Modification and evaluation of the DECIDE intervention to improve parent-provider interactions in low-income parents of adolescents with Disruptive Impulse Control, and Conduct Disorders

NCT number: NCT04445155

Date: 12/06/2022

**INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR RESEARCH**

**Modification and evaluation of the DECIDE intervention to improve parent-provider interactions in low-income parents of adolescents with Disruptive Impulse Control, and Conduct Disorders**
**Parent Consent**
**IRB #1911897011**

**ABOUT THIS RESEARCH**
You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

**TAKING PART IN THIS STUDY IS VOLUNTARY**
You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with your health care provider or Indiana University.

**WHY IS THIS STUDY BEING DONE?**
The purpose of this study is to compare two different programs utilized by healthcare providers and guardians 21 years and older of children and adolescents aged 3 to 17 who are diagnosed with Disruptive, Impulse-Control, and Conduct disorders (DIC). This includes children with behavior problems, such as Oppositional Defiant disorder, Conduct disorders, or Intermittent Explosive disorders). We will be studying outcomes in guardians.

You were selected as a possible participant because you are a guardian (biological parent, adoptive parent, step parent, foster parent, or legal guardian) 21 years or older who has a child or adolescent aged 3 to 17 who has a diagnosis of DIC that receives mental health treatment. If foster parent, must have been the primary caregiver for a child with DIC now or in the past.

The study is being conducted by Dr. Susan Perkins at Indiana University and Dr. Ukamaka Oruche at University of South Florida and their research team. It is funded by the National Institutes of Health.

**HOW MANY PEOPLE WILL TAKE PART?**
If you agree to participate, you will be one of 101 people taking part in this study (21 behavioral healthcare providers and 80 parents).

**WHAT WILL HAPPEN DURING THE STUDY?**

If you agree to be in the study, you have the possibility of doing the following things:

**Patient/patient representative**

Before the training

1. Complete survey about your age, sex, gender, education, and employment history; tells us what you know and would like to improve about your interactions with your child or adolescent's provider; and your input and contributions in treatment decision about your child or adolescent.
2. Complete survey about your child or adolescent's age, sex, gender, and mental health history. It will take about 15 minutes to complete the surveys.

During study

3. Complete two 60-minute training sessions with a trained care manager through Indiana University. These sessions will be recorded and completed at times that are convenient for you. Parents can receive CEUs upon completion of this training.

After the training

4. Complete a final set of surveys. It will take about 20-25 minutes to complete the surveys.
5. Finally, complete an oral interview to tell us about your experience with the study. This interview will take about 15-20 minutes

For the training, you will participate in the DECIDE training, survey completion, and oral interview remotely (e.g., via phone, Zoom Health, or similar HIPAA approved telemedicine platform such as WebEx).

You will be involved with the study for a period of 2 to 4 weeks, depending on your availability.

**WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?**

While participating in the study, the risks, side effects, and/or discomforts include:

- Discomfort sharing thoughts and opinions regarding interactions with providers
- Discomfort sharing and discussing your adolescent's mental health and treatment
- Discomfort for you if your oral interview is recorded
- A potential loss of confidentiality

Several things will be done to minimize yours risks of taking part in the study:

- While completing training or talking to the researcher, you can tell the researcher that you feel uncomfortable or that you do not want to answer a particular question or discuss a particular topic.
- You can stop the task(s) at any time.
- Audio recordings will not be shared with anyone other than the researchers.

- All information about you will be saved on password-protected computers.

**WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THE STUDY?**

There will be no direct benefits of this study. We hope to learn things that will help scientists in the future.

**HOW WILL MY INFORMATION BE PROTECTED?**

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. No information which could identify you will be shared in publications about this study. Only certain investigators will have access to any recordings.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the Indiana University Institutional Review Board or its designees, Indiana University, and state or federal agencies who may need to access the research records (as allowed by law). State and federal agencies may include the "Office for Human Research Protections (OHRP)" for federally-funded research, and/or "National Institutes of Health (NIH)" for research funded or supported by NIH], etc.]

For the protection of your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers may not disclose or use any information, documents, or specimens that could identify you in any civil, criminal, administrative, legislative, or other legal proceeding, unless you consent to it. Information, documents, or specimens protected by this Certificate may be disclosed to someone who is not connected with the research:

(1) if there is a federal, state, or local law that requires disclosure (such as to report adolescent abuse or communicable diseases);
(2) if you consent to the disclosure, including for your medical treatment;
(3) if it is used for other scientific research in a way that is allowed by the federal regulations that protect research subjects;
(4) for the purpose of auditing or program evaluation by the government or funding agency;

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself. 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.

**WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?**

Information for this study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any

information is shared. Since identifying information will be removed, we will not ask for your additional consent.

A description of this clinical trial will be available on 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.

**WILL I BE PAID FOR PARTICIPATION?**

You will receive a $25 gift card for each of the two times you complete surveys. You will also receive a $25 gift card if you complete an oral interview. You will receive $10 for each training session attended. Parents can receive CEUs upon completion of this training.

**WILL IT COST ME ANYTHING TO PARTICIPATE?**

There is no cost to you for taking part in this study.

**WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?**

For questions about the study or in the event of an emergency, you may contact either of the lead researchers, Dr. Susan Perkins (Indiana University) at (317) 274-2626 or Dr. Ukamaka Oruche (University of South Florida) at (813) 396-2524.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact the IU Human Subjects Office at 800-696-2949 or at irb@iu.edu.

**CAN I WITHDRAW FROM THE STUDY?**

If you decide to participate in this study, you can change your mind and decide to leave the study at any time in the future. The study team will help you withdraw from the study safely. If you decide to withdraw, notify one of the researchers.

Modification and evaluation of the DECIDE intervention to improve parent-provider interactions in low-income parents of adolescents with Disruptive Impulse Control, and Conduct Disorders

NCT number: R21MD015150

Date: 10/12/2022

**INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR RESEARCH**

**Modification and evaluation of the DECIDE intervention to improve parent-provider interactions in low-income parents of adolescents with Disruptive Impulse Control, and Conduct Disorders**
**Bowen Center Healthcare Provider**
**IRB #1911897011**

**ABOUT THIS RESEARCH**

You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

**TAKING PART IN THIS STUDY IS VOLUNTARY**

You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with Bowen Center or Indiana University

**WHY IS THIS STUDY BEING DONE?**

The purpose of this study is to compare two different programs utilized by healthcare providers and guardians (biological parent, adoptive parent, step parent, foster parent, or legal guardian) aged 21 years and older of children and adolescents aged 6 to 17 who are diagnosed with Disruptive, Impulse-Control, and Conduct disorders (DIC). This includes children with behavior problems, such as Oppositional Defiant disorder, Conduct disorders, or Intermittent Explosive disorders). We will be studying outcomes in guardians.

You were selected as a possible participant because you are a healthcare provider that provides mental health treatment at Bowen Center for children and adolescents aged 6 to 17 who are diagnosed with DIC.

The study is being conducted by Dr. Susan Perkins at Indiana University and Dr. Ukamaka Oruche at

University of South Florida and their research team. It is funded by the National Institutes of Health.

**HOW MANY PEOPLE WILL TAKE PART?**

If you agree to participate, you will be one of 101 people taking part in this study (21 behavioral healthcare providers and 80 parents).

**WHAT WILL HAPPEN DURING THE STUDY?**

If you agree to be in the study, you will do the following things:

**Healthcare Providers (e.g., administrator, nurse, social worker, case manager, physician, advanced practice provider)**

1. Complete demographic surveys or questionnaires about you including age, gender, race/ethnicity, education, and years of practice, and experiences with working with parents. These surveys will take about 10 minutes.
2. Complete a self-paced on-line training (about 2.5 hours). You will receive CEUs upon completion of this training.
3. Within 1-4 weeks of completing the on-line training, participate in a recorded individual interview via Zoom Health to share feedback about your participation/experiences. This will take about 20-30 minutes. At this time, you will also be asked to complete the final set of surveys about your experiences working with parents.
4. Invite parents that have children/adolescents from ages 6-17 who are diagnosed with Disruptive, Impulse-Control, and Conduct disorders (DIC) on your case list to participate in the Parent version of the DECIDE training.

You will participate in the DECIDE training, survey completion, and oral interview remotely (e.g., via phone, zoon, or similar HIPPA approved telemedicine platforms such as WebEx.)
You will be involved in the study for an estimated period of 2 to 10 weeks, depending on your availability.

**WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?**

While participating in the study, the risks, side effects, and/or discomforts include:

- Discomfort answering questions regarding your interactions with your patients and their parents
- Discomfort related to feedback
- Discomfort related to having the oral interview recorded
- A potential loss of confidentiality

Several things will be done to minimize yours risks of taking part in the study:

- While completing the training workshops or talking to the researcher, you can tell the researcher that you feel uncomfortable or that you do not want to answer a particular question

or discuss a particular topic.

