NYU Langone Health

Research Subject
Informed Consent Form

Title of Study:	COPE Study: COVID-19 and Perinatal Experiences
Principal Investigator:	Moriah Thomason, PhD Child and Adolescent Psychiatry NYU Langone Health 1 Park Avenue, New York, NY 10016
Emergency Contact:	**Harini Srinivasan** Phone: (212) 404-3505

1. About volunteering for this research study.
You are being asked to participate in a study about young families and their experiences during the COVID pandemic. Your participation in this study is entirely voluntary. Your decision whether or not to participate will not impact your medical care. If you wish to participate in this study, you must read this form. Before you can decide whether you wish to participate, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. After you feel that you understand the what this study involves, you will be asked if you agree or decline opportunity to participate.

2. What is the purpose of this study?
The purpose of this study is to learn about early human brain development and how it can be influenced by the environment.

3. How long will I be in the study? How many other people will be in the study?
The exact length of the study is related to the age of your child. Presently, we do not have a limit to how many families we plan to enroll.

4. What will I be asked to do in the study?

Questionnaires: We will ask you to complete questionnaires to share some basic information about yourself, your child, and to provide information about your experiences and feelings. You will also be asked to complete a questionnaire about your experience with the Tasso device (described below).

Biospecimen Collection: All biospecimen collection methods have been developed to be conducted in person or remotely. We will ask for saliva, nail clippings and blood. For **nail clippings**, we will ask you to provide nail clippings from each finger and toe. Nail polish and chemical products will need to be removed in advance of trimming. For **saliva** samples we will ask you to collect your spit with a swab or plastic tube. For **blood** samples, we will obtain less than a tablespoon of your blood. You will be given a Tasso, which is a little device, about the size of a walnut, that attach to the skin with a sticker. The Tasso has a button that you will push to activate a tiny lancet that will quickly make a poke in the skin. Because the Tasso is attached by a sticker, after about 5 minutes a very small tube will fill with several drops of your blood that come about naturally after the initial poke.

Optional Future Use and Storage of Biological Specimens: Samples collected as part of this study can be used to measure chemicals, microbes, hormones, immune markers, DNA, and many other things. We will collect and store your samples for future unspecified research. All biological samples collected as part of this study will be stored with code numbers and not names or personal information. Only the study team will have access to the key that links the code to your identity. De-identified biospecimens will be stored at secure facilities such as the PI's laboratory (One Park Ave, New York, NY) or the Langone Center for BioSpecimen Research & Development (CBRD; 550 1st Avenue, New York, NY). If any third-party is given access to samples that come from this study, for example, if another lab is asked to analyze the samples or samples are shared, the third-party will only receive de-identified data. Meaning, they will not have access to any names or personal information about you. After this study is over, we will keep any remaining samples in storage indefinitely so

that researchers can possibly use these in the future. If you later wish to withdraw your specimens for future research, you may send a written request to the PI (contact information is found on page 1 of this document).

Future Data Sharing: Sharing of de-identified data will occur with researchers at institutions that are working independently on projects that address similar types of research questions. These individuals may utilize the shared data in their own fashion as part of their research goals and/or we may work with them to produce research products together. De-identified data will also be shared with Tasso, Inc., the manufacturer of the Tasso devices for the purpose of improving communication materials as well as to support applications to the Food and Drug Administration (FDA) for continued marketing of the Tasso devices. No identifiable information will be shared with Tasso, Inc. Data may also be shared via public research databases, such as the NIH NDA database, or OSF. When study data are shared on research databases only minimal required personal health information will be shared, and this information will not include your name or any information that could be used to identify you as an individual.

5. What are the possible risks or discomforts?
The risks associated with completing this study are minimal. Two possible risks are loss of confidentiality and being uncomfortable with some of the questions asked in the surveys or with biospecimen collection. Loss of confidentiality refers to a situation in which your data are accessed by unintended individuals. The researchers will lessen this risk by keeping data on secure computer servers and in secure locations. Before sharing your data in databases or with other researchers, we will remove all information that would identify you as an individual person. Your individual identity and history of participating in this study will not be shared with anyone outside of the research team. Regarding biospecimens, collection of nail cuttings is associated with risk of skin injury and some people report that collection of nails is undesirable or inconvenient. Blood collection with a skin poke can cause temporary redness at the location of the poke and also temporary discomfort at the time of the poke.

6. What if new information becomes available?
You will be told about new information that may affect your health, welfare, or willingness to stay in the study.

7. What are the possible benefits of the study?
As a participant in this research study, there is no known direct benefit for you. However, information from this study may benefit other people or children now or in the future.

8. What other choices do I have if I do not participate?
You do not have to take part in this research study. If you decide not to participate, or leave the study, your decision will not interfere with your future care, payment for your health care or your eligibility for health care benefits. If you decide to participate, you are free to leave the study at any time.

9. Will I be paid for being in this study?
Participants will receive a $45 Amazon Gift card for inconvenience associated with study participation. Gift cards will be provided to you after samples are received in the lab.

10. Will I have to pay for anything?
You will not be charged for any of the study procedures. If biospecimen collection occurs remotely, we will provide pre-paid mailing envelopes or boxes for you to mail materials to our research team.

11. What happens if I am injured from being in the study?
We do not anticipate any injuries from being in the study. However, due to the coronavirus public health crisis (COVID-19), the federal government has issued an order that may limit your right to bring a claim if you are injured or harmed while participating in this COVID-19 clinical study. If the order applies to this study, it limits your right to bring a claim against the researchers, healthcare providers, and any study sponsor, manufacturer, and/or distributor involved with the study. However, the federal government has a program that may provide compensation to you or your family if you experience serious physical injuries or death. To find out more about this “Countermeasures Injury Compensation Program” go to https://www.hrsa.gov/cicp/about/index.html or call

1-855-266-2427. If you feel you have been harmed as a result of participating in this study, please contact the Principal Investigator listed at the beginning of this form. Also, if you are experiencing a medical emergency, please contact 911.

12. How will you protect my confidentiality?
Your medical information is protected health information, or "PHI", and is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act, or HIPAA. This includes information in your research record as well as information in your medical record at NYU Langone Health. In compliance with NYU Langone Health policies and procedures and with HIPAA, only those individuals with a related job purpose can access this information.

13. What information may be used or shared with others in connection with this study?
All information collected for this study may be used and shared with the following individuals:

- The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study
- Governmental agencies responsible for research oversight (e.g., the Food and Drug Administration or FDA)
- Other study sites involved in the research.

Additionally, information collected for this study may be shared with researchers outside of the study after all personal information linking you to your data is removed.

14. What if I do not want to give permission to use and share my information for this study?
Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

15. Can I change my mind and withdraw permission to use or share my information?
Yes, you may withdraw or take back your permission to use and share your health information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator of the study listed at the beginning of this form.

16. How long may my information be used or shared?
Your permission to use or share your information for this study will never expire unless you withdraw it.

17. The Institutional Review Board (IRB) and how it protects you
The IRB reviews all human research studies, including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU IRB Office number is (212) 263-4110. The NYU School of Medicine's IRB is made up of doctors, nurses, non-scientists, and people from the community.

18. Who can I call with questions, or if I'm concerned about my rights as a research subject?
If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research participant, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at (212) 263-4110.

19. How do I tell you if I want to take part in this study?

Please indicate whether you provide your consent to participate in this study using the check boxes below:
(__) Yes, I would like to participate in the study.
(__) No, I would not like to participate in the study.

When you agree to participate, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Participant:

_____
Full Name

_____
Signature

_____
Date

Person Obtaining Consent:

_____
Full Name

_____
Signature