

Request for Approval under the “Generic Clearance for the Collection of Routine Customer Feedback” (OMB Control Number: 0925-0643)

TITLE OF INFORMATION COLLECTION: Non-Medically Indicated Induction Prior to 39 Weeks of Gestation Focus Groups

PURPOSE:

Research has shown that early elective delivery without medical or obstetrical indication is linked to neonatal morbidities with no benefit to the mother or infant.¹

Despite the American Congress of Obstetricians and Gynecologists (ACOG) guidelines outlining criteria for medically indicated births prior to 39 weeks, elective inductions of labor and elective cesarean section deliveries prior to 39 weeks are increasing.² The rise of non-medically indicated induction of labor is present in all racial groups with the highest increase in non-Hispanic whites.³

The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) National Child and Maternal Health Education Program (NCMHEP) would like to educate healthcare providers and patients about possible short- and long-term adverse outcomes that can occur after non-medically indicated (elective) inductions/cesareans prior to 39 weeks of gestation.

Partnering with Engine Pictures, the NCMHEP created a video titled, *Is It Worth It?*, to educate and raise awareness among pregnant women that, if given the choice, they should allow their pregnancies to naturally progress to labor and avoid a non-medically indicated induction/cesarean prior to 39 weeks of gestation. The video presents advice by physicians with expertise in women’s health as well as a mother’s testimony about the death of her preterm baby. The main message of the video is that if there is no medical indication for early delivery, then the mother has a choice to wait to deliver. The video is available in 3-minute, 60-second, and 30-second versions.

The goals of the proposed focus group research are to better understand the target audiences’:

- Knowledge, attitudes, behaviors, and beliefs related to non-medically indicated inductions/cesareans prior to 39 weeks gestation.
- Reactions to the *Is It Worth It?* video.
- Suggestions for effective communication channels and venues in which to raise awareness of this topic and to promote viewing the *Is It Worth It?* video (as well as companion materials).

¹ Tita ATN, Landon MB, Spong CY, Lai Y, Leveno KJ, Varner MW, et al. Timing of elective cesarean delivery at term and neonatal outcomes. *The New England Journal of Medicine* 2009 January;360:111-20.

² (a) Martin JA. United States vital statistics and the measurement of gestational age. *Paediatric and Perinatal Epidemiology* 2007 Sep;21 Suppl 2:13-21; (b) Martin JA, Kung HC, Mathews TJ, Hoyert DL, Strobino DM, Guyer B, et al. Annual summary of vital statistics: 2006. *Pediatrics* 2008 Apr;121(4):788-801; (c) Martin J, Hamilton B, Sutton P, et al. Births: Final data for 2006, National Vital Statistics Reports, Division of Vital Statistics (Percentages were prepared by the March of Dimes). Atlanta, GA: National Center for Health Statistics; 2009.

³ Elimination of non-medically indicated (elective) deliveries before 39 weeks gestational age. A California toolkit to transform maternity care. California Department of Public Health. August 31, 2011. Available at: <http://www.cdph.ca.gov/programs/mcah/Documents/MCAH-EliminationOfNon-MedicallyIndicatedDeliveries.pdf>

Is an incentive (e.g., money or reimbursement of expenses, token of appreciation) provided to participants? Yes No

Respondents will receive remuneration through recruitment companies contracted to obtain participants. The amount of remuneration is based on pay scales these companies follow. Based on feedback from recruitment professionals, caregivers will receive \$40 for participating in a 90-minute focus group.

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.^{5,6} 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.

BURDEN HOURS

Category of Respondent	No. of Respondents	Participation Time (in hours)	Total Burden Hours
Individuals or Households	45	1.50	68
Totals	45	1.50	68

FEDERAL COST: The estimated annual cost to the Federal government is \$13,000.

If you are conducting a focus group, survey, or plan to employ statistical methods, please provide answers to the following questions:

The selection of your targeted respondents

1. Do you have a customer list or something similar that defines the universe of potential respondents and do you have a sampling plan for selecting from this universe?
 Yes No

If the answer is yes, please provide a description of both below (or attach the sampling plan)? If the answer is no, please provide a description of how you plan to identify your potential group of respondents and how you will select them?

⁵ Singer E and Kulka RA. Paying respondents for survey participation. In Ver Ploeg M, Moffitt RA, Citro CF (eds). Studies of Welfare Populations: Data collection and Research Issues. National Academy Press: Washington, DC 2001. Available at <http://www.nap.edu/openbook/0309076234/html>. Accessed on May 13, 2008.

⁶ Kovac MD, Markesich J. Tiered incentive payments: getting the most bang for your buck. Presentation at the Annual Conference of the American Association for Public Research, 2002.

Using a structured recruitment screener, a professional recruitment vendor will identify eligible participants, contact them by telephone, explain the focus group study, invite them to participate, and schedule their focus group participation. The recruitment facility will recruit 12 individuals for each of the focus groups with the aim of accepting a maximum of 9 per focus group. (Qualitative research experience has shown that no-show rates for focus groups are typically about 20%.)

The recruitment facility maintains a database of people who have participated in previous focus groups and/or who have volunteered to take part in research. This database includes demographic information such as gender, age, education, and job status. Using the approved screener criteria (e.g., currently pregnant women, fathers/partners of those women), the firm will contact individuals in the database to identify focus group participants. If additional people need to be identified, the recruitment firm will reach out to appropriate organizations (e.g., National Healthy Mothers, Healthy Babies Coalition) and screen and identify the focus group participants.

Administration of the Instrument

1. How will you collect the information? (Check all that apply)
 - Web-based or other forms of Social Media
 - Telephone
 - In-person
 - Mail
 - Other, Explain
2. Will interviewers or facilitators be used? Yes No

Please make sure that all instruments, instructions, and scripts are submitted with the request.