**Participant Information Sheet**

**Study Title: The effect of parental indirect and direct expressions of anxiety on infant behavioural, emotional and physiological reactions**

Researchers: Francesca Zecchinato and Ruth Webster

ERGO number: 53477

You are being invited to take part in the above research study. To help you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve. Please read the information below carefully and ask questions if anything is not clear or you would like more information before you decide to take part in this research. You may like to discuss it with others, but it is up to you to decide whether or not to take part. If you are happy to participate you will be asked to indicate your consent via a tick box for the online questionnaires in the online session as well as in the in-person session at the University of Southampton.

**What is the research about?**

Francesca is a PhD student in Psychology and Ruth is a trainee clinical psychologist at the University of Southampton, supervised by Dr Pete Lawrence and Dr Jana Kreppner.

We are interested in how infants learn from their parents during social situations and how this links with the development of childhood social anxiety. Existing research has examined processes behind the transmission of anxiety from mothers to infants. We know that how parents interact with strangers can affect how their infants further interact with these strangers: when parents behave in an anxious manner with a stranger, their infant is more likely to go onto behave in an anxious manner with the same stranger as well. Studies have not yet investigated whether infants’ anxious behaviours with strangers result from one or both of a) only observing their parent interact with a stranger or b) receiving direct communication from their parent during their parent’s interaction with a stranger.

We also know that infant temperament can play an important role in how infants interact with strangers, after observing their parents interact with strangers. Therefore, the aim of this study is to investigate whether, in the context of interactions with strangers, parental indirect (observed by the infant) expression of anxiety or direct (communicated to the infant) expressions of anxiety differentially affect infant behavioural, emotional and physiological reactions while they interact with strangers. The findings of this research will further our understanding of the underlying anxiety transmission processes from mother to infant during social situations.

**Why have I been asked to participate?**

You have been approached to participate in this study because you are a parent aged 18 years or older, fluent in English, with no anxiety diagnosis, and have an infant aged 12-14 months old who was born full-term (i.e. birth weight > 2500g and born at 37+ weeks’ gestation) and without any additional needs (such as congenital health difficulties or developmental delays) and no complex medical conditions, skin allergies and heart conditions. The study aims to recruit 68 parent-infant dyads (34 mother-infant dyads and 34 father-infant dyads) within Southampton and the surrounding area (as we can cover up to £30 of travel expenses).

**What will happen to me if I take part?**

If you think you would like to take part in the study after reading this sheet, we will ask you to give your informed consent to participate, and to complete some **online screening questions** to confirm your eligibility for the study (this will take approximately 20mins). Additionally, we will ask you to provide your contact details. If you are eligible for our study, we will then contact you to arrange a suitable time for you and your infant to **attend the University of Southampton** to take part in the study (the in-person session will take approximately 45 minutes).

**Please, be aware that both the screening session and the in-person session at the university need to be completed by the time your baby is 14 months and 7 days. We recommend to keep this in mind when planning your participation in this study.**

When you attend the University of Southampton you will have the opportunity to read through this electronic Participant Information Sheet again and ask questions to the researcher. You will then be asked to give full informed consent via an electronic form and to complete a short questionnaire about your mood. You will also be provided with a brief overview of the experimental procedure. After this, you will help your baby undress and apply three small electrodes that will allow the recording of their heart rate. The device will be in contact with you baby’s skin, is comfortable and safe, and the baby will have time to settle. The equipment will be cleaned after each use. Next, you and your infant will be asked to take part in two short tasks, each lasting 3 minutes. The tasks will involve you being in a room with your infant. A ‘stranger’ (a member of our research team) will join you. They will chat with you and your infant and will offer your infant a toy.

You will be given specific instructions about how we would like you to act in each of the two tasks. The instructions involve you watching a demonstration video showing how you will be asked to act throughout the experiment and there will be an opportunity to ask questions. During the task, your infant will be strapped in a highchair and you will be seated in a chair close to them. You will be asked to behave anxiously with the stranger and there will be two conditions: one where you gaze towards your infant and the other where you do not gaze towards your infant.

These two tasks will be video recorded and these recordings will be coded for the purpose of the study. Because the original footages represent significant research data, we will ask for your consent to securely store the video footages for 10 years via an electronic form before the lab session and again after the lab session (you will receive an email shortly after your lab visit detailing this), and you will have the opportunity to retrospectively withdraw your consent at any time following the lab visit.

