UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Baby Reward Project – Longitudinal Survey Arm

Names, degrees, and affiliations of the principal investigator and study coordinator (if applicable):

- Julie Lumeng, MD, University of Michigan Department of Pediatrics Ashley Gearhardt, PhD, University of Michigan Department of Psychology

Principal Investigator: Julie Lumeng, MD

1.1 Key Study Information

You and your baby may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study.

Please take time to review this information carefully. After you have finished, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or doctors) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Research studies have different kinds of risks and risk levels, depending on the type of study. You may also need to think about other requirements for being in the study. For example, you may be asked to allow a researcher to view your medical chart. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you and your baby. This research collects health-related information to better understand infant eating. We are interested in learning more about eating behavior in children ages 2 to 24 months. This research study will include multiple medical chart reviews by a trained researcher from the time your baby is 2 months old to when they turn 18 years old. There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include feeling stressed about having to respond to some of the survey questions. More detailed information will be provided later in this document. This study may not offer any benefit to you now but may benefit others in the future by improving knowledge about eating behaviors in children in this age group. More information will be provided later in this document. We expect the amount of time you will participate in the study will be up to 2 hours to respond to questionnaires and allowing the study team to review your and your baby's medical chart over the course of 18 years. You can decide not to be in this study. Even if you decide to join the study now, you are free to leave at any time if you change your mind. More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:
In this study we are interested in learning more about eating behavior in children.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?
Healthy babies and their mothers can take part in this study.

3.2 How many people are expected to take part in this study?
2000 people (1000 mothers and 1000 babies) are expected to participate

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?
We will ask you to do the following for this study:

- Fill out some questionnaires about you and your baby (approximately 1.5 hours), by using a computer. Some questionnaires may include sensitive questions (e.g. substance use) related to you and your family, you do not need to answer any questions that you do not want to.
- Allow the study team to review your and your baby's medical chart until they turn 18 years old. For example, we would like to look at your baby's growth.
- Allow the study team to link your survey responses to your obstetrics biospecimen data. This will only apply if you participated in the U-M Pregnancy Biobank study.

Besides the information about the main study, the following information is specific to unspecified future use of identifiable data. We would also like your permission to keep some of your information collected in the main study, so that we may study it in future research. The future research may be similar to this study or may be completely different.

You can take part in the main study even if you decide not to let us keep your information for future research.

If you give us your permission, we will use your information for future research. Even if you give us permission now to keep some of your information, you can change your mind later and ask us to destroy it. Keep in mind, however, that once we have analyzed your information, we may not be able to take the information out of our research.

We may share your information with other researchers, so that they can use it in their research. Their research may be similar to this study or may be completely different. Once we have shared your information with other researchers, we will not be able to get it back.

Future use of your identifiable data and/or specimens will be conducted in compliance with applicable regulatory requirements.

You will not find out the results of future research on your information. Allowing us to do future research on your information will not benefit you directly.

With appropriate permissions, your information may also be shared with other researchers here, around the world, and with companies.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future studies without additional informed consent.

Research can lead to new discoveries, such as new tests, drugs or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will have no rights to these discoveries or any proceeds from them.

4.2 How much of my time will be needed to take part in this study?
About 2 hours will be needed to respond to study questionnaires. The study team will review your and your baby's medical charts until your baby turns 18 years old, but you will not be asked to do anything during this time.

4.3 When will my participation in the study be over?
We would like to keep in touch with you to invite you and your baby to participate in follow-up study activities in the future, indefinitely. This would be your choice. We will call you periodically and send you postcards to keep in touch. You are welcome to stop participating at any time. We will keep the information collected from you and your baby (without your names attached) in a password-protected file, which may be used by the researchers indefinitely to study future research questions. Your permission to retain and store the data and samples collected from the study is optional to participate in this study. Please indicate in section 12 to allow the researchers to keep all of this information for unspecified future use and storage of data.

4.4 What will happen with my information used in this study?

Your and your child's study data will be retained and stored for unspecified future use after this study is completed or if you end your participation in the study early. The future research may be similar to this study or may be completely different. Even if you give us permission now to keep some of your study data, you can change your mind later and ask us to destroy it. Keep in mind, however, that once we have analyzed your study data, we may not be able to take the information out of our research.

Your collected information may be shared with the American Heart Association.

With appropriate permissions, your collected information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The known or expected risks are: Completing some of the questionnaires may be stressful for some mothers. There is also a risk of breach of confidentiality.

