Parent-Adolescent Training on Neurofeedback and Synchrony
NCT03929263
Informed Consent and Assent Documents
5/20/2019

OKLAHOMA STATE UNIVERSITY
Center of Health Sciences
PARTICIPANT INFORMATION AND CONSENT FORM

Title: **DIBS: Dyadic Inter-Brain Study – Screening Protocol**

Investigator: **Amanda Sheffield Morris, Ph.D., IMH-E®**
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Phone: 405-332-6746

"You" refers to the participant, either the parent or your adolescent.
"We" refers to the research team at Laureate Institute for Brain Research (LIBR).

You are being asked to participate in this research study because you were determined eligible during the previous screening component and you are a biological parent of an adolescent aged 13 -17 years old.

What you should know about participating in a research study:
Participation in research is a voluntary choice, and this consent form will provide you with information about the risks, benefits or alternatives to participation in the study.

- Someone will explain this research study to you.
- You may volunteer to be in a research study.
- Whether or not you take part is up to you.
- You can choose not to take part in the research study.
- You can agree to take part now and later change your mind.
- Whatever you decide it will not be held against you.
- Feel free to ask all the questions you want before you decide.

Who can you talk to?
Although this consent form provides detailed information about this study, a research team member is available to answer any questions you may have about this study and/or participation in it. If you have questions, concerns, or complaints, or think the research has hurt you, talk to the researcher or identified members of the research team at 918-502-2223.

This research has been reviewed and approved by the Oklahoma State University Center for Health Sciences Institutional Review Board (IRB). You may contact the chairperson of this committee at 918-561-1400 for any of the following:

- Your questions, concerns, or complaints are not being answered by the researcher or research team.
- You cannot reach the researcher or a member of the research team.
- You want to talk to someone other than the researcher or the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research or your experience in this research study.

Why are we doing this research?
The purpose of the research is to assess how parents and adolescent sons or daughters interact to determine eligibility for participating in a later Magnetic Resonance Imaging (MRI) study. We are looking at how parenting style affects an adolescent's ability to overcome adversity and the risk processes related to depression.

How long will the research last?
We expect the screening visit will take up to three hours to complete in one day.

How many people will be studied?
We expect about 110 parents and 110 adolescents to be enrolled into this study.

What happens if you say yes, you want to be in this research?
After being consented to the study, both you and your adolescent may complete an in-person lab visit at LIBR to determine eligibility for the MRI study. This visit may take up to 3 hours.

During this visit, you and your adolescent may each complete the following procedures:

- Demographic and medical history evaluation
- Measurement of head circumference
- Psychiatric interviews
- Self-report surveys

Head circumference measurements are taken for sizing of a cap that will be used in the MRI study. The self-report surveys may assess handedness, nicotine dependence, parent-child relationship, emotion awareness, and mental health. Based on data collected from the screening visit, you and your adolescent may then be invited to participate in the MRI study. If you are invited to participate in the MRI study, you will be provided with further information about the study at the end of today's visit. If you and/or your adolescent require prescription glasses, you may also be fitted with MRI-safe goggles to wear during the scan.

Follow-Up
You and your adolescent may be contacted on two occasions to complete a 45-minute follow-up phone/electronic survey. You will be contacted both 1 and 2 years from now. We will also be in contact with you periodically during this 2-year period. You will choose what method we use to contact you.

What happens if you say no, you do not want to be in this research?
You may decide not to take part in the research and it will not be held against you. A refusal to participate in this research study will involve no penalty or loss of benefits to which you are otherwise entitled.

What happens if you say yes, but you change your mind later?
You can agree to take part in the research now and stop at any time. It will not be held against you. Discontinuing participation will not result in penalty or loss of benefits to which you are otherwise entitled. However, you may not be paid the full amount of the study compensation if you discontinue participation.

If you stop participating in the research study, we can remove your data with written request. However, data already collected may not be removed from the study database if it has already been analyzed or shared with a research partner.

Is there a risk to being in this study?
Participation in this study may involve risks or discomforts. These include the following:

1. It is possible you and/or your adolescent may become tired, bored, or frustrated during the study sessions. You and your adolescent may take a break and/or stop at any time.

