

# Supporting Statement B

## Title of the Data Collection

OMB Control No. 0915-XXXX

### A. Collection of Information Employing Statistical Methods

#### 1. Respondent Universe and Sampling Methods

As a preface to the description of the respondent universe and sampling methods for each data collection, we summarize in **Table B.1** the number of persons who will respond to each data collection (by strata where applicable) and the anticipated response rate.

**Table B.1 Description of the Respondent Universe and Response Rate, by Data Collection**

Data Collection	Number of Respondents	Anticipated Response Rate
Small group discussions	32 total, 4 per group: 15–17 year old English speaking girls 18–24 year old English speaking women 15–17 year old English speaking boys 18–24 year old English speaking men 15–17 year old Spanish speaking girls 18–24 year old Spanish speaking women 15–17 year old Spanish speaking boys 18–24 year old Spanish speaking men	80%
Web surveys	500 per survey (baseline, 3 months, 6 months, and 9 months)	80%
In-depth interviews with case participants	100	90%
In-depth interviews with providers	30	90%

#### 1.1 *Small Group Discussions*

The sample for this data collection will be a non-probability, purposeful quota-based sample of HIV-positive, youth/young adults aged 15 to 24 residing in North Carolina, where RTI is based. Therefore, the results are not generalizable to the general population. We do intend to oversample racial and ethnic minority youth, the primary audience for the subsequent intervention. RTI will work within their network of CBOs and clinical care providers who will

assist with participant recruitment by posting and/or distributing flyers to potentially eligible clients/patients (see flyer in **Appendix A**).

For this one-time data collection, we anticipate screening 128 individuals in order to obtain a sample of 32 participants who will participate in one of eight small group discussions (4 per group), with an estimated response rate of 80%.

Statistical power is not applicable because this is a qualitative data collection.

## **1.2 Intervention Study**

The sample for the intervention study will be a non-probability based sample of English- or Spanish-speaking, HIV-positive, youth or young adults (aged 15–24) who receive services at a participating Ryan White clinic (up to 10 in the previously identified southern states); have cell phones; allow access to their medical records; and are amenable to receiving text messages during the six month intervention period. Sampling will continue until the desired sample size is achieved. We do intend to establish targets based on gender and race/ethnicity to ensure an adequate mix of participants (e.g., adequate representation of racial/ethnic minorities).

It is anticipated that we will screen 1,000 individuals total to achieve the overall desired sample size of 500 intervention participants (250 in each study condition). An estimated 400 participants (80%) will complete all four Web-based surveys. The estimate for the 20% attrition rate is based on a combination of our experience conducting the AHRQ study (12% attrition over a 3-month intervention period) and the attrition rate found in a similar study with in-care, same-aged, HIV-positive youth/young adults (16% in a 24-week study with 5 survey time points; Dowshen et al., 2013). For this study, we increased the attrition rate to reflect the fact that our data collection period is longer than in the Dowshen and AHRQ studies and includes youth whereas the AHRQ study did not.

With 500 participants enrolled in the study and a 20% attrition rate, the effective sample size is 400. Using the PASS software program (Hintze, 2011), we estimated statistical power for a multiple regression model of the intervention effect (intervention vs. control) on a continuous outcome (e.g., number of days missed medication), assuming a  $p$ -value of 0.05 and inclusion of 10 control variables accounting for 20% of the variance in the outcome. With the given sample size, the study would have 89% power or higher to detect an intervention effect accounting for 2% of the variance in the outcome.

A subsample of case participants will be asked to participate in an in-depth interview during the intervention period. Participants will be sampled based on their age, gender, and racial/ethnic characteristics to ensure an adequate participant mix. Only those who provide consent to be re-contacted should they be selected to participate in an in-depth interview will be eligible. We anticipate that to achieve the desired sample size of 100 participants, we will need to contact 120 cases, with an estimated response rate of 90%. This estimate is based on the attrition rate found in the AHRQ study and through RTI's other research with patient populations. Statistical power is not applicable because this is a qualitative data collection.