- You can stop the task(s) at any time
- Audio recordings will not be shared with anyone other than study staff unless required by law. Recordings will be stored in a secure, HIPPA compliant database.
- All information about you will be saved on password-protected computers

**WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THE STUDY?**

There will be no direct benefits to taking part in this study. We hope to learn things that will help scientists in the future.

**HOW WILL MY INFORMATION BE PROTECTED?**

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. No information which could identify you will be shared in publications about this study. Only investigators will have access to any recordings.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the Indiana University Institutional Review Board or its designees, Indiana University, and state or federal agencies who may need to access the research records (as allowed by law). State and federal agencies may include the "Office for Human Research Protections (OHRP)" for federally-funded research, and/or "National Institutes of Health (NIH)."

For the protection of your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers may not disclose or use any information, documents, or specimens that could identify you in any civil, criminal, administrative, legislative, or other legal proceeding, unless you consent to it. Information, documents, or specimens protected by this Certificate may be disclosed to someone who is not connected with the research:

(1) if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases);
(2) if you consent to the disclosure, including for your medical treatment;
(3) if it is used for other scientific research in a way that is allowed by the federal regulations that protect research subjects;
(4) for the purpose of auditing or program evaluation by the government or funding agency;

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself. 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.

**WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?**

Information for this study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, we will not ask for your additional consent.

A description of this clinical trial will be available on 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.

**WILL I BE PAID FOR PARTICIPATION?**

We will offer continuing education units (CE) for the DECIDE training. Bowen Center will also provide training credit.

**WILL IT COST ME ANYTHING TO PARTICIPATE?**

There is no cost to you for taking part in this study.

**WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?**

For questions about the study or in the event of an emergency, you may contact either of the lead researchers, Dr. Susan Perkins (Indiana University) at (317) 274-2626 or Dr. Ukamaka Oruche (University of South Florida) at (813) 396-2524.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact the IU Human Subjects Office at 800-696-2949 or at irb@iu.edu.

**CAN I WITHDRAW FROM THE STUDY?**

If you decide to participate in this study, you can change your mind and decide to leave the study at any time in the future. The study team will help you withdraw from the study safely. If you decide to withdraw, notify one of the researchers.

**PARTICIPANT'S CONSENT**

In consideration of all of the above, I agree to participate in this research study. I will be given a copy of this informed consent document to keep for my records.

**Participant's Printed Name**: _____

**Participant's Signature**: _____ **Date**: _____

v

**Printed Name of Person Obtaining Consent: _____**

**Signature of Person Obtaining Consent**: _____**Date**: _____

v

Modification and evaluation of the DECIDE intervention to improve parent-provider interactions in low-income parents of adolescents with Disruptive Impulse Control, and Conduct Disorders

NCT number: R21MD015150

Date: 11/23/2022

**INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR RESEARCH**

**Modification and evaluation of the DECIDE intervention to improve parent-provider interactions in low-income parents of adolescents with Disruptive Impulse Control, and Conduct Disorders**
**Centerstone Healthcare Provider-Group Training**
**IRB #1911897011**

## ABOUT THIS RESEARCH

You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

## TAKING PART IN THIS STUDY IS VOLUNTARY

You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with Centerstone or Indiana University

## WHY IS THIS STUDY BEING DONE?

The purpose of this study is to compare two different programs utilized by healthcare providers and guardians (biological parent, adoptive parent, step parent, foster parent, or legal guardian) aged 21 years and older of children and adolescents aged 6 to 17 who are diagnosed with Disruptive, Impulse-Control, and Conduct disorders (DIC). This includes children with behavior problems, such as Oppositional Defiant disorder, Conduct disorders, or Intermittent Explosive disorders). We will be studying outcomes in guardians.

You were selected as a possible participant because you are a healthcare provider that provides mental health treatment at Centerstone for children and adolescents aged 6 to 17 who are diagnosed with DIC.

The study is being conducted by Dr. Susan Perkins at Indiana University and Dr. Ukamaka Oruche at University of South Florida and their research team. It is funded by the National Institutes of Health.

## HOW MANY PEOPLE WILL TAKE PART?

If you agree to participate, you will be one of 101 people taking part in this study (21 behavioral healthcare providers and 80 parents).