2. It is possible that being asked about feelings, mood, or about experiences with alcohol, tobacco, or drugs may make you and/or your adolescent feel uncomfortable. You and your adolescent may skip questions that make you feel uncomfortable.

3. There is risk of possible loss of confidentiality. The study will be conducted under a Certificate of Confidentiality. However, if some of the information collected, such as use of illegal substances, were to become known outside of this research setting, it may place you and/or your adolescent at risk for criminal or civil liability or may be damaging to your ability to get a job, affect personal reputation, or have otherwise unknown outcomes.

4. Additional Psychological or Social Risks Associated with Loss of Privacy
While we believe that the risks to you and your family are very low, we are unable to tell you exactly what all of the risks are. Below are some potential risks:

Your privacy is very important to us and we will use many safety measures to protect your privacy. However, even with all the safety measures that will be used, we cannot guarantee that your identity will never become known.

While the controlled-access databases used to share data from this project will not contain information that is traditionally used to identify you or your adolescent, such as name,

address, and telephone number, people may develop ways in the future that would allow someone to link your mental health or medical information in these databases back to you. For example, someone could compare information in our databases with information from you (or a family member) in another database and be able to identify you or family members. Nevertheless, research data will be kept in a separate database from identifying information (name, address, social security number), to further protect confidentiality.
In addition to these risks, this research may harm you or your adolescent in ways that are unknown and unforeseeable. If we learn of new risks that we think might affect your desire to stay in the research we will tell you. If major risks are discovered after the study is finished, it is possible that the sponsor may attempt to contact you.

Finally, you should know the research team can take steps, such as telling authorities (for example, the Police) if 1) you tell us of plans to seriously hurt yourself, 2) you tell us of plans to hurt another person, or 3) we learn that a child or elder has been or is being abused.

What if you are injured or made sick from the research?
If you are injured by way of the study, or require emergency care, the PI will direct you to emergency care. If you or your adolescent has insurance for medical care, your insurance carrier will be billed in the usual manner. As with any medical insurance, any costs that are not covered or are in excess of what are paid by your insurance, including deductibles, will be your responsibility. Oklahoma State University does not provide compensation for lost wages, disability, pain, or discomfort unless required by law to do so. However, this does not mean that you and your adolescent are giving up any legal rights that you may have. You may contact the researcher for more information.

What benefits can be reasonably expected?
There is no anticipated direct benefit to you or your adolescent from participation in this study. The investigators, however, may learn more about the neurological effects of parenting on child and adolescent mental health and brain development and functioning. Such understanding may aid in the creation of targeted, individualized interventions based on emotion regulation and parent-child relationships that emerge during adolescence.

Will it cost you anything to be in this study?
There will be no cost to you or your adolescent for participating in this study.

Will you be compensated for participating in this study?
If you agree to take part in this research study, we will pay you $75 each for the 3-hour study visit. If you complete the follow-up surveys, you will receive $20 and your adolescent will receive $30 at each timepoint. You will be paid through a ClinCard (similar to a debit card) that may be used once it is activated, which will take no longer than 2 business days after the study visit.

What are your responsibilities?
Tell the researcher or research study staff about any medications you are taking.

:

Can you be removed from the research without your permission?
The investigators (or the sponsor) can remove you and your adolescent from the research study without your approval. Possible reasons for removal include:

- If the investigator considers it in your best interest
- The investigator (or sponsor) can also end the research study early.

What will be done with your Personally Identifiable Information (PII)?
Your PII will be collected and entered in a database along with the information from other people taking part in this study. However, these data will be kept in a separate database from your research data.

Why are you being asked to release it?
Your PII will be used for study eligibility, for contact purposes, payment and for the MRI safety screen. It will not be released for any other reasons except those listed in this form.

What will be released?
To complete this research study, we will need to collect and release (disclose) information about you. This information may include

- Your date of birth, name, contact information, and social security number (for payment only).

