Balance After Baby Intervention

New Information Collection Request

Supporting Statement: Part A

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Program Official/Project Officer
Shin Kim, MPH
Center for Disease Control and Prevention
Division of Reproductive Health
4770 Buford Hwy NE, MS F-74
Atlanta, GA 30341
Telephone Number: 770-488-6281
Fax Number: 770-488-6283
Email address: Skim1@cdc.gov

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Goal of the Study: Balance after Baby Intervention (BABI) aims to evaluate the effectiveness of a web-based lifestyle intervention program as a potential public health weight loss tool.

Intended Use: Investigators will administer questionnaires, physical assessments, and laboratory tests to compare control and intervention groups.

Methods to Collect: The questionnaires will be administered to control and intervention participants at the following postpartum time points: 6-weeks, 6-months, 12-months, 18-months, and 24 months.

Subpopulation: The study population is ethnically diverse postpartum women with recent gestational diabetes mellitus (GDM).

How Data is to be Analyzed: The results of the two study arms, intervention and control, will be compared to assess whether the intervention significantly: increased postpartum weight loss; increased the number of women who reach a weight within 0.5 kg of their pre-pregnancy weight; and increased the number of women who lose $\geq$ 5% of their 6-week postpartum weight, among those who were overweight or obese pre-pregnancy.

PART A. JUSTIFICATION

A.1 Circumstances making the collection of information necessary

Background. The Centers for Disease Control and Prevention (CDC), Division of Reproductive Health (DRH), focuses on understanding and preventing complications due to pregnancy and the development of chronic diseases in reproductive age women. Gestational diabetes mellitus (GDM) is one of the most common pregnancy complications in the US, affecting approximately 3-13% of pregnancies, or approximately 200,000 cases annually. As defined by the American Diabetes Association (2003), GDM is glucose intolerance that first presents during pregnancy after the first trimester. Women with a history of GDM have a substantially increased risk of developing type 2 diabetes mellitus (T2DM) within 5 to 16 years after their index pregnancy (Kjos & Buchanan, 1999; Persson, Hanson, Hartling, & Binder, 1991; Damm, Kuhl, Bertelsen, & Molsted-Pedersen, 1992; Coustan, Carpenter, O'Sullivan, & Carr, 1993; Metzger, Cho, Roston, & Radvany, 1993; Kjos et al., 1995; Yun, Kabeer, Zhu, & Brownson, 2007). Behaviors and attitudes of these women may contribute to increased risk of T2DM, such as having a distorted perception of their risk for T2DM development, being physically inactive, not breastfeeding, and retaining weight postpartum (Kim et al., 2002).

It has also been shown that many women with a history of GDM gain weight after pregnancy (Stage, Ronneby, & Damm, 2004), increasing their risk for obesity, which itself is a strong risk factor for repeat GDM and T2DM (Fehler, Kennedy, McCargar, Bell, & Ryan, 2007; Sjogren, Robeus, & Hansson, 1994). Because of this, as US obesity prevalence continues to increase, there has been a concurrent rise in the incidence and prevalence of GDM and T2DM, the latter of which has resulted in a large disease burden on individuals, families, and society. To assist in reducing this national disease burden, it is critical to develop and implement successful interventions that reduce the annual number of newly diagnosed T2DM cases, especially in increased risk populations, such as women with a history of GDM (Dornhorst & Rossi, 1998); (Kim et al., 2002 and 2006).

The Diabetes Prevention Program (DPP) demonstrated that an intensive lifestyle intervention (16 face-to-face sessions over a 24-week period) that promotes physical activity, healthy eating, and weight reduction significantly decreased T2DM incidence by 58% in high risk patients (Knowler et al., 2002). A post hoc analysis of the DPP demonstrated that women with a self-report of GDM in the lifestyle program had similar reduction in risk of T2DM as the overall study population (Ratner et al., 2008). However, the DPP included predominantly older individuals whose ability to attend group meetings and adopt healthy lifestyle changes is different than younger postpartum women.

