Impact Evaluation of CDC's Colorectal Cancer Control Program (CRCCP)

OMB Supporting Statement

Part B: Statistical Methods

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TABLE OF CONTENTS

LIST OF ATTACHMENTS

1. Authorizing legislation, Sections 301 (a) of the Public Health Service Act
2. FRN and Comments on FRN
    a. Federal Register Notice
    b. Comments on Federal Register Notice
3. Screener for the Colorectal Cancer Population Survey
4. Colorectal Cancer Population Survey
    a. Colorectal Cancer Population Survey
    b. Screen Shots of the CATI Administration of the Colorectal Cancer Population Survey
5. Colorectal Cancer Screening Practices Survey of Primary Care Providers
    a. Colorectal Cancer Screening Practices Survey of Primary Care Providers Survey
    b. Invitation/Cover Letter
    c. Advance Fax
    d. Reminder Fax
    e. Second Mailing Cover Letter
    f. Third Mailing Cover Letter
6. Site Visit Planning
    a. Site Visits Suggested Interviewee Form
    b. Site Visit Instruction Template
    c. Grantee Site Visit Introductory Letter/Email
    d. Non-Grantee Site Visit Introductory Letter/Email
    e. Site Visit Confirmation Email
7. CRCCP Grantee (Intervention) Case Studies
    a. Grantee Program Staff Interview Guide
    b. Grantee Evaluator Interview Guide
    c. Grantee Partner Interview Guide
    d. Informed Consent Form
8. Non-Grantee (Control) Case Studies
    a. Non-Grantee Program Staff Interview Guide
    b. Non-Grantee Evaluator Interview Guide
    c. Non-Grantee Partner Interview Guide
    d. Informed Consent Form
9. Document Review Form
10. Observational Assessment Guide
11. Non-Disclosure agreement for Data Collection Contractors
12. ICF Macro IRB Approval

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

B-1. Respondent Universe and Sampling Methods

Three different populations will be participating in this evaluation:

- **Population survey:** A randomly selected, representative sample of individuals 50-75 year of age from each of the six states.
- **Provider survey**: A randomly selected, representative sample of primary care providers from each of the six states.
- **Case studies:** A purposeful sample of respondents who fall into the general categories of 1) State health department program staff, 2) affiliated partners, and 3) other stakeholders from each of the six states. For both CRCCP grantee (intervention sites) and non-grantee programs (control sites), we anticipate these interviews will include project directors/ program coordinators, evaluators, data managers, program staff from the Comprehensive Cancer Control Program (CCC), WISEWOMAN, National Breast and Cervical Cancer Early Detection Program and central cancer registries, CCC coalition members, and other private sector and community based partners. For CRCCP grantees, we expect these partners to also include representatives from health care systems, worksites, professional organizations, and community based organizations. For the CRCCP grantees, we also anticipate interviewing providers affiliated with the state CRC screening programs and Medical Advisory Boards (MAB) that were convened to help establish policies and procedures for the state CRC screening board.

Table B-1.1 Respondent Universe

Data Collection Activity	Potential respondents
Population Survey	• Individuals 50-75 years old who reside in Nebraska, Alabama, and Minnesota (CRCCP grantees) and Oklahoma, Tennessee, and Wisconsin (Non-grantees)
Provider survey	• Primary care physicians who practice in Nebraska, Alabama, and Minnesota (CRCCP grantees) and Oklahoma, Tennessee, and Wisconsin (Non-grantees)
Case studies- Grantee Programs	• CRCCP Program Director • Program staff • Program data management and evaluation staff • State and Local Partners • Private Sector Partners (e.g. physicians, representatives from health care systems, employers, health insurers, medical advisory board members, professional organizations community based or non-profit organizations)
Case Studies Non-Grantee Programs	• Program Director • Program staff • Program data management and evaluation staff

	• State and Local Partners • Private Sector Partners (e.g. physicians, representatives from health care systems, employers, health insurers, professional organizations community based or non-profit organizations)

Below is a more detailed description of the sampling methods for each data collection activity.

Population Survey. The cross-sectional, population survey will be conducted via telephone with participants from each participating state. Eligibility criteria for participation are that the individual must reside in a participating state and they must be 50-75 years of age.