What happens to the information we collect?
Efforts will be made to limit your personal information, including study data, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information for quality assurance and data analysis include:

- The researcher and his/her research study staff
- Oklahoma State University IRB or its agents
- Laureate Institute for Brain Research
- National Institutes of Health (NIH)
- Other collaborating institutions

The only people who will know that you are a research subject are members of the research team. No information about you, or provided by you during the research, will be disclosed to others without your written permission, except if necessary to protect your rights or welfare (for example, if you are injured and need emergency care) or if required by law. You will be asked to sign an Authorization to Release Research + Health Information.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

How long will this authorization last?
This authorization has no expiration date.

Can you stop your PII from being used?
You can tell us to stop collecting health information that can be traced to you or your adolescent at any time. We will stop, except in very limited cases if needed to comply with law, protect your safety, or make sure the research was done properly. We can

remove data with written request unless it has already been analyzed or shared with a research partner. If you have any questions about this please ask.

If you want us to stop, you must tell us in writing. Write or email Amanda Morris, Ph.D., at amanda.morris@okstate.edu or amorris@LIBR.net, or Jerzy Bodurka, Ph.D., at jbodurka@LIBR.net, or Kara Kerr, Ph.D., at kara.kerr@okstate.edu.

Certificate of Confidentiality:
We will do everything we can to keep others from learning about your participation in this study. To further help us protect your privacy, we have obtained a Certificate of Confidentiality from the United States Department of Health and Human Services (DHHS). With this Certificate, we cannot be forced (for example by court order or subpoena) to disclose information that may identify you in any federal, state, local, civil, criminal, legislative, administrative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except to prevent serious harm to you or others, and as explained below.

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 study.

If an insurer or employer learns about your participation, and obtains your consent to receive research information, then we may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy. Disclosure will be necessary, however, upon request of DHHS for the purpose of audit or evaluation, and is limited only to DHHS employees involved in the review.

What happens if you do not want us to collect and release your information?
If you decide not to authorize release of your PII as part of this study, your decision will in no way affect your medical care or cause you to lose any benefits to which you are entitled. You cannot participate in this research study if you do not authorize the use or release of your PII for purposes stated in this form.

When will it be destroyed?
We do not know when your information will no longer be used therefore the information will be kept for an indefinite length of time.

What else do you need to know?
If any significant new findings develop during the course of the research which may relate to your willingness to continue participation, we will provide that information to you.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Whom should you call if you have questions or problems?
If you have questions, concerns, or complaints about the study or have a research-related injury, contact the Principal Investigator, Amanda Sheffield Morris, Ph.D., IMH-

E®, at 918-594-8207, amanda.morris@okstate.edu, or amorris@LIBR.net, or Jerzy Bodurka, Ph.D., at 918-502-5101 or jbodurka@LIBR.net, or Kara Kerr, Ph.D., at 405-332-6746 or kara.kerr@okstate.edu.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

Signature Block for Capable Adult

Your signature below documents your consent to take part in this research and to the use and disclosure of your protected health information. You will receive a signed copy of this complete form.

_____	_____
Signature of participant	Date
_____	
Printed name of participant	
_____	_____
Signature of person obtaining consent	Date
_____	
Printed name of person obtaining consent	

Signature Block for Parent

Your signature below documents your permission for the adolescent named below to take part in this research and to the use and disclosure of this adolescent's protected health information. You will receive a signed copy of this complete form.

_____	
Printed name of adolescent	
_____	_____
Signature of parent or guardian	Date
_____	❑ Parent ❑ Legal Guardian (See note below)
Printed name of parent or guardian	

Note on permission by legal guardians: An individual may provide permission for a adolescent only if that individual can provide a written document indicating that he or she is legally authorized to consent to the adolescent's general medical care. Attach the documentation to the signed consent.

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Title: **DIBS: Dyadic Inter-Brain Study – Screening Protocol**

Investigator: **Amanda Sheffield Morris, Ph.D., IMH-E®**
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Sub-Investigators: **Jerzy Bodurka, Ph.D.**
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Director, MRI-EEG Facility
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Phone: 918-502-5101

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Oklahoma State University
Human Development & Family Science
Email: kara.kerr@okstate.edu; kkerr@LIBR.net
Phone: 405-332-6746

"You" refers to the participant.
"We" refers to the research team at Laureate Institute for Brain Research (LIBR).

