Supporting Statement: Part B

Information Collection Request: Monitoring and Evaluation for the Zika Contraception Access Network (Z-CAN)

Request for OMB approval of an Emergency ICR

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ACRONYMS

CDC	Centers for Disease Control and Prevention
ICR	Information collection request
IIF	Information in identifiable form
PRAMS	Pregnancy Risk Assessment Monitoring System
PROGyn	Puerto Rico Obstetrics and Gynecology
SORN	System of Records Notice
TSI	Total Solutions, Inc.
UPR	University of Puerto Rico
Z-CAN	Zika Contraception Access Network

B. STATISTICAL METHODS

1. Respondent Universe and Sampling Methods

This information collection request (ICR) consists of three different data collection activities: (1) focus groups with women aged 18 years or older and able to conceive in Puerto Rico; (2) semi-structured, individual interviews with physicians and clinic staff participating in the Zika Contraception Access Network (Z-CAN) program; and (3) online surveys with Z-CAN physicians, clinic staff, and patients. The respondent universe and sampling methods differ based on the data collection activity and target population within each data collection activity and are described below.

Activity 1: Focus groups with women aged 18 years or older and able to conceive in Puerto Rico

The respondent universe includes women aged 18 years or older and able to conceive in Puerto Rico meeting the eligibility criteria: not currently pregnant or seeking pregnancy; able to become pregnant; currently sexually active (vaginal sexual intercourse in the past three months); residing in Puerto Rico; and fluent in Spanish. Using purposive sampling, approximately 240 women will be included in focus group discussions. A maximum of 24 focus group discussions with 8-10 women in each group will be convened until the point that saturation is reached. Half of the focus groups (n=12 groups and 120 women) will be conducted with women who participated in Z-CAN, while the remaining groups will be with women who have not received Z-CAN services. These groups will be further stratified by age (i.e., women who are ages 18-24 years and those ages 25 and older) to assess barriers and facilitators that may affect access to and use of Z-CAN services. We estimate the need to screen approximately 300 women to identify 240 that meet eligibility criteria. As of 01/13/2017, approximately 4,900 women have enrolled in the Z-CAN program, with approximately 500 newly enrolled women per week.

A range of recruitment strategies will be utilized to recruit participants. Flyers posted at Z-CAN clinics will be used to recruit women who have received Z-CAN services. The same flyer will also be posted in community settings and businesses frequented by women of reproductive age (e.g., grocery stores, shopping areas), principally to recruit women who have not accessed Z-CAN services. The recruitment flyer will contain a brief description of the purpose of the focus group, who is eligible to participate, what is expected of the participant, the token of appreciation for participation, and how to register if they are interested in participating. The recruitment flyer is included in **Attachment E-1** (English) and **Attachment E-2** (Spanish). In addition, advertisements will be posted through media outlets (e.g., radio, newspaper, and internet) to ensure a diverse sample of participants. Potential focus group participants will be screened in person or online (**Attachment F-1** for English, **Attachment F-2** for Spanish, **Attachment F-3** for Spanish screen shots of online version), and will be accepted based on participant eligibility criteria until established quotas are met for the following characteristics: participation in the Z-CAN program and age group (18-24 years vs. 25 and older).

Activity 2: Semi-structured, individual interviews with Z-CAN physicians and clinic staff

For semi-structured, individual interviews with Z-CAN physicians (to be conducted approximately 3 months after beginning to provide Z-CAN services), the respondent universe is physicians who have been trained and proctored on providing women of reproductive age with client-centered contraceptive counseling and reversible contraceptive services (n=163). For semi-structured, individual interviews with Z-CAN clinic staff (to be conducted approximately 3 months after beginning to provide Z-CAN services), the respondent universe is clinic staff from Z-CAN clinics (n=150) who have been trained and proctored on providing women of reproductive age with client-centered contraceptive counseling and reversible contraceptive services. Using purposive sampling, approximately 25 Z-CAN physicians and 25 Z-CAN clinic staff will be selected to participate. Purposive sampling will be used to ensure a range of representation of different clinics throughout Puerto Rico. Key selection criteria will include practice type (e.g., community health center, private practice) and geographic location (i.e., region in Puerto Rico). Clinic staff trained as part of the Z-CAN program consist of individuals fulfilling a diverse array of roles, including but not limited to nurses, administrators, health educators, and medical assistants. As the majority of staff in Z-CAN are nurses, we will actively recruit nursing staff to participate in the individual interviews. However, we will allocate one-fourth of interviews to individuals who fulfill other roles within the clinic setting to ensure that findings reflect the range of perspectives of those involved in implementing the Z-CAN program.

