



# REQUEST FOR DETERMINATION OF RESEARCH STATUS

To be completed by the staff member with lead responsibility for the project and approved by branch chief (if applicable) and Division ADS. A separate PGO funding memo is required if project is research and involves human subjects regardless of the CDC staff role.

- Instructions:**
- (1) Use this form to declare: (a) the research status of any project, (b) role or roles of CDC staff
  - (2) A short summary should be attached offering specific details about the project and the role of staff.
  - (3) Be sure to complete all applicable items, obtain appropriate signatures and submit this form for approval.

**Tracking Number:** TBD  
 (Use PGO number if cooperative agreement, grant, etc.)

**Date submitted:** 03/07/2016  
**Title of Project:** Assisted Reproductive Technology (ART) Data Collection  
**Dates for project period:** **Dates for funding (if applicable):**  
**Beginning:** 10/15/2016 **Beginning:** \_\_\_\_\_  
**Ending:** 12/31/2020 **Ending:** \_\_\_\_\_

**Project is (choose one):**  
*NOTE: Revision, as used below, refers to any substantive change made to the project including scope of project, funding restrictions, personnel, role of CDC staff member, determination of research status, etc.*  
 **New**  **Revision**  
 **Continuation, without revision(s)**  **Continuation, with revision(s)**

<b>Lead staff member:</b>	<b>Contact information:</b>	<b>Please indicate your role(s) in this project:</b>	
<b>Name:</b> <u>Dmitry Kissin</u>	<b>Division:</b> <u>DRH</u>	<input checked="" type="checkbox"/> <b>Project officer</b>	<input type="checkbox"/> <b>Technical monitor</b>
<b>User ID:</b> <u>DTK3</u>	<b>Telephone:</b> <u>770-488-6408</u>	<input type="checkbox"/> <b>Principal investigator</b>	<input type="checkbox"/> <b>Investigator</b>
<b>Scientific Ethics number:</b> <u>2043</u>	<b>Mailstop:</b> <u>F74</u>	<input type="checkbox"/> <b>Consultant</b>	<input type="checkbox"/> <b>Other (please explain)</b>

1. Are any or all of the activities within this project DESIGNED to contribute to generalizable knowledge (i.e., research)?  
 **YES**  **NO**  
**If YES, list those activities which are research:**  
 \_\_\_\_\_
2. **Is this CDC project research or public health practice (check all that apply)?**  
 **Research**  **Public health practice**  
**Check one:** **Check all that apply:**  
 **Human subjects involved**  **Emergency Response**  **Surveillance**  
 **Human subjects not involved**  **Program evaluation**  **Other (please explain)**  
 \_\_\_\_\_
3. **If RESEARCH involving human subjects, has the project or research activities been reviewed by the CDC IRB for human subjects protection?**  
 a.  **NO, New project, not yet reviewed** d.  **YES, Reviewed and approved by CDC**  
 b.  **NO, Existing project, not ready to submit** **If YES, please list protocol number and expiration date** \_\_\_\_\_  
 c.  **NO, Submitted for approval**  
 e.  **NO, RESEARCH, no CDC investigators (CDC IRB not required)**  
 f.  **N/A (Not Applicable)**

**If RESEARCH, list any other CDC staff involved in this project, please include the name, role, and scientific ethics number**

Name	Role (project officer, investigator, consultant, etc.)	Scientific ethics number Prin
Dmitry Kissin		2043

**IF YOU THINK THE RESEARCH PROJECT MIGHT QUALIFY AS EXEMPT RESEARCH (as identified in 45CFR46.101), PLEASE ANSWER questions 4-6, OTHERWISE SKIP TO question 7.**

4. Does the proposed research involve prisoners?  
 YES If YES, this research cannot be exempted and must be reviewed by an IRB (skip to question 7).  
 NO
5. Does the proposed research involve fetuses, pregnant women, or human in vitro fertilization as targets (such that Subpart B would apply)?  
 YES If YES, this research cannot be exempted and must be reviewed by an IRB (skip to question 7).  
 NO

### Educational Research

- 6.1 Is this research conducted in established or commonly accepted educational settings, AND does the research involve normal educational practices (e.g., research on regular and special education strategies or research on the effectiveness of, or comparison among instructional techniques, curricula or classroom management methods)?  
 YES  NO

### Research Involving Surveys, Interview Procedures (including Focus groups), Observation of Public Behavior, or Educational Tests

- 6.2 Will this research use educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior?  
 YES  NO If NO skip 6.3

Will children (<18 years of age) be research subjects?

- YES If YES, this research cannot be exempted and must be reviewed by an IRB (skip to item 7)  
 NO

- 6.2.1 Is the information obtained recorded in such a manner that human subjects can be identified directly or indirectly through identifiers (such as a code) linked to the subjects;  
 YES  NO

- 6.2.2 Will any disclosure of the human subjects' responses outside of the research setting have the potential to place the subjects at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability or reputation? (Examples here may include: the collection of sensitive data regarding the subjects' (or relatives' or associates') possible substance abuse, sexuality, criminal history or intent, medical or psychological condition, financial status, or similarly compromising information).  
 YES  NO

- 6.3 Will this research use educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior but the research is not exempt under paragraph 6.2 of this section:

YES  NO If NO skip to 6.4

- 6.3.1 Will this research involve human subjects that are elected or appointed public officials or candidates for public office?

YES  NO

- 6.3.2 Does federal statute(s) require(s) without exception that confidentiality of the personally identifiable information will be maintained throughout the research and thereafter? (Note: CDC can use this exemption criterion only in the case where a 308(d) Assurance of Confidentiality has been obtained to cover the research).

