Research/non-research determination

Please be brief as you provide the following information.

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Background (One brief paragraph)
Zika virus disease is an emergent health issue with serious health consequences, particularly for the developing babies of pregnant women. Laboratory cases of Zika virus disease have been confirmed in 49 of the 50 U.S. states and in 3 of its 4 territories. CDC, as the nation's health protection agency, needs to fulfill its mission by creating messages and materials that will combat misinformation and improve knowledge, attitudes and uptake of recommended behaviors by target populations at the highest risk of Zika transmission.

Project Goals & Objectives (You can elaborate as extensively as necessary in this section: Why are you collecting the data; how will the data be used; how will you share results)
The purpose of this data collection is to conduct message and material testing to ensure that Zika prevention messages are clearly understood, culturally competent, relevant, and acceptable to target audiences, and provide information that is helpful and actionable. Previous Zika message testing and formative research has been reviewed to inform what gaps in knowledge are still present and what audiences we need feedback from. Information from this data collection will be used to revise previous messages and materials with target populations at high risk for negative Zika-related outcomes including pregnant women, women who may become pregnant, and their male partners and for community leaders who have influence in promoting Zika prevention measures in a community, e.g., homeowner association leaders, neighborhood association leaders, etc.. The revised messages and materials will then be used to update the Zika response websites and be disseminated when appropriate to educate the community about actions that can be taken to prevent the spread of the Zika virus to everyone, but especially to pregnant women and their developing babies.

Projected time frame for the project
The message and material testing is expected to begin in June 2017 over a two-week period, with a topline report of the findings to be prepared and delivered to CDC within the following week.

Methods (brief overview, 1 paragraph) : Two sets of focus groups will be conducted to test materials and messages. The first set of focus groups will test materials and messages about personal protection against mosquitoes. For those focus groups we will be contacting individuals (from any and all racial/ethnic groups) screened by telephone (10 minutes) for their age (18-69 yrs), sex, pregnancy status (pregnant and non-pregnant women), and current relationship status (men in a relationship with a women) using an available market research panel. Eligible individuals (n= 24) will be invited to participate in a 75 minute in-person focus group to provide feedback on two revised and one new Zika messaging and materials. The second set of focus groups will target community leaders age 18-69 to test materials and messages about Zika transmission risks and mosquito prevention. The contractor will use local recruitment connections with local health departments, Community Based Organizations, etc. to identify the target population. Eligible individuals (n= 24) will be invited to participate in a 75 minute in-person focus group to provide feedback on revised Zika messaging and materials.

Data collection (How; from whom—attach any data collection instrument or discussion guide you have)
: Individuals will be offered up to $75 remuneration to participate in an in-person 75-minute focus group. Groups will be conducted in New Orleans, LA and Miami, FL. (See below sampling tables for the breakdowns

by language, location and audience type).

US Testing (all focus groups are with 6 people each)							
	English (New Orleans)		**English (Miami)**		**Spanish (Miami)**		
	# of Groups	# of Ps	# of Groups	# of Ps	#of Groups	# of Ps	TOTAL Ps
Men and women of reproductive age (18-49; pregnant women ok but not necessary)	2	6	1	3	1	3	**12**
		6		3		3	**12**
Community leaders	2	12	1	6	1	6	**24**
Total	4	**24**	2	**12**	2	**12**	**48**

The focus groups will be guided by a trained moderator from Abt Associates who will rely on a CDC-approved moderator's guide. Each focus group will be audio recorded and will include a note taker from Abt. The focus group moderator will ask participants on their opinions on 3 materials undergoing revisions or development for Zika Prevention health education in the United States. Specific feedback will be requested of participants related to the messages, images, and layout, including (1) impressions and comprehension, (2) feedback on images and depictions, and (3) level of motivation to take actions to protect against Zika. All participants will be given a factsheet at the end of the group session outlining ways to avoid Zika transmission.

