U.S Food and Drug Administration

Evaluation of the FDA's General Market Youth Tobacco Prevention Campaigns (OMB Control No. 0910-0753)

The Food and Drug Administration is submitting this nonmaterial/non-substantive change request to update materials related to the Public Education on Teen Tobacco (ExPECTT) due to changes requested by FDA's IRB. The FDA IRB will no longer provide IRB oversight for research in which FDA staff are not directly engaged. FDA has updated the following language to clarify that the FDA will not have direct involvement with human subjects to adhere to the new FDA IRB policy.

Track Changed Documents

Attachment 2. ExPECTT II Youth Instr	ExPECTT II Youth Instrument_2nd follow-up Routing for Consent ExPECTT	 Remove the RIHSC number Updated OMB expiration date Updated OMB expiration date
Attachment 6_E2a. Routing for Consent E 6_E2b3 Attachment 6_E2b3. Parent Permission Ex	Parent Permission ExPECTT II FU 2-3	Remove the RIHSC number Updated OMB expiration date
6_E2c2 Attachment 6_E2c2. Youth Assent under 1	Youth Assent under 18 EXPECTT II	 Remove the RIHSC number Updated OMB expiration date
6_E2d Attachment 6_E2d. Youth Consent 18 and	Youth Consent 18 and up ExPECTT II	 Remove the RIHSC number Updated OMB expiration date
O8_E2b Attachment 08_E2b. Study Description ExP	Study Description ExPECTT II FU 2-3	 Remove the RIHSC number Updated OMB expiration date

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10_E2d	Lead Letter ExPECTT II 1st and	Remove the RIHSC number
Attachment 10_E2d Læd Letter ExPECTT II	2 nd FU	Updated OMB expiration date
11_E2b Attachment 11_E2b. Q&As about ExPECTT	Q&A about ExPECTT II FU 1-3	 Remove the RIHSC number Updated OMB expiration date
12_E2b Attachment 12_E2b. Telephone Verification	Telephone Verification Survey EXPECTT II FU 2-3	 Remove the RIHSC number Updated OMB expiration date
13_E2a Attachment 13_E2a Notifications ExPECTT	Notifications ExPECTT	 Remove the RIHSC number Updated OMB expiration date
15_E1 Attachment 15_E1. Panel Maintenance Ex	Panel Maintenance ExPECTT	Updated OMB expiration date
18_E2d Attachment 18_E2d. Survey Invitation Ema	Survey Invitation Email EXPECTT II FU 2-3	 Remove the RIHSC number Updated OMB expiration date
19_E2e Attachment 19_E2e. Email Reminder 1 ExP	Email Reminder 1 ExPECTT II FU 2-3	 Remove the RIHSC number Updated OMB expiration date

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20_E2d Attachment 20_E2d. Email Reminder 2 ExP	Email Reminder 2 ExPECTT II FU 2-3	 Remove the RIHSC number Updated OMB expiration date
21_E2d Attachment 21_E2d. Email Reminder 3 ExP	Email Reminder 3 ExPECTT II FU 2-3	 Remove the RIHSC number Updated OMB expiration date
Attachment 22. Reminder Letter ExPB	Reminder Letter ExPECTT II FU 1-3	 Remove the RIHSC number Updated OMB expiration date