## **1.3 Provider Interviews**

The respondent universe for this data collection is direct-service providers (e.g., physicians, nurses, social workers) from the selected Ryan White clinics. Up to 50 providers will be recommended to participate in an in-depth interview by the selected clinics' onsite study coordinators to achieve a desired sample size of 30; however, the anticipated response rate for

those with scheduled appointments is expected to be about 90% as we will reschedule interview appointments for providers who cannot make it at the last minute due to their work responsibilities. This estimate is based on the research team's prior experience with the AHRQ study and other data collections with healthcare providers. Statistical power is not applicable because this is a qualitative data collection.

## **2. Procedures for the Collection of Information**

### **2.1 Small Group Discussions**

Recruitment for this one-time data collection will be accomplished through RTI's extensive network of local CBOs (e.g., Alliance of AIDS Services-Carolinas, El Centro Hispano) and HIV primary care clinics (e.g., UNC, Duke). The team's experience has shown that it is preferable to work with CBOs to recruit young people because CBOs have in-depth knowledge of the targeted community, they are typically accessible locations in which to conduct interviews, and they have trained and experienced staff persons who can serve as adolescent advisors during the assent process (see **Section A.10.1**).

Recruitment will begin at least 5 weeks before the groups are scheduled. Network CBOs and clinics will be asked to distribute English- and/or Spanish-language flyers to their age-appropriate clients/patients (**Appendix B**). The flyers will feature a local or toll-free number for RTI that prospective participants can call to be screened for eligibility. Also, the data collection will be announced via an e-mail list or electronic bulletin board (**Appendix Q**).

Potential participants will call the telephone number listed on the recruitment flyer or other announcement to initiate the screening process (see screener in **Appendix B**). Once phone contact is made with a prospective participant, the bilingual RTI recruiter will tell the individual that we are conducting a study to discuss HIV-related topics and that if he or she is interested in participating we must ask some personal questions to determine eligibility. RTI staff will obtain verbal consent/assent over the phone and conduct eligibility screening as described in *Supporting Statement A*, **Section 10.1**.

To be eligible, persons must be HIV positive, be aged 15 to 24, and speak English or Spanish. If the prospective participant meets the eligibility requirements, he or she will be told that they will be assigned to a small group for the discussion with other people with similar characteristics. At this point, prospective participants will be told that they must provide contact information (first name and last initial, month and year of birth, phone number; and e-mail address) so that RTI can confirm their appointment 1 to 2 days prior to the group. (See **Appendix R** for reminder phone call/e-mail script.) Reminder letters/e-mails for the small group discussions will be sent to potential participants 1 week prior to the data collection giving them directions to the data collection site. Confirmation calls will also be made 1–2 days prior to the groups to assure that all recruits are confirmed.

RTI staff will select appropriate community-based field sites (e.g., CBOs, clinics, churches) in which to conduct the data collection. The sites will be strategically located so as to reduce respondent burden, increase participant comfort, and perhaps to lessen concerns about stigma or confidentiality.

The group discussions will be segmented to help ensure participants' comfort during data collection. The makeup for each four-person group will be as follows:

- 15- to 17-year-old English-speaking girls
- 18- to 24-year-old English-speaking women
- 15- to 17-year-old English-speaking boys
- 18- to 24-year-old English-speaking men
- 15- to 17-year-old Spanish-speaking girls
- 18- to 24-year-old Spanish-speaking women
- 15- to 17-year-old Spanish-speaking boys
- 18- to 24-year-old Spanish-speaking men

Transgender individuals will select which gender group they wish to join.

Upon arrival at the field site, participants will be greeted by study staff (an RTI facilitator and/or note-taker). The first name and month of birth will be used to identify individuals on the check-in sheet. Prospective participants who are more than 30 minutes late will not be allowed to join the group (which is explained during screening). We will implement the informed consent procedures described in *Support Statement A*, **Section 10.1** prior to data collection (**Appendices K1 and K2**).