Are there any ethical considerations? How do you plan to prevent potential ethical concerns?
We believe there are no potential ethical considerations or concerns in conducting this type of qualitative assessment. Participants will be told by the group moderator at the beginning of each session that they will be asked their opinion only and no personal information, that everything they say will be kept private, their participation in the group is completely voluntary and can be terminated by them at any time, and they may choose not to answer any specific question posed either to the group as a whole or to them individually. Also, participants will be told the session will be recorded, but only first names (or a fabricated made up name if preferred) will be used throughout.

Abt Associates will facilitate and manage recruitment of all participants. Personal identification information (contact information) will be supplied through secure digital data files by a third-party vendor to Abt only for recruitment. Once recruitment is complete, neither Abt nor CDC will have access to potential participants' PII. As participants are recruited, grids will be prepared to keep track of participants' first names and select demographic information including age, ethnicity, education status, and relationship status obtained from the screener. The recruitment grids will be stored in a locked file cabinet or on a secure password-protected Abt project share drive. Recruitment staff will use contact information to send reminder e-mails and make reminder phone calls for upcoming data collection, but the information will not be recorded elsewhere. All personal identifiers needed to locate potential participants will be stored either in separate locked file cabinets or in password-protected electronic files. They will be maintained and protected to the extent allowable by law and

destroyed at the completion of data collection.

As mentioned in-person focus groups will be audio recorded and stored on a secure password-protected share drive. Recordings will be transcribed, and all transcripts will be de-identified and shared with CDC via encrypted email. Once original transcripts are de-identified and checked, they will be destroyed. No PII will be sent to CDC from focus groups or questionnaire responses. No PII will be filed or retrievable by CDC; only de-identified data will be shared with CDC. No additional individually identifiable information is being collected.

The data collected will be retained by Abt during the contract period. After the contract between CDC and Abt expires Abt will destroy all data files. Data transferred to CDC will be stored on a secure password-protected share drive behind the CDC firewall. Federal records management standards dictate that these data will be maintained for a minimum of 11 years by CDC.

The proposed data collection will pose little or no risk to participants. Data will always be reported in a de-identified manner. Participants will not be able to be identified either directly or indirectly from the information that appears in the final data set. Disclosure of the subjects' responses outside of the project setting (such as in a journal publication) would not have the potential to place the subjects at risk of criminal or civil liability or be otherwise damaging. The subject matter will not contain sensitive information and responses will not be traceable to the subjects.

Verbal agreement will be obtained from focus group participants before each focus group session. All participants will be reminded of the need to keep information shared during the focus groups confidential, and assured that the information discussed during the focus groups will be used only for the purpose of this Zika communication initiative and will be kept private to the extent allowable by law. Participants will be told that the information obtained from the data collection activity will be combined into a summary report so that details of individual responses cannot be linked to a specific participant.

All potential participants will be explicitly asked before they are consented whether they are 18 over. All participants will provide verbal consent prior to participating in the focus group. The information sheet will be made available by the focus group facility and given to participants when they arrive. Participants will be offered to read the form or have it read to them, and asked for their verbal consent. Only those who agree to participate will participate in the focus group.

In your opinion, is your project human subjects research? If not, briefly explain why.
The information we collected from the focus groups participants is specific to revising the messages and materials for the Zika fact sheets and communication products. A final report may be shared with local health departments and community groups that help with recruitment so they can apply this information to their own Zika communication and health education efforts. However they will only receive a final summary report with information at aggregate level so that details of individual responses cannot be linked to a specific participant. Though not generalizable, these data may offer lessons learned to inform future communications on infectious disease outbreaks and may be shared with others in the field through publications and presentations.

The subsequent revisions of communication products that will be developed from this information will utilize well-accepted or evidence-based methods and strategies, and will not represent an advancement in communication or behavioral sciences. Therefore, the principal investigators request non-research determination for this data collection effort.