

**Human Smoking Behavior Study**  
(OMB no. 0920-0736, exp. date 3/31/2010)

Change Request  
July 16, 2009

**Summary**

We are requesting changes to enhance recruitment for an ongoing data collection (approved in March 2007). The proposed changes are specifically designed to improve recruitment of smokers who prefer “ultra-light” and “light” cigarettes. The revised recruitment strategy includes (1) modified advertisements to target potential study participants, (2) addition of a completion bonus, (3) direct contact with potential participants, and (4) addition of a referral bonus. The proposed changes have been approved by the CDC Institutional Review Board, and will *not* result in a change in the approved burden estimate.

**Attachments**

- A. Study Design
- B. IRB Approval of Changes
- C-1. Revised Recruitment Advertisement/Flyer
- C-2. Revised Recruitment Advertisement/Doorhanger
- D. Revised Consent Document

**Justification for Proposed Changes**

The study design calls for the collection of information from 360 established adult smokers (90 smokers of “ultra-light” cigarettes, 90 smokers of “light” cigarettes, 90 smokers of full-flavor non-menthol cigarettes, and 90 smokers of full-flavor menthol cigarettes). A summary of study design issues, including specific aims and statistical power, is provided in **Attachment A**. Information is collected during and between two clinic visits. The currently approved recruitment plan provides a \$30 payment for completion of the first study visit and a \$50 incentive for completion of the second study visit.

The study continues to progress, as participants continue to be screened and recruited, and to complete study procedures. In the past 6 months, we have handed out 400 flyers; attended 5 festivals and community celebrations/activities; and visited 4 local hospitals/medical centers. We have also run 16 advertisements in local newspapers, magazines, and a money mailer, and run 20 advertisements in local college and university newspapers.

By the end of June 2009, 690 individuals had been screened and 477 had been found eligible to participate in the study. Of the 477 eligible, 229 participants (64% of target 360) enrolled and completed both clinic visits. While the approved recruitment methods have been successful, locating and enrolling “ultra light” and “light” smokers has been more challenging than locating and enrolling full-flavor cigarette smokers.

We propose several modifications to the approved protocol to enhance our efforts to reach the target response rates, especially among “ultra light” and “light” smokers. All modifications have

been reviewed and approved by the CDC's Institutional Review Board (see **Attachment B**). The IRB concluded that none of the above modifications will increase participant burden or risks associated with study participation.

### **Modifications**

- A. Modify recruitment advertising to target potential study participants. These advertisements will be printed in local newspapers, distributed on cars, gate latches and doors, and handed out to potential participants. The revised recruitment advertisement/flyer is included as **Attachment C-1** and the revised recruitment advertisement/doorhanger is included as **Attachment C-2**.
- B. Add a completion bonus. Every individual who completes the study will receive a \$25 dollar bonus payable via a gift certificate for Wal-Mart or local gas stations. The proposed completion bonus is an additional incentive over and above the previously approved payments.
- C. Distribute flyers to individuals seen smoking near the laboratory with a number to call if they are interested in hearing more about laboratory research opportunities related to smoking. Only a brief overview of the lab and the fact that tobacco research is conducted there would be provided at the direct point of contact. Study specific information or eligibility requirements would be handled directly by laboratory staff answering phones and screening potential participants.
- D. Add a referral bonus. If the referred person enrolls in the study, the referring individual receives a \$25 referral bonus.

### **Explanation of Increased Payment or Gift to Respondents**

Some eligible callers decline participation because they feel the incentive is not significant enough (36 individuals declined participation before starting the study and 6 dropped out of the study after clinic visit 1 for this reason). While not coercive or an undue influence, the completion bonus is expected to decrease drop out rates and increase participation among individuals that judge the previously approved payment of \$80 to be inadequate for participation in a clinical study.

The referral bonus will supplement currently approved efforts to locate potential participants needed to reach the final recruitment goal of 360.

### **Effect of Proposed Changes on Currently Approved Instruments and Attachments**

Title of IC: Human Smoking Behavior Study  
Changes to Instruments: None  
Changes to Attachments: See **Attachment C-1 and C-2**, Revised Recruitment Advertisements and **Attachment D**, Revised Informed Consent Document  
Add Bonus for completing all parts of the study -- Gift certificate worth \$25 for a local merchant  
Add If you enroll in the study and also refer another person who enrolls in the study you will receive a \$25 referral bonus