SUPPORTING STATEMENT B: DATA COLLECTION PROCEDURES (IN PLACE OF STATISTICAL METHODS) FOR PAPERWORK REDUCTION ACT SUBMISSION

for

Qualitative Evaluation of HIV Counseling, Testing, and Referral Services in Non-Health Care Settings: Eliciting Consumer Views

New OMB Application

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B. DATA COLLECTION PROCEDURES (IN PLACE OF STATISTICAL METHODS)

Statistical methods will not be used to select respondents for this qualitative research study.

1. Respondent Universe and Sampling Methods

Description of Study Population. FGs will be conducted with persons who are either HIV-positive or at risk for HIV. FGs will take place in Miami, FL; Los Angeles, CA; New York, NY; and Chicago, IL. These cities were selected to achieve geographic diversity and because they are among the top 10 metropolitan areas for cumulative reported adult or adolescent AIDS cases through 2004 (CDC, 2005). We are aiming to distribute the FGs as evenly as possible, thus three cities will likely have five FGs and one city will have six FGs However, this will be determined in part based on ability to recruit certain client segments and subgroups in each city.

Estimated Number of Participants. We will conduct 21 FGs. We expect that an average of 9 people will attend and participate in each FG; however, up to 12 people will be allowed in each FG. A minimum of 4 people will be required. In total, we expect that 189 participants will enroll in the study. The minimum number will be 84 and the maximum will be 252.

Case Definitions and Composition of the FGs. The FGs will be segmented into three groups:

- **Past CTR client (HIV-positive):** Includes someone who reports an HIV diagnosis within the past 5 years. These individuals are not required to meet sexual or injection drug use risk criteria to be eligible. We will require documentation of HIV serostatus.
- **Past CTR client (HIV-negative or unknown status):** Includes someone who has been tested for HIV in a health care or non-health care setting in the past 12

months and either tested negative or did not receive their results. These individuals must meet sexual or injection drug use risk criteria to be eligible to participate.

- **Potential CTR client:** Includes someone who has either 1) never been tested for HIV or 2) previously tested negative for HIV but has not been tested in the past 5 years. These individuals must meet sexual or injection drug use risk criteria to be eligible to participate.

We will also further divide participants into subgroups to increase group homogeneity so that participants are comfortable discussing personal experiences and preferences regarding CTR services (see ***Exhibit 5***). The subgroups will consist of: Adult homosexual men, adult heterosexual men, adult females, MTF transgender persons, adult IDUs, male adolescents (aged 15-17), and female adolescents (aged 15-17).

Exhibit 5. Distribution of FGs by Audience Segment and Subgroup

	Adult Subgroups					
Adult Client Segments	**Homo-sexual Men**	**Hetero-sexual Men**	**Women**	**Male to Female Transgender Persons**	**Injection Drug Users**	**Total No. FGs (average no. participants)**
Past HIV-positive CTR clients	1	1	1	1	1	5 (45)
Past HIV-negative or status unknown CTR clients	1	1	1	1	1	5 (45)
Potential CTR clients	1	1	1	1	1	5 (45)
Total	3	3	3	3	3	15 (135)

Adolescent Client Segments	Adolescent Subgroups		
	Female (15-17)	**Male (15-17)**	**Total No. FGs (average no. participants)**
Past HIV-positive CTR clients	1	1	2 (18)
Combined: Past HIV-negative or status unknown CTR clients and potential CTR clients	2	2	4 (36)
Total	3	3	6 (54)

Inclusion Criteria.

Behavioral Risk Inclusion Criteria.

HIV-negative or status unknown past and potential CTR clients must meet one of the following HIV risk criteria to be eligible:

- Reports injecting drugs in past 12 months AND reports sharing needles, syringes, or other injection equipment with someone else in past 12 months
- Reports unprotected vaginal or anal sex with 2 or more partners in past 12 months
- Reports unprotected vaginal or anal sex with a person who was either known or thought to be HIV positive in past 12 months

Additional Inclusion Criteria.

- For persons who are HIV-positive, must have tested HIV positive within the past 5 years AND must provide acceptable[1] documentation of HIV status

[1] Acceptable documentation includes at least one of the following: a filled HIV prescription bottle with the participant's name on it; a letter from physician, provider, or agency (including a case manager) that states the participant's name and positive HIV status; AIDS Drug Assistance Program (ADAP) documentation; or a positive

- For persons who have previously been tested (with negative or unknown status), must have tested either within the last year or more than 5 years ago
- Willingness/ability to provide written informed consent or assent
- Willingness to provide a phone number so that participation can be confirmed prior to the FG
- Aged 15 to 64 years of age

Exclusion criteria for FGs include the following:

- Non-English speakers
- Participation in an HIV-related study in the past 6 months
- Participation in any FG in the past 6 months
- Unwilling to participate in assigned group (described below)
- Unwilling to provide first name, phone number, and month/year of birth
- Refusal to answer key screener questions (to determine eligibility)

2. Procedures for the Collection of Information

***Recruitment, Screening, and Enrollment*.** Recruitment will be implemented by staff from RTI, one professional FG firm from each of the 4 study cities, and community partners (i.e., CBOs). Staff from RTI and professional FG firms will be the only ones who screen and schedule participants, and they will use identical procedures. Community partners will consist of CBOs based in each study city and specialize in serving one or more of the prioritized populations (e.g., IDUs, adolescents).

