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Permission to Take Part in a Human Research Study



University at Buffalo Institutional Review Board (UBIRB)

Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federal wide Assurance ID#: FWA00008824

Adult Consent to Participate in a Research Study and Parent Permission for a Child to Participate in a Research Study

Title of research study: *Promoting healthier eating among children in restaurants (Full study)*

Version Date: *March 31, 2023*

Investigator: *Dr. Stephanie Anzman-Frasca, PhD*

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

You are being invited to take part in a research study because you are at least 18 years old and have a child age 4 to 8 who is healthy (has not been diagnosed with any physical or mental health conditions) and eats at restaurants.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

The overall purpose of this study is to learn about families' experiences eating in restaurants and what children like to order and eat.

How long will the research last and what will I need to do?

This research will take place across 8 sessions at Anderson's restaurant, which will include today's, plus 7 more over a span of about 5 months. We expect that you will be in this research study for about 30 minutes during sessions 1 & 8 and 10 minutes during sessions 2-7, in addition to the amount of time it takes your family to eat their meal.

You will be asked to attend 8 sessions at Anderson's restaurant. During the first and last session, we will be present in the restaurant and will help you to complete survey questions about your child's order, other foods eaten, and demographics. We will also ask your child some survey questions about his/her meal and experience in the restaurant. In addition, staff will package up your child's leftovers (to weigh them, to learn about what children eat). You will also be asked to complete brief, weekly online surveys during a two month period between your first and last restaurant visit.

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More detailed information about the study procedures can be found under ***“What happens if I say yes, I want to be in this research?”***

Is there any way being in this study could be bad for me?

There are no known risks to participating in this study.

Will being in this study help me in any way?

We cannot promise any benefits to you or your child from your taking part in this research. However, a potential benefit to your child includes enjoying his/her meal experiences at the restaurant and enjoying sharing his/her opinions with the study staff.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You may choose not to enroll in this study.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 716-829-6269 or ubhablab@gmail.com. You may also contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu.

This research has been reviewed and approved by an Institutional Review Board (“IRB”). An IRB is a committee that provides ethical and regulatory oversight of research that involves human subjects. You may talk to them at (716) 888-4888 or email ub-irb@buffalo.edu if:

- You have questions about your rights as a participant in this research
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You want to get information or provide input about this research.

How many people will be studied?

We expect about 930 parents and their 4-to-8-year-old children in this research study.

What happens if I say yes, I want to be in this research?

After you sign up, you and your child will participate in 8 sessions at this Anderson’s restaurant location. At your first session, today, your family will order your meals like you normally would, not throwing away any food or food packaging until you wave us over at the end of your meal. At the end of the meal, we will package up your child’s leftovers (to weigh them, to learn about what children eat) and will ask you survey questions about your child’s order, other foods eaten that day, and demographics. We will ask your child some survey questions about his/her experience in the restaurant that day too. We will also confirm your mailing address, so that we can mail you some study materials (placemat, frequent diner card information) in advance of your second Anderson’s visit as part of the study.

Sessions 2-7 will occur over a specified period of about 2 months. Your child can use his/her frequent diner card during this time to earn a free kids’ meal. You will receive an email, phone call, or text message prior to Session 2, reminding you when you can use this card at Anderson’s. You will visit

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Anderson's and eat with your family like you normally would during this period. During this time, you will also be asked to complete a brief online survey once per week during this ~2 month period about your experiences in the restaurant which should take no more than 5 minutes.

After Sessions 2-7, your family will be invited back to Anderson's restaurant for one more visit (Session 8), which will take place within a specified period of about 1 month. During this visit, you can redeem your free kids' meal (if earned with the frequent diner card). When you arrive at the restaurant, our staff will be in the restaurant wearing UB shirts. You will identify yourself to them and show them the frequent diner card you received. Then you'll order your meals like you normally would, again not throwing away any food or food packaging until you wave us over at the end of your meal. At the end we will package up your child's leftovers and will ask you survey questions about your child's order, other foods eaten that day, and your experiences in the restaurant. We will also ask your child some survey questions about his/her meal and experience in the restaurant. Finally, families will be prompted to complete an online survey about their child's dietary intake the day after this last session.