You are being asked to participate in this research study because you were determined eligible during the previous screening component and you are an adolescent between the ages of 13 -17 years old.

What you should know about participating in a research study:
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How many people will be studied?
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about the study at the end of today's visit. If you require prescription glasses, you may also be fitted with MRI-safe goggles to wear during the scan.

Follow-Up
You may be contacted on two occasions to complete a 45-minute follow-up phone/electronic survey. You will be contacted both 1 and 2 years from now. We will also be in contact with you periodically during this 2-year period. You will choose what method we use to contact you.

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You can agree to take part in the research now and stop at any time. It will not be held against you. Discontinuing participation will not result in penalty or loss of benefits to which you are otherwise entitled. However, you may not be paid the full amount of the study compensation if you discontinue participation.

If you stop participating in the research study, we can remove your data with written request. However, data already collected may not be removed from the study database if it has already been analyzed or shared with a research partner.

Is there a risk to being in this study?
Participation in this study may involve risks or discomforts. These include the following:

1. It is possible you may become tired, bored, or frustrated during the study sessions. You may take a break and/or stop at any time.

2. It is possible that being asked about feelings, mood, or about experiences with alcohol, tobacco, or drugs may make you feel uncomfortable. You may skip questions that make you feel uncomfortable.

3. There is risk of possible loss of confidentiality. The study will be conducted under a Certificate of Confidentiality. However, if some of the information collected, such as use of illegal substances, were to become known outside of this research setting, it may place you at risk for criminal or civil liability or may be damaging to your ability to get a job, affect personal reputation, or have otherwise unknown outcomes.

4. Additional Psychological or Social Risks Associated with Loss of Privacy
While we believe that the risks to you and your family are very low, we are unable to tell you exactly what all of the risks are. Below are some potential risks:

Your privacy is very important to us and we will use many safety measures to protect your privacy. However, even with all the safety measures that will be used, we cannot guarantee that your identity will never become known.

While the controlled-access databases used to share data from this project will not contain information that is traditionally used to identify you, such as name, address, and telephone number, people may develop ways in the future that would allow someone to link your mental health or medical information in these databases back to you. For example, someone could compare information in our databases with information from you (or a family member) in another database and be able to identify you or family members. Nevertheless, your research data will be kept in a separate database from your identifying information (name, address, social security number), to further protect your confidentiality.

In addition to these risks, this research may harm you in ways that are unknown and unforeseeable. If we learn of new risks that we think might affect your desire to stay in the research we will tell you. If major risks are discovered after the study is finished, it is possible that the sponsor may attempt to contact you.

Finally, you should know the research team can take steps, such as telling authorities (for example, the Police) if 1) you tell us of plans to seriously hurt yourself, 2) you tell us of plans to hurt another person, or 3) we learn that a child or elder has been or is being abused.

What if you are injured or made sick from the research?
If you are injured by way of the study, or require emergency care, the PI will direct you to emergency care. If you have insurance for medical care, your insurance carrier will be billed in the usual manner. As with any medical insurance, any costs that are not covered or are in excess of what are paid by your insurance, including deductibles, will be your responsibility. Oklahoma State University does not provide compensation for lost wages, disability, pain, or discomfort unless required by law to do so. However, this does not mean that you are giving up any legal rights that you may have. You may contact the researcher for more information.

What benefits can be reasonably expected?
There is no anticipated direct benefit to you from participation in this study. The investigators, however, may learn more about the neurological effects of parenting on child and adolescent mental health and brain development and functioning. Such understanding may aid in the creation of targeted, individualized interventions based on emotion regulation and parent-child relationships that emerge during adolescence.

Will it cost you anything to be in this study?
There will be no cost to you for participating in this study.

Will you be compensated for participating in this study?
If you agree to take part in this research study, we will pay you $75 for the 3-hour study visit. If you complete the follow-up surveys, you will receive $30 at each timepoint. You will be paid through a ClinCard (similar to a debit card) that may be used once it is activated, which will take no longer than 2 business days after the study visit.

