DATE: June 28, 2012

FROM: Reports Clearance Officer, HRSA

TO: Office of Information and Regulatory Affairs, OMB

SUBJECT: HRSA Request for Non-Substantive Change to the Evaluation of the Text4baby Program (OMB Control No. 0915-0347)

On February 28, 2012, OMB approved the Health Resources and Services Administration's (HRSA) request for clearance of the Evaluation of the Text4baby Program. The Control Number is 0915-0347 and the expiration date is 2/28/15. HRSA submitted the revisions based on the requested changes to OMB on 3/6/12. With this memorandum, HRSA is notifying OMB of several non-substantive changes to the text4baby methodology and survey instrument. The changes originated from two sources: (1) Health Center Controlled Networks (HCCN) and Health Center (HC) requirements for release of contact information, and (2) IRB requirements.

HCCN/HC Requirements

HRSA's original text4baby evaluation OMB submission assumed that health centers would identify eligible pregnant women for the Safety Net Consumer Survey, transmit the contact information to the contractor, and then the contractor would obtain verbal consent for all eligible pregnant women at the start of the computer-assisted telephone interview (CATI) and, in addition, obtain parent/guardian permission for eligible minors to participate. We learned subsequent to the submission of the original OMB package that health centers would not be able to release contact information to the contractor without the consent of the pregnant woman. HRSA then resubmitted the package to OMB with revisions to the recruitment/consent method and modifications to the instrument screener to accommodate health centers obtaining consent. Additional negotiations with the selected health centers followed after HRSA received OMB clearance and while we were proceeding with the IRB process. As we noted in the original OMB submission, we are tailoring the consent process to the requirements and needs of the health centers, and as a result, HRSA has now created a methodology and instrument screener to account for two different methods of obtaining consent.

- ***Model 1.*** The health center will approach eligible pregnant women and obtain their written consent to participate in the survey or, for eligible minors, approach their parent/guardians for written permission for the minors to participate. The health center will fax the signed consent forms or permission forms to the contractor's secure fax machine. In addition, the health center will fax weekly de-identified, de-duplicated lists of all pregnant women approached so the contractor can calculate a valid response rate.
- ***Model 2.*** The health center will approach eligible pregnant women and ask if they will permit the center to release their contact information to the contractor; the contractor would then telephone and obtain verbal consent at the outset of the CATI interview. The model 2 health centers also will fax weekly de-identified, de-duplicated lists of all pregnant women approached so the contractor can calculate a valid response rate.

Of the four selected health centers, we anticipate that two will use Model 1 and two will use Model 2. The use of Model 2 reduces the burden to health centers for obtaining adult prenatal consent from 130 hours to 65 hours, and the burden to health centers for obtaining Parent-of-Minor permission from 49 hours to 24.5 hours. Contractor staff will use the 65 hours for obtaining adult prenatal consent and the 24.5 for obtaining Parent-of-Minor permission.

The following Screener questions have language variations based on whether the contractor is calling a Model 1 woman (consent already obtained) or Model 2 woman (consent not yet obtained): WhatAbout, Deceased, SampMemb, NoRecall, and Box T1 (which skips Model 1 women to T2, and Model 2 women to T4 and T4a). In addition, the method of obtaining parent/guardian permission for minors to participate in the study now differs based on the "model." For Model 2 women, the contractor staff will obtain parent/guardian permission. Thus, HRSA has added some of the original language back into the screener to accommodate this situation. See questions T1 – T2 (obtain permission from a parent or guardian who is at home during the call to the minor) and Section B (obtain permission from a parent or guardian who was NOT at home during the call to the minor and therefore had to be contacted separately). These changes are highlighted in yellow in Part A, Attachment B1, Safety Net Consumer Survey (Round 1 Pregnant Women) questionnaire.

IRB Requirements

The contractor submitted the data collection protocols and instruments to its Institutional Review Board (IRB), Public/Private Ventures (P/PV) and P/PV requested a small number of non-substantive changes. The IRB requested that we provide instructions to interviewers if any participants will not permit the focus group or key informant interview to be taped. These changes have been made to the instruments below:

- Consumer Focus Group Discussion Guide. Part A, Attachment D1.
- Key Informant Discussion Guide. Part A, Attachment E.

The IRB also requested slight language modifications to the Safety Net Consumer Survey (Round 1 Pregnant Women). Below is a summary of the instrument changes.

- Explicitly mention the contractor name in the introduction to respondents (SampMemb, NoRecall). (This was originally presented as a probe.)
- Make the question "When is your due date?" less abrupt by adding "May I ask..."
- Revise the introduction to the list of participant rights accommodate the two models. See question T4.
- The IRB also requested new items that offer toll-free referrals to women who reported drinking more than 7 alcoholic drinks in an average week (see Q.8.6) or who reported smoking more than 20 cigarettes per day on average (see Q.8.7).

Table 1 summarizes the changes to the Safety Net Consumer Survey as a result of the HCCN/HC requirements and the IRB requirements.

Table 1. Crosswalk to Changes in the Safety Net Consumer Survey (Round 1 Pregnant Women)

Question Name/Number	Page Number	Nature of Change
WhatAbout	2	Text differs based on whether the respondent is in Model 1 or Model 2 health center.
Deceased	5	Text differs based on whether the respondent is in Model 1 or Model 2 health center.
SampMemb	8	Text differs based on whether the respondent is in Model 1 or Model 2 health center. Added reference to contractor name as part of introduction rather than as a probe.
NoRecall	9	Text differs based on whether the respondent is in Model 1 or Model 2 health center. Added reference to contractor name as part of introduction rather than as a probe.
Box T1	16	Depending on whether the respondent is from a Model 1 or Model 2 health center and whether she is an adult or minor, Box T1 skips her to the next appropriate question.
T1, T1a, T1b	18 - 19	Added so minor respondents from Model 2 health centers will be asked to bring a parent or guardian to the telephone so the contractor can ask permission for the minor to participate.
Section B.2	12 - 17	If the parent or guardian is not home when the contractor calls (T1) to obtain permission for the minor to participate, Section B.2 provides text for a later call back to speak with the parent or guardian.
T2	19	Returns the phone to the minor respondent after parent/guardian permission is obtained.
T3	19	Adds softer introduction “May I ask ....”
T4	20	Adds softer introduction “Before we start” Text differs based on whether the respondent is in Model 1 or Model 2 health center. In addition, adds reason for selection to first bullet point: You were selected for the survey because you received services from [HEALTH CENTER NAME] and are pregnant.
8.6 – 8.6.a	62 - 63	New question requested by IRB: On average, the respondent consumes 7 or more alcoholic drinks in a week: would she like to receive information to help her quit drinking? If yes, provide toll-free phone number at 8.6a.
8.7 – 8.7a	63	New question requested by IRB: On average, the respondent smokes 20 or more cigarettes per day: would she like to receive information to help her quit smoking? If yes, provide toll-free phone number at 8.7a.