YES  NO

### Existing Data Which Is Publicly Available or Unidentifiable

- 6.4 Does this research involve only the collection or study of existing\* data, documents, records, pathological or diagnostic specimens? (\* 'existing' means existing before the study begins)?

YES  NO If NO skip to 7

- 6.4.1 Is this material or information publicly available?

YES  NO

6.4.2 Is this material or information recorded in such a manner by the investigator that the subjects cannot be identified directly or indirectly through identifiers linked to the subjects?

(Note: If a link is created by an investigator even temporarily, for research purposes, this criterion is not met. If a temporary link is created by clinical staff who already have access to the data, this criterion is met).

- YES (there are no identifying information and no unique identifiers or codes) YES  
 NO (there are identifiers (including codes))

7. Please prepare and attach a short summary paragraph (<1 page); if this is new:

- a. Be sure to include the purpose of the project, specific details about the project and the role of the CDC staff member (s) in the project. In explaining one's role as a consultant be particularly careful to identify involvement in things like: study design decisions, oversight of protocol development, participation in review of data collection procedures, and participation in data analysis and/or manuscript preparation, as well as whether there will be access to identifiable or personal data.
- b. Explain your project status selection (research--non-exempt, exempt, no CDC investigator or not involving human subjects; public health practice). If you selected research not involving human subjects be sure to indicate if the data includes any personal information (e.g., name, SSN), linkable study identification numbers or codes, or geographical information.

The purpose of this project is to comply with the Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA), Section 2(a) of P.L. 102-493(42 U.S.C. 263(a)-1) which mandates that all assisted reproductive technology (ART) clinics in the U.S. report annual success rate data to the Secretary of Health and Human Services through the CDC in a standardized fashion. Annual clinic and cycle specific data from all practicing ART clinics in the U.S. will be collected via the National ART Surveillance System (NASS) and used by CDC to produce annual surveillance reports of pregnancy success rates for the public, as required in the FCSRCA.

CDC first implemented the FCSRCA in 1997 and has obtained and published data for ART procedures through contracts with the Society for Assisted Reproductive Technology (SART) and Westat. The current contract with Westat expires on 12/31/17, with 2016 being the last reporting year covered by an existing contract. In order to ensure a seamless transition of responsibilities such that NASS is fully functional to receive data on a daily basis, a new contract needs to be in place by October 15, 2016.

Under the new contract, CDC staff members will be responsible for overseeing clinic tracking, data collection, quality assurance, and data validation processes for all ART procedures performed in a single calendar year. CDC staff members will also be responsible for overseeing production of annual surveillance reports using this data.

This project has been categorized as public health practice/surveillance because, as a national surveillance system, the primary intent of the NASS is to collect information on pregnancy success rates resulting from ART procedures performed in the U.S. and its territories. The intended benefits of this surveillance system are to provide patients, providers, and policy makers with standardized information on fertility clinic pregnancy success rates to better inform ART decision-making.

8. Please list the primary project site and all collaborating site(s).

Explanation of project components:

9. If project involves research that is funded extramurally, list amount of award that should be restricted pending IRB approval and describe which project components will be affected, if known:

Approvals (signature and position title)	Date	Research Determination / Remarks
Linda Hannon-hall - PUBLIC HEALTH ADVISOR	03/07/2016	<input checked="" type="checkbox"/> Public health practice <input type="checkbox"/> Research not involving human subjects <input type="checkbox"/> Research involving human subjects, no CDC investigators <input type="checkbox"/> Research involving human subjects, CDC investigators, exempt <input type="checkbox"/> Research involving human subjects, CDC investigators, not exempt  (check if applicable) <input type="checkbox"/> Local IRB <input type="checkbox"/> CDC Exemption <input type="checkbox"/> CDC IRB  <u>Comments:</u> Reviewed and approve
staff member completing this form		

Linda Hannon-hall - PUBLIC HEALTH ADVISOR          Team Lead	03/08/2016	<input checked="" type="checkbox"/> Public health practice <input type="checkbox"/> Research not involving human subjects <input type="checkbox"/> Research involving human subjects, no CDC investigators <input type="checkbox"/> Research involving human subjects, CDC investigators, exempt <input type="checkbox"/> Research involving human subjects, CDC investigators, not exempt  (check if applicable) <input type="checkbox"/> Local IRB <input type="checkbox"/> CDC Exemption <input type="checkbox"/> CDC IRB  <u>Comments:</u> Approved
Karen Pazol - Deputy ADS          Division ADS	03/08/2016	<input checked="" type="checkbox"/> Public health practice <input type="checkbox"/> Research not involving human subjects <input type="checkbox"/> Research involving human subjects, no CDC investigators <input type="checkbox"/> Research involving human subjects, CDC investigators, exempt <input type="checkbox"/> Research involving human subjects, CDC investigators, not exempt  (check if applicable) <input type="checkbox"/> Local IRB <input type="checkbox"/> CDC Exemption <input type="checkbox"/> CDC IRB  <u>Comments:</u>
Joan Redmond Leonard - PUBLIC HEALTH ANALYST          CUC ADS, Deputy ADS, or Human Subjects Contact	03/11/2016	<input checked="" type="checkbox"/> Public health practice <input type="checkbox"/> Research not involving human subjects <input type="checkbox"/> Research involving human subjects, no CDC investigators <input type="checkbox"/> Research involving human subjects, CDC investigators, exempt <input type="checkbox"/> Research involving human subjects, CDC investigators, not exempt  (check if applicable) <input type="checkbox"/> Local IRB <input type="checkbox"/> CDC Exemption <input type="checkbox"/> CDC IRB  <u>Comments:</u>