Multiple weight loss studies of women in the postpartum period employing face-to-face methodologies like the DPP generally show disappointing efficacy and retention. Multiple barriers to lifestyle change have been identified among postpartum women with recent GDM,

including limited time and resources, fatigue, and childcare demands (Swan, Kilmartin, & Liaw, 2007). For this reason, successful adaptations of the DPP that address barriers in postpartum women with recent GDM need to be identified and tested. This data collection request aims to address this need through the conduct of an intervention trial of a website-based lifestyle program, Balance After Baby, that is adapted from the DPP and tailored specifically for postpartum women with recent GDM. This trial supports CDC's mission as authorized in Section 301 of the Public Health Service Act [42 U.S.C. 241] (**Attachment 1**), specifically as it relates to research, investigations, experiments, demonstrations, and studies relating to the treatment, control, and prevention of diseases, such as T2DM. BABI is classified as a new data collection request, seeking a three year approval.

A.2 Purpose and use of the information collection

The purpose of the proposed information collection is to evaluate the web-based Balance after Baby Intervention (BABI) through a randomized controlled trial in a racially and ethnically diverse population of postpartum women who experienced GDM during their most recent pregnancy. For BABI, women will be recruited using two sites, the Brigham and Women's Hospital (BWH) and University of Colorado Hospital (UCH). Participants will be followed for 24 months postpartum, which will allow sufficient time to observe weight change dynamics with regard to loss, increase, or weight maintenance over time.

Participants randomized to the intervention group will have access to an interactive version of the BABI website, which participants will be able to view on mobile devices such as smartphones or tablets with features that will allow for participant interaction. Intervention participants will be instructed to log-on to the BABI website once a week to view educational modules regarding healthy lifestyle options and to enter and track their weight and physical activity against their self-appointed goals. They will also have access to a web-based Lifestyle Coach who will communicate with them throughout the first year of their participation as well as a private, on-line forum to discuss questions, progress, and encouragement with the other intervention participants and Lifestyle Coaches.

Control participants will have access to a "control version" of the BABI website that is not interactive and contains more routine GDM post-partum information such as the "It's Never too Early to Prevent Diabetes" tip sheet and links to other related public websites. The breakdown of interventions vs. control group activities is displayed in **Table A.2-1** below.

Table A.2-1. Study Activities Table

Activity	Intervention Group	Control Group
Access to "control version" of BABI Website		X
Access to full, interactive BABI Website Modules	X	
Weekly entry of weight and physical activity, with feedback	X	
Web-based interaction with Lifestyle Coach	X	
Access to BABI online forum	X	
Study Assessment Visits:		
6-Week Visit	X	X
6-Month Visit	X	X
12-Month Visit	X	X
18-Month Visit	X	X
24-Month Visit	X	X

All participants are to be followed for two years with five clinical assessment visits. Beginning at 6 weeks postpartum, control and intervention participants are to return to their original recruitment site, BWH or UCH, approximately every 6 months to complete a total of five study-visits; the 6 week visit followed by visits at 6-, 12-, 18-, and 24 months postpartum. The study visits will involve the completion of visit-specific surveys including food frequency questionnaires, as well as laboratory testing, and the collection of physical measurements such as height and weight. The results of the two study arms, intervention and control, will be compared to assess whether the intervention significantly:

- Increased postpartum weight loss;
- Increased the number of women who reach a weight within 0.5 kg of their pre-pregnancy weight; and
- Increased the number of women who lose ≥ 5% of their 6-week postpartum weight, among those who were overweight or obese pre-pregnancy.
- Reduced glucose intolerance (defined as diabetes, impaired fasting glucose or impaired glucose tolerance) as compared to control.

In addition to the resulting data captured from the BABI study assessment visits (e.g. surveys, laboratory results, physical measurements), data on website viewing will be passively collected from intervention group participants. BABI website use statistics (e.g., frequency of participant visits to the site, materials viewed, as well as what materials were accessed least frequently or not at all) may provide useful correlates to main analytic findings (e.g. more viewing associated with healthier lifestyle habits).

The BABI protocol requires participants to complete a total of six questionnaires over the course of two years. The BABI Screener Questionnaire (**Attachment 2**) is administered by study staff to confirm eligibility prior to initiation of the informed consent process. Subsequent to consent and enrollment, five visit-specific questionnaires are to be completed by participants at the associated study-visit: 1) BABI 6-Week Questionnaire (**Attachment 3**); 2) BABI 6-Month Questionnaire (**Attachment 4**); 3) BABI 12-Month Questionnaire (**Attachment 5**); 4) BABI 18-Month Questionnaire (**Attachment 6**); and 5) BABI 24-Month Questionnaire (**Attachment 7**).

