***Sample Consent Form (Complex) for Research which is minimal to more-than-minimal risk and includes, for example, an intervention or increased risk.***

Instructions:

1. The red text relates to red text sections in the [consent form template](https://research.calpoly.edu/HS-forms-and-links/#icformtemplate).
2. If you use this sample form for a template, please make sure all text is changed to black, and delete this box.

INFORMED CONSENT TO PARTICIPATE IN A RESEARCH PROJECT:

*“Influence of Bottle Type on Infant Feeding”*

INTRODUCTION

This form asks for your agreement to participate in a research project on different bottle types for feeding infants. Your participation involves you attending 3 research sessions in a laboratory at Cal Poly in which the researchers will take measurements of you and your baby; completing daily food logs; answering some questions about you, your baby, and how you feed your baby; and allowing the researchers to video record you while you feed your baby with different types of bottles. It is expected that your participation will take approximately 7-8 hours over an 8-day period. The potential risks from this project are considered minimal. You may personally benefit from this study and others may also benefit from your participation. If you are interested in participating, please review the following information.

PURPOSE OF THE STUDY AND PROPOSED BENEFITS

* The purpose of the study is to examine how different bottle types might influence infant feeding in order to promote healthy feeding during infancy.
* Potential benefits associated with the study include being able to provide information to others on health feeding of their babies. You may also benefit directly as you may enjoy becoming more aware of your infant’s behaviors; and you may appreciate learning about new research in nutrition, food preferences, and mother-infant interactions.

YOUR PARTICIPATION

* If you agree to participate, you and your baby will be asked to visit the researcher’s laboratory at Cal Poly, San Luis Obispo, on 3 separate days for approximately 2 hours each day. Your visits will occur at the same time on all days. At the start of each visit, we will measure your baby’s weight and length, and also your weight and height.

For the 3 days leading up, and on the days of your visits, you will be asked to complete daily food logs of when and what you fed your baby. We also will call you during this 3-day period to remind you to fill out the logs and ask you about other feeding behaviors.

* During each visit, a trained research assistant will ask you to feed your infant as you normally would at home using a typical clear bottle; however, during some of the visits, you will use a standard clear bottle and during other visits, we will place an experimental, opaque, weighted sleeve on the bottle. The entire feeding session will be video-recorded, with the camera being placed at the far corner of the room, about 10-12 feet from you and your infant. The research assistant will be present, but hidden behind a partition during the feeding.
* After you feed your infant, the research assistant will ask you some questions about the feeding and questions related to your infant’s personality and how confident you feel responding to your infant. You will also be asked about your infant feeding attitudes and practices, health history, and eating behaviors.
* Your participation will take approximately 7-8 hours over an 8-day period. During days 1-3, you will fill out the feeding logs for your infant; this should take you about 15 minutes per day. You also will receive daily check-in calls during days 1-3 that should last no longer than 5 minutes. On days 4-8, you and your infant will visit the laboratory 3 times, for about 2 hours each time to allow time for you to feed your infant, answer our questionnaires, and be assessed.
* As an incentive, you will be offered a total of $75 to compensate you for your time and travel: this includes $20 for each of 3 visits and $15 to cover parking and travel costs.

PROTECTIONS AND POTENTIAL RISKS

* Please be aware that you are not required to participate in this research, refusal to participate will not involve any penalty or loss of benefits to which you are otherwise entitled, and you may discontinue your participation at any time. If you decide to withdraw your participation, you must notify the researcher and your compensation will be limited to each visit you have completed ($25 per visit). If you decide you do not want to be part of the study, we may still keep your information and use it for the research.
* The researcher may terminate your participation at any time. Possible reasons for removal are: if all or part of the study is stopped for any reason by the investigator or Cal Poly; if you are a student and participation in the study is adversely affecting your academic performance; if you fail to adhere to the requirements for participation established by the researcher.

The possible risks or discomforts are anticipated to be minimal but might include: you or your infant may dislike the bottles we offer during the infant feeding, or your breast milk or formula could sour or spoil if not handled correctly during your transit to the laboratory. Additionally, it is possible that your infant may be allergic to the materials used to make the bottles and nipples used in the study. Also, you may feel uncomfortable answering the questions we ask you; you may omit responses to any questions you choose not to answer and you can discontinue your participation at any time. There also may be unforeseeable risks related to your participation.

* Your confidentiality will be protected as all information collected from you, including videotapes, data sheets, and questionnaire responses, will be coded, instead of using your name. We will use the codes, instead of your name, to analyze and report on the information learned from you, so that your identity cannot be traced. All records and videotapes will be stored in a locked file that only project personnel will have access to.

In any written or oral presentation of this research, your identity will be kept private. Records that identify you may be inspected by authorized individuals such as the Cal Poly Institutional Review Board or employees conducting peer review activities. Your agreement to participate indicates consent to such inspections and to the copying of excerpts of your records, if required by any of these representatives.

* Identifying data will be removed from your private information and that, after such removal, the information could be used for future research studies or distributed to another researcher for future studies without additional informed consent.
* All study personnel have been trained at Cal Poly on the rights of human subjects, and they are familiar with the rules for handling personal information.

RESOURCES AND CONTACT INFORMATION

* If you should experience any negative outcomes from this research, please be aware that you may contact the researcher for assistance.
* This research is being conducted by Dr. Julie Investigator in the Department of Kinesiology at Cal Poly, San Luis Obispo. If you have questions regarding this study or would like to be informed of the results when the study is completed, please contact the researcher at 805-111-1111 or jinvest@email.com.
* If you have concerns regarding the manner in which the study is conducted, you may contact Dr. Michael Black, Chair of the Cal Poly Institutional Review Board, at (805) 756-2894, mblack@calpoly.edu, or Ms. Trish Brock, Director of Research Compliance, at (805) 756-1450, pbrock@calpoly.edu.

AGREEMENT TO PARTICIPATE

If you are 18 or older and agree to voluntarily participate in this research project as described, please indicate your agreement by initialing on the line and signing below.

\_\_\_ I have read the information provided and have had all my questions related to my participation answered. I understand that I may ask additional questions during the study if I need any other information.

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Signature of Volunteer Date

If you agree to allow your infant to participate in this research project as described, please indicate your agreement by signing below.

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Signature of Volunteer Date

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Signature of Researcher Date

Please keep a copy of this form for your reference, and thank you for your participation in this research.