**WHAT WILL HAPPEN DURING THE STUDY?**

If you agree to be in the study, you will do the following things:

**Healthcare Providers (e.g., administrator, nurse, social worker, case manager, physician, advanced practice provider)**

1. Complete demographic surveys or questionnaires about you including age, gender, race/ethnicity, education, and years of practice, and experiences with working with parents. These surveys will take about 10 minutes.
2. Complete a live training (about 1.5 hours). You will receive CEUs upon completion of this training.
3. Within 1-2 weeks of completing the training, you will be asked to complete the qualitative interview questions and surveys about your experiences working with parents.

You will participate in the DECIDE training and survey completion remotely (e.g., via phone, Zoom, or similar HIPPA approved telemedicine platforms such as WebEx).

You will be involved in the study for an estimated period of 2 to 4 weeks, depending on your availability.

**WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?**

While participating in the study, the risks, side effects, and/or discomforts include:

- Discomfort answering questions regarding your interactions with your patients and their parents
- Discomfort related to feedback
- A potential loss of confidentiality

Several things will be done to minimize yours risks of taking part in the study:

- While completing the training workshops or talking to the researcher, you can tell the researcher that you feel uncomfortable or that you do not want to answer a particular question or discuss a particular topic.
- You can stop the task(s) at any time
- All information about you will be saved on password-protected computers

**WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THE STUDY?**

There will be no direct benefits to taking part in this study. We hope to learn things that will help scientists in the future.

**HOW WILL MY INFORMATION BE PROTECTED?**

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. No information which

could identify you will be shared in publications about this study. Only investigators will have access to any recordings.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the Indiana University Institutional Review Board or its designees, Indiana University, and state or federal agencies who may need to access the research records (as allowed by law). State and federal agencies may include the "Office for Human Research Protections (OHRP)" for federally-funded research, and/or "National Institutes of Health (NIH)."

For the protection of your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers may not disclose or use any information, documents, or specimens that could identify you in any civil, criminal, administrative, legislative, or other legal proceeding, unless you consent to it. Information, documents, or specimens protected by this Certificate may be disclosed to someone who is not connected with the research:

(1) if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases);
(2) if you consent to the disclosure, including for your medical treatment;
(3) if it is used for other scientific research in a way that is allowed by the federal regulations that protect research subjects;
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**WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?**

Information for this study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, we will not ask for your additional consent.

A description of this clinical trial will be available on 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.

**WILL I BE PAID FOR PARTICIPATION?**

If you decide to participate, you will receive $100 Supplemental Pay and continuing education units (CE) for the DECIDE training.

**WILL IT COST ME ANYTHING TO PARTICIPATE?**

There is no cost to you for taking part in this study.

**WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?**

For questions about the study or in the event of an emergency, you may contact either of the lead researchers, Dr. Susan Perkins (Indiana University) at (317) 274-2626 or Dr. Ukamaka Oruche (University of South Florida) at (813) 396-2524.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact the IU Human Subjects Office at 800-696-2949 or at irb@iu.edu.

**CAN I WITHDRAW FROM THE STUDY?**

If you decide to participate in this study, you can change your mind and decide to leave the study at any time in the future. The study team will help you withdraw from the study safely. If you decide to withdraw, notify one of the researchers.

**PARTICIPANT'S CONSENT**

**In consideration of all of the above, I agree to participate in this research study. I will be given a copy of this informed consent document to keep for my records.**

**Participant's Printed Name: _____**

**Participant's Signature: _____Date: _____**

**Printed Name of Person Obtaining Consent: _____**

**Signature of Person Obtaining Consent: _____Date: _____**

Modification and evaluation of the DECIDE intervention to improve parent-provider interactions in low-income parents of adolescents with Disruptive Impulse Control, and Conduct Disorders

NCT number: R21MD015150

Date: 10/13/2022

**INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR RESEARCH**

**Modification and evaluation of the DECIDE intervention to improve parent-provider interactions in low-income parents of adolescents with Disruptive Impulse Control, and Conduct Disorders**
**Centerstone Healthcare Provider**
**IRB #1911897011**

**ABOUT THIS RESEARCH**
You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

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You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with Centerstone or Indiana University

**WHY IS THIS STUDY BEING DONE?**
The purpose of this study is to compare two different programs utilized by healthcare providers and guardians (biological parent, adoptive parent, step parent, foster parent, or legal guardian) aged 21 years and older of children and adolescents aged 6 to 17 who are diagnosed with Disruptive, Impulse-Control, and Conduct disorders (DIC). This includes children with behavior problems, such as Oppositional Defiant disorder, Conduct disorders, or Intermittent Explosive disorders). We will be studying outcomes in guardians.