Each visit-specific questionnaire includes a variety of domains, including demographics, medical history, risk perception, physical activity, diet/nutrition, sleep, breastfeeding, social support, postnatal depression, perceived stress, self-efficacy, readiness to change, and participant satisfaction. Additionally, respondents in the intervention group will be asked a series of evaluation questions to provide feedback regarding their interactions with the website and Lifestyle Coach. A table mapping visit-specific content domains and/or individual questions within the domains is included as **Attachment 8**. At the end of each survey, the participants will also complete an on-line version of the Block© Food Frequency Questionnaire (see **Attachment 9**).

Participant responses to these questionnaires will provide the data needed for monitoring and assessing changes in:

- physical activity levels
- diet quality
- fruit and vegetable intake; and
- portion sizes.

The BABI questionnaires have been designed to collect the minimum amount of information necessary to meet the study's objectives on gestational diabetes mellitus and type 2 diabetes mellitus, obesity, and related topics. Questions about other factors with the potential to have mediating or moderating effects on primary outcomes have been considered and included. This is important to assist in generating robust data that can test the intervention and provide practical information about its application (MacKinnon D., 2011).

As importantly, data provided by the completion of these questionnaires will be used for ongoing monitoring of exclusion criteria, and evaluation of outcomes in the context of covariates, and reported mediating and moderating variables that could impact weight loss. The specific purpose and use of the questionnaire content domains are outlined below.

Demographics. Demographic data will be used to describe the diversity of the BABI participant population overall and to ensure both study arms are comparable with regard to key demographic variables (e.g., age, race/ethnicity, educational status, income,

marital status). This domain also includes additional questions regarding internet and cell phone access to ensure initial participant eligibility during completion of the BABI Screener Questionnaire and to monitor continued website access throughout the study. Specific questions regarding texting and data plans are included to assess each participant's ability to receive motivational texts from the Lifestyle Coach and her ability to access BABI website content. Household composition questions are included to assess the existence of potential barriers to lifestyle change, such as might be the case for a participant with multiple young children to care for at home versus those with fewer or one.

Medical History. The medical history questions, administered at each study visit, will be used to monitor participants for potential medical exclusion criteria, including diagnosis with glucose metabolism-associated diseases; use of certain prescription medications, including high dose glucocorticoids, atypical antipsychotics associated with weight gain, or weight loss medications; personal history of breast cancer or any other type of cancer other than a basal cell skin cancer; personal history of cardiovascular disease, kidney disease, liver disease, venous or arterial thromboembolic disease, adrenal insufficiency, or depression requiring hospitalization within the past 6 months; underlying disease or treatment that might interfere with participation in/completion of the study; and current pregnancy. This domain also contains questions about tobacco use, which is important for understanding possible relationships between tobacco and weight loss in the BABI population.

Risk Perception. Risk perception is a mediating variable. Respondents' interpretation of their vulnerability for T2DM may present a barrier or facilitator to their adoption of lifestyle changes. While previous research has confirmed that women with recent GDM-affected pregnancies correctly perceive they are at increased risk for T2DM from delivery to 12 months postpartum (Zera, Nicklas, Levkoff, & Seely, 2013), it is important for future research to monitor risk perception further into the postpartum period to determine the ideal intervention window.

Physical Activity. Physical activity is a key behavioral outcome. BABI aims for respondents to gradually increase physical activity to > 150 minutes per week, including resistance training. The physical activity questions will determine whether respondents attain BABI goals and investigate the relationship between physical activity and weight loss.

Diet/Nutrition. Diet/nutrition is a key behavioral outcome. BABI participant aims include reducing portion sizes and increasing the consumption of fiber, whole grains, lean proteins, fruits and vegetables, as well as using healthy vs. unhealthy fats. Responses to the food frequency questionnaire will be used to monitor changes in consumption of these types of foods over the course of the study. The BABI study has integrated the online version of the 2005 Block© Food Frequency Questionnaire (FFQ) (see **Attachment 9**) into the study data collection process.

Sleep. Sleep is a moderating variable for BABI as it may increase self-efficacy and it has been shown in the general population that inadequate amounts of sleep are correlated with increased weight and weight gain. For BABI, the association of sleep and weight over time will be examined.

Breastfeeding. Breastfeeding duration and intensity have been shown to reduce women's risk of both T2DM (Schwarz et al., 2010; Stuebe, Rich-Edwards, Willett, Manson, & Michels, 2005) and obesity (Stuebe & Rich-Edwards, 2009; Harder, Bergmann, Kallischnigg, & Plagemann, 2005; Sharma, Dee, & Harden, 2014). BABI will assess breastfeeding duration and intensity in participants throughout the study to assess its impact on weight loss. Based on responses, those women who report breastfeeding will be characterized based on high and low breastfeeding energy expenditure.

