Protocol Title: Promoting Empathy and Affiliation in Relationships (PEAR) Study
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Description of Study Population: Children, Adults
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Study Summary

Thank you for agreeing to participate in the Promoting Empathy and Affiliation in Relationships (PEAR) Study. The first lab visit will be completed today, and the second visit will occur in approximately two years (when your child is 5 or 6 years old). We will contact you at various points during your participation in this study. The lab visits will take place at a psychology lab at the University of Pennsylvania and will take approximately two and a half to three hours. This consent form describes your and your child's participation in the first visit of the study.

We will ask you to complete any remaining questionnaires during today's lab session. We will also ask you and your child to (1) participate in games, tasks, and discussions together, (2) separately each complete games on a computer or tablet, and (3) watch age-appropriate video clips. We will record you and your child's heart rate throughout the lab visit and information about you and your child's sweat response during some tasks. We will also record you and your child's eye movement for some tasks during the visit using special eye-tracking glasses or cameras.

Potential risks include (1) discomfort or distress in response to questionnaires or tasks, (2) a risk of loss of privacy or confidentiality, and (3) minor discomfort during the application and removal of electrodes. See the section *Potential Risks* below for more detail.

Introduction

This form will provide important information about you and your child participating in PEAR. Please ask if you have any questions about the research or any part of this form. Taking part in PEAR is up to you. If you decide to participate, we will ask you to sign this form. We will give you a copy of the signed form.

The person in charge of this study is Dr. Waller, who can be reached at rwaller@sas.upenn.edu**.** We refer to this person as the "researcher" throughout this form.

What should I know about a research study?

Participation in research is voluntary. It is your choice whether you and your child participate in the study. If you choose to participate now, you may change your mind and stop participating later. If you decide not to participate, that decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

Why is this study being done?
The purpose of this study is to learn more about how children learn about and experience emotions, empathy, and relationships.

Who is Funding the Study?
The study is funded by **the National Institutes of Health.**

How long will I take part in this research study?
We expect you and your child to be in this research study for **around two years**. During this time, we will ask you to make **two** study visits to the EDEN Lab at the University of Pennsylvania**. The first visit is today, and the second will occur in approximately two years.** We will contact you at various times throughout your participation.

What will happen if I take part in this research study?
If you agree for you and your child to take part in this study, we will ask you to sign the consent form before we conduct any study procedures.

What will happen today (Study Lab Visit 1)?
The lab visit will take about 2 ½ – 3 hours. We will ask you and your child to:

- Wear electrodes to continuously record your and your child's heart rate. For this, we use electrodes that are hypoallergenic, light-weight, and designed for safe use with young children. We will place 11 electrodes on both you and your child located on your neck and chest. A trained researcher can apply the electrodes or show you how to do it yourself in privacy if you choose. Wires connect the electrodes to fabric belts that you and your child will wear around your chests.
- Wear 2 electrodes on the palm of the hand to record your and your child's sweat response during a few tasks, but you won't wear them when you aren't doing these specific tasks. The monitor is attached using Velcro and is worn on the wrist like a bracelet.
- Play games together and have guided discussions.
- Watch short video clips from age-appropriate movies (e.g., Disney movie).
- Play age-appropriate games on a computer or tablet
- Complete a task where a research assistant your child has never met will introduce themselves and show your child new toys while you are in the room.
- Complete activities where we collect information about where you/your child are looking (i.e., eye-tracking) either using a camera in front of a computer screen or from special glasses that record where you are looking which you'll wear for a few tasks.

What are the risks of taking part in this research study?
Risks of Completing Tasks
You/your child may get tired during the tasks. You can both rest at any time.

Questionnaire/Survey Risks
You may feel emotional or upset when answering some of the questions. Tell the researcher at any time if you want to take a break or stop responding.

Electrodes
Removing electrodes from the skin at the end of the visit could cause minor discomfort. Although removing the electrodes is typically less painful than removing a Band-Aid, they may leave residue around the outline of the electrode similar to that of a Band-Aid, or you may see faint redness at the application site after they are removed. This is normal and will fade within a day. We will provide you with a dish soap and water solution to weaken the adhesive, but not all participants need this. We will also offer your child prizes for removing the electrodes to make the process more enjoyable.

Loss of Confidentiality
The main risk of allowing us to use and store your information for research is a potential loss of privacy. We will protect your privacy by labeling your information with a code and keeping the key to the code in a password-protected computer and on a secure server.

You will be informed of any significant new findings developed during the course of this research that may affect your willingness to continue participation.

Mandatory Reporting
Reporting child abuse: If, during your participation in this study, we have reasonable cause to believe that child abuse is occurring, we must report this to authorities as required by law. The researcher will make every reasonable effort to protect the confidentiality of your research information. However, it might be possible that a civil or criminal court might demand the release of identifiable research information.