Activity 3: Online surveys with Z-CAN physicians, clinic staff, and patients

Online surveys with Z-CAN physicians and clinic staff

For online surveys with Z-CAN physicians (to be conducted approximately 6 months after beginning to provide Z-CAN services), the respondent universe is physicians who have been trained and proctored on providing women of reproductive age with client-centered contraceptive counseling and reversible contraceptive services (n=163). For online surveys with Z-CAN clinic staff (to be conducted approximately 3 months after beginning to provide Z-CAN services), the respondent universe is clinic staff from Z-CAN clinics (n=150) who have been trained and proctored on providing women of reproductive age with client-centered contraceptive counseling and reversible contraceptive services. Related to sampling, all Z-CAN physicians and one Z-CAN staff member from each clinic that provides Z-CAN services will be invited to participate in the online surveys. Every Z-CAN physician will be invited to participate since all Z-CAN physicians have agreed to participate in general monitoring and evaluation activities as part of their contractual responsibilities as a Z-CAN provider. For clinics with more than one Z-CAN staff member, one staff member will be invited at random to participate. If the staff member declines or does not respond after three reminders, another staff member from that clinic will be invited to participate. If no staff member responds, then the clinic staff for that clinic will be considered nonresponsive. Data from only one staff member from each clinic will be included in the analysis.

Online surveys with Z-CAN patients

For online surveys with Z-CAN patients (to be conducted approximately 6 and 12 months after Z-CAN enrollment), the respondent universe is Z-CAN patients aged 18 and older who complete a 2-week patient satisfaction survey, an effort funded by the CDC Foundation and determined to

be part of regular Z-CAN program activities that received a non-research determination from CDC in August 2016 (**Attachment O**-1), with a revision approved in October, 2016 (**Attachment O-2**). We aim to invite the first 3,200 women who participated in the 2-week patient satisfaction survey to also participate in the 6- and 12-month follow-up surveys. All potential participants will receive invitations to complete the 12-month survey, regardless of whether or not they completed the 6-month survey.

To determine the number of Z-CAN patients desired in our sample, we consulted with a statistician to assist with power calculations. Sample size estimates were generated assuming various levels of contraceptive method continuation at 12 months (our key outcome of interest) (i.e., 50-80%), various levels of attrition (none, 25%, 50%), and various levels of confidence interval widths (i.e., 0.05, 0.10, 0.15, and 0.20). Ultimately, the number of patients needed to estimate the contraceptive method continuation rate at 12 months among Z-CAN patients was determined to be 3,200 (assuming 50% contraceptive method continuation rate, 50% attrition, and confidence interval width of 0.05).

As of 12/31/2017, approximately 730 Z-CAN patients had participated in the 2-week patient satisfaction survey (out of 2,500 invitations sent) translating to ~36% response rate. As the number of Z-CAN patients enrolling each week continues to increase, we expect the number of Z-CAN patients participating in the 2-week patient satisfaction survey to also increase.

2. Procedures for the Collection of Information

Activity 1: Focus groups with women aged 18 years or older and able to conceive in Puerto Rico

The focus groups with women aged 18 years or older and able to conceive will be conducted in-person. All focus groups will be conducted in Spanish by an experienced facilitator. Women must provide informed consent to participate in the focus groups (**Attachment G**). The facilitator will encourage women to choose a pseudonym to use throughout the focus group to avoid using real names to identify themselves. Focus groups will be digitally recorded so that the moderator will be able to focus on engaging with and eliciting responses from all participants. A note taker will also be present at each focus group discussion in order to assure key points are captured, including any non-verbal cues and dynamics within the focus group. After each focus group discussion, the moderator and the note taker will type up short summary notes in English. A naming scheme to identify the focus groups will be developed based on participant make-up (Z-CAN vs. non-Z-CAN) and age cohort (18-24 vs. 25-44). Recordings of the focus groups will be transcribed into Microsoft Word in Spanish, translated into English, and imported into qualitative analysis software (such as MAXQDA, ATLAS.ti, or Nvivo) for coding. All copies of notes, consent forms, and any other written materials will be kept securely on a password-protected computer and only shared with members of the Z-CAN staff who are authorized to access the information. Audio-recordings will be destroyed immediately after transcription and translation has been completed and verified.