All group discussions will be moderated by experienced RTI facilitators. The facilitator will be assisted by a note-taker, also from RTI. For the Spanish-language groups, both the facilitator and note-taker will be bilingual.

We will use the discussion guide included in **Appendix C** to facilitate the discussion and audio-tape the discussions (participants will be informed of this during the consent process). Before starting the audiotape, participants will be asked to share information about themselves using only their first or a false name. The group discussion will cover a variety of topics. Examples include comprehension and relevance of the sample messages; participants' interest in the topics addressed; the novelty of the messages; the extent to which the messages are motivational, credible, useful, offensive, believable, actionable, or stigmatizing; and preference for wording, phrases, and acronyms. Potential domains of messages to be tested include medication adherence, sexual risk reduction, substance use risk reduction, adolescent health and wellness, social support, patient involvement and retention in care, and medical appointment reminders. Topics for the discussion do not include sensitive subjects like personal HIV risk behaviors. At the beginning of the discussion, participants will be reminded that they can stop participating at any time.

During the discussion, an RTI note-taker will enter notes directly into a Microsoft Word data matrix on an encrypted RTI laptop, which will be powered down immediately following the group. The notes will not contain any identifying information, but will be labeled with an interview label, date, and note-taker identification. The audio files will also be transcribed by an RTI staff person.

The entire session will last up to two hours depending on how engaged participants are in the discussion. The incentive payment (\$50) will be given to participants after the group ends.

## 2.2 *Intervention Study*

This section encompasses all of the procedures that will be undertaken with all intervention participants (2.2.1) and the subset of cases who participate in in-depth interviews (2.2.2).

### 2.2.1 *Intervention Participants*

To make potentially eligible participants from the selected Ryan White clinics aware of the study, recruitment flyers will be posted within the clinics and handed out individually to patients by providers (see **Appendix D**). Potential participants will call the telephone number listed on the recruitment flyer or other announcement to initiate the screening process with the clinic's onsite study coordinator (**Appendix E**). Each clinic will have an onsite study coordinator [a direct service provider (e.g., nurse, case manager, social worker) trained on all study procedures by RTI] who will be the point of contact for the intervention study. Once phone contact is made with a prospective participant, the onsite study coordinator will provide an overview of the study and mention that if he or she is interested in participating, the study coordinator must ask the individual some personal questions to determine eligibility (see screener in **Appendix E**). The onsite study coordinator will obtain verbal consent/assent over the phone and conduct eligibility screening as described in *Supporting Statement A, Section 10.2*.

If the prospective participant meets the eligibility requirements - English- or Spanish-speaking, HIV-positive, youth or young adults (aged 15–24) who receive services at a participating Ryan White clinic; have cell phones; allow access to their medical records; and are amenable to receiving text messages during the six month intervention period - and agrees to participate, he or she will be randomly assigned to a study condition (case or control). Informed consent will follow per the procedures described in **Section A.10.2** (see consent forms in **Appendices L1 and L2**). We will also ask participants to provide their e-mail address to enable us to remind them of upcoming appointments.

All participants will be asked to complete a baseline web-based survey using a private computer terminal at their clinic (the follow-up surveys will be administered in the same location). It is anticipated that participants will complete the baseline survey at enrollment. The onsite study coordinator will schedule the follow-up surveys to coincide (to the extent possible) with routine clinic visits to limit burden and be available during the data collection to answer questions. Each survey will take approximately 45 minutes to complete. For the follow-up surveys, the onsite study coordinator will confirm participants' appointments via text, e-mail, or telephone even if their survey appointment coincides with routine care visits (participants will tell us their preferred mode of contact at enrollment).

The surveys include questions to assess demographic characteristics; use of technology; treatment adherence; social support; HIV stigma; HIV knowledge, attitudes, and beliefs; self-efficacy for disease self-management; sexual behaviors; smoking and substance use; patient satisfaction with care; and message reactions and receptivity (follow-up surveys only). The baseline and follow-up survey are in **Appendices F and G**. We will give participants their incentive payment upon completion of the surveys (\$25 per survey).

