# Change Request

August 1, 2016

**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.

CDC obtained the current approval to revise the ART information collection in July 2015. The revision ICR contained a detailed list of variables that were to be added, dropped, modified, or left unchanged ("Att. C6 Detailed List of NASS changes", from the July 2015 approval). Screen shots of the information collection system, with slight modifications were approved through the change mechanism in October 2015 ("Att. C1b\_v2 Future NASS screens for 2016", from the approved change).

CDC is now requesting to add one additional response for stimulation protocol, commonly known as "minimal stimulation IVF cycle", to reflect the current ART practices. The purpose of this change is to explicitly incorporate this data element into the approved screen shots to better identify the efficacy of using lower doses of oral medication for IVF cycles and the associated treatment outcomes (e.g. reducing risks for ovarian hyperstimulation and multiple gestations). The proposed response option change is illustrated below.

## Proposed changes in NASS screens:

## **Currently Approved:**

	OVARIAN STIMULATION AND MEDICATIONS
35	Was there stimulation for follicular development?
	⊖Yes ⊖ No
	[IF NO STIMULATION OR FROZEN CYCLE, SKIP #36-39]

#### Proposed:

	OVARIAN STIMULATION AND MEDICATIONS
35A	Was there stimulation for follicular development? [IF NO STIMULATION OR FROZEN CYCLE, SKIP #36-39]
	Was this a minimal stimulation cycle?
35B	
	⊖Yes ⊖ No

The proposed data element will allow for the most efficient capture of stimulation protocol without additional time burden. There is no change to the estimated burden per response. Screenshots are attached with this change request application and show how we propose this new data element be added ("Att. C1b\_v3 (Proposed) Future NASS screens for 2017").

CDC plans to begin administering the revised instruments in 2017. OMB approval is requested, effective immediately.