RTI INTERNATIONAL | Memorandum

To: Matia Johnson
Center for Tobacco Products (CTP)
U.S. Food and Drug Administration
From: RTI Project Team
Date: November 30, 2016
Subject: HPHC2 Facility and Recruitment Plan

FDA's Center for Tobacco Products (CTP) and RTI International (RTI) are conducting a study that builds on prior research to gain insight on consumer comprehension of information about harmful and potentially harmful constituents (HPHCs) in tobacco products and tobacco smoke, which are chemicals or chemical compounds in a tobacco product or tobacco smoke that cause, or could cause, harm. Examples of HPHCs include toxicants, carcinogens, and addictive chemicals and chemical compounds. To assist FDA-CTP and complete this research, RTI International will conduct a series of 50 individual in-depth interviews (IDIs) with adults and youth to gather information about different ways of presenting HPHC information by brand and by quantity in each brand and subbrand in a format that is understandable and not misleading to a lay person.

Segmentation

Interviews will be held with adults (18+ years old) and youth (14-17 years old). Adults will be segmented by use of tobacco products: cigarette users, smokeless users, and former users. Youth will be segmented by use of tobacco products: cigarette or smokeless users and susceptible to use. **Table 1** shows the distribution of IDIs by segment and by location.

Table 1. Segmentation of IDIs

	Pensacola, FL	Birmingham, AL	San Diego	Total
Adult cigarette users	3	3	4	**10**
Adult smokeless users	3	3	4	**10**
Adult former users	4	3	3	**10**
Youth users (smokeless and/or cigarette)	3	3	4	**10**
Youth susceptible	3	4	3	**10**
Total	**16**	**16**	**18**	**50**

Interviews will be conducted in 3 locations (Pensacola, FL, Birmingham, AL, and San Diego, CA). Locations were chosen to maximize geographic distribution while ensuring that research would be conducted in markets with high rates of tobacco use. In choosing these locations, CTP and RTI considered rates of tobacco use, availability of suitable recruitment and market research facilities, and previous studies with specific facilities.

Facilities

RTI has contacted facilities in each of the proposed locations. RTI solicited bids from facilities in the identified cities by detailing the services required (number of interviews and screening criteria). **Table 2** shows identified facilities in each city.

Table 2. Facilities by City

City	Facility
Pensacola, FL	Graham and Associates will recruit and host interviews in a hotel.
Birmingham, AL	Graham and Associates
San Diego, CA	Taylor Research

All facilities will have the following amenities: availability of Focus Vision or other suitable videostreaming capabilities, audio recording capabilities, climate controlled observation room, and stated ability and willingness to recruit the desired numbers and segments of participants. In Pensacola, there will be no videostreaming available, but there will be an observation room and audio recording.

Recruitment Procedures

After all OMB, FDA RIHSC, and RTI IRB approvals have been received, RTI will contact the selected facilities, confirm pricing or obtain updated quotes (if needed), and schedule interviews. Interviews will be conducted in the morning, afternoon, and evening and will be scheduled in consultation with facilities to ensure the highest show rates possible. RTI will schedule at least 15 minutes between interviews and will schedule breaks for lunch and dinner.

Facilities will recruit participants using the approved screener and will identify potential interviewees from their participant databases. Adult participants will be contacted based on their previous stated interest in research. Youth participants will be contacted through their parents, who will be members of the facility databases. Facilities will conduct screening using a screener supplied by RTI. To the extent possible, facilities will recruit a diverse sample in terms of race, age, and educational attainment.

When a participant qualifies, the facility will schedule the participant. Facilities will schedule extra participants (number will depend on location and segment) to help ensure that the target number of

interviews in each location and segment is reached. RTI will monitor recruitment daily. Should questions or concerns emerge, RTI will communicate with CTP to resolve issues quickly.

Facilities will contact participants with reminders 24 hours before their scheduled interview. During this contact, if a participant indicates that they can no longer participate, the facilities will attempt to schedule an alternate participant.

RTI will provide regular updates on recruitment to CTP and will provide a participant grid for each day of research no later than 24 hours beforehand. Up-to-date grids will be available in hard copy format at each of the facilities at the beginning of each day of research.