After the baseline survey has been completed and the participant profile created, cases will begin receiving text messages within seven days, which will continue for 6 months. (An inventory of sample text messages is shown in **Appendix S**) Case participants will receive 1–4 text messages per day. Controls will not receive any text messages during the intervention period.

The text messages are designed to convey relevant information to participants spanning a variety of content domains (See **Table B.2.2.1**). Each content domain serves a specific purpose whether it is to encourage or support ART adherence, retention in care, information seeking behaviors, behavior change, etc.

**Table B.2.2.1 Text Message Content Domains, Purpose and Delivery Schedule**

<b>Content Domains</b>	<b>Purpose</b>	<b>Delivery Schedule</b>
Adherence	Encourage/support ART adherence	Varies depending on participants' adherence and dosing schedules
Appointment reminders (ad hoc, timed to appointment schedule)	Support retention in care	All participants (timed to individual appointment schedules, sent 1–3 days prior to appointments)
HIV/AIDS: The Basics	Increase HIV knowledge	All participants (weekly)
ART	Encourage/support ART adherence and increase knowledge of ART's benefits, side effects, etc.	All participants who take ART (weekly)
Seeing an HIV care provider	Increase self-efficacy for disease management, encourage/support retention in care	All participants (weekly)
Patient involvement in care	Promote patient-provider communication, increase self-efficacy for disease management	All participants (weekly)
Sexual risk reduction	Support sexual risk reduction	All participants who have been sexually active in the past 3 months (weekly)
Substance use risk reduction	Support substance use risk reduction	All participants who have misused alcohol or used nonprescription drugs or prescription drugs for non-medical purposes in the past 3 months (weekly)

<b>Content Domains</b>	<b>Purpose</b>	<b>Delivery Schedule</b>
Health and wellness <ul style="list-style-type: none"> <li>• Smoking cessation</li> <li>• Mental health</li> <li>• Oral health</li> <li>• Nutrition</li> <li>• Exercise</li> <li>• Stress</li> <li>• Immunizations</li> <li>• Reproductive health</li> <li>• Preconception counseling</li> </ul>	Promote health and healthy living, improve knowledge, linkage to support services	All participants will receive messages related to mental health, oral health, nutrition, exercise, stress, immunizations, and reproductive health messages. Only current smokers will receive smoking cessation messages. Only females will receive preconception counseling messages. (weekly)
Social support	Promote social connectedness	All participants (weekly)
Life skills <ul style="list-style-type: none"> <li>• Job skills</li> <li>• Education</li> <li>• Budgeting</li> <li>• Independent living</li> <li>• Disease self-management</li> </ul>	Improve independent living skills, linkage to support services	All participants (weekly)

The short-message service (SMS) communications protocol is most commonly used for person-to-person messaging, but text messages can also be sent using a Web-based utility, such as RTI's ARTEMIS platform. ARTEMIS is a network service that is based on web technologies and is built on top of the Adobe ColdFusion application server and Microsoft SQL Server database engine. The platform consists of the following core components: a messaging communications module that sends messages via SMS gateway directly to all major mobile carriers; a message campaign manager to allow running multiple simultaneous interventions; scheduling and logging features for customization and reporting; and a connector to the research profiles that enable messaging to be tailored for individual subjects. Participant data in ARTEMIS will be kept private, and access to the system will be handled using a website front-end for site coordinators to access administrative controls that is password protected, employing Extended Validation SSL certificates that provide 256-bit encryption.

After the participant completes the last (9-month) survey, the onsite study coordinator will confirm and record that the participant's unique identification number has been deactivated. No personal identifiers will be collected or stored as a part of the Web surveys. Survey data will be stored on secure RTI servers and will be archived for statistical analysis and managed by project leadership in accordance with all of RTI's confidentiality procedures and IRB policies.