The sample of potential participants will be created based on a stratified, list-assisted random digit dialing (RDD) sample. The RDD sample will be restricted to 1+ block of exchanges. Once an individual is contacted to participate in the study and verbal consent for participation in the telephone survey is secured, respondents will be asked a series of screening questions to ensure their eligibility. Approximately 2400 households per state will be sampled in order to reach the goal of 800 completed surveys, for a total of 4800 completed surveys across six states. The survey will be administered in Fall 2013 and Fall 2015.

The derivation of sample sizes the population survey utilized state-level screening rate estimates (or other estimated proportions or percentages) for the subgroup of eligible adults of age 50 and older. The sample sizes developed here will generate estimates within +/- 5% (95% confidence levels) for each state. Design effects (DEFFs) will be similar to those obtained in the BRFSS; for most states, and most estimates, design effects range from 1.5 to 2.5. For each state, we conservatively assume DEFF=2.0 and a DEFF of 3.0 for the combined sample.

To obtain 800 completed surveys with eligible adults in a state, we inflated the sample size by the hit rate (incidence or age-eligibility rate) defined as the percentage of households with eligible adults. Based on state data from the recent 2008 American Community Survey, we estimated that at least 1/3 of the households (33.3%) contacted and screened will contain an age-eligible respondent.

Provider Survey. The longitudinal provider survey will be conducted via Priority mail mailing with primary care providers from each participating state. Eligibility criteria for participation are that the individual must be a primary care provider, which also includes general practitioners, family practitioners, or internists, in a participating state. The contract vendor, ICF Macro will randomly select primary care providers from a list purchased from the American Medical Association (AMA).

Physicians will receive an initial mailing which will include the survey, a self-addressed, and stamped return envelope and a $25personalized check) to encourage survey completion. The survey will contain a toll-free number to fax back their response if they so choose.

Approximately1000 primary care physicians per state will be sampled in order to reach the goal of 400 participants per state completing the survey, for a total of 2400 completed surveys across six states. The survey will be administered in Fall 2013 and Fall of 2015. For the second survey (Fall 2015), only respondents from the first survey will be sampled along with an additional 100 primary care physicians per state who will be added to the study sample in order to account for attrition.

The derivation of sample sizes for the provider survey utilized state-level estimated proportions (or percentages); e.g., the proportion of physicians adopting certain practices or recommendations. The sample sizes were designed to generate estimates within +/- 5% (95% confidence levels) for each state. The precision will be similar for change estimates, as well as for estimates that aggregate the 3 states in each grouping (intervention versus comparison group). Because the sample will be selected using with stratified random sampling with minimal or no oversampling, design effects (DEFFs) will be very close to 1.0. Therefore, we will only need n=400 completed surveys to achieve the required precision levels in each state. Conservatively, we assume a design effect of 2.0 for the combined sample so that an effective sample size of about 600 is anticipated for aggregate analysis at the level of each group (intervention and comparison groups). To attain 400 completed surveys with eligible providers in a state, we inflated the sample size by the combined eligibility and response rate. Based on our experience with provider surveys adopting similar methods, the combined rate will be at least 60%. Under our conservative approach, we plan to select approximately 1,000 eligible physicians in each state.

Case Studies. Sampling and data collection for the case studies do not involve the use of statistical methods. The CRC screening -related efforts of each of the participating states comprise a case, for a total of six cases. For each case, interviews will be conducted with CRC program staff, partners and other stakeholders. Interviews will be conducted during site visits to each participating state. Purposeful sampling will be used to identify the most knowledgeable staff, partners and other stakeholders in each state. Approximately 12-15 individuals will be interviewed at each site. The number of participants will vary depending on the number of relevant individuals at each site. In total, a maximum of 90 individuals will be interviewed across all six sites visits during each of the two waves of case study data collection –Fall 2013 and Fall 2015. It is important to note that control states may not have a CRC screening program. Instead their CRC screening efforts may fall under a broader, more comprehensive state program, such as the comprehensive cancer control (CCC) program, which focuses on cancer control for all cancers. In these instances, the lead program administrators of the CDC-funded CCC programs will be contacted. The case studies will be conducted in Fall 2013 and Fall 2015.

Program recipients, or patients who received CRC screening services through any State-funded program, will not be interviewed for the case studies.