Reporting Suicidal Risk: If, during your participation in this study, we have reason to believe that you are at risk for being suicidal or otherwise harming yourself, we are required to take the necessary actions. This may include notifying your doctor, your therapist, or other individuals. If this were to occur, we would not be able to assure confidentiality.

Are there any benefits from being in this research study?
There are no benefits to you from taking part in this research. Others may benefit in the future from the information that is learned in this study.

What alternatives are available?
You may choose not to take part in this research study.

Study Participation and Early Withdrawal
Taking part in this study is your choice. You can stop taking part or withdraw at any time for any reason. No matter what you decide, there will be no penalty or loss of benefit to which you are entitled. If you decide to withdraw from this study, the information that you have already provided will be kept confidential.

The researcher may also take you out of this study without your permission. This may happen because:

- The researcher thinks it is in your best interest
- You can't make the required study visits
- Other administrative reasons

Audio/Video Recording

We would like to audio/video record you and your child during this study. If you are **audio/video recorded,** it **may** be possible to identify you. We will store these recordings on our computer and secure server approved for storing protected information; only approved study staff can access the recordings. We will label these recordings with a code instead of your name. **Recordings will not be deleted unless participants request this in writing after completing the study.**

Do you agree to allow us to audio/video record you and your child during this study?

_____YES _____NO

How Will You Keep My Study Records Confidential?

We will keep the records of this study confidential by labeling your information with a study ID instead of your real name. We will make every effort to keep your records confidential. However, there are times when federal or state law requires the disclosure of your records.

The following people or groups may review your study records for purposes such as quality control or safety:

- The Researcher and any member of their research team
- The Institutional Review Board at Boston University. The Institutional Review Board is a group of people who review human research studies for safety and protection of people who take part in the studies.
- The sponsor or funding agency for this study
- Federal and state agencies that oversee or review research
- Central University Offices

Files will be stored indefinitely on a secure server approved for storing protected information. Identifiable data can be removed from these servers upon request after the completion of the study.

De-identified data may be shared with publicly available databases or databases available to BU and Penn researchers and may be included in current and future research. The data will not include identifiers like your name or address. Researchers will not try to re-identify you. Any future use of your de-identified data will be overseen by relevant review boards like the one overseeing this research.

The results of this research study may be published or used for teaching. We will not include identifiable information on data used for these purposes.

Certificate of Confidentiality
The National Institutes of Health (NIH) issues "Certificates of Confidentiality" to all studies like ours. This is an additional way to protect the privacy of your data. However, there are still some exceptions, for example, the mandatory reporting described earlier. You can read more about it below.

The National Institutes of Health (NIH) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless: there is a law that requires disclosure (such as to report child abuse or communicable diseases, but not for legal proceedings); you have consented to the disclosure, including for your medical treatment; or the research information is used for other scientific research, as allowed by federal regulations protecting research participants.

Disclosure is required, however, for audits or program evaluations requested by the agency that is funding this project or for information that may be required by the Food and Drug Administration (FDA). Any research information that is placed in your medical record would not be covered.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If others obtain your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

Will I get paid for taking part in this research study?
You will be compensated $150 after completing these questionnaires and the first lab visit (i.e., time and travel) and $170 after you complete the second lab visit and questionnaires in two years.

What will it cost me to take part in this research study?
There are no costs to you for taking part in this research study.

What happens if I am injured as a result of participating in this research study?
If you or your child are injured as a result of taking part in this research study, we will assist you in getting medical treatment. However, your insurance company will be responsible for the cost. The University of Pennsylvania does not provide any other form of compensation for injury.

Who do I ask if I have questions or concerns about this research study?
Please contact us with any concerns or questions about the research, or any research-related problems:

You can reach the Principal Investigator, Dr. Rebecca Waller, at (215) 537-2201 or rwaller@upenn.edu. You can reach the Senior Research Coordinator, Yuheiry Rodriguez, at (215) 839-8593 or PennPEAR@bu.edu.

If a member of the research team cannot be reached or if you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

If you have questions about your rights as a research participant, or if you have any complaints or concerns and want to speak with someone independent of the research team, you may contact the Boston University Charles River Campus Institutional Review Board at 617-358-6115. The IRB Office webpage (https://www.bu.edu/researchsupport/compliance/human-subjects/research-participation/) has information where you can learn more about being a participant in research, and you can also complete a Participant Feedback Survey.

Statement of Consent

I have read the information in this consent form including risks and possible benefits. I have been given the chance to ask questions. My questions have been answered to my satisfaction, and I agree to participate in the study.

Do you agree to participate in this study?

- ☐ Yes
- ☐ No

SIGNATURE

_____ _____

Name of Study Participant Date

Please sign by typing your full name

I have explained the research to the research participant and answered all their questions. I will give a copy of the signed consent form to the participant.

_____ _____

Name of Person Obtaining Consent Date

Please sign by typing your full name