

Change Request

May 4, 2018

“Balance After Baby Intervention”

OMB no. 0920-1115, exp. date 6/30/2019

Background and Justification

CDC is approved to collect information needed to evaluate the web-based Balance After Baby Intervention. This information includes access to an interactive version of the Balance After Baby Intervention (BABI) website for the intervention group and a “control version” for the control group, and clinical assessment visits for both groups that include visit-specific surveys and laboratory tests.

CDC obtained approval for information collection in June 2016, and an approval for a Change Request in November 2017. Two additional changes are being requested.

Change #1.

Due to study timing and availability of funding, the last study visit may occur at 12-months or 18-months for some participants. For participants who will not complete the full 24 months of the study, we would like to administer the 24-month questionnaire at the last scheduled study visit (in place of the 12-month or the 18-month questionnaire) to ensure that all participants receive the 24-month questionnaire. It is important that all participants complete the 24-month questionnaire because this survey ascertains feedback about Balance After Baby that is not captured on other surveys. Since the 24-month questionnaire may be completed at the 12-, 18-, or 24-month visits, we will now refer to it as the “End of Study Questionnaire” to appropriately reflect the timing of this survey. The changed title for this questionnaire is reflected in Attachment 7 and 7s.

Timeline and Impact on Burden

In total, it is anticipated that 15 participants will not complete the 12-month questionnaire, and 81 participants will not complete the 18-month questionnaire. Annualized over the 3 year study period, this will result in an average of 5 and 27 fewer respondents per year completing the 12-month and 18-month surveys, respectively.

For the Food Frequency Questionnaire (FFQ; scheduled for administration at each visit), the number of responses will decrease for women whose last study visit occurs at 12- or 18-months. In total, we anticipate 96 fewer responses, resulting in 32 fewer responses per year annualized over the 3 year study period. Therefore, per respondent, the average number of responses to the FFQ will be reduce to 4.5 per year annualized over the 3 year study period.

Overall, for all aforementioned changes, we estimate an annualized reduction of 18 burden hours. The approved and proposed annualized burden hour tables are listed below:

Estimated Annualized Burden Hours Before Proposed Changes

| Type of Respondents | Form Name | Number of Respondents | Average Number of Responses per Respondent | Average Burden Hours per Response | Total Burden Hours |
|--|--------------------------------------|-----------------------|--|-----------------------------------|--------------------|
| Provider or self-referred postpartum women with recent GDM diagnosis | BABI Screener Questionnaire | 98 | 1 | 8/60 | 13 |
| Consented and enrolled postpartum women with recent GDM diagnosis | BABI 6-Week Questionnaire | 63 | 1 | 17/60 | 18 |
| | BABI 6-Month Questionnaire | 60 | 1 | 20/60 | 20 |
| | BABI 12-Month Questionnaire | 57 | 1 | 16/60 | 15 |
| | BABI 18-Month Questionnaire | 54 | 1 | 14/60 | 13 |
| | BABI 24-Month Questionnaire | 51 | 1 | 15/60 | 13 |
| | Block FFQ (Completed at each visit.) | 63 | 5 | 18/60 | 95 |
| Total | | | | | 187 |

Estimated Annualized Burden Hours After Proposed Changes

| Type of Respondents | Form Name | Number of Respondents | Average Number of Responses per Respondent | Average Burden Hours per Response | Total Burden Hours |
|--|--------------------------------------|-----------------------|--|-----------------------------------|--------------------|
| Provider or self-referred postpartum women with recent GDM diagnosis | BABI Screener Questionnaire | 98 | 1 | 8/60 | 13 |
| Consented and enrolled postpartum women with recent GDM diagnosis | BABI 6-Week Questionnaire | 63 | 1 | 17/60 | 18 |
| | BABI 6-Month Questionnaire | 60 | 1 | 20/60 | 20 |
| | BABI 12-Month Questionnaire | 52 | 1 | 16/60 | 14 |
| | BABI 18-Month Questionnaire | 27 | 1 | 14/60 | 6 |
| | BABI End of Study Questionnaire | 51 | 1 | 15/60 | 13 |
| | Block FFQ (Completed at each visit.) | 63 | 4.5 | 18/60 | 85 |
| Total | | | | | 169 |

Change #2.

We would like to add two approved questions from the 24-month questionnaire to the 12-month questionnaire (Attachment 5 [all versions] – page 35 of English version) and the 18-month questionnaire (Attachment 6 [all versions] – page 21 of English version). We would like to add these two approved questions to monitor how participants’ satisfaction changes during the course of the study.

The questions to add are:

Overall, how satisfied are you with the program?

- Extremely satisfied
- Satisfied
- Neutral (neither satisfied or dissatisfied)
- Dissatisfied
- Extremely dissatisfied

How much do you agree with the following statement: I would recommend the program to a family member, friend, or colleague who had gestational diabetes.

- Strongly agree
- Agree
- Neither agree or disagree
- Disagree
- Strongly disagree

Change #2 will have minimal impact on the time burden in that it adds just 2 questions to surveys with 103 and 101 questions:

| Attachment | Instrument | No. of Questions under Current Approval |
|-------------------|------------------------------------|--|
| 5 (all versions) | 12-Month Questionnaire Screenshots | 103 |
| 6 (all versions) | 18-Month Questionnaire Screenshots | 101 |