	Instrument	Attachment No.	No. Respondents in IC #1	No. Respondents in IC #2	Total Respondents over 3 years	Annualized No. of Respondents
Colorectal Cancer Population Survey						
General Population	Screener for CRC Population Survey	3	14,400	14,400	28,800	9,600
	Colorectal Cancer Population Survey	4A, 4B	4,800	4,800	9,600	3,200
Colorectal Cancer Screening Practices: Survey of Primary Care Providers						
Eligible Primary Care Providers	Colorectal Cancer Screening Practices: Survey of Primary Care Providers	5A	2,400	2,400	4,800	1,600
	Invitation/Cover Letter for Provider Survey	5B	6,000	3,000	9,000	3,000
Case Study Planning						
CRCCP and Non-Grantee Program Directors	Site Visit Suggested Interviewee Form	6A	6	6	12	4
CRCCP and Non-Grantee Program Directors	Site Visit Instruction Template	6B	6	6	12	4
Implementation Case Studies						
CRCCP Grantee Program Staff	Interview Guide: Grantee Program Staff	7A	18	18	36	12
CRCCP Grantee Evaluators	Interview Guide: :Grantee Evaluators	7B	6	6	12	4
CRCCP State and Local Sector Partners	Interview Guide: Grantee Partner	7C	6	6	12	4
CRCCP Private	Interview Guide: Grantee Partner	7C	6	6	12	4

Sector Partners						
Non-Grantee Program Staff	Interview Guide: Non-Grantee Program Staff	8A	18	18	36	12
Non-Grantee Evaluators	Interview Guide: Non-Grantee Evaluators	8B	6	6	12	4
Non-Grantee State and Local Sector Partners	Interview Guide: Non-Grantee Partner	8C	6	6	12	4
Non-Grantee Private Sector Partners	Interview Guide: Non-Grantee Partner	8C	6	6	12	4

B-2. Procedures for the Collection of Information

The data collection procedures for each data collection activity is described in detailed below:

Population Survey. A state-based, representative, cross-sectional sample of adults aged 50–75 will be surveyed to assess knowledge, attitudes, intentions, and behavior around CRC screening. Based on a small pilot test, the telephone survey will take approximately 28 minutes to complete in its entirety. The survey will be fielded at two time points, pre- and post-intervention (Fall 2013 and Fall 2015).

Response burden for the population survey will be minimized by using Computer-Assisted Telephone Interviewing (CATI) technology. ICF project staff will identify households using the Genesys-ID system. This system contains information on area code-exchange combinations that have been assigned and Census-based demographic information for individuals and households for geographic areas defined by ZIP codes and Census tracts. This system will be used to quickly and economically generate a productive and statistically valid Random Digit Dial (RDD) sample, while removing much of the burden of telephone sample generation that is typically borne by dialing business, non-working and electronic-oriented telephone numbers. The generated sampling frame will then be used to randomly select a sample large enough to produce the desired number of interviews using Genesys estimates of the proportion of Working Residential Numbers (WRNs). Once a household is contacted, we will do a household enumeration to determine how many age eligible adults reside in the household. If there is more than one age-eligible adult in the household, the person who was initially chosen by random selection will be asked to complete the survey. This within household sampling approach is used to minimize the gender bias towards females that

frequently occurs in telephone based survey studies. All skip patterns in the survey (that is, questions that are only appropriate for a proportion of respondents) will be automatically programmed into the CATI survey, thus further minimizing the burden on respondents in terms of their time.

Each participant in the telephone survey will be assigned a random digit identification number. The identification number will be used to link participant information to survey responses for internal purposes of data tracking. Separate databases will be used to house participants' telephone number and participants' survey responses; each will be stored in a separate secure file on a secure network server. Only ICF project staff will have access to these data. Only aggregate responses will be used in the report of study results. A de-identified data file will be created to share the data with CDC. In addition, all surveyors will be trained on the project's specific security requirements and will sign an agreement to keep the data secure.

Provider Survey. A state-based, representative, longitudinal sample of primary care providers will be surveyed to assess provider knowledge, attitudes and behaviors with respect to CRC screening. Sampled primary care providers will first receive an advance fax informing them about the survey and its impending arrival. Within 2-3 days, primary care providers will receive a packet including a cover letter, paper survey, stamped and addressed envelope and a $25 personalized check as an incentive to complete the survey. The survey packet will be delivered via Priority mail delivery. The survey cover letter will be personally addressed to each provider. The letter will be printed on CDC letterhead and signed by the CDC study leader. The letter will give the respondents a toll-free telephone number to call if they have questions regarding the study. The survey cover letter and the first page of the survey questionnaire constitute the informed consent. They describe how the survey data will be used, by whom, and describe the steps to protect the privacy of the data. They also clearly indicate that participation in the survey is voluntary.