Quality Control. To ensure credibility of the data, prior to translation into English, each transcript will be checked by the data collection team lead by listening to sections of the

recordings and cross-checking the transcripts. If discrepancies are identified, the entire transcript will be sent back for re-transcription and the cross-checking will recur. If minor errors are found, the data collection team lead will discuss the transcript with the focus group facilitator to work towards an agreed upon decision regarding the discrepancy. If a transcription is not agreed upon, another member of the data collection team will resolve the discrepancy. Once the transcript is prepared, it will be translated into English. Subsequently, another bilingual person, external to the focus group discussions and prior translation process, will review the English translation and compare it to the original Spanish transcript to check the validity of the translation. If inconsistencies are found, a committee consisting of the data collection team lead, focus group facilitator, translator, and the external reviewer will meet with the purpose of ensuring equivalence between the original Spanish transcript and the final English translation.

Activity 2: Semi-structured, individual interviews with Z-CAN physicians and clinic staff

The semi-structured, individual interviews with physicians and clinic staff may be conducted either in-person, by telephone, or through a web-based communication platform (e.g., Skype, videoconferencing, etc.). In all cases, the interviews will be conducted in private spaces to ensure confidentiality. In case of technical difficulties, a back-up mode for communication will be identified (i.e., alternate phone number or software application). Interviews may be conducted in either English or Spanish, based on the preferred language of the physician or clinic staff member. Z-CAN physicians and staff must provide informed consent to participate in the individual interviews; the consent form for physicians is included in **Attachment -1** and the consent form for staff is included is **Attachment J-2**. Interviews will be digitally audio-recorded to collect data and assist with analysis and preparation of reports. The interviewer may take shorthand notes during the interview; however, the interviewer will primarily focus on engaging with and eliciting responses from the interviewee. After each interview, the interviewer will type up short summary notes in English into Microsoft Word and label the file with the Z-CAN identification number of the physician or Z-CAN clinic number of the clinic staff member that was interviewed. Audio recordings of the interviews will be transcribed into Microsoft Word in the original language of the interview (Spanish or English), translated into English (as needed), and imported into qualitative analysis software (such as MAXQDA, ATLAS.ti, or Nvivo) for coding. Once data are transcribed and prepared for analysis, any identifying information, including Z-CAN identification number, will be removed. No identifying information will be retained in the transcripts for data analysis and reporting. Audio-recordings will be destroyed immediately after transcription and translation have been completed and verified.

Quality Control. To ensure credibility of the qualitative data, prior to data analysis, each English language transcript will be checked by the data collection team lead by listening to sections of the recordings and cross-checking the transcripts. If discrepancies are identified, the entire transcript will be sent back for re-transcription and the cross-checking will recur. If minor errors are found, the data collection team lead will discuss the transcript with the interviewer to agree on the transcription. If a transcription is not agreed upon, another member of the data collection team will resolve the discrepancy. Similarly, transcripts of interviews conducted in Spanish will be checked for validity by the data collection team lead by listening to the audio-recordings and cross-checking the transcripts. However, the Spanish language transcripts will require additional quality checks in the translation from Spanish to English. The Spanish transcript will be

translated into English and then reviewed by another person who is external to the interview and the translation process. This reviewer will compare the English translation with the original Spanish transcription. If inconsistencies are found, a committee consisting of the data collection team lead, focus group facilitator, translator, and external reviewer will meet with the purpose of ensuring equivalence between the original Spanish transcript the final English translation.

Activity 3: Online surveys with Z-CAN physicians, clinic staff, and patients

For the online surveys with Z-CAN physicians, clinic staff, and patients, invitations to participate will be sent via email or text message and will include an electronic link to the survey. Invitations to participate will be sent three times. Z-CAN physicians, clinic staff, and patients must provide informed consent electronically to participate in the online surveys; the consent form for physicians is included in **Attachment M-1**, the consent form for clinic staff is included in **Attachment M-2**, and the consent form for patients is included in **Attachment Q**. Surveys will be self-administered electronically on personal devices (e.g., computers, smart phones). Data will be collected via a secure, web-based survey platform (i.e., HIPPA-compliant version of Survey Monkey). Each participant will be asked to provide consent electronically prior to beginning the electronic survey. The data collection contractors will regularly download the survey data and strip any identifying information other than the patient's unique Z-CAN identification number which will be used for linking purposes with programmatic data. Survey data transmitted to CDC at the end of the data collection period will not contain any information in identifiable form (IIF).

Quality Control. Surveys will be conducted using a secure, web-based survey platform, which will eliminate the need for data transcription, reducing data entry errors. The survey will be programmed to limit out of range values and to reduce problems following skip patterns. All skip patterns will be verified prior to launching the surveys.

