

Tucker Reinders, L., Buckingham-Schutt, L.

A study to determine the effect of the Count the Kicks (CTK) app on the rate of stillbirth

Appendix 4

INFORMED CONSENT DOCUMENT

Title of Study: A pilot study to validate the *Count the Kicks* survey, as part of the research study *A study to determine the effect of the Count the Kicks (CTK) app on the rate of stillbirth*

Who is conducting this study?:

Lina Tucker Reinders, MPH – Healthy Birth Day, Inc., Co-Principal Investigator, Associate Director of Programs

Dr. Lyndi Buckingham-Schutt – Drake University, Co-Principal Investigator, Associate Director of Wellness & Nutrition Policy, The Harkin Institute for Public Policy & Citizen Engagement

Dr. Pamela A. Duffy – Des Moines University, Associate Professor, Department of Public Health

Kerry Biondi-Morlan – Healthy Birth Day, Inc., Founder and Board Vice-President

Mr. Benjamin Williamson – Des Moines University, Master of Public Health Research Assistant

Introduction

This is a pilot study of a larger study about monitoring fetal movement. You have been asked to participate in the pilot study because you have a relationship with Healthy Birth Day, Inc. and insight into pregnancy, the *Count the Kicks* app, changes in fetal movement, and/or loss from stillbirth or perinatal death. This form describes the research project. It has information to help you decide whether or not you wish to participate. Research studies include only people who choose to take part—your participation in this pilot is completely voluntary. You are welcome to discuss any questions you have about the study or about this form with the project staff before deciding to participate. Healthy Birth Day, Inc. (HBD) is the sponsor of this research study. HBD is the nonprofit organization that created the *Count the Kicks* stillbirth prevention campaign.

What is the purpose of the pilot study?

The purpose of this pilot study is to validate and assess the appropriateness of the survey designed to be presented to participants in the research study *A study to determine the effect of the Count the Kicks (CTK) app on the rate of stillbirth*. Pilot study participants will be asked to inform the researchers if the questions are clear and of appropriate sensitivity to ask of women who may have lost children to stillbirth, and if the skip pattern of the survey design is logical. Feedback from pilot participants will be used to improve the survey before implemented in the aforementioned study.

What will I be asked to do?

If you agree to participate, you will be asked to complete a 15-minute survey that will be given to participants of the larger study and asks them to recall information about using the *Count the Kicks* app, their pregnancy, and delivery of their baby(babies) in 2017. You will also be asked to give feedback to the research team on the question phrasing, skip pattern logic, and the potential

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emotional impact of any of the questions. Your feedback will help the research team improve the survey design and minimize risk to the study participants.

Why am I invited to participate in this study?

You are being invited to participate in the pilot study because you have a relationship with Healthy Birth Day, Inc. and insight into pregnancy, the *Count the Kicks* app, changes in fetal movement, and/or loss from stillbirth or perinatal death. You may choose not to take part in the pilot study or to stop participating at any time, for any reason, without penalty or negative consequences. You may skip any survey questions you do not want to answer.

How will the study be carried out?

At the bottom of this page you will be asked if you agree to participate in the pilot study. If you answer yes, you will continue immediately with the survey. If you answer no, you will be removed from the study and your data will not be included in the research project.

Are there any risks involved?

While participating in this pilot study you may experience the following risks: emotional distress if your pregnancy and/or birth of your child(ren) was a traumatic experience. If you are negatively impacted at any time during or after this study, please contact the project investigator at Reinders.Lina@healthybirthday.org or 515-608-9643 or Drake IRB at irb@drake.edu or 515-271-3472. If you are seeking pregnancy loss resources, please visit www.pregnancylossdirectory.com.

Are there any benefits to me?

You may not receive any direct benefit from taking part in this study. We hope that the information gained in this study will benefit society by improving awareness of stillbirth prevention strategies.

Will I be paid to participate?

There is no compensation for participating in the pilot study.

What are my rights?

Your participation in this pilot study is completely voluntary and you may refuse to participate or leave the study at any time. If you decide to not participate in the pilot study or leave the study early, it will not result in any penalty or loss of benefits to which you are otherwise entitled. If you agree to participate in the survey, you can skip any questions that you do not wish to answer.

How will you assure confidentiality?

Any information obtained in connection with this research study that can be identified with you will be disclosed only with your permission; your results will be kept confidential. In any written reports or publications, no individual participant information will be identified or be identifiable and only group data will be presented. However, Healthy Birth Day, Inc., federal government

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regulatory agencies, auditing departments of Drake University, and the Institutional Review Boards (a committee that reviews and approves human subject research studies) of Drake University and Des Moines University may inspect and/or copy study records for quality assurance and data analysis. These records may contain private information.

To ensure confidentiality to the extent permitted by law, the following measures will be taken: Any information that could identify you as the survey respondent will be coded for anonymity. Only the researchers listed above will have access to the coding system. All the researchers have completed training on the importance of and methods for protecting identifiable information. Survey data will be stored in a password protected computer file maintained by Healthy Birth Day, Inc. Any printed copies of the data will be kept in a locked filing cabinet within a locked office maintained by Healthy Birth Day, Inc. Only the researchers will have access to the file cabinet key. Data will be stored for a minimum of 3 years after completion of the study.. No publication resulting from the study will contain any identifiable information.

Whom may I contact if I have questions?

You are encouraged to ask questions at any time during this study.

- For further information about the study contact Lina Tucker Reinders, Associate Director of Programs, Healthy Birth Day, Inc. at Reinders.Lina@healthybirthday.org or 515-608-9643.
- If you have any questions about the rights of research subjects or research-related injury, please contact the IRB Administrator, (515) 271-3472, irb@drake.edu.

Please download a copy of this form for your records.

How do I agree to participate and take the survey?

Answering yes to the following question is considered consent to participating in the pilot study. Please consider t question carefully.

1. Do you agree to participate in the pilot study to help determine the appropriateness of the larger study survey? Yes / No