



# 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:** DP08-801  
(Use PGO number if cooperative agreement, grant, etc.)

**Date submitted:** 12/29/2010

**Title of Project:** Indicators of the performance of local, state, territorial, and tribal education agencies in HIV prevention, coordinated school health programs, and asthma management activities for adolescent and school health programs.

|                                     |   |
|-------------------------------------|---|
| <b>Dates for project period:</b>    | <b>Dates for funding (if applicable):</b> |
| <b>Beginning:</b> <u>06/01/2011</u> | <b>Beginning:</b> _____                   |
| <b>Ending:</b> <u>05/31/2014</u>    | <b>Ending:</b> _____                      |

**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.*

- |   |  |
|---|--|
| <input checked="" type="checkbox"/> <b>New</b>                    | <input type="checkbox"/> <b>Revision</b>                       |
| <input type="checkbox"/> <b>Continuation, without revision(s)</b> | <input type="checkbox"/> <b>Continuation, with revision(s)</b> |

|  |                                       |   |
|--|---------------------------------------|---|
| <b>Lead staff member:</b>                    | <b>Contact information:</b>           | <b>Please indicate your role(s) in this project:</b>              |
| <b>Name:</b> <u>Catherine Rasberry</u>       | <b>Division:</b> <u>DASH</u>          | <input type="checkbox"/> <b>Project officer</b>                   |
| <b>User ID:</b> <u>FHH6</u>                  | <b>Telephone:</b> <u>770-488-5635</u> | <input type="checkbox"/> <b>Technical monitor</b>                 |
| <b>Scientific Ethics number:</b> <u>9625</u> | <b>Mailstop:</b> <u>K33</u>           | <input type="checkbox"/> <b>Principal investigator</b>            |
|  |                                       | <input type="checkbox"/> <b>Investigator</b>                      |
|  |                                       | <input type="checkbox"/> <b>Consultant</b>                        |
|  |                                       | <input checked="" type="checkbox"/> <b>Other (please explain)</b> |
|  |                                       | <u>Oversees data analysis.</u>                                    |

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 type="checkbox"/> <b>Human subjects <u>not</u> involved</b> | <input type="checkbox"/> <b>Surveillance</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

|             |   |                                 |
|-------------|---|---------------------------------|
| <b>Name</b> | <b>Role (project officer, investigator, consultant, etc.)</b> | <b>Scientific ethics number</b> |
|             |   |                                 |

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 to 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)  
 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 assess programmatic activities among local, state, territorial, and tribal education agencies (LEA, SEA, TEA, and TG) funded by the Centers for Disease Control and Prevention (CDC), Division of Adolescent and School Health (DASH) through funding announcement DP08-801. The Indicators for School Health Programs (Indicators) are a set of four questionnaires that are used to provide basic process evaluation data on HIV prevention activities, coordinated school health program for physical activity, nutrition, and tobacco-use prevention (CSHP/PANT) activities, and asthma management activities conducted under FOA DP08-801. The CDC staff members involved in the project will provide assistance in the analysis and reporting of the data.

The Indicators provide basic program evaluation data on the activities of DASH-funded partners as part of routine public health practice. The data (basic process evaluation data) describe activities such as the types of materials distributed, the number of professional development events held, and the topics of technical assistance provided. All data collected are representative of education agency activities. No information is collected about individuals; no personal data are collected.

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  |
|--|------------|---|
| Catherine Rasberry - HEALTH SCIENTIST<br><br><br><br><br><br><br><br>staff member completing this form | 12/29/2010 | <input checked="" type="checkbox"/> Public health practice<br><input type="checkbox"/> Research not involving human subjects<br><input type="checkbox"/> Research involving human subjects, no CDC investigators<br><input type="checkbox"/> Research involving human subjects, CDC investigators, exempt<br><input type="checkbox"/> Research involving human subjects, CDC investigators, not exempt<br><br>(check if applicable)<br><input type="checkbox"/> Local IRB<br><input type="checkbox"/> CDC Exemption<br><input type="checkbox"/> CDC IRB<br><u>Comments:</u> |
| Stephen Banspach - ASSOCIATE DIRECTOR FOR SCIENCE<br><br><br><br><br><br><br><br>Team Lead             | 12/29/2010 | <input checked="" type="checkbox"/> Public health practice<br><input type="checkbox"/> Research not involving human subjects<br><input type="checkbox"/> Research involving human subjects, no CDC investigators<br><input type="checkbox"/> Research involving human subjects, CDC investigators, exempt<br><input type="checkbox"/> Research involving human subjects, CDC investigators, not exempt<br><br>(check if applicable)<br><input type="checkbox"/> Local IRB<br><input type="checkbox"/> CDC Exemption<br><input type="checkbox"/> CDC IRB<br><u>Comments:</u> |

|  |                   |  |
|--|-------------------|--|
| <p>Stephen Banspach - ASSOCIATE<br/>DIRECTOR FOR SCIENCE</p><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br>Division ADS                             | <p>12/29/2010</p> | <p><input checked="" type="checkbox"/> Public health practice<br/> <input type="checkbox"/> Research not involving human subjects<br/> <input type="checkbox"/> Research involving human subjects, no CDC investigators<br/> <input type="checkbox"/> Research involving human subjects, CDC investigators, exempt<br/> <input type="checkbox"/> Research involving human subjects, CDC investigators, not exempt</p> <p>(check if applicable)<br/> <input type="checkbox"/> Local IRB<br/> <input type="checkbox"/> CDC Exemption<br/> <input type="checkbox"/> CDC IRB</p> <p><u>Comments:</u></p> |
| <p>Joan Redmond Leonard - PUBLIC<br/>HEALTH ANALYST</p><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br><br>ADS, Deputy ADS, or Human Subjects<br>Contact | <p>01/22/2011</p> | <p><input checked="" type="checkbox"/> Public health practice<br/> <input type="checkbox"/> Research not involving human subjects<br/> <input type="checkbox"/> Research involving human subjects, no CDC investigators<br/> <input type="checkbox"/> Research involving human subjects, CDC investigators, exempt<br/> <input type="checkbox"/> Research involving human subjects, CDC investigators, not exempt</p> <p>(check if applicable)<br/> <input type="checkbox"/> Local IRB<br/> <input type="checkbox"/> CDC Exemption<br/> <input type="checkbox"/> CDC IRB</p> <p><u>Comments:</u></p> |

