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: _____

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

Date submitted: 10/27/2016

Title of Project: Formative assessment regarding contraception use in the U.S. Virgin Islands (USVI) in the context of Zika

Dates for project period:

Beginning: 11/01/2016

Ending: 02/01/2017

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: Anna Brittain

User ID: AVG8

Scientific Ethics number: _____

Contact information:

Division: DRH

Telephone: 770-488-5515

Mailstop: F74

Please indicate your role(s) in this project:

[X] **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** [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**

[ ] **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
Anna Brittain		

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.

Increasing access to contraception among women who choose to delay pregnancy in USVI is a primary strategy to reduce Zika-related adverse outcomes. There are an estimated 21,000 USVI women of reproductive age (WRA), approximately 12,000 of whom are at risk of unintended pregnancy. There is an urgent need for effective messaging about contraception and contraceptive access. DESIGN: CDC staff will conduct 6 focus groups with USVI women and men(18-44 years) to assess knowledge, attitudes, and beliefs regarding contraception use and access within the USVI. CDC staff will also assess preferred communication channels for receiving messages. Each group will be a maximum size of 12. We propose to conduct 5 focus groups with WRA that are stratified by age(i.e., 18-24 years vs. 25-44 years). We will conduct 1 focus group with men (not stratified by age) because of the important role they play in decisions about contraceptive use. DATA COLLECTION: Trained CDC project team members will conduct focus groups in-person using semi-structured focus group guide developed by the project team. Before the focus group, each participant will receive an informed consent form, including the purpose, as well as benefits and risks of participation. The guide and the consent form will be reviewed by partners in the USVI to ensure that they are culturally appropriate. Each focus group is expected to last from 90 to 120 minutes. A note taker will be present to observe the focus groups and capture salient points discussed, as well non-verbal cues within the group. In addition, the focus groups will be audio-recorded. DATA ANALYSIS: CDC team members will analyze the data manually and/or using a qualitative software package. A thematic analysis approach will be used to determine common themes related to the categories addressed in the discussion guides. Codes will be developed based on themes and applied to the text, and the data will be synthesized. All information collected will be held in confidence to the extent allowed by law. All individuals involved in data collection will receive ethics training as well as training concerning procedures and practices to ensure privacy of data. No personal identifying information will be collected during the focus groups or maintained in any data files. No data will be collected other than what is collected during the focus groups. All audio-recordings will be destroyed after notes have been verified. CDC will summarize the information for use in developing messaging specific to contraception as part of emergency response. If a description of focus group findings is published, data will be reported in aggregate and will not include information that may be used identify respondents directly or indirectly.
This activity is public health practice as the data will identify, characterize, and solve an immediate health problem and the knowledge gained will directly benefit only those communities of focus group participants.

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

	Site Name	**Site Location**	**Assurance Number (FWA, MPA or SPA) if applicable**
Primary Site	Community based organization,, e.g. Women's Coalition of St. Croix	St. Croix	

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
Anna Brittain - HEALTH COMMUNICATIONS SPECIALIST staff member completing this form	10/27/2016	[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: Thank you for your review! -Anna
Lee Warner - RESEARCH SCIENCE OFFICER Team Lead	10/27/2016	[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: hi shanna, per discussion yesterday here is the RD form for the USVI for Zika for the EOC. thanks in advance for your help
Shanna Cox - Associate Director for Science Division ADS	10/29/2016	[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	10/31/2016	[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: