checkbox"/> Fresh embryos <input type="checkbox"/> Frozen embryos</p>
10A	<p>If intent is to use FRESH EMBRYOS, specify intended oocyte source. Select all that apply:</p> <p><input type="checkbox"/> Fresh patient oocytes <input type="checkbox"/> Frozen patient oocytes</p> <p><input type="checkbox"/> Fresh donor oocytes <input type="checkbox"/> Frozen donor oocytes</p> <p>If intent is to use FROZEN EMBRYOS, specify intended oocyte source. Select all that apply:</p> <p><input type="checkbox"/> Fresh patient oocytes <input type="checkbox"/> Frozen patient oocytes</p> <p><input type="checkbox"/> Fresh donor oocytes <input type="checkbox"/> Frozen donor oocytes <input type="checkbox"/> Unknown (select only if oocyte source is unknown)</p>

Currently Approved:

14	<p>Embryo source (select all that apply):</p> <p><input type="checkbox"/> Patient embryos</p> <p><input type="checkbox"/> Donor embryos [IF ONLY DONOR EMBRYOS SELECTED, SKIP TO #15]</p>
14A	<p>If FRESH EMBRYOS were used, specify intended oocyte source. Select all that apply:</p> <p><input type="checkbox"/> Patient oocytes</p> <p><input type="checkbox"/> Fresh oocytes <input type="checkbox"/> Frozen oocytes</p> <p><input type="checkbox"/> Donor oocytes</p> <p><input type="checkbox"/> Fresh oocytes <input type="checkbox"/> Frozen oocytes</p> <p>If FROZEN EMBRYOS were used, specify intended oocyte source. Select all that apply:</p> <p><input type="checkbox"/> Patient oocytes</p> <p><input type="checkbox"/> Fresh oocytes <input type="checkbox"/> Frozen oocytes</p> <p><input type="checkbox"/> Donor oocytes</p> <p><input type="checkbox"/> Fresh oocytes <input type="checkbox"/> Frozen oocytes <input type="checkbox"/> Unknown (select only if oocyte source is unknown)</p>

Proposed:

14	<p>Embryo source (select all that apply): [IF ONLY DONOR EMBRYOS SELECTED, SKIP TO #15]</p> <p><input type="checkbox"/> Patient embryos</p> <p><input type="checkbox"/> Donor embryos</p> <p><input type="checkbox"/> Fresh embryos <input type="checkbox"/> Frozen embryos</p>
14A	<p>If FRESH EMBRYOS were used, specify intended oocyte source. Select all that apply:</p> <p><input type="checkbox"/> Fresh patient oocytes <input type="checkbox"/> Frozen patient oocytes</p> <p><input type="checkbox"/> Fresh donor oocytes <input type="checkbox"/> Frozen donor oocytes</p> <p>If FROZEN EMBRYOS were used, specify intended oocyte source. Select all that apply:</p>

	<input type="checkbox"/> Fresh patient oocytes <input type="checkbox"/> Frozen patient oocytes <input type="checkbox"/> Fresh donor oocytes <input type="checkbox"/> Frozen donor oocytes <input type="checkbox"/> Unknown (select only if oocyte source is unknown)
--	---

Additional question:

	<p>[IF OOCYTE SOURCE = PATIENT AND DONOR, ANSWER THIS QUESTION]</p> <p>Youngest oocyte source</p> <input type="checkbox"/> Patient [SKIP TO Q25] <input type="checkbox"/> Donor [CONTINUE TO Q24B]
--	---

24A

A revised version of Attachment C1b_v2 (Proposed) Future NASS screens for 2016 is attached to the Change Request.

There is no change to the estimated burden per response, however, the improved formatting collects accurate information and effectively reduces the number of response boxes to check. CDC plans to begin administering the revised instruments in 2016. OMB approval is requested, effective immediately.