The researchers will try to minimize these risks by: You do not have to answer any questions that you do not want to. If you agree to participate, you can decide to discontinue your participation in a given section of the study at any point without affecting your participation in the rest of the study. All of the data will be kept on computers that are password-protected or in a locked cabinet in a private research office. All of the collected information will be handled in a confidential manner and will be labeled with a code. As with any research study, there may be additional risks that are unknown or unexpected.

See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?
The researchers have taken steps to minimize the risks of this study. Even so, you or your baby may still have problems, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries or other problems that you have during this study.

5.3 If I take part in this study, can I also participate in other studies?
Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could my baby and I benefit if we take part in this study? How could others benefit?
You and your baby may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?
Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?
Your participation is voluntary and your other option is to not participate.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?
You and your baby are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your

reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 “Contact Information”.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?
No

7.3 Could the researchers take me out of the study even if I want to continue to participate?
Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?
There are no costs or billing for this study. By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?
At the initial 2-month time point, you will receive $40 compensation on a gift card for your time in completing the study questionnaires.

8.3 Who could profit or financially benefit from the study results?
No individual, company, or organization has a financial interest in the outcome of this study. Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information?
Your research information will be stored in a password-protected file that only members of the study team have access. Research records will be kept in a separate research file that does not include names or other information that is likely to allow someone other than the researchers to link the information to you.

This research will be covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information or documents that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or

other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information or documents protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the SPONSOR which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse and neglect, or harm to self or others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

This study will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials. This Web site will not include information that can identify you. You can search this Web site at any time.

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you and your child for this study, and is required in order for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you and your child may be obtained from your Michigan Medicine patient record including:

- Hospital/doctor's office records, including test results and dental records
- Demographic information
- Billing information
- Personal identifiers

There are many reasons why information about you and your baby may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you and your baby can take part in the study.

- University, Food and Drug Administration (FDA), and/or other government officials may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Analyze the results of the study
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, social security number, payment amount, and related information for tax reporting purposes.
- If you tell us or we learn something that makes us believe that your child or others have been or may be harmed, we may be required to report that information to the appropriate agencies.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

Your data may be managed with the use of REDCap (Research Electronic Data Capture), a web-based electronic data capture system available under contract to the University of Michigan. REDCap can only be used by the Principal investigators of the study and study team members, and only those authorized will have access to your research data.

The results of this study may be published or presented at a scientific meeting. If your pictures or other information that might identify you or your baby will be used in the publications or presentations, the researchers will ask for your separate written permission.

9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?
As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have left the study or the study is over. Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly.

9.4 When does my participation in the study end?
Your participation ends at the end of the study, unless you leave it sooner. You may withdraw from this study at any time by contacting the researchers listed in Section 10 "Contact Information" (below).

10. CONTACT INFORMATION

10.1 Who can I contact about this study?
Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan

- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Julie Lumeng, MD
Mailing Address: 300 North Ingalls St, 10th floor, University of Michigan, Ann Arbor, MI 48109-5406

Study team contact number: 734-647-1087

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies, include the appropriate calling codes.)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.
When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file.)*

12. SIGNATURES

Parent's Own Consent to Participate in the Research Study

I understand the information printed on this form. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Type in Parent/Guardian's Legal Name: _____

Date (mm/dd/yy): _____

Legally Authorized Representative or Parent Permission

Child's Legal Name (please print): _____

Type in name of Person Legally
Authorized to Give Consent: _____Date(mm/dd/yy):_____

Address: _____

Relationship to subject: Parent, Legal guardian, Other (E*xplain:* _____)

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☐_____In the event that you have not been able to contact me, I give my permission to use Internet searches or Facebook messaging as a method to contact me. I understand that you will only use this method if identifying information on Facebook makes it clear that the profile represents me.

☐_____I give permission for my survey responses to be linked to my and my child's biospecimen data from the UM-Pregnancy Biobank, and be retained and stored for unspecified future use after this study is completed or if I end my participation in the study early.

☐_____I give permission for my and my child's study data to be retained and stored for unspecified future use after this study is completed or if I end my participation in the study early.
Type in name of Person Legally
Authorized to Give Consent: _____Date(mm/dd/yy):_____

If this consent is for a child who is a ward of the state (for example a foster child), please tell the study team immediately. The researchers may need to contact the IRBMED.