

Official Title:	Developing Tailored Clinical Resources for Promoting Children's Healthy Food Preferences
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University at Buffalo Institutional Review Board (UBIRB)

Office of Research Compliance | Clinical Research Institute on Addictions

1021 Main Street | Buffalo, NY 14203

UB Federalwide Assurance ID#: FWA00008824

Adult Consent to Participate in a Research Study

Title of research study: *Developing tailored clinical resources for promoting children's healthy food preferences*

Version Date: *March 25thst, 2025*

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, have a child ages 18-36 months old who is healthy (has not been diagnosed with any physical or mental health conditions), and have met other eligibility criteria related to English fluency, primary caregiver status, and child eating habits.

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 purpose of this study is to measure children's reactions to eating vegetables. This research will help inform future efforts to help make it easier for children to like and accept vegetables.

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

We expect that you will be in this research study for about 6 weeks. The study involves 2 visits to our laboratory, which will be no more than 60 minutes each, plus some at-home activities and surveys.

During the lab visits, your child will be served a vegetable to eat, and you will be asked to answer some questions about you and your child's demographics and your perception of their liking of the vegetable. Your child's leftovers will also be weighed to determine how much was eaten.

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?

Children may experience some anxiety when interacting with unfamiliar study staff and/or may dislike the vegetable served. However, we anticipate this feeling will be temporary and children can decide at any time that they do not wish to try the vegetable.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, potential benefits to your child include enjoyment and development of their social skills when interacting with our research team, and greater liking of vegetables over time.

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.

The study involves 2 visits to our laboratory, which will be no more than 60 minutes each, plus some at-home activities and surveys. Additional information about each visit is detailed below.

Visit 1 on UB South Campus:

Your child will be served a vegetable to eat, and we will ask you questions about your perception of your child’s liking of the vegetable. You will also complete survey questions about you and your child (e.g., demographics).

At the end of the visit, you will be assigned to one of two study groups, which will be chosen by chance, like flipping a coin. Neither you nor the study experimenter will choose which group you are assigned to. You and your child will have a 50-50 chance of being assigned to either group. Group 1 will receive small portions of a vegetable and a dip to complete two vegetable taste tests per week at home over the next four weeks. Group 2 will receive small portions of a vegetable, with enough included for tastings to be completed by both parent and child twice per week at home over the next four weeks. Step-by-step instructions guiding you through the tastings will be provided in each group. Parents/Guardians in both groups will receive brief weekly electronic messages from our research team throughout this period. The messages will contain reminders about study tasks and a link to an online survey with a few short questions regarding your family’s experience with the study tasks.

Visit 2 on UB South Campus:

This visit will occur approximately one month after your first visit with us. During this visit, your child will taste small portions of a vegetable again. While your child is completing these

activities, we will ask you about your child's liking of the vegetable. Then, we will ask you some questions about your experiences in the study. These interviews will be audio or video recorded.

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 716-829-6694 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 40 families (each with one parent/guardian and one 18-to-36-month-old child participating) will be in this research study.

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

If you passed the initial screening over the phone or via the online survey, you and your child will be invited to attend two visits, scheduled at your convenience at 151 Farber Hall at the University at Buffalo's Child Health and Behavior Lab on UB's South Campus. These visits will be about one hour long, and you will receive an overview of the study at the start of the first appointment. You will be asked to review and sign consent forms. After signing the consent forms at the first visit, study procedures detailed above will begin. Only study staff from this team will have access to the data from this study. Survey and paper data (for example, this consent form) will be securely stored in locked filing cabinets within our lab (151 Farber Hall) or in encrypted, password-protected computer files on UB's network (i.e., S drive). Any identifying data, such as your signature on this form, will be destroyed within 10 years of the end of the study.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for attending the two study sessions in our lab and completing taste tests with your child two times per week for four weeks between the two lab visits. You will also be responsible for completing brief (<5 minute) weekly online surveys during these four weeks.

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.

There is a small chance that someone who is not authorized could see your private study information. We are taking steps so that does not happen. More information can be found in ***“What happens to the information collected for the research?”***

What happens to the information collected for the research?

As mentioned above, only study staff from this team will have access to the data from this study. Survey and paper data will be securely stored in locked filing cabinets within our lab (151 Farber Hall) or in encrypted, password-protected computer files on UB’s network (i.e., S drive). Any identifying data, such as your signature on this form, will be destroyed 10 years after publication of study findings. Information about the study will be made publicly available on ClinicalTrials.gov. This trial is registered, and summary results will be posted without identifying individual participants to maintain confidentiality.

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical or education records, 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. If information that identifies you is removed from your study information, it could be used for future research studies or given to other researchers without your additional consent.

Can I be removed from the research without my OK?

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

What else do I need to know?

Who is paying for this research?

This research is being funded by the University at Buffalo’s Clinical and Translational Science Institute’s Pilot Studies grant program.

Will I get paid for my participation in this research?

If you agree to take part in this research study, we will pay you \$30 for the first lab visit, up to \$15/week for successfully completing at-home activities and surveys, \$50 for successfully completing the second lab visit, and a \$10 bonus if all appointments were kept as originally scheduled (\$150 total).

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 deposit of \$100 or greater (this does not include U.S. Bank Prepaid Debit Cards), 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.

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

Signature of person obtaining consent

Date

Printed name of person obtaining consent

*[Check the below box and obtain the signature of the witness if a witness will observe the consent process, e.g. illiterate subjects or short form of consent documentation. *Note: you must have prior IRB approval to utilize the short form of consent documentation.]*

☐ My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of witness to consent process

Date

Printed name of person witnessing consent process

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

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.

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

*[Check the below box and obtain the signature of the witness if a witness will observe the consent process, e.g. illiterate subjects or short form of consent documentation. *Note: you must have prior IRB approval to utilize the short form of consent documentation.]*

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