In addition to the free kids' meal (if earned), you will receive \$50 for completing activities that are part of session 1, a total of \$120 for activities that are part of sessions 2-7, \$20 for arriving to session 8 at the originally-scheduled time, \$50 for completing session 8, \$25 for completing an online survey at the end of the study. Over the course of this study, about 93 families will also be selected for observation in the restaurant. These families will be notified and receive an additional \$35. If families do not wish to participate in the observation they will have the ability to opt out and will receive all other payments for completed sessions as described here. All payments will be made via an automated system (an electronic debit card, described in detail below) over time as study sessions are completed. Children will also receive stickers at the sessions, including each time their frequent diner card is used and will also have the opportunity to receive a fun placemat during each visit to the restaurant.

The data collected from this study will be stored for up to ten years after the completion of this study. Only investigators and staff from this team will have access to the data, which will be securely stored.

What happens if I say yes, but I change my mind later?

You can leave the research at any time, and it will not be held against you.

Is there any way being in this study could be bad for me? (Detailed Risks)

There are no known risks associated with these procedures.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information collected as part of this research study to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization. In the case of any suspected abuse or neglect, we may contact the appropriate authorities. Information or bio-specimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Can I be removed from the research without my OK?

The principal investigator of the study can remove you from the research study without your approval. Possible reasons for removal include failure to follow instructions. We will tell you about any new information that arises that may affect your health, welfare, or choice to stay in the research.

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What else do I need to know?

Who is paying for this research?

This research is being funded by The National Institutes of Health (NIH).

Will I get paid for my participation in this research?

If you agree to take part in this research study, you will receive a free kids' meal (if earned) and up to \$265 for completing the main study tasks described above. Your child will receive stickers and placemats.

The Study Card Program Group, under The University at Buffalo's Office of Financial Management, in conjunction with U.S. Bank, will manage study compensation by providing a Reloadable Focus Blue Card, which is a prepaid debit card. When you complete a visit, the amount outlined in the Informed Consent Form will be automatically approved and applied to your U.S. Bank Focus Blue Card balance. If you receive your bank card at the study visit, your payment will be available no later than the next business day. The Study staff will provide you with additional information about how the bank card works. In order for U.S. Bank to be able to reimburse you using the Focus Blue Card, only your first and last name (required), physical address (required), and birth date (required) will be shared with U.S. Bank. The Study Card Program Group, under The University at Buffalo Office of Financial Management, will also have access to this information and UB affiliated Researchers and staff, within the same university department as the Investigator of this study, may also have access to this information. By agreeing to use the U.S. Bank Card service, you are authorizing the release of this information to U.S. Bank and authorizing access to this information to Study Card Program Group, under The University at Buffalo Office of Financial Management and other UB affiliated Researchers and staff. No protected health information will be shared with the U.S. Bank or the Study Card Program Group.

Please note that a fee of \$2 per month will be deducted from your card balance after 365 days of card inactivity. Your card will be considered activated as of today's date.

Please also note that U.S. Bank may use your personal contact information to market the bank's other products and services to you. You may limit U.S. Bank's direct marketing to you by visiting U.S. Bank online at <http://www.usbank.com/privacy>.

If you receive a single gift card or debit card deposit of \$50 or greater, you will be asked to complete an IRS Form W-9. This form will be held confidentially by the research team and those responsible for administering research funds. Payments that you receive for your participation in this research are considered taxable income. If the amount of payment that you receive reaches or exceeds \$600.00 in a calendar year, you will be issued a form 1099.

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Signature Block for Capable Adult

Your signature documents your permission to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

Signature of subject

Date

Printed name of subject

Phone number of subject

Signature of person obtaining consent

Date

Printed name of person obtaining consent

Permission to Take Part in a Human Research Study

Signature Block for Parental Permission

Your signature documents your permission for the named child to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

Printed name of child

Age of child

Signature of parent or individual legally authorized to
consent to the child's general medical care

Date

Printed name of parent or individual legally authorized to
consent to the child's general medical care

- ☐ Parent
☐ Individual legally
authorized to consent to
the child's general
medical care (See note
below)

Note: Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child's general medical care. Contact legal counsel if any questions arise.

[The Assent Box, which is applicable to the subject named in this consent document, must be checked]

- Assent ☐ Obtained
☐ Not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.

Signature of person obtaining consent

Date

Printed name of person obtaining consent