### 2.2.2 *In-depth Interviews with Case Participants*

RTI will work with the onsite study coordinators to select a purposeful sample of 20 cases per clinic based on their socio-demographics to ensure that we get feedback from a diverse subsample of participants (see segments for the small group discussions). The onsite study

coordinator will only provide RTI with the first names and telephone numbers of recommended cases. An RTI staff person will call selected case participants to reconfirm their interest in taking part in an interview. Should an individual decline, the staff person will refer to the sample list to identify an age- and gender-matched replacement of the same race/ethnicity (to the extent possible). Recruitment will continue until the desired sample size is achieved. RTI will schedule 1-hour telephone interviews with cases who accept the invitation.

RTI will send reminder e-mails or make confirmation calls 1-2 days prior the data collection. The interviews will be conducted via telephone by RTI staff with expertise in qualitative research methods and vast substantive knowledge of HIV/AIDS and who also conducted qualitative data collection for the AHRQ study. The introduction to the interview will serve as a reconfirmation of informed consent (**Appendix O**). The interviews will address topics such as implementation effectiveness, patient satisfaction, barriers to implementation and sustainability, and recommendations for improvement (**Appendix O**). At the end of the interviews, we will send participants the incentive payment (\$25) in the form of an online gift card for a retailer such as Amazon.

Interviews will be audio-recorded (at participants' discretion). The recording will only be used to verify the notes. Once the notes are verified, the audio recordings will be destroyed.

Interviews will be conducted by two-person teams: The interviewer and a note taker. The discussion will be audio recorded as a backup to the notes; however, the notes and audio recordings will not include participant or clinic names and will be maintained on the project's share drive, accessible only to staff who work on the project.

### **2.3 Provider Interviews**

The onsite study coordinator from each clinic will recommend five staff (three primary and two alternates) for inclusion in an interview. The type of staff interviewed will include health care providers (e.g., physicians, nurses, nurse practitioners, etc.), social service workers (e.g., case managers, social workers, etc.), and the onsite study coordinator. RTI will contact the recommended staff via e-mail to assess their willingness and interest in participating. If someone should decline to be interviewed, we will ask the onsite study coordinator to recommend a suitable replacement. RTI will schedule 1-hour telephone interviews with staff who accept our invitation.

RTI will send reminder e-mails or make confirmation calls 1–2 days prior to the data collection. RTI interviewers will conduct the data collection. Prior to initiating data collection, RTI will obtain verbal consent from participants following the procedures detailed in **Section A.10.3**. Providers will be asked questions to assess organizational context and readiness to change, implementation policies and practices, facilitators and barriers to program implementation and sustainability, implementation climate, value-fit, and recommendations for improvement (**Appendix H**).

Interviews will be conducted by two-person teams: The interviewer and a note taker. The discussion will be audio recorded as a backup to the notes; however, the notes and audio recordings will not include participant or clinic names and will be maintained on the project's share drive, accessible only to staff who work on the project.

### **3. Methods to Maximize Response Rates and Deal with Nonresponse**

For all data collections, the estimated response rate is 80% based on the research team's prior experience conducting research of a similar nature with HIV-positive individuals and health care/social service providers. The following procedures will be used to maximize cooperation and to achieve the desired participation rates:

#### **Small Group Discussions**

- RTI will send reminder letters/e-mails with directions to the research site approximately 1 week prior to the data collection.
- RTI will make reminder phone calls 1–2 days prior to the scheduled data collection.
- A modest payment will be provided to participants after the discussion to thank them for their time and effort in the study (see **Section A.9** for more information).

#### **Web-based Surveys**

- The onsite study coordinator will remind participants of their survey appointment via e-mail, text, or telephone 1–2 days prior to the data collection.
- A modest payment will be provided to participants after completing each survey to thank them for their time and effort in the study (see **Section A.9** for more information).
- Cases will receive text messages on a daily basis which will help with retention as they will serve as a consistent reminder of the study.
- The participants will all be patients of the clinics they were recruited from, and as HIV patients there, it is expected they will be at the clinic with some regularity. Thus, they will have time to interact with the onsite study coordinator at the clinics which will help to reduce attrition
- To the extent possible, survey appointments will be scheduled to occur before or after routine care appointments to reduce burden.

