



# 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: 200-2007-20015/2007-C-009  
 (Use PGO number if cooperative agreement, grant, etc.)

Date submitted: 05/05/2010

Title of Project: Development and Marketing of Youth Eagle Books

Dates for project period:

Beginning: 08/28/2007

Ending: 08/24/2012

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.

New

Revision

Continuation, without revision(s)

Continuation, with revision(s)

Lead staff member:

Name: LEMIRA DEBRUYN

User ID: LDD5

Scientific Ethics number: 8172

Contact information:

Division: DDT

Telephone: 505-232-9906

Mailstop: \_\_\_\_\_

Please indicate your role(s) in this project:

Project officer  Technical monitor

Principal investigator  Investigator

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  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:

Human subjects involved

Human subjects not involved

Check all that apply:

Emergency Response

Program evaluation

Surveillance

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

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 program evaluation is to gather qualitative data through focus groups and individual interviews about 1) the use and impact of the original Eagle Books for grade school children in communities that also use the Diabetes Education in Tribal Schools curriculum (the DETS curriculum K-4 lessons incorporate Eagle Book messages) and 2) determine the potential for integration into the DETS school curriculum the newly developed Youth Eagle books for middle school children that will be completed by 2012. CDC staff will oversee and participate in gathering qualitative data in 12 American Indian/Alaska Native communities over 3 years who have used the Eagle Books and the DETS curriculum. Westat staff and contract evaluator will complete the evaluation team. Focus groups will be conducted with teachers, parents, and children who have familiarity with the Eagle Books and the DETS curriculum. Interviews will be conducted with school administrators. Data will be aggregated with no identifiers and will be used to disseminate Eagle Books to appropriate audiences with messages gained from data gathered.

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

See Attached

Explanation of project components:

The remaining 12 sites represent school districts that will provide the data for the evaluation effort. All are using the Diabetes Education in Tribal Schools (DETS) curriculum and all have used the Eagle Books. The messages of the new Eagle Books for middle school children will be tested at these sites in conjunction with questions about the DETS curriculum and the original Eagle Books.

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
LEMYRA DEBRUYN - DIRECTOR REGULATORY  staff member completing this form	05/13/2010	<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> Bob, please look at the 684 and see if ready for Darlene to review. I am in tomorrow morning and then back next Tuesday, May 18th. Thanks for your help! Lemyra
ROBERT LIEB - PUBLIC HEALTH ADVISOR  Team Lead	05/14/2010	<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>

<p>DARLENE THOMAS - PROGRAM ANALYST</p>          <p>Division ADS</p>	<p>05/14/2010</p>	<p><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</p> <p>(check if applicable)  <input type="checkbox"/> Local IRB  <input type="checkbox"/> CDC Exemption  <input type="checkbox"/> CDC IRB</p> <p><u>Comments:</u>                  Because this is a contract, OMB approval will be obtained for the data collection.</p>
<p>ADS, Deputy ADS, or Human Subjects Contact</p>		<p><input 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</p> <p>(check if applicable)  <input type="checkbox"/> Local IRB  <input type="checkbox"/> CDC Exemption  <input type="checkbox"/> CDC IRB</p> <p><u>Comments:</u></p>

**List of Grantees**

**Grantee #**

**Grantee Name**

**Primary project site:**

	<b>Site name and Location</b>	<b>Assurance Number (FWA, MPA or SPA) if applicable</b>
Primary Site	Westat, Inc. Atlanta, Georgia	00005551
Site 2	Lower Kuskokwim School District Bethel, Alaska	n/a
Site 3	Dena'ina Health Clinic Kenai, Alaska	n/a
Site 4	Rocky Mountain School Good News Bay, Alaska	n/a
Site 5	Ramah Navajo School District Pine Hill, New Mexico	n/a
Site 6	Santo Domingo Schools Santa Domingo Pueblo, New Mexico	n/a
Site 7	Hannahville Indian School Hannahville, Michigan	n/a
Site 8	L'Anse and Baraga Public Schools Baraga, Michigan	n/a
Site 9	Standing Rock Schools Fort Yates, South Dakota	n/a
Site 10	Ahfachkee Day School Clewiston, Florida	n/a
Site 11	Poplar Elementary School Poplar, Montana	n/a
Site 12	Rocky Boy School Rocky Boy, Montana	n/a
Site 13	Warm Springs Elementary School Warm Springs, Oregon	n/a