## List of Grantees

| <u>Grantee #</u> | <u>Grantee Name</u>                                       |
|------------------|---|
| 1189             | Tennessee Department Of Education                         |
| 1214             | Texas Education Agency                                    |
| 1187             | Utah State Department of Health                           |
| 1262             | Vermont Department Of Education                           |
| 1199             | Virginia Department Of Education                          |
| 1216             | Virginia Department of Health                             |
| 1264             | Washington Office Of Superintendent Of Public Instruction |
| 1218             | West Virginia Department Of Education                     |
| 1231             | Winnebago Tribe of Nebraska                               |
| 1204             | Wisconsin Department Of Public Instruction                |
| 1236             | Wyoming Department Of Education                           |
| 1226             | Alabama Department Of Education                           |
| 1210             | Alaska Department Of Education and Early Development      |
| 1221             | Albuquerque Public Schools                                |
| 1309             | American Samoa Department of Education                    |
| 1246             | Arizona Department Of Education                           |
| 1181             | Arkansas Department Of Education                          |
| 1258             | Baltimore City Public School System                       |
| 1271             | Boston Public Schools                                     |
| 1180             | California Department Of Education                        |
| 1233             | Charlotte-Meckleburg Schools                              |
| 1208             | Cherokee Nation Health Service Group                      |
| 1234             | Chicago Public Schools                                    |
| 1205             | Clark County School District                              |
| 1232             | Colorado Department Of Education                          |
| 1186             | Common Wealth of the Northern Marianas Islands            |
| 1229             | Confederated Salish & Kootenai Tribes                     |
| 1193             | Connecticut State Department of Education                 |
| 1254             | Dallas Independent School District                        |
| 1255             | Delaware Department of Education                          |
| 1206             | District of Columbia Department of Education              |
| 1265             | Duval County Public Schools                               |
| 1239             | Florida Department Of Education                           |
| 1241             | Fresno Unified School District                            |
| 1307             | Georgia Department Of Community Health.                   |
| 1270             | Georgia Department Of Education                           |
| 1185             | Guam Public School System                                 |
| 1203             | Hawaii Department of Education                            |
| 1224             | Hillsborough County Public Schools                        |
| 1179             | Houston Independent School District                       |
| 1269             | Idaho Department Of Education                             |
| 1220             | Illinois State Board Of Education                         |
| 1178             | Indiana Department Of Education                           |
| 1192             | Iowa Department Of Education                              |
| 1188             | Kansas State Department Of Education                      |
| 1195             | Kentucky Department of Education                          |
| 1201             | Los Angeles Unified School District                       |
| 1243             | Louisiana Department Of Education                         |
| 1209             | Louisiana Department Of Education                         |
| 1253             | Maine Department of Education                             |
| 1202             | Maryland State Department Of Education                    |
| 1251             | Massachusetts Department Of Education                     |
| 1215             | Memphis City Schools                                      |
| 1213             | Michigan Department Of Education                          |
| 1196             | Milwaukee Public Schools                                  |
| 1256             | Minnesota Dept of Education                               |
| 1237             | Mississippi Department Of Education                       |
| 1252             | Missouri Department Of Elementary And Secondary Education |
| 1230             | Montana Office Of Public Instruction                      |
| 1225             | Native Village of Kotzebue                                |
| 1260             | Nebraska Department Of Education                          |

1227 Nevada Department Of Education  
1217 New Hampshire Department Of Education  
1263 New Jersey Department of Education  
1190 New Mexico Public Education Department  
1200 New York City Department Of Education  
1194 New York State Department of Education  
1240 Newark Public Schools  
1238 Nez Perce Tribe  
1259 NORTH CAROLINA DEPARTMENT OF PUBLIC INSTRUCTION  
1235 North Dakota Department of Public Instruction  
1250 Ohio Department of Education  
1197 Oklahoma State Department Of Education  
1212 Oneida Tribe of Indians of Wisconsin  
1191 Orange County Public Schools  
1228 Oregon Department Of Education  
1207 Pennsylvania Department of Education  
1248 Public Health Institute  
1303 Puerto Rico Department Of Education  
1245 Republic Of Palau Ministry Of Education  
1392 Republic of the Marshall Islands  
1261 Rhode Island Department of Elementary & Secondary Education  
1211 San Bernardino City Unified School District  
1182 San Diego Unified School District  
1177 San Francisco Unified School District  
1223 School Board of Broward County, Florida  
1198 School board of Miami-Dade County, Florida  
1249 School Board of Palm Beach County  
1242 School District Of Philadelphia  
1222 School District of the City of Detroit  
111222 School District of the City of Detroit  
1257 Seattle Public Schools  
1244 South Carolina Department Of Education  
1247 South Dakota Department Of Education  
1219 State Of Ohio Department Of Health