Based on the results of a small pilot test, the survey will take 12 minutes to complete. For those providers who do not respond to the initial mailing, a second and third mailing of the survey package will be conducted. A $25 personalized check will be included the third mailing of the survey package to physicians who have not returned a survey in response to the previous two requests. The survey will be fielded at two time points, pre- and post-intervention (Fall 2013 and Fall 2015).

For the Wave 2 administration of this survey, mailed forms will be sent to all providers who indicate they are willing to participate in Round 2. We estimate that approximately 100 providers in each state may be lost between Rounds 1 and 2, so we will supplement the sample by an additional 100 providers per state, if needed.

Case Studies. The purpose of the case studies is to describe how the state health departments in the intervention and control states implement their CRC screening programs/efforts and how implementation change over time. The data from this case study will be used to help assess the extent to which the CRCCP impacted changes in CRC screening prevalence as well as the accuracy of the program theory of change. ICF, the contract vendor will send a two-

person team to conduct each 2½-day site visit. This team will consist of a lead site visitor and a support site visitor. During the first 2 days of the site visit, the team will conduct one 2-hr long interview with the lead program administrator and approximately 10-11, 1-hr long interviews with various program staff, including the program directors, program staff, evaluators, stakeholders, and partners. The interviews may take place in staff offices or at other locations more convenient for respondents. On the third day of the site visit, the lead program administrator will convene a small group of stakeholders to debrief from site visit. The case study interview guides for CRCCP grantee programs are available in Attachments 7A-7C. The guides for the non-grantee programs are available in Attachments 8A-8C.

The primary study contact for each participating grantee program will be the program director for the CRCCP. For the non-grantee programs, the primary contact will be either the program director for the state's National Breast and Cervical Cancer Early Detection Program (NBCCEDP) or the program director for the state's National Comprehensive Cancer Control (CCC) Program (NCCCP). Both the NBCCEDP and the NCCCP are funded by DCPC. Program consultants in the Division of Cancer Prevention and Control will facilitate communications with the six states. ICF staff will work closely with the primary study contacts will be provided with templates and asked to assist with 1) scheduling the site visit dates; 2) identifying potential interviewees; and 3) obtaining background documents pertinent to the case study.

The ICF site visit team will obtain informed consent from all respondents. All interviews will be audiotaped and transcribed for data analysis using Atlas.Ti .

B-3. Methods to Maximize Response Rates and Deal with Non-response

Every effort is being made to maximize the response rates to the provider and patient surveys. Multiple methods studies, reviews and meta-analyses have been conducted to determine which factors lead to an increase in response rates to mail surveys. Preliminary notification, multiple follow-ups with respondents, monetary incentives, use of Express Mail or first class stamped envelopes and appropriate salutations have positive effects on response rates and will be utilized for this study. The approaches that we will use to maximize the response rates, as well as deal with non-responses, for each of the data collection activities are described below.

Population Survey. Multiple strategies were used during the conception and design of the population survey to support maximizing response rates. To the extent possible, the questions for the survey were adapted and/ or taken verbatim from previously validated national surveys

The population survey was pilot tested with fewer than ten members of the target audience to ensure survey clarity and assess ease of completion within the allotted time frame. The inclusion of skip patterns in the survey makes it easier for respondents to complete given the elimination of irrelevant questions.

The method chosen for survey administration, CATI, was selected to minimize burden. The software contains branching logic that is designed to customize the flow of the questions asked based on the answers provided, as well as information that has already been collected on the participant. As a result, it is much easier to accommodate the skip patterns that are built into the survey. Not only does this facilitate administration, but it reduces the number of irrelevant questions that a respondent is asked, thus reducing the burden of administration on the respondent.

