**National Panel of Tobacco Consumer Studies (OMB Control Number 0910-0815)**

**Change Request (83-C)**

**Jul 18, 2017**

The Food and Drug Administration is submitting this nonmaterial/non-substantive change request (83-C) to increase the total number of household screening respondents that will be interviewed during the panel recruitment effort.

**Overview of the Change Request**

To date, we have enrolled 3,830 (95%) of the expected 4,000 panel members. However, our household eligibility rates among young adults age 18-25 have been lower than what was originally estimated. To increase the yield among young adult tobacco users who are being oversampled for the panel, we need to screen additional households in the remaining weeks of panel recruitment. Specifically, we are requesting permission to conduct screening interviews with up to 6,500 additional household respondents. This will increase the total number of household screening respondents from 29,385 to 35,885. The average annual burden hours will increase by 278 hours, from 1,261 to 1,539 hours. An increase in the total sample to be fielded and screened was approved by the Institutional Review Board at RTI International (RTI) on June 30, 2017. We request OMB approval of this modification by July 14, 2017.

Table 1 summarizes the changes made to the Supporting Statement. These include the increase in the maximum number of mail mode participants from 400 to 800 approved by OMB on April 25, 2017.

**Table 1. Summary of Changes to Supporting Statement**

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| **Page Number** | **Change and Rationale** | **Prior Approval Given by OMB** |
| 5-6 | Updated text in Section A.2.1 related to number of mail mode participants  **RATIONALE:** Reflect increase in maximum number of mail mode participants from 400 to 800 per non-substantive changes approved by OMB on 4/25/17 | Protocol approved by OMB on 4/25/17 |
| 27 | Updated estimated annualized response burden and estimated annual reporting burden in Exhibits A.12.1 and A.12.2  RATIONALE: Increase estimated number of household screening respondents from 29,385 to 35,885 to increase recruitment yields | Protocol approved by OMB on 6/8/16 |
| 28 | Updated text in Section A.14 on annualized cost to the federal government  ***RATIONALE:*** Increase number of sampled addresses to include reserve sample; increase estimated number of household screening respondents from 29,385 to 35,885 to increase recruitment yields | Protocol approved by OMB on 6/8/16 |
| 31 | Updated text in Section B.1.1 on overview of sample design  **RATIONALE:** Increase number of sampled addresses to include reserve sample | Protocol approved by OMB on 6/8/16 |
| 46-47 | Updated text in Section B.2.3.1 related to number of mail mode participants  **RATIONALE:** Reflect increase in maximum number of mail mode participants from 400 to 800 per non-substantive changes approved by OMB on 4/25/17 | Protocol approved by OMB on 4/25/17 |

Track change document