Although the tasks are short, we suggest that participating in the study could take up to 45 minutes to make sure that your infant can settle into a new environment and you will be given time before each task to go through the instructions about how to act.

After you have completed the tasks, the videos will be watched back by the research team. We want to study if parents acting in a different ways in the two tasks leads to any changes in how their infant responds to the strangers.

A full debrief will be given after the experiment has finished.

**Are there any benefits to me taking part?**

The data gained within this study could further our understanding of the transmission of anxiety from parents to infants during social situations. This is important for the development of interventions that effectively prevent or minimise the occurrence of social anxiety in childhood. Participation in this study will also contribute to the existing research within the wider area of how social anxiety develops during childhood. As a reimbursement for your time, you will receive a £20 Amazon voucher upon completion of the experiment. We will also reimburse your travel expenses to and from the University of Southampton (40p per mile, or public transport costs, up to £30).

**Are there any risks involved?**

There are no risks associated with this study that are greater than those within everyday life. Parents may experience some psychological distress due to the sensitive nature of the questionnaires that measure their mental health and their infant’s temperament. If you have any concerns regarding you or your infant’s wellbeing, we suggest that you contact your GP or health visitor.

The experiment requires you to communicate direct and indirect anxiety to your infant which may cause some psychological distress in your infant. However, the experimental task is six minutes in total, so it is expected that the duration will minimise the effect of this psychological distress. If you have any concerns regarding you or your infant’s wellbeing following participation in the research project, we suggest that you contact your GP or Health Visitor. A member of the research team will be able to support you to contact these services if needed.

Participants must be aware of the limitations of confidentiality and that the research team have a duty of care to raise any safeguarding concerns with the parent’s GP/Health Visitor.

All researchers involved in the project, including those acting as the ‘strangers’ in the tasks, will have full DBS clearance.

**What data will be collected?**

We will ask you to complete some questionnaires, which will collect demographic information about you and your infant (e.g., age, gender, household), and will ask about your infant’s temperament and your mood and anxiety.

We will also record the heart rate of your baby via a widely used ECG device, which is non-invasive and comfortable to wear.

The experiment will be audio/video recorded, and these videos will be used to code the parent-infant interaction, and the infant’s behaviour and emotion, as well as responses to the stranger as part of the research project. Members of the research team will code these videos at the University of Southampton.

**Will my participation be confidential?**

Your participation and the information we collect about you and your infant during the course of the research will be kept strictly confidential.

Only members of the research team and responsible members of the University of Southampton may be given access to data about you for monitoring purposes and/or to carry out an audit of the study to ensure that the research is complying with applicable regulations. Individuals from regulatory authorities (people who check that we are carrying out the study correctly) may require access to your data. All of these people have a duty to keep your information, as a research participant, strictly confidential.

All information collected from you will be stored securely. Questionnaire responses will be stored on a university networked drive, within a limited access and password protected folder. If you are not eligible to take part in the lab session, your non-identifiable data will be stored securely on a university networked drive for the duration of the study for publication purposes. Video recordings will be stored securely, on a password protected university computer and will be kept for 10 years on the University server with an access limited to the research team and password-protected. Only members of the research team (researcher, project supervisors and voluntary research assistants) will have access to participant data and this data will not be shared beyond the research team.

To ensure personal information remains confidential and anonymous, research codes will be given to each participant and used to identify non-identifiable participant data, such as the video recordings. The research code key will be stored separately to identifiable and non-identifiable participant data on a university password protected computer. Once the study has been completed, all collected data will be destroyed in line with the University of Southampton’s policies. As recruitment and attendance at the laboratory will be arranged via email, the researcher will keep contact details for each participant for the duration of the study. These details will be destroyed once the project is complete and we have sent you a summary of what we find. Only if you consent to be contacted for future opportunities, the School of Psychology will store your contact information securely for 3 years on the university server. You can withdraw your consent at any time by emailing the research team (f.zecchinato@soton.ac.uk). If you are not eligible to attend the lab session, your contact details will be destroyed as soon as we have informed you about your ineligibility.