The accuracy of contacting households with age eligible adults will be enhanced by they use of the Genesys-ID system. This system contains information on area code-exchange combinations that have been assigned and Census-based demographic information for individuals and households for geographic areas defined by ZIP codes and Census tracts. This system will be used to quickly and economically generate a productive and statistically valid Random Digit Dial (RDD) sample, while removing much of the burden of telephone sample generation that is typically borne by dialing business, non-working and electronic-oriented telephone numbers.

The DCPC conservatively estimates that the response rate for population survey will be approximately 33%. To maximize this response rate, calls will be made to these households on varying days of the week at different times to maximize the probability of contacting respondents, and attempts will be routinely made to convert initial refusals into completed interviews. The contract vendor, ICF Macro, and DCPC will monitor non-response rates. If non-response rates are high, we will assess the reasons for non-response rates and modify the approach to address these issues. For example, potential solutions may include calling on a specific time or day in order to increase the likelihood of participation by eligible respondents.

Provider Survey. It is well known that primary care physicians who spend most of their time on direct patient care, and have no particular allegiance or prior involvement with the study are an especially difficult group to survey. As a result, multiple strategies were used during the development and conceptualization of the survey administration process to support maximizing response rates.

To the extent possible, questions for the survey were adapted and/ or taken verbatim from previously validated national surveys. Drafts of the survey data collection instrument and protocol were shared with internal CDC stakeholders for review and feedback throughout the development process. The provider survey was pilot tested with fewer than ten members of the target audience to ensure survey clarity and assess ease of completion within the allotted time frame. The inclusion of skip patterns in the survey makes it easier for respondents to complete due to the elimination of irrelevant questions. The survey layout was designed to include easy to read font, sufficient white space, and easy to understand directions.

Similar care was given to planning the administration of the survey. Since many medical practices have administrative personnel assigned to sort through mail and telephone messages and only pass on to physicians those most in need of his/her direct attention. To increase the likelihood these survey is deemed in most need of the physician's attention, an advanced fax will be sent to the office to let the staff and physician know that the survey is coming and to

provide a brief explanation of the purpose and importance of the survey. Within 2-3 days of the fax, the survey will be sent by Express Mail because it gets the physician's attention and is unlikely to be screened by office staff. Research and practice have also shown that enclosing a monetary incentive along with the survey increases the likelihood the physician will respond. A $25 check made payable to the physician will be included in survey packet.

Both the advance fax and survey cover letter which will be on CDC letterhead and signed the by the CDC study leader, will stress the importance of the study and will be personally addressed to the physician. The cover letter will give respondents the direct telephone number for the Principal Investigator and the ICF Study Director to call if they have questions regarding the study.

Response rates will also be maximized by using a systematic communication process, based on the Dillman method[1], to notify respondents of the survey, distribute the survey, and provide reminders to respondents to complete the survey. In the process described below, primary care providers will receive:

1) an advanced fax on CDC letterhead informing them about the survey they will receive in 2-3 days after the fax;
2) a priority mail package including a cover letter on CDC letterhead, the survey, a self-addressed, postage stamped envelope and $25 check payable to the primary care provider as an incentive;
3) a reminder fax sent approximately 2 weeks after the initial mailing of the survey packet
4) a second mailing of the cover letter, the survey, a self-addressed, postage stamped envelope; sent approximately 2 weeks after the reminder fax
5) and if necessary, a third mailing of the cover letter, the survey, a self-addressed, postage stamped envelope to the primary care provider. This third mailing will occur approximately 2 weeks after the second mailing. An additional check for $25 made payable to the provider will be included in this last mailing as further incentive to complete the survey.

ICF has previously used this methodology in several surveys conducted with primary care physicians and the response rates have ranged from 35% to 74%. CDC conservatively estimates that the response rate for the provider survey will be approximately 40%. This estimate is in line with research conducted by CDC indicating that physician response rates on health surveys tends to fall between 40% -50%. (Burt and Woodwell, 2005) ICF Macro will carefully monitor non-response rates and the potential for bias. If non-response rates are high, we will assess the reasons for non-response rates and modify the approach to address these issues.

Case Studies. In order to maximize response rates, several strategies have been incorporated into the study design. An introductory letter, co-signed by the DCPC Technical Monitor, will be sent to the program director detailing the study and requesting participation. After

[1] Dillman, DA, Mail and Internet Survey: The Tailored Design Method. (2006) NY. Wiley Publishing

agreement is obtained, an additional letter will be sent along with the request of background information and instructing the program director about the site visit and interview scheduling. Additionally, the interviews will be conducted in their offices or an easily accessible location of their choosing, eliminating issues of transportation and reducing time burden. Appointments will be scheduled at a time most convenient to the respondent. Site visitors also will follow-up with difficult to schedule participants and "no shows" or cancellations to attempt to reschedule interviews on-site or via telephone.