3. Methods to Maximize Response Rates and Deal with No Response

The following procedures will be used to maximize cooperation and to achieve the desired participation rates:

Activity 1: Focus groups with women aged 18 years or older and able to conceive in Puerto Rico

- Recruitment will take place at venues most appropriate to identify women who meet the eligibility criteria.
    - For women who have received services through the Z-CAN program, flyers will be placed within clinics offering Z-CAN services across Puerto Rico. Additionally, information will be shared with Z-CAN physicians and clinic staff to support recruitment.
    - For women who have not received Z-CAN services, flyers will be placed at venues where the general public tends to gather, as recommended by local partners. Advertisements will be posted through media outlets (e.g., radio, newspaper, and internet).

- Local partners will aid in the determination of locations that are convenient for women to access (i.e., transportation, parking, etc.).
- Reminder emails/texts will be sent with directions to the research site and reminder phone calls placed 1 to 2 days prior to the scheduled data collection. Participants will not be contacted again after the focus group is completed.
- A token of appreciation will be provided to thank participants for their time and effort in the study.
- Additionally, facilitators will encourage all focus group participants to engage and contribute to the discussion.

Activity 2: Semi-structured, individual interviews with Z-CAN physicians and clinic staff

- Depending on participant preference, interviews will be conducted either in-person, by video conference, or by phone. In-person interviews will be held at their clinic/office or a location outside of their workplace that is convenient to them.
- Interviews will be conducted with only a single physician or clinic staff member at a time to safeguard each participant's confidentiality.
- Reminder emails/texts will be sent with directions to the meeting site (if needed) and reminder phone calls placed 1 to 2 days prior to the scheduled interview.
- For clinic staff, a token of appreciation will be provided to thank participants for their time and effort in the study.

Activity 3: Online surveys with Z-CAN physicians, clinic staff, and patients

- The survey instruments have been developed to minimize the time required for completion (approximately 10 minutes for Z-CAN patients and 15 minutes for Z-CAN physicians and clinic staff).
- Z-CAN patients are notified about the potential to be contacted to participate in follow-up online surveys at the time of their enrollment in Z-CAN (as part of regular Z-CAN programmatic activities).
- Z-CAN patients participating in the 2-week satisfaction survey (as part of regular Z-CAN programmatic activities) will receive a thank you message via email or text message approximately two months after completion of the 2-week survey to maintain interim contact before the 6-month and 12-month survey pre-notifications are sent.
- Approximately 1-2 weeks before the invitations to participate in the 6-month and 12-month survey are distributed, a pre-notification will be sent via email or text message.
- A total of three reminders (via email, text, and/or phone) will be sent to each participant to request participation in the survey.
- A token of appreciation will be provided to Z-CAN patients who participate to thank them for their time and effort in the study.
- Data may be weighted to correct for nonresponse to ensure representativeness of the entire Z-CAN patient population, which will be known using Z-CAN programmatic data.

4. Tests of Procedures or Methods to Be Undertaken

All instruments will be created in English and translated into Spanish, with specific focus on using appropriate Spanish for the local context in Puerto Rico. Materials will be reviewed by the University of Puerto Rico (UPR) to ensure cultural appropriateness and understanding of the issues addressed. Once translated, qualitative instruments (i.e., focus group guides and interviews instruments) will be reviewed by local partners to address any potential problems or concerns prior to data collection. Prior to implementing the online surveys, Centers for Disease Control and Prevention (CDC) staff and contractors will test the entire process of self-administering the surveys to pilot test survey programming and logic. All instrumentation is new, but several items from the online surveys have been modified from other instruments such as the Pregnancy Risk Assessment Monitoring System (PRAMS) and data collection surveys included as part of "Monitoring Changes in Attitudes and Practices among Family Planning Providers and Clinics" (OMB Control No. 0920-0969; Expiration Date: 05/31/2014).

5. Individuals Consulted on Statistical Aspects and Individuals Collecting or Analyzing Data

Individuals consulted on statistical aspects and/or contributed to the design of the data collection activities and/or will contribute to data analysis include, but are not limited to, the following:

Name	Organization	Role
Eva Lathrop, MD, MPH*# wuu7@cdc.gov, 770-833-1884	CDC/Emory University	CDC project lead
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*Contributed to design of the data collection activities.

#Will contribute to data analysis.

Several iterations of feeback on study design and data collection instruments were sought. All feedback received was fully considered as a collaborative group and incorporated, as appropriate.