Participants must be aware of the limitations of confidentiality and that the research team have a duty of care to raise any concerns with the parent’s GP/Health Visitor. Parents will have provided their name and GP surgery on the EPDS form so the researchers will have access to this information should it be required.

**Do I have to take part?**

No, it is entirely up to you to decide whether or not to take part. If you decide you want to take part, you will be asked to indicate your consent via a tick box for the online questionnaires and again when you come to meet us at the lab to complete tasks at the University of Southampton.

**What happens if I change my mind?**

If you decide to withdraw from the study while you are at the University of Southampton to complete the study tasks with your infant you will still be reimbursed travel expenses for your travel to and from the University, but only participants who complete both the questionnaires and the tasks at Southampton University will receive the £20 Amazon voucher.

You can choose not to complete the on-line questionnaires or you can e-mail f.zecchinato@soton.ac.uk if you choose to withdraw from the study following completion of the questionnaires and the data collected can be deleted.

You can choose to withdraw when attending the University of Southampton to complete the parent and baby tasks by informing any member of the study’s research team that you meet. After attending the University of Southampton to complete these tasks you are still able to withdraw by contacting the researcher (f.zecchinato@soton.ac.uk) and data collected will be destroyed. **The latest date you can withdraw your data from the study is 7 days after completing the laboratory visit**; after this time we will have started coding and analysing the data. **You can withdraw your consent to the storage of the original video footages anytime within the 10 years.**

**What will happen to the results of the research?**

Your personal details will remain strictly confidential. We plan to place unidentifiable data on an open access scientific database (Open Science Framework). Research findings made available in any reports or publications will include no information that could identify you. No one would be able to identify you, or know that you or your infant participated.

The results will be written up and submitted for publication in a scientific journal, and as part of Francesca Zecchinato and Ruth Webster’s theses.

**Where can I get more information?**

If you have any questions about the research or the project, then please contact a member of the research team on F.Zecchinato@soton.ac.uk.

**What happens if there is a problem?**

If you have a concern about any aspect of this study, you should speak to the researchers who will do their best to answer your questions. If you remain unhappy or have a complaint about any aspect of this study, please contact the University of Southampton Research Integrity and Governance Manager (023 8059 5058, rgoinfo@soton.ac.uk).

**Data Protection Privacy Notice**

The University of Southampton conducts research to the highest standards of research integrity. As a publicly funded organisation, the University has to ensure that it is in the public interest when we use personally identifiable information about people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use information about you in the ways needed, and for the purposes specified, to conduct and complete the research project. Under data protection law, ‘Personal data’ means any information that relates to and can identify a living individual. The University’s data protection policy governing the use of personal data by the University can be found on its website (<https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page>).

This Participant Information Sheet tells you what data will be collected for this project and whether this includes any personal data. Please ask the research team if you have any questions or are unclear what data is being collected about you.

Our privacy notice for research participants provides more information on how the University of Southampton collects and uses your personal data when you take part in one of our research projects and can be found at:

<http://www.southampton.ac.uk/assets/sharepoint/intranet/ls/Public/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf>

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to the University’s policies in line with data protection law. If any personal data is used from which you can be identified directly, it will not be disclosed to anyone else without your consent unless the University of Southampton is required by law to disclose it. The results of this study will be written up anonymously as part of my thesis, so it will not be possible to trace these back to you or your infant.

Data protection law requires us to have a valid legal reason (‘lawful basis’) to process and use your Personal data. The lawful basis for processing personal information in this research study is for the performance of a task carried out in the public interest. Personal data collected for research will not be used for any other purpose.

For the purposes of data protection law, the University of Southampton is the ‘Data Controller’ for this study, which means that we are responsible for looking after your information and using it properly. The University of Southampton will keep identifiable information about you until the study has finished (December 2024), after which time any link between you and your information will be removed.

To safeguard your rights, we will use the minimum personal data necessary to achieve our research study objectives. Your data protection rights – such as to access, change, or transfer such information - may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with your personal data that you would not reasonably expect.

If you have any questions about how your personal data is used, or wish to exercise any of your rights, please consult the University’s data protection webpage (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page) where you can make a request using our online form. If you need further assistance, please contact the University’s Data Protection Officer (data.protection@soton.ac.uk).

Thank you for your time in reading this and considering participating in this research.

**If you do not wish to take part in this study, please leave the page; otherwise, please click on the ‘next’ button.**