Social Support. Social support is a mediating variable for BABI. Social support can impact the participation in behavioral programs and may act as a facilitator or barrier. There is some evidence that pregnant women with GDM perceive social support differently than pregnant women without GDM. The relationship between social support and lifestyle change will be examined in BABI.

Postnatal Depression. The respondent's postpartum depression rating is a moderating variable for BABI given it may be a barrier to adopting and maintaining healthy lifestyle changes (Nicklas et al., 2013). We will examine the relationship between postpartum depressive symptoms and adoption and maintenance of lifestyle changes throughout the study.

Perceived Stress. Perceived stress is a moderating variable for BABI. Previous studies have shown that increased perceived stress is associated with unhealthy eating habits in pregnant women with GDM on insulin. We will examine the relationship between perceived stress and lifestyle changes among women in the BABI study.

Self-Efficacy. Self-Efficacy is a mediating variable for BABI. Studies of postpartum eating and physical activity in women with a history of GDM demonstrated that a high level of self-efficacy and social support were key to the adoption of adequate dietary habits and/or physical activity.

Readiness to Change. Readiness to change is a mediating variable for BABI. The stage of change may be an important factor for the adoption and maintenance of lifestyle changes. It has been reported that the majority of postpartum women with recent GDM are in the pre-action phase for behavior change. BABI is designed to help women progress in stages of change. We will assess if the intervention has an impact on the readiness to change. We will also determine if and how the readiness to change affects the adoption of lifestyle changes.

Participant Satisfaction. Participant satisfaction questions are intended to capture periodic participant feedback on their satisfaction with weight loss progress and changes they have made toward adopting a healthier lifestyle. We will assess if the intervention has an impact on women's level of satisfaction.

Evaluation. The BABI 24-Month Questionnaire will include specific questions for the intervention group only. The goal of these questions is to obtain participants' input and feedback on specific website features and functions for the purposes of evaluating their usefulness. Because the control group participants will not be using the interactive BABI website, they will not be asked these evaluation questions. We will use these responses to determine if there are technical problems or revisions that need to be addressed for future rounds of data collection.

A.3 Use of improved information technology and burden reduction

All study visit questionnaires are to be completed by the participant electronically using computer assisted self-interview (CASI). See **Attachments 3 through 7 and Attachment 9** for screenshots of the questionnaires. CASI provides quick and effortless navigation of the instruments, which are designed to be self-administered during participants' study assessment visits at the clinic. By programming questionnaire logic and skips that ensure respondents are only presented with questions that apply specifically to their circumstances, CASI reduces respondent burden.

The BABI Screener Questionnaire, used to confirm participant eligibility prior to consent, will be administered to potential participants by trained BABI research staff using a paper and pencil instrument (PAPI). Women may be recruited during their third trimester or up to 10 weeks postpartum and thus may be recruited in a variety of BWH and UCH settings. Given this, previous studies in these settings found the use of a PAPI format for questionnaire administration was less intrusive and faster than having research staff administer it using a laptop.

A.4 Efforts to identify duplication and use of similar information

While there have been other interventions with the aim of reducing type 2 diabetes mellitus development in women with a history of GDM, the BABI is the only web intervention that is based on the Diabetes Prevention Program's (DPP) lifestyle guidelines and modified to specifically target women during the postpartum period following a GDM-affected pregnancy. Further, the BABI website includes unique components and content that allows intervention participants to have the convenience of 24-hour a day access to content that is more expansive and includes a series of modules about healthy eating and physical activity; modules with information targeted to the family; exercise videos; information about breastfeeding; and on-line access to a Lifestyle Coach.

A.5 Impact on small businesses or other small entities

This collection does not involve any small businesses or other small entities.

A.6 Consequences of collecting the information less frequently

The postpartum period is a time when many changes occur in a woman's life, including competing responsibilities that alter sleep patterns, work schedules, eating patterns, exercise regularity, and time allocation (Walker & Grobe, 1999); (Swan et al., 2007). BABI will assess when postpartum women are most receptive to a lifestyle intervention program, given these physical and social barriers. In addition to assessing its impact from the standpoint of measureable increases in a healthy lifestyle and weight loss, BABI was designed to longitudinally assess women's receptivity to implementing healthy lifestyle changes over the course of two years. Collecting information less frequently may not permit this determination.

A.7 Special circumstances relating to the guidelines of 5 CFR 1320.5

This collection does not have any special circumstances that would require data to be collected in a manner inconsistent with 5 CFR 1320.5.

A.8 Comments in response to the federal register notice and efforts to consult outside agency

A 60-day Federal Register Notice was published in the *Federal Register* on August 28, 2015, Vol. 80, No. 167, pp. 52292-52294 (see **Attachment 14**). CDC did not receive public comments related to this notice.

A.9 Explanation of any payment or gift to respondents

As a study population, postpartum women are particularly challenging to reach due to the heightened demands associated with caring for an infant. The GDM target study population at Brigham and Women's Hospital (BWH) and University of Colorado Hospital (UCH) is comprised of a socio-economically diverse population and this diversity is crucial for the generalizability of the study findings. Providing a token of appreciation to cover out-of-pocket

travel and childcare expenses helps to reduce the burden that may disproportionately discourage disadvantaged women from participating in the study. In an effort to ensure respondents are in no way financially burdened by study participation and to maximize response rates, participants will be provided with a standard, non-negotiable token of appreciation for their time and expenses associated with completion of each of the five in-person clinic visits.

Amounts were estimated to cover a flat rate of $22 for transportation costs (e.g., gas and tolls) and a babysitting stipend of approximately $15/hour. Because three clinic visits include oral glucose tolerance testing, or OGTT, the duration of the visits at the 6-Week, 12-Month, and 24-Month intervals are to be about 3 hours. The duration of the 6- and 18-Month Visits, which do not include OGTT, will be less than 2 hours. We estimated 6 hours of childcare for the 3 hour visits (i.e., the 6-Week, 12-Month, and 24-Month visits) and 4 hours of childcare for the 2 hour visits (i.e., the 6-Month and 18-Month visits). In addition, a parking voucher will be provided to participants that drive to the clinic visits. These vouchers are worth $3 per hour.

The amounts are structured as shown in **Table A.9-1** below: $100 following completion of the 6 week & 12 month visits, $80 following completion of the 6 month & 18 month visits, and $140 following the 24 month visit. The amounts are slightly shifted towards the final visit to encourage all study participants to attend the final, 24-month post- partum visit. In order to preserve good will and communication with the participants, investigators also plan to give small “Thank You” gifts to all participants, such as baby socks, magnets, or picture frames, with each costing less than $2 and totaling approximately $20 per participant.

In addition to the funds described above, intervention participants will be provided a scale and a pedometer upon enrollment. These items help ensure that these women have access to these standard tools that can be voluntarily used for monitoring progress. The total value of these items is $50.

Table A.9-1. BABI visit schedule and gifts

	Intervention Group	**Control Group**
6 Week Visit	$100	$100
6 Month Visit	$80	$80
12 Month Visit	$100	$100
18 Month Visit	$80	$80
24 Month Visit	$140	$140
Thank You Gifts	$20	$20
Study Supplies (scale, pedometer)	$50	0

A.10 Protection of the privacy and confidentiality of information provided

Upon initiation of the research contract, the CDC Office of the Chief Information Security Officer Privacy Act clearance determination was as follows:

While the Privacy Act is not applicable, the appropriate security controls and Rules of Behavior should be incorporated to protect the confidentiality of information, proprietary, sensitive, and Personally Identifiable Information (PII) the Contractor may come in contact with during the performance of this contract.

The compilation of individual research results and responses into a study database for BABI will be used only for research purposes. The paragraphs below describe the protections in place to preserve privacy.

The data collection system will consist of information collected via the BABI Screener Questionnaire, the study visit questionnaires, and the clinical and laboratory measurements. The BABI Screener Questionnaire, used to confirm participant eligibility prior to consent, will be administered to potential participants by trained BABI research staff using a paper and pencil instrument (PAPI). Responses captured on the BABI Screener Questionnaires will be routinely entered into an electronic database and hardcopies subsequently destroyed. The password-protected personally identifying information will only be accessible to BWH and UCH study staff and will not be shared with Westat or CDC. All study visit questionnaires are to be completed by the participant electronically using computer assisted self-interview (CASI). In addition to the resulting data captured from the BABI study visits (e.g. surveys, laboratory results, physical measurements), data related to the intervention participants' website viewing practices will also be tracked to gather potentially meaningful information regarding compliance.

As described in section A.2, the study visits will involve the completion of visit-specific questionnaires, laboratory testing, and the collection of physical measurements such as height and weight. Each visit-specific questionnaire includes a variety of domains, including demographics, medical history, risk perception, physical activity, diet/nutrition, sleep, breastfeeding, social support, postnatal depression, perceived stress, self-efficacy, readiness to change, and participant satisfaction. Additionally, respondents in the intervention group will be asked a series of evaluation questions to provide feedback regarding their interactions with the website and Lifestyle Coach.

In terms of data sharing, there are three main entities involved in the conduct of BABI: the clinical sites--Brigham and Women's Hospital (BWH), University of Colorado Hospital (UCH); and Westat. Westat is responsible for processing and providing quality control of the research data and preparing the final analytic datasets that are to be delivered to BWH and CDC. While BWH and UCH will maintain local subject personally identifiable information (PII), only de-identified and anonymized data will be transmitted to Westat and CDC.

PII will be collected but identifiers will be maintained separately from response and biometric data as a safeguard against inadvertent disclosure or identification of respondents. As part of BABI, BWH and UCH will collect and maintain subject PII that will include: name, date of birth, contact information, date of most recent child's delivery, and date of visit. BWH and

UCH clinical site staff will protect the privacy of participant data and research records by assigning a unique subject identifier to each participant. This subject ID will be the only identifier associated with a subject's response and biometric data, such as their electronically captured survey responses, lab values, and weight measurements. The linking file that is separate from the response and biometric data will be kept at each site and provide the link between the unique subject IDs and associated PII (e.g. names, dates of birth, contact information, etc.). Subject PII will never be transmitted outside the clinical sites as the data files transmitted to Westat and CDC will only contain study data identified by subject ID code. Resulting reports or publications regarding this research are to be reported in aggregate and ensure individuals cannot be identified.

Topics related to privacy and the voluntary nature of participation will be discussed during the administration of the informed consent document. BWH and UCH investigators will explain to respondents that participation is voluntary, they are not required to answer any questions to which they would prefer not to respond, and they can end their participation at any time without negative consequences. See **Attachment 10** and **Attachment 11,** Study Informed Consent Documents, for specific language regarding a participant's rights as a research subject. The informed consent documents clearly explain that the study findings will be compiled and only presented on a group level, with no individuals identified. Participants are also told that relevant test results may also be shared with their doctors and added to their medical records unless they decline this option. In addition, within the informed consent document, there is a separate item where the participant must check "Yes" or "No" regarding their approval to allow researchers store study samples and health information for future research.

Both the BWH and UCH sites are committed to data security. Paper documentation, such as the hardcopy BABI Screener Questionnaires and documentation of informed consent, will be stored in a designated and secured office area and similarly designated and locked filing cabinet within BWH's Division of Endocrinology, Diabetes, and Hypertension and UCH's Anschutz Health and Wellness Center. Research data kept online will be kept secure on the BWH/Harvard servers, which will require user authentication and anonymity. The BWH and Colorado study staff have completed training in the protection of human research participants (CITI).

A.11 Institutional Review Board (IRB) and justification for sensitive questions

The study protocol, informed consent forms, and data collection forms have received preliminary IRB approvals at all study sites (**Attachment 13**, IRB approval letters). The participating IRBs will also conduct continuing reviews of routine annual data points as well as required review of any adverse events or protocol violations as needed. Some data to be collected for BABI may be sensitive in nature to some respondents. To reduce the sensitivity of these questions, respondents will be informed at the time of consent and reminded at the time that they complete the questionnaire that they are not required to answer any questions to

which they would prefer not to respond. See **Attachment 10** and **Attachment 11** for the Informed Consent documents. Further, since the questionnaires are designed for conduct as CASI, this method likely reduces the potential for subject embarrassment. A brief description of topics that may be perceived by subjects as sensitive follows:

- *Race/Ethnicity*. Race/ethnicity is a key covariate for the BABI population, as persons of different racial/ethnicity groups may experience different levels of healthcare disparities. Additionally, BABI must ensure the control and intervention groups are comparable at baseline to ensure the conclusions about the intervention are valid.

- *Alcohol and Tobacco*. The 2005 Block© Food Frequency Questionnaire, **Attachment 9,** contains three questions on alcohol consumption that will be asked at each of the five clinical visits. Due to the calories introduced by the consumption of alcoholic beverages and their potential effect on body weight, this information is required for obtaining a complete dietary assessment. The BABI Screener Questionnaire contains three questions on tobacco use, and the questionnaires at the five clinical visits contain two questions on tobacco use. Longitudinal assessment of tobacco use is needed given its association with reduced weight.

- *Postpartum Depression.* All respondents will be asked the 10-question Edinburgh Postnatal Depression Scale at all five clinical assessment visits. Postnatal depression symptoms are important moderating variables that can affect the study outcomes. A score of ≥ 9 on the Edinburgh Postnatal Depression Scale or an answer of yes on the question about thoughts of self-harm to herself or to others will prompt evaluation by one of the study physicians, consistent with the standard outpatient care within the BWH obstetric practices. Any respondent who is deemed acutely suicidal upon evaluation will be sent to the ED for emergent evaluation by psychiatry. Respondents deemed to be at risk for depression, but not acutely suicidal, will be referred to a designated OB social worker for further evaluation and assistance.

A.12 Estimates of annualized burden hours and costs

Data collection activities include completion of an initial paper BABI Screener Questionnaire and five additional electronic questionnaires over the course of the 24 month follow-up period. Following completion of the BABI Screener Questionnaire and consent, subjects in each of the randomized study arms, or groups, are to return to the BWH or UCH clinic to complete questionnaires at a 6-week, and 6-, 12-, 18-, and 24-Month study assessment visits.

A.12.1 Burden Hours

Over a three-year clearance period, Brigham and Women's Hospital (BWH) and University of Colorado Hospital (UCH) are to recruit and enroll a total of 250 women for BABI. To reach this goal, approximately 293 women will be screened. Recruitment will be accomplished with the help of provider referrals and self-referral, facilitated by the placement of study flyers and brochures (**Attachment 12**) on hospital postpartum floors, in the antepartum clinics and a variety of other affiliated women's health and OB/Gyn clinic practices.

BABI study staff will use the BABI Screener Questionnaire to confirm the eligibility of women identified as interested in BABI participation. Because it is administered prior to initiation of the consent process, the burden estimate for administration of the BABI Screener Questionnaire is based on a larger pool of individuals than that of individuals eligible and consented for follow-up. The remainder of the burden estimate is based on completion of questionnaires by consented subjects at the five study visits that are to occur at 6- weeks, and 6-, 12-, 18-, and 24 months postpartum.

Further, in addition to incorporating the time to complete each of the visit-questionnaires in the burden estimate calculations, the number of participants who are expected to complete each of the individual questionnaires was derived using participant rates of eligibility, consent, and return, and the rate of exclusion and attrition between study visits as reported for similar studies among this population (Nicklas et al., 2014). As a result, approximately 293 women (98 annualized over 3 years) with recent GDM will need to complete the BABI Screener Questionnaire of which 5% (n≈15) are expected to be excluded based on questionnaire responses. Of the remaining women expected to be found to be eligible, 90% (n=250) are expected to consent for the BABI.

Between the time of consent and the 6-week postpartum study visit where women will be randomly assigned to the intervention or control group, 5% (n≈13) are expected to be medically excluded and of the remaining (n=237), 80% are expected to present for the visit and complete the associated BABI 6-Week Questionnaire (n=190, 63 annualized). While it is possible that the show-rate for study participants may be higher than 80% at individual visits, this conservative estimate was applied to remaining eligible women for each study-visit across the 24 month period. A constant 5% rate of exclusion and attrition was also applied to the eligible remaining study population at the time of the previous visit to determine the number who would be eligible to return for any given current study-visit.

The result of a constant application of these rates is a steady decrease in the number of subjects eligible to return for individual visits over time. It is possible that the exclusion rate may actually increase slightly over the follow-up period due to the inherent increased risk for T2DM development or pregnancy. Should this be the case, two factors have been considered that will compensate for any additional net loss: 1) greater focus in BABI on retention efforts to help

ensure a decrease in the number of missed appointments or participant drop-out and 2) the perception that women who make it to the one year follow-up visit likely represent more committed participants who will be more likely to continue with the study for the duration of the second year.

As exhibited in **Table A.12-1**, the total number of participants estimated for the completion of each questionnaire will be equally divided across the two study arms, intervention and control, annualized over a 3-year period. Therefore, of the 190 women (63 annualized) who attend the 6-week visit, the estimated number of participants returning for the 6-month visit is reduced to 180 (60 annualized), followed by 172 (57 annualized), 162 (54 annualized), and 154 (51 annualized) for the 12-, 18-, and 24-month visits respectively. The average burden per questionnaire ranges from 8 minutes for the BABI Screener Questionnaire up to 18 minutes for the BABI 6-Month Questionnaire. The average burden for the Block © Food Frequency Questionnaire is 18 minutes for the electronic version which is shorter than the paper version. The average burden hours per response for the 6-Week (**Attachment 3**), 6- (**Attachment 4**), 12- (**Attachment 5**), 18- (**Attachment 6**), 24-Month (**Attachment 7**), and Block © Food Frequency (**Attachment 9**) Questionnaires are shown in Table A.12-1 below.

Table A.12-1. Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	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	18/60	18
	BABI 12-Month Questionnaire	57	1	14/60	13
	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	183

A.12.2 Cost to Respondents

The cost to respondents was calculated using the median hourly rate in the state of Massachusetts according to the most recent data on the U.S. Bureau of Labor Statistics' website, which at the time of BABI OMB clearance preparation was for May 2013. These labor rates may vary during the conduct of the study, both across years and across sites, but these variations are not expected to result in significant differences in costs to respondents. **Table A.12-2** exhibits the annualized costs as they relate to each of the questionnaires to be completed.

Table A.12-2. Estimated annualized cost to respondents

Type of Respondents	Form Name	Number of Respondents	Number of Responses Per Respondent	Hourly Wage Rate	Total Burden Hours	Total Cost
Provider or self-referred postpartum women with recent GDM diagnosis	BABI Screener Questionnaire	98	1	$21.07	13	$274
Consented and enrolled postpartum women with recent GDM diagnosis	BABI 6-Week Questionnaire	63	1	$21.07	18	$379
	BABI 6-Month Questionnaire	60	1	$21.07	18	$379
	BABI 12-Month Questionnaire	57	1	$21.07	13	$274
	BABI 18-Month Questionnaire	54	1	$21.07	13	$274
	BABI 24-Month Questionnaire	51	1	$21.07	13	$274
	Block FFQ (Completed at each visit.)	63	5	$21.07	95	$2002
					Total	$3,856

A.13 Estimates of other total annual cost burden to respondents or record keepers

The BABI incentive plan was designed to avert potential costs to respondents (e.g., childcare, transportation, lab tests). However, respondents in the intervention arm of BABI may incur an increased cost in food and/or data usage rates through intervention participation.

A.14 Annualized cost to the federal government

The annualized cost to the federal government is approximately $500,000 during the 3-year data collection period. The total over the four year contract period is $2 million, which includes: $20,000 for CDC DRH program participation and oversight, and a 4-year contract to the investigators at Westat, BWH, and UCH in the amount of $1.9 million dollars. The BABI research period consists of a 3-year base period and 1-year option period.

Table A.14-1. Estimated Annualized Cost to the Federal Government

Institution	Annualized Cost	Role
CDC DRH	$20,000	Oversite and participation in Working Group meetings
Subcontractors (Westat, BWH, UCH)	$480,000	Study design, instrument development, website development and maintenance, participant recruitment and enrollment, data collection, data management, data analysis, and report writing

A.15 Explanation for program changes or adjustments

This is a new collection of information.

A.16 Plans for tabulation and publication and project time schedule

A three-year OMB clearance is requested to cover all data collection activities. **Table A.16-1** below outlines the project time schedule. BABI data will be released in two formats: cleaned datasets and final reports. The final datasets will be formatted as de-identified restricted-use files. The final report will include a study overview, work plan, and a summary of scientific findings. Initial datasets and the base period contract report will be delivered to CDC in October 2017. If the contract option is exercised, an additional final dataset will be submitted to CDC in July 2018. The final option period report will be based on this dataset and be submitted to CDC in October 2018.

Table A.16-1. Project Time Schedule

Activity	Time Schedule
Recruitment	Start 1-2 months after OMB approval, continue for up to 19 months
Information/Data Collection	Start 1-2 months after OMB approval, continue through March 2018
Validation and Compilation of Base Period Analytic Dataset	April – September 2017
Deliver Base Period Findings Report	October 2017
Validation and Compilation of Option Period Analytic Dataset	April – July 2018
Deliver Option Period Findings Report	October 2018

A.17 Reason(s) display of OMB expiration date is inappropriate

The display of the OMB expiration date is not inappropriate.

A.18 Exceptions to certification for Paperwork Reduction Act submissions

There are no exceptions to the certification.

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