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: DP15-1513

(Use PGO number if cooperative agreement, grant, etc.)

Date submitted: 12/11/2017

Title of Project: Zika Reproductive Health and Emergency Response Call-Back Survey, 2018

Dates for project period:

Beginning: 01/30/2018

Ending: 03/29/2020

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**

[X] **Revision**

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

[ ] **Continuation, with revision(s)**

Lead staff member:

Name: Karen Pazol

User ID: IJB2

Scientific Ethics number: 17083

Contact information:

Division: DRH

Telephone: 770-488-6305

Mailstop: F74

Please indicate your role(s) in this project:

[ ] **Project officer**

[ ] **Technical monitor**

[X] **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** [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:

[X] **Emergency Response**

[ ] **Program evaluation**

[X] **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
Karen Pazol	Principal Investigator	17083

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.

During the 2015 Zika virus outbreak it was determined that infection in pregnancy is a cause of microcephaly and other birth defects. Because of these outcomes, as a part of preconception counseling, CDC developed recommendations that healthcare providers screen women of reproductive age (WRA) for possible exposure to Zika and discuss travel plans, which may expose WRA to additional infectious diseases that affect pregnancy.

While the unique needs of WRA were recognized during the Zika outbreak, more recently in 2017 the importance of identifying the needs of WRA became apparent during public health response efforts to hurricanes in the Gulf Cost and Caribbean, given that natural disasters have been associated with adverse pregnancy outcomes and a wide range of needs specific to women and children.

To assess the preparedness of US jurisdictions for meeting the needs of WRA, this survey will address the following objectives: 1) Are WRA being screened for potential travel related exposures and are they knowledgeable about recommendations for pregnancy timing in regards to Zika exposure? 2) Are WRA prepared for natural disasters and other types of public health emergencies? and 3) Do WRA show variation in their level of knowledge and preparedness based on their current plans for achieving or avoiding pregnancy and responsibility for children?

This survey will contain questions used in 2017 for a similar assessment of WRA in Puerto Rico, with the exception that some questions related to Zika have been replaced with more general emergency preparedness questions. The survey conducted in 2017 was determined to be surveillance/emergency response (HSR #26964). As with the 2017 survey, the currently proposed survey will use methods from CDC's Behavioral Risk Factor Surveillance System (BRFSS) to conduct a phone survey. WRA participating in the 2018 BRFSS (Protocol #2988) who agree during their initial interview will be contacted again for this survey.

CDC staff involved in the survey will work with jurisdictional partners on the following: survey and sampling design, questionnaire development, monitoring the progress of the assessment, data analysis, and report writing and dissemination. The role of the jurisdictional partners will primarily be to carry out the interviews and keep CDC updated on progress. Preparation of data files for analysis will be carried out by the BRFSS staff at CDC/Atlanta; no personally identifying information or data keys will be included in the files received by CDC.

The findings from this survey will be used to guide emergency responses preparedness. The information collected in each jurisdiction will not be not generalizable to other settings or situations and will be used for preparedness planning and public health response.

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:

Tracking NO. DP15-1513

Approvals (signature and position title)	Date	Research Determination / Remarks
Karen Pazol - Deputy ADS staff member completing this form	12/11/2017	[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:
Karen Pazol - Deputy ADS Team Lead	12/11/2017	[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:
Karen Pazol - Deputy ADS Division ADS	12/11/2017	[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:
Joan Redmond Leonard - PUBLIC HEALTH ANALYST CUC ADS, Deputy ADS, or Human Subjects Contact	12/12/2017	[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:

List of Grantees

Grantee #	Grantee Name
6015	Alabama Department Of Public Health
6018	Arizona Department Of Health Services

6031	District Of Columbia Department Of Health
6033	Florida Department Of Health
6036	Georgia Department of Public Health
6037	Guam Department Of Public Health And Social Services
6026	Louisiana Dept of Health & Hosptials,Office Of Public Health
6039	Maryland Department Of Health And Mental Hygiene
6053	Mississippi State Department Of Health
6057	Puerto Rico Department of Health
6050	State of New Mexico Department of Health
6055	Texas Department Of State Health Services
6062	Virgin Islands Department Of Health