



# 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:** To Be Determined  
 (Use PGO number if cooperative agreement, grant, etc.)

**Date submitted:** 09/30/2014  
**Title of Project:** DD15-1506: Surveillance of Congenital Heart Defects Focusing on Adolescents and Adults  
**Dates for project period:** **Dates for funding (if applicable):**  
**Beginning:** 09/01/2015 **Beginning:** 09/01/2015  
**Ending:** 08/31/2019 **Ending:** 08/31/2016

**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>Pamela Costa</u>	<b>Division:</b> <u>DBDDD</u>	<input checked="" type="checkbox"/> <b>Project officer</b>	<input type="checkbox"/> <b>Technical monitor</b>
<b>User ID:</b> <u>PIC9</u>	<b>Telephone:</b> <u>404-498-3488</u>	<input type="checkbox"/> <b>Principal investigator</b>	<input type="checkbox"/> <b>Investigator</b>
<b>Scientific Ethics number:</b> <u>13674</u>	<b>Mailstop:</b> <u>E86</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)?

- |   |  |
|---|--|
| <input type="checkbox"/> <b>Research</b>                    | <input checked="" type="checkbox"/> <b>Public health practice</b>  |
| <i>Check one:</i>   | <i>Check all that apply:</i>   |
| <input type="checkbox"/> <b>Human subjects involved</b>     | <input type="checkbox"/> <b>Emergency Response</b> <input checked="" type="checkbox"/> <b>Surveillance</b> |
| <input type="checkbox"/> <b>Human subjects not involved</b> | <input type="checkbox"/> <b>Program evaluation</b> <input type="checkbox"/> <b>Other (please explain)</b>  |

3. If RESEARCH involving human subjects, has the project or research activities been reviewed by the CDC IRB for human subjects protection?

- |  |  |
|--|--|
| a. <input type="checkbox"/> <b>NO, New project, not yet reviewed</b>         | d. <input type="checkbox"/> <b>YES, Reviewed and approved by CDC</b>                         |
| b. <input type="checkbox"/> <b>NO, Existing project, not ready to submit</b> | <b>If YES, please list protocol number and expiration date</b>                               |
| c. <input type="checkbox"/> <b>NO, Submitted for approval</b>                | e. <input type="checkbox"/> <b>NO, RESEARCH, no CDC investigators (CDC IRB not required)</b> |
|  | f. <input type="checkbox"/> <b>N/A (Not Applicable)</b>                                      |

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

## Tracking NO. To Be Determined

Name	Role (project officer, investigator, consultant, etc.)	Scientific ethics number Prin
Pamela Costa		13674

**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

**Tracking NO. To Be Determined**

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.

This new, competitive FOA will expand the National Center on Birth Defects and Developmental Disabilities' programs conducting birth defects surveillance with a focus on congenital heart defects (CHDs) among individuals of all ages.

The National Center on Birth Defects and Developmental Disabilities (NCBDDD), Division of Birth Defects and Developmental Disabilities (DBDDD) seeks to fund collaborative projects to:

1) Build on existing infrastructure for population-based CHD surveillance among adolescents and adults to (i) conduct longitudinal follow up of adolescents and adults identified with CHDs, (ii) identify factors associated with optimal healthcare and improved outcomes, (iii) evaluate factors that impede appropriate transition of care, and (iv) develop pilot projects to translate best practices into action (Category A); and

2) Develop and implement innovative approaches for conducting population-based surveillance of structural, congenital heart defects (CHDs) by linking existing data sources across the lifespan (children, adolescents, and adults) in sites not funded under FOA #DD12-1207; surveillance data will be used to examine healthcare utilization and referral to timely and appropriate services (Category B).

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
William Paradies - PUBLIC HEALTH ANALYST  staff member completing this form	09/30/2014	<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>

Margaret Honein - BRANCH CHIEF          Team Lead	09/30/2014	<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
Jon Baio - BEHAVIORAL SCIENTIST          Division ADS	10/02/2014	<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>
Scott Campbell - Health Scientist          CUB ADS, Deputy ADS, or Human Subjects Contact	10/02/2014	<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>