What are your responsibilities?
Tell the researcher or research study staff about any medications you are taking.

Can you be removed from the research without your permission?
The investigators (or the sponsor) can remove you from the research study without your approval. Possible reasons for removal include:

- If the investigator considers it in your best interest.
- The investigator (or sponsor) can also end the research study early.

What will be done with your Personally Identifiable Information (PII)?
Your PII will be collected and entered in a database along with the information from other people taking part in this study. However, these data will be kept in a separate database from your research data.

Why are you being asked to release it?
Your PII will be used for study eligibility, for contact purposes, payment, and for the MRI safety screen. It will not be released for any other reasons except those listed in this form.

What will be released?
To complete this research study, we will need to collect and release (disclose) information about you. This information may include

- Your date of birth, name, contact information, and social security number (for payment only).

What happens to the information we collect?
Efforts will be made to limit your personal information, including study data, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information for quality assurance and data analysis include:

- The Researcher and his/her research staff
- Oklahoma State University IRB or its agents
- Laureate Institute for Brain Research
- National Institutes of Health (NIH)
- Other collaborating institutions

The only people who will know that you are a research subject are members of the research team. No information about you, or provided by you during the research, will be disclosed to others without your written permission, except if necessary to protect your rights or welfare (for example, if you are injured and need emergency care) or if required by law. You will be asked to sign an Authorization to Release Research + Health Information.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

How long will this authorization last?
This authorization has no expiration date.

Can you stop your PII from being used?
You can tell us to stop collecting health information that can be traced to you at any time. We will stop, except in very limited cases if needed to comply with law, protect your safety, or make sure the research was done properly. We can remove your data with written request

unless it has already been analyzed or shared with a research partner. If you have any questions about this please ask.

If you want us to stop using your data, you must tell us in writing. Write or email Amanda Morris, Ph.D., at amanda.morris@okstate.edu or amorris@LIBR.net, or Jerzy Bodurka, Ph.D., at jbodurka@LIBR.net, or Kara Kerr, Ph.D., at kara.kerr@okstate.edu.

Certificate of Confidentiality:
We will do everything we can to keep others from learning about your participation in this study. To further help us protect your privacy, we have obtained a Certificate of Confidentiality from the United States Department of Health and Human Services (DHHS). With this Certificate, we cannot be forced (for example by court order or subpoena) to disclose information that may identify you in any federal, state, local, civil, criminal, legislative, administrative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except to prevent serious harm to you or others, and as explained below.

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 study.

If an insurer or employer learns about your participation, and obtains your consent to receive research information, then we may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy. Disclosure will be necessary, however, upon request of DHHS for the purpose of audit or evaluation, and is limited only to DHHS employees involved in the review.

What happens if you do not want us to collect and release your information?
If you decide not to authorize release of your PII as part of this study, your decision will in no way affect your medical care or cause you to lose any benefits to which you are entitled. You cannot participate in this research study if you do not authorize the use or release of your PII for purposes stated in this form.

When will it be destroyed?
We do not know when your information will no longer be used therefore the information will be kept for an indefinite length of time.

What else do you need to know?
If any significant new findings develop during the course of the research which may relate to your willingness to continue participation, we will provide that information to you.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Whom should you call if you have questions or problems?
If you have questions, concerns, or complaints about the study or have a research-related injury, contact the Principal Investigator, Amanda Sheffield Morris, Ph.D., IMH-

E®, at 918-594-8207, amanda.morris@okstate.edu, or amorris@LIBR.net, or Jerzy Bodurka, Ph.D., at 918-502-5101 or jbodurka@LIBR.net, or Kara Kerr, Ph.D., at 405-332-6746 or kara.kerr@okstate.edu.

Do not sign this assent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

Signature Block for Capable Adolescent

Your signature below documents your assent to take part in this research and to the use and disclosure of your protected health information. You will receive a signed copy of this complete form.

Signature of participant	Date
Printed name of participant	
Signature of person obtaining assent	Date
Printed name of person obtaining assent	