#### **In-Depth Case Participant Interviews**

- RTI will send reminder letters/e-mails approximately 1 week prior to the data collection.
- RTI will make reminder phone calls 1–2 days prior to the data collection.
- RTI will recontact those who miss their interview appointment in an effort to reschedule the data collection. Should an individual miss their rescheduled appointment, RTI will not attempt further follow up.
- A modest payment will be provided to participants after the interview to thank them for their time and effort in the study (see **Section A.9** for more information).
- Cases will receive text messages on a daily basis which will help with retention as they will serve as a consistent reminder of the study.
- The participants will all be patients of the clinics they were recruited from, and as HIV patients there, it is expected they will be at the clinic with some regularity. Thus, they will have time to interact with the onsite study coordinator at the clinics which will help to reduce attrition

## **Provider Interviews**

- RTI will send reminder letters/e-mails approximately 1 week prior to the data collection.
- RTI will make reminder phone calls 1–2 days prior to the data collection.
- RTI will recontact those who miss their interview appointment in an effort to reschedule the data collection. Should an individual miss their rescheduled appointment, RTI will not attempt further follow up.

### **4. Tests of Procedures or Methods to be Undertaken**

As mentioned throughout this document, the research team completed a similar text-messaging intervention study with HIV-positive MSM in 2012. An OMB clinical exemption was received for this AHRQ-sponsored data collection. Study procedures and instrumentation for the UCARE4LIFE study were adapted based on this prior experience both to reduce burden and improve utility. Our testing procedures are described below.

#### ***4.1 Testing the Data Collection Procedures***

Project team members conducted mock interviews and provided affirmative responses to most or all questions that branched to further follow-up questions; thus the burden estimate most closely resembles a maximum average burden, since almost all questions were presented in the interview.

Before implementing the surveys, RTI and the onsite study coordinator will test the entire process of self-administering the online survey, receiving the same questions that will be posed to participants. This will enable us to pilot test the survey programming and logic and correct any potential problems before the surveys are implemented with the actual sample of participants and to confirm that the surveys last on average 45 minutes.

For the group discussions and interviews, we rely on our team's extensive experience conducting group discussions and interviews with consumers and providers across multiple HIV-related studies over the past decade.

#### ***4.2 Testing of Messages to be delivered by Text Message***

Many of the messages were developed during the AHRQ study. However, these messages will be tested and adapted as necessary to address the needs of this study's target population based on the findings from the small group discussions.

#### ***4.3 Testing Message Delivery System***

The SMS Gateway is a web-based service for managing the flow of messages during the intervention phase. Although the requirements of the system were defined and documented for the AHRQ study, we will undergo certain steps to ensure that the highest quality standards are maintained for this study.

1. System verification will be completed before initiating data collection. Following the configuration of the system for use on this project, a robust, dynamic testing plan will be developed and executed. Working closely with HRSA and representatives from our pilot clinical sites, we will ensure that the system is fully implemented as described in the requirements specifications and document the results of stability and reliability exercises, peak performance checks, and the continuity of two-way data exchange.

2. A test device will be maintained to monitor the health and status of the SMS gateway in real time. During the data collection phase, the technical development task leader will monitor the status of the gateway by activating a mobile device to receive all outgoing messages.
3. Performance of a systematic and serial review of the ARTEMIS platform components will be completed. Project team members with access to ARTEMIS will personally check and document the functionality of the UCARE implementation and system status indicators. A communications protocol will be developed to ensure timely reporting of any issues observed by the project team's SMS monitors or as indicated by automated error messaging from ARTEMIS.
4. The ARTEMIS contingency plans will be closely monitored to ensure continued coverage. The technical task lead has compared the project requirements to the standard internal business continuity plan and disaster recovery plan and has found both to be acceptable in support this effort. In addition, our project team will have the ARTEMIS Systems Architect, an RTI employee, assigned to support the UCARE pilot throughout the project lifecycle.

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

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