B-4. Tests of Procedures or Methods to be Undertaken

Drafts of the survey data collection instrument and protocol were shared with internal CDC stakeholders for review and feedback throughout the development process. Survey questions underwent cognitive testing to assess how well respondents could interpret the questions and instructions, and to assess their understanding of the meaning of survey questions.

The medical mistrust question was adapted from a survey developed by Thompson et al. (2004). The authors originally used the terms healthcare system as the referent but we decided to broaden it because the target population for our survey is likely to visit many different kinds of health care providers and we wanted them to be as inclusive as possible when they think of their "healthcare system." The medical mistrust questions went through cognitive and pilot testing and respondents did not report any problems with the questions. During the cognitive testing, one respondent wanted to add health insurance company in their personal definition of "health care system.". Since this not what we meant by providers we added a specific instruction to clarify that health insurance and drug companies were not included.

The population screener and survey were piloted tested using the CATI system with nine members of the target audience to ensure clarity of the instrument and to assess time to complete the survey. The average time for respondents to complete the population survey was 23 minutes. Similarly, the written provider survey was cognitively tested with six members of the target audience to ensure clarity of content and instrument layout. The average time for providers to complete the survey was 12 minutes. Neither providers nor respondents to the population survey reported major problems in completing the surveys. Minor modifications to the surveys' questions and response categories were made based on the feed-back received during the pilot tests. The method for administering the provider survey is based on widely accepted Dillman approach for conducting surveys.

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

Amy DeGroff, PhD., of the Division of Cancer Prevention and Control, is the Principal Investigator and Technical Monitor for the study, and has overall responsibility for overseeing the design, conduct, and analysis of the study. She will also approve and receive all contract deliverables. Telephone: 770-488-2415.

The survey instrument, sampling and data collection procedures, and analysis plan were designed in collaboration with researchers at ICF Macro. ICF is conducting data collection and will perform data analysis, in consultation with the CDC investigators. Michelle Revels, MA [404-592-2156] has overall technical and financial responsibility for the study at ICF. Ms. Revels worked closely with several ICF staff including Marnie House, EdD, Ronaldo Iachan, PhD, Anya Kriveylova, MA to design this protocol. She will direct the overall data collection and analysis effort. She will also be responsible for writing the project reports.

The ICF project team assisting with data collection, analysis and report writing for each of the data collection activities is described below.

Population and Provider Surveys. For the population and provider surveys, several highly trained staff with ICF Macro, the contracted vendor, have extensive experience in quantitative data analysis, including simpler methods such as descriptive statistics as well as executing more complicated analyses such a linear, multiple, and logistic regression as well as hierarchical linear modeling. The individuals, Helen Connolly, PhD, and Simone Peart Boyce PhD will be primarily responsible for data analysis. Naomi Freedner-Maguire and Kelley Maranville will be primarily responsible for data collection and data entry. The individuals involved with data collection and analyses are listed in Table B5.1.

Table B5.1 Individuals Responsible Data Collection and Analyses: Population and provider Surveys

Name	Agency	Telephone Number	Email
Michelle Revels, MA	ICF Macro	404-321-3211	mrevels@icfi.com
Marnie House, EdD	ICF Macro	404-321-3211	mhouse@icfi.com
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Kelley Maranville	ICF Macro	802-264-3730	kmaranville@icfi.com
Helen Connolly, PhD	ICF Macro	404-321-3211	hconnolly@icfi.com
Ronaldo Iachan, PhD	ICF Macro	404-321-3211	riachan@icfi.com

Case Studies. No statistical sampling or estimation procedures are used in this data collection; therefore no individuals were consulted on the statistical aspects of the design.

The individuals involved with data collection and qualitative data analyses are listed in Table B5.1. 3

Table B5.1.3 Staff Responsible Data Collection and Analyses for the Case Studies

Name	Agency	Telephone Number	Email
Michelle Revels, MA	ICF Macro	404-321-3211	mrevels@icfi.com

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