The following strategies will be used to recruit participants: (1) RTI and FG firm staff will place advertisements in publications or on electronic bulletin boards aimed at the target audiences (Attachments **7** and **8**); (2) RTI, FG firm, and CBO staff will post or distribute paper

test result with the participant's name.

flyers in locations frequented by the target audiences (**Attachment 9**); (3) FG firms will use their own proprietary databases to help recruit prospective participants, calling or emailing them to inform them about the study and invite them to be screened (see recruitment email in **Attachment 10**); and (4) CBO staff will distribute paper flyers to their clients (**Attachment 9**).

During screening, we will tell prospective participants about the study and the screening process, which involves some personal questions to determine eligibility (see **Attachment 6** for the introductory script and screening questions). Recruiters will obtain verbal consent/assent before proceeding. For adolescents, three questions (see Attachment 6, Screening Instrument, Section 2.1a-2.1c) will be asked after the verbal assent and before the screening takes place to make sure they comprehend the verbal assent. If the prospective participant is eligible for the study, he/she will be assigned to a FG based on client segment (i.e., past HIV-positive client, past HIV-negative/unknown status client, and potential client) and subgroup (e.g., adult heterosexual men, adult women). If the prospective participant accepts the assignment and participation, we will collect contact information (first name, phone number, month/year of birth, e-mail address, mailing address) so that we can send reminder letters or emails with directions to the focus group location beforehand and make reminder calls 1-2 days ahead of time (see Attachment 11 for reminder letter/email). At a minimum, all participants must provide a first name, phone number, and month/year of birth. The first name and month/year of birth will also be used for the check-in process at the FG.

Once an individual is deemed ineligible via the screener, the recruiter will discontinue the screening interview. However, the recruiter will ask three "decoy" questions prior to ending the interview (see Attachment 6, Screening Instrument, Section 8). These questions are not related to the study, and we will not use this information in any part of the analysis. This is a common

practice to prevent individuals from learning the eligibility criteria so they cannot share this information with others or try to re-screen for the study themselves.

FGs with adult homosexual men, heterosexual men, women, and MTF transgender persons will take place at professional FG firms and those with adolescents and adult IDUs will take place at local CBOs (some of which will have assisted with recruitment). Holding FGs with adolescents and IDUs at CBOs will reduce barriers to participation caused by lack of transportation or concerns about stigma or confidentiality.

Written informed consent/assent will be required for participation in the FG (**Attachments 5** and **6**). Adolescent participants will meet privately with an advisor, an employee from the CBO where the FG is being held, to discuss any concerns they may have prior to signing the assent. As with the verbal assent during screening, adolescents will be asked three comprehension questions before being allowed to participate in the focus group. After these questions have been asked and correctly answered, the advisor will sign the assent as a witness.

For the FGs involving HIV positive past clients, verification of HIV status will take place prior to consent. These individuals will be asked during recruitment to bring appropriate documentation of their HIV status to the FG (see footnote 3). If the individual does not bring appropriate documentation, they will not be eligible to participate in the FG.

All FGs will be moderated by the same trained and experienced facilitator who is a member of the RTI study team. A co-facilitator will also participate, but will not lead the discussion. We will audio-record the FG discussion and one study staff person will take notes. The tapes will later be transcribed by a professional transcription firm. Separate semi-structured FG discussion guides will be used for adults who are HIV-positive, adults who are HIV-negative

or status unknown past clients, adults who are potential clients, adolescents who are HIV-positive past clients, and adolescents who are HIV-negative or status unknown past clients (**Attachment 12**). At the end of the FG session, participants will receive $50 for their time and effort.

3. Methods to Maximize Response Rates and Deal with Nonresponse

The following methods will be used to maximize response rates:

- We will use professional staff to recruit participants using a standardized protocol.
- All staff who are involved with recruitment will undergo a standardized training on study procedures and the screening instrument.
- Trained and experienced RTI study staff will moderate the FGs.
- We will provide a monetary incentive to FG participants.
- We plan to use multiple recruitment methods and venues.
- We will partner with CBOs to recruit hard-to-reach populations.
- We will conduct FGs with hard-to-reach populations at CBOs.
- We will schedule the FGs at times and locations that are convenient to participants.

We intend to track study participation rates. On the last page of the screening instrument (**Attachment 6**), recruiters will mark a checkbox to indicate whether the prospective participant is eligible and scheduled to participate, eligible but not scheduled to participate, eligible but refused to participate, or ineligible. These data will be monitored as recruitment progresses. The response rate will be the number of people who are eligible and scheduled to participate divided by the total number of people who are eligible. The FG participation rate will be the number of

people who are scheduled for and participate in a FG divided by the number of people who were scheduled. Based on previous experience in conducting focus group research with similar populations, we anticipate that a minimum of 85% of those who are scheduled for a FG will participate.

4. Test of Procedures or Methods to be Undertaken

To estimate the burden for administering the screening questionnaire, two different project team members were consulted. The project team members conducted mock screening interviews and provided affirmative responses to most or all questions that branched to further follow-up questions. In this way, the burden estimate most closely resembles a maximum average burden, since almost all screening questions were presented in the interview. In addition, the project team members deliberately read each item at a slow rate of speed. The project team members estimated the maximum average burden to be 20 minutes for the screening instrument. The estimated burden for the FG session is based on actual burden from previous FG studies of a similar nature. The two-hour timeframe includes approximately 30 minutes for check-in and informed consent/assent and 1.5 hours for the FG discussion. After each FG, the project team will debrief to discuss the FG session and any refinements to the discussion guides that need to be made.

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

There are no statistical aspects to this data collection. RTI International is the contractor who will collect the data. The following individuals were consulted on other aspects of the data collection:

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