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: 12/05/2012

Title of Project: Sudden Death in the Young Registry

Dates for project period:

Beginning: 04/01/2013

Ending: 12/31/2018

Dates for funding (if applicable):

Beginning:

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.

[X] **New** [ ] **Revision**

[ ] **Continuation, without revision(s)** **[ ] Continuation, with revision(s)**

Lead staff member:

Name: Lena Camperlengo

User ID: GTX6

Scientific Ethics number:

Contact information:

Division: DRH

Telephone: 770-488-6322

Mailstop: K23

Please indicate your role(s) in this project:

[X] **Project officer** [ ] **Technical monitor**

[ ] **Principal investigator** [ ] **Investigator**

[X] **Consultant** [ ] **Other (please explain)**

1. Are any or all of the activities within this project DESIGNED to contribute to generalizable knowledge (i.e., research)?

[ ] **YES** [X] **NO**

If YES, list those activities which are research:

2. Is this CDC project research or public health practice (check all that apply)?

[ ] **Research**

Check one:

[ ] **Human subjects involved**

[ ] **Human subjects not involved**

[X] **Public health practice**

Check all that apply:

[ ] **Emergency Response** [X] **Surveillance**

[ ] **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**

b. [ ] **NO, Existing project, not ready to submit**

c. [ ] **NO, Submitted for approval**

d. [ ] **YES, Reviewed and approved by CDC**

If YES, please list protocol number and expiration date

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
Lena Camperlengo		

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 instrucational 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 particpation 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.

a. The purpose of the Sudden Death in the Young (SDY) Registry is to monitor trends in SDY.

The SDY Registry has four objectives:
•Develop a surveillance system to comprehensively identify Sudden Cardiac Death in the Young and Sudden Unexpected Death in Epilepsy cases for individuals up to 24 years of age;
•Create a registry of clinical information about cases;
•Collect and store biospecimens from registry cases; and
•Establish a resource that will be used by the National Institutes of Health National Heart, Lung and Blood Institute- (NHLBI) and National Institute of Neurological Disorders and Stroke (NINDS) funded researchers to investigate Sudden Cardiac Death in the Young and Sudden Unexpected Death in Epilepsy.

NHLBI and NINDS will work with the CDC via an Interagency Agreement and an Inter-Departmental Delegation of Authority to develop a prospective, population-based SDY registry that builds upon the CDC's Sudden Unexpected Infant Death (SUID) Case Registry. By collaborating with CDC's SUID Case Registry, the SDY registry can maximize resources for surveillance. All infant deaths ascertained in the SUID Case Registry would be potential SDY cases. This registry will result in the first prospective, population-based data system compiled for the comprehensive evaluation of Sudden Cardiac Death in the Young and Sudden Unexpected Death in Epilepsy in the United States. The SDY Registry will include data from death certificates, medical records, death scene investigations, and pathology reports. In addition, a serum sample for DNA extraction will be collected from a subset of cases. It will provide the opportunity to estimate incidence more precisely than any previous study and to establish an infrastructure for future expanded use.

The biologic specimen repository sub-contractor for the SDY Registry shall be in compliance with all federal and State requirements and current best practices for the collection, storage, retrieval and distribution of biological material for scientific research. The sub-contractor shall follow current best practices and the NHLBI Biologic Specimen and Data Repository Operational Guidelines for acquiring and distributing biospecimens.
The primary purpose of this project is public health surveillance. The data collection activities will be done through a contracted data coordinating center.
b. Project status selection: Research, not involving human subjects as all cases are deceased.
c. CDC staff will not be engaged in research. CDC will provide technical assistance, receive de-identified data for quality assurance activities and surveillance reports. CDC will co-author manuscripts, but will be first author on any manuscript describing major findings.

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
Carrie Shapiro-Mendoza - Health Scientist staff member completing this form	12/05/2012	[X] Public health practice [X] Research not involving human subjects [ ] Research involving human subjects, no CDC investigators [ ] Research involving human subjects, CDC investigators, exempt [ ] Research involving human subjects, CDC investigators, not exempt (check if applicable) [ ] Local IRB [ ] CDC Exemption [ ] CDC IRB Comments:
Jennifer Legardy-Williams - 05/ASSOCIATE SERVICE FELLOW Division ADS	12/14/2012	[ ] Public health practice [X] Research not involving human subjects [ ] Research involving human subjects, no CDC investigators [ ] Research involving human subjects, CDC investigators, exempt [ ] Research involving human subjects, CDC investigators, not exempt (check if applicable) [ ] Local IRB [ ] CDC Exemption [ ] CDC IRB Comments:
Joan Redmond Leonard - PUBLIC HEALTH ANALYST CUC ADS, Deputy ADS, or Human Subjects Contact	02/12/2013	[X] Public health practice [ ] Research not involving human subjects [ ] Research involving human subjects, no CDC investigators [ ] Research involving human subjects, CDC investigators, exempt [ ] Research involving human subjects, CDC investigators, not exempt (check if applicable) [ ] Local IRB [ ] CDC Exemption [ ] CDC IRB Comments: