Mini Supporting Statement A

**A Generic Submission for Formative Research, Pretesting, and Customer Satisfaction of NCI’s Communication and Education Resources (NCI)**

OMB#: 0925-0046

Exp: July 31, 2019

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**List of Attachments**

Attachment 1: Prescreener recruit email

Attachment 2: Online prescreener

Attachment 3: Telephone prescreener

Attachment 4: Discussion guide

Attachment 5: Messaging and visual testing materials for discussion guide

Attachment 6: Images for discussion guide

**Mini Supporting Statement A**

**A.1 Circumstances Making the Collection of Information Necessary**

Like the National Cancer Institute’s (NCI) Office of Communications and Public Liaison (OCPL), the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) Office of Communications (OC) conducts various types of research to identify and learn about target audiences. Specifically, OC conducts market and user-centered research and evaluation in order to:

* Identify perceived health-related needs of diverse audiences
* Inform the design and development of NICHD resources and ensure that they are appropriate and effective, and reach the intended audiences
* Monitor audience trends
* Build on and advance the Institute's knowledge base and positioning in the field of user-centered informatics research
* Assess the impact of resources and activities

The research conducted by OC helps ensure that NICHD communication and education resources are appropriate, useful, and effective. Information programs and campaigns within NICHD create and use a variety of media including print (e.g., brochures, posters, fact sheets, information kits), broadcast (e.g., public service announcements, video news releases), and electronic formats (e.g., Internet, listservs), as well as direct response (NICHD Information Resource Center) to inform and educate the public and health care providers about the health of children, adults, families, and communities. Production of these materials is the major way that NICHD conveys messages to the audiences.

It is OC’s responsibility to ensure that the materials produced by NICHD can be understood and are well-received by intended audiences (Formative Research/Pretesting) and meet the satisfaction of NICHD’s audiences (Customer Satisfaction). Formative research/pretesting helps ensure that messages have the potential to be received, understood, and accepted by those for whom they are intended; while the customer satisfaction research helps NICHD ensure the relevance, utility, and appropriateness of the many educational programs and products that the Office produces.

NICHD OC is requesting approval of this substudy to continue conduct formative research, pretesting, and customer satisfaction activities for a new public health campaign on maternal obesity.

**A.2 Purpose and Use of the Information Collection**

NICHD is developing an initiative on maternal obesity for as part of its National Child and Maternal Health Education Program (NCMHEP), targeting both patients (pregnant women with a BMI over 30) and health care providers (HCPs) who work with these women. Obesity increases the risk of several health problems for both mother and baby. The mother is at a higher risk for gestational diabetes, preeclampsia, sleep apnea, infection, labor problems, miscarriage, and stillbirth. The baby is at risk for birth defects, chronic conditions, macrosomia, and being born prematurely ([ACOG, 2016](http://www.acog.org/Patients/FAQs/Obesity-and-Pregnancy)). While the best prevention is for the mother to lose weight prior to getting pregnant, because nearly one-half of all pregnancies are unintended ([CDC, 2011](https://www.cdc.gov/reproductivehealth/unintendedpregnancy/)) many obese women find themselves pregnant before this can occur.

Results from recent studies among obese pregnant women indicate that they need individualized care and interventions ([Nyman, Prebensen, & Flensner, 2010](https://www.ncbi.nlm.nih.gov/pubmed/19100667)). The most recent statistics from the Centers for Disease Control and Prevention (CDC) showed that 65,000 women were hospitalized in 2011 due to complications from maternal obesity ([CDC, 2011](http://www.cdc.gov/reproductivehealth/maternalinfanthealth/severematernalmorbidity.html)).In addition, many women reported negative experiences with health care providers related to the women’s weight during pregnancy ([Nyman, Prebensen, & Flensner, 2010](https://www.ncbi.nlm.nih.gov/pubmed/19100667); [Furber & McGowan, 2011](https://www.ncbi.nlm.nih.gov/pubmed/20483513); [Olander, Berg, McCourt, Carlstrom, & Dencker, 2015](https://www.ncbi.nlm.nih.gov/pubmed/25885178)). As a result of these and other study findings, the goal of the NICHD’s initiative is to educate and empower patients and guide HCPs to have conversations sensitive to both patient feelings and the facts around maternal obesity. To date, no research has been conducted to inform message and materials development to meet this goal.

This request is to allow us to collect feedback from members of the target audience (i.e., pregnant or recently-pregnant obese women) to ensure that the initiative’s future messaging and materials are authentic, easy-to-understand, discuss weight in an appropriate (not insulting) manner, and effectively emphasize the importance for these individuals to seek out prenatal care and have open conversations with their healthcare providers about their pregnancies.

Respondents will be women who meet specific screening criteria and consent to share their perspectives. Respondents will include pregnant women and women who were recently pregnant. All respondents will also have Body Mass Indexes[[1]](#footnote-1) of at least 30 at the start of their pregnancy and have/had prenatal care during their most recent pregnancy. Respondents will also include a mix of races and ethnicities, ages, socio-economic statuses, number of children in the household, and will live in various regions of the country.

A brief online pre-screener will be sent to a targeted sample of 500 women of childbearing age from an “opt-in” database of potential research participants. Those who meet the initial criteria of being pregnant currently or having given birth in the past 9 months will be invited to participate in a telephone screener to determine if they meet the other specific qualifications necessary for this project. We anticipate that of the 500 who complete the online pre-screener, 120 respondents will qualify for the telephone screener (based on being currently pregnant or having had given birth in past 9 months). Of the 120 telephone screener respondents, we expect 10 to qualify for the focus groups and 20 to qualify for in-depth interviews (based on a qualifying BMI of 30+ at the start of pregnancy, and are receiving/did receive prenatal care during pregnancy). Telephone screener respondents will be invited to a focus group or in-depth interview if they meet all qualifications in the telephone screening questionnaire ***and*** if they are available at the time of the focus groups or during the timeframe that we are conducting in-depth interviews.

**A.3 Use of Information Technology to Reduce Burden**

This research will be conducted using virtual focus groups and in-depth interviews that rely on technology to reduce the burden on participants. Focus groups traditionally take place in-person with a moderator facilitating a discussion regarding a product, issue, or program with a small group of individuals in a designated physical location. Using virtual focus groups and in-depth interviews that utilize video- and teleconferencing, we eliminate the need for in-person participation and the other burdens that accompany it.

**A.4 Efforts to Identify Duplication**

Because the maternal health field is so diverse and complex, and each message is essentially different, new data collection instruments generally must be prepared for each pretest. As each new message, strategy, or product is developed, NICHD reviews existing literature and data bases, including pretesting reports on existing messages and materials, and consults with outside experts to evaluate available information on similar messages with comparable audiences. After consulting the available evidence and other sources, NICHD could find no research conducted to inform message and materials development to meet the goal of communicating specific health needs of obese pregnant women to those women or their providers.

**A.5 Impact on Small Businesses or Other Small Entities**

N/A

**A.6 Consequences of Collecting the Information Less Frequently**

As is usual for formative research and pretesting responses will be collected only one time for each participant.

**A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

This information collection will be implemented in a manner that fully complies with 5 C.F.R. 1320.5.

**A.8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency**

N/A

**A.9 Explanation of Any Payment of Gift to Respondents**

All research participants will receive incentives after participating. Specifically, the focus group participants will receive a total of $75 incentive after participating in their 120-minute focus group. Individuals who participate in the in-depth interviews will receive a total of $40 incentive.

We understand that the OMB guidance about incentives for participation in research is based on the principles of the 2006 memo: *Guidance on Agency Survey and Statistical Information Collections.[[2]](#footnote-2)* This memo states its purpose as “to improve the quality of Federal surveys and statistical information.” When it comes to qualitative research, it is standard practice in commercial market research to offer recruited respondents some form of remuneration for the time they spend engaged in a focus group. Small amounts of money, a free meal or snack scheduled around the time of the focus group, and/or remuneration for parking and/or transportation are most often used.

There is extensive literature to support the use of incentives, primarily monetary incentives, as a supplement or complement to other efforts of encouragement to ensure recruitment of a representative sample, especially among not-yet-served and minority populations.[[3]](#footnote-3),[[4]](#footnote-4) In studies for both commercial market research and social sciences, findings indicate that respondents who receive these tokens of appreciation provide valid input, and their inclusion makes for a more representative sample.

Additional information about the incentive amounts is detailed below:

* ***Data Quality:*** As noted above, the purpose of the research described here is to offer guidance to NICHD to develop communication messaging and materials pertinent to obese pregnant women, especially those who do not show a strong interest in, nor see the importance of, an open doctor-patient relationship with their prenatal care providers. It is therefore imperative that the qualitative insights are gleaned by hearing the opinions of a diverse range of the American public. Limiting incentives would do an irreparable harm to this objective by increasing non-response bias. Offering no incentive or a small incentive will limit participation to individuals with personal or vested interest in the topic matter, thus limiting the range of opinions expressed in qualitative discussions. In addition, this would also potentially exclude sections of the population who cannot afford to attend the focus groups, either due to the cost of childcare or the cost of missing work (see below). This, in turn, would limit the qualitative insights gathered to the opinions of the very select individuals willing to participate in the research without any or with very low incentives, severely biasing the information needed to develop strategic efforts to inform future outreach. The suggested incentive amounts will assure participation by the broader spectrum of American public and thus decrease non-response bias.
* ***Complex study design***: These in-person focus groups and IDIs employ highly-restrictive criteria for participation. Research participation is segmented by Body Mass Index, or BMI (only those with self-reported BMIs over 30 can participate), as well as how long the potential participant has been pregnant, her age, race, and ethnicity. Proposed incentives are more likely to secure the participation of individuals meeting the screening requirements, making recruitment more effective and thus saving government money in recruitment costs.
* ***Improved coverage of specialized respondents, rare groups, or minority populations*:** All of the research phases associated with this project will include low-income participants. The research team for this effort was selected largely due to their vast experience in conducting research among low-income and hard-to-reach populations. In the similar work they have conducted among this audience, participants have been burdened with additional transportation and child care costs which have prevented them from participating in focus groups or led to high no-show rates. These costs have been incorporated into the incentive amounts for each research event.
* ***Homework Assignment Completion:*** For the homework assignment, respondents will be asked to collect 7 to 10 pictures representing their thoughts about wellness. Respondents may have to purchase magazines at newsstand prices to collect these pictures. The incentive will thus cover the cost of at least 5 magazines, assuming the newsstand price of approximately $5 per magazine.

**A.10 Assurance of Confidentiality Provided to Respondents**

Information provided by respondents will be kept confidential and private, except as otherwise required by law. This will be communicated to respondents by means of explanatory text at the beginning of the prescreener and scripts read prior to the telephone prescreener, focus groups and telephone interviews. Respondents will also be advised of the following: the nature of the activity; the purpose and use of the data collected; NICHD sponsorship; and the fact that participation is voluntary at all times. Because responses are voluntary, respondents will be assured that there will be no penalties if they decide not to respond, either to the information collection as a whole or to any particular questions.

As a further guarantee of confidentiality, all presentation of data in reports will be in aggregate form, with no links to individuals preserved. Reports will be used only for research purposes and for the development of communication messages and educational materials. The information collected from the online pre-screener by our professional recruiting partners will not be shared with the researchers. Our recruiting partners store the pre-screener data on their secure servers for a period of 60 days. At the end of those 60 days, they destroy the files. Server security includes the following: **network safeguards** (redundant firewalls, multiple firewall layers, end-to-end client encryption, intrusion detection system and network monitoring), **application safeguards** (password-protection, automatic logoff, administration auditing, logging and log retention, antivirus, security patches and updates, and mobile device security), and **data safeguards** (disk subsystem design, nightly backups, and offsite backup storage and retention). The online prescreener screener will be sent through Constant Contact, which is covered under an NIH umbrella Privacy Impact Assessment for Third Party Websites/Applications.

Only NICHD staff and contractor personnel conducting the information collection will have access to individual-level interview and focus group data. All project/contractor staff conducting the information collection will sign a confidentiality agreement, and all electronic and hard-copy data will be maintained securely throughout the information collection and data processing phases. While under review, electronic data will be stored in locked files on secured computers; hard-copy data will be maintained in secure building facilities in locked filing cabinets.

Although some personally identifiable information will be collected, data will not be retrieved by personal identifiers unless the respondent voluntarily agrees to provide the information, so he/she can be contacted for to participate in a focus group or in-depth interview. No personally identifiable information will be associated with focus group or in-depth interview responses.

**A.11 Justification for Sensitive Questions**

Personally identifiable information (PII) such as race/ethnicity, income, education and/or medical/health status, are required to be asked on the initial screening questionnaire used for recruiting purposes only. Potential participants are informed that this is being done to make sure that NICHD speaks with the kinds of people for whom its messages are intended. Again, respondents are assured that the information is voluntary and will be treated as confidential. All information on race/ethnicity will comply fully with the standards of OMB Statistical Policy Directive No. 15, October 1997. (<http://www.whitehouse.gov/omb/fedreg/1997standards.html>).

Because this initiative is concerned with health and weight, some questions ask about (or discuss) how one perceives her own personal risk for serious illness and current weight. Fears of illness and experiences with HCPs will also be covered. This information is needed to gain a better understanding of the target audience so that the messages, strategies, and materials designed will be appropriate and sensitive. Participants are informed in advance about the nature of the activity and the voluntary nature of their participation. The interviewer/moderator makes it clear that they do not have to respond to any question that makes them uncomfortable, and that no questions of a sensitive nature will be asked in the course of collecting information from respondents.

Raw data from data collections that include sensitive information (for example, screening questionnaires and audio tapes) are not retained once the data have been extracted and aggregated; nor does the information become part of a system of record containing permanent personally identifiable information that can be used for retrieval.

**A.12.1 Estimated Annualized Burden Hours**

**A.12-1 Estimated Annualized Burden Hours**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Form Name and Type of Respondent**  | **No. of Respondents** | **No. of Responses per Respondent** | **Time perResponse(in hours)** | **Total BurdenHours** |
| General Public: Online Prescreener  | 500 | 1 | 1/60 | 8 |
| General Public: Telephone Screener | 120 | 1 | 10/60 | 20 |
| General Public: Discussion Guide-Focus Groups  | 10 | 1 | 2 | 20 |
| General Public: Discussion Guide-IDIs  | 20 | 1 | 1 | 20 |
| **Totals** | 500 | 500 |  | 68 |

*Note: The same discussion guide is used for both focus groups and IDIs. However, the time to complete the focus group is expected to be longer so the instrument is recorded twice.*

**A.12-2 ANNUALIZED COST TO RESPONDENTS**

|  |  |  |  |
| --- | --- | --- | --- |
| Type of Respondent  | Average Burden Per Response (in hours) | Hourly Wage Rate\* | Respondent Cost |
| Individuals | 68 | $17.81[[5]](#footnote-5) | $1211.08 |

**A.13 Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers**

As noted in Section A.9, respondents may have to purchase magazines for the homework assignment. The incentive will provide reimbursement for any magazine purchases.

**A.14 Annualized Cost to the Federal Government**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Staff** | **Grade/Step** | **Salary** | **% of Effort** | **Fringe (if applicable)** | **Total Cost to Gov’t** |
| **Federal Oversight** | 14/4 | 123,223 | 5% |  | 6,161.15 |
| **Contractor Cost** |  |  |  |  | $52,000\* |
| Travel |  |  |  |  | $0 |
| Other Cost |  |  |  |  | $0 |
| **Total**  |  |  |  |  | $58,161 |

\*Based on a firm fixed-price contract

**A.15 Explanation for Program Changes or Adjustments**

N/A

**A.16 Plans for Tabulation and Publication and Project Time Schedule**

The information collected from the online pre-screener by our professional recruiting partners will not be shared with the researchers. Our recruiting partners store the pre-screener data on their secure servers for a period of 60 days. At the end of those 60 days, they destroy the files.

**A.17 Reason(s) Display of OMB Expiration Date is Inappropriate**

We are not requesting an exemption to the display of the OMB Expiration date.

**A.18 Exceptions to Certification for Paperwork Reduction Act Submissions**

This information collection will comply with the requirements in 5 CFR 1320.9.

1. We will ascertain respondents approximate BMIs by asking respondents their heights and weights. [↑](#footnote-ref-1)
2. http://www.cio.noaa.gov/itmanagement/pdfs/OMBSurveyGuidance\_0106.pdf [↑](#footnote-ref-2)
3. 3 Yu S, Alper HE, Nguyen A-M, et al. The effectiveness of a monetary incentive offer on survey response rates and response completeness in a longitudinal study. *BMC Medical Research Methodology*. 2017;17:77.doi:10.1186/s12874-017-0353-1. [↑](#footnote-ref-3)
4. 4 Knoll M, Soller L, Ben-Shoshan M, et al. The use of incentives in vulnerable populations for a telephone survey: a randomized controlled trial. *BMC Research Notes*. 2012;5:572. doi:10.1186/1756-0500-5-572. [↑](#footnote-ref-4)
5. <http://www.bls.gov/oes/current/oes_nat.htm#00-0000> (all Occupations) [↑](#footnote-ref-5)