You were selected as a possible participant because you are a healthcare provider that provides mental health treatment at Centerstone for children and adolescents aged 6 to 17 who are diagnosed with DIC.

The study is being conducted by Dr. Susan Perkins at Indiana University and Dr. Ukamaka Oruche at University of South Florida and their research team. It is funded by the National Institutes of Health.

**HOW MANY PEOPLE WILL TAKE PART?**
If you agree to participate, you will be one of 101 people taking part in this study (21 behavioral healthcare providers and 80 parents).

**WHAT WILL HAPPEN DURING THE STUDY?**

If you agree to be in the study, you will do the following things:

**Healthcare Providers (e.g., administrator, nurse, social worker, case manager, physician, advanced practice provider)**

1. Complete demographic surveys or questionnaires about you including age, gender, race/ethnicity, education, and years of practice, and experiences with working with parents. These surveys will take about 10 minutes.
2. Complete a self-paced on-line training (about 2.5 hours). You will receive CEUs upon completion of this training.
3. Within 1-4 weeks of completing the on-line training, participate in a recorded individual interview via Zoom Health to share feedback about your participation/experiences. This will take about 20-30 minutes. At this time, you will also be asked to complete the final set of surveys about your experiences working with parents.
4. Invite parents that have children/adolescents from ages 6-17 who are diagnosed with Disruptive, Impulse-Control, and Conduct disorders (DIC) on your case list to participate in the Parent version of the DECIDE training.

You will participate in the DECIDE training, survey completion, and oral interview remotely (e.g., via phone, zoon, or similar HIPPA approved telemedicine platforms such as WebEx.)
You will be involved in the study for an estimated period of 2 to 10 weeks, depending on your availability.

**WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?**

While participating in the study, the risks, side effects, and/or discomforts include:

- Discomfort answering questions regarding your interactions with your patients and their parents
- Discomfort related to feedback
- Discomfort related to having the oral interview recorded
- A potential loss of confidentiality

Several things will be done to minimize yours risks of taking part in the study:

- While completing the training workshops or talking to the researcher, you can tell the researcher that you feel uncomfortable or that you do not want to answer a particular question or discuss a particular topic.
- You can stop the task(s) at any time
- Audio recordings will not be shared with anyone other than study staff unless required by law. Recordings will be stored in a secure, HIPPA compliant database.
- All information about you will be saved on password-protected computers

**WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THE STUDY?**

There will be no direct benefits to taking part in this study. We hope to learn things that will help scientists in the future.

**HOW WILL MY INFORMATION BE PROTECTED?**

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For the protection of your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers may not disclose or use any information, documents, or specimens that could identify you in any civil, criminal, administrative, legislative, or other legal proceeding, unless you consent to it. Information, documents, or specimens protected by this Certificate may be disclosed to someone who is not connected with the research:

(1) if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases);
(2) if you consent to the disclosure, including for your medical treatment;
(3) if it is used for other scientific research in a way that is allowed by the federal regulations that protect research subjects;
(4) for the purpose of auditing or program evaluation by the government or funding agency;

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself. 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.

**WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?**

Information for this study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, we will not ask for your additional consent.

A description of this clinical trial will be available on 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.

**WILL I BE PAID FOR PARTICIPATION?**

If you decide to participate, you will receive $100 Supplemental Pay and continuing education units (CE) for the DECIDE training.

**WILL IT COST ME ANYTHING TO PARTICIPATE?**

There is no cost to you for taking part in this study.

**WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?**

For questions about the study or in the event of an emergency, you may contact either of the lead researchers, Dr. Susan Perkins (Indiana University) at (317) 274-2626 or Dr. Ukamaka Oruche (University of South Florida) at (813) 396-2524.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact the IU Human Subjects Office at 800-696-2949 or at irb@iu.edu.

**CAN I WITHDRAW FROM THE STUDY?**

If you decide to participate in this study, you can change your mind and decide to leave the study at any time in the future. The study team will help you withdraw from the study safely. If you decide to withdraw, notify one of the researchers.

**PARENT RECRUITMENT ASSISTANCE**

If you decide to participate in this study, we have an option to help you with parent recruitment. The research team can share your name with the Centerstone Research Institute, and they will generate a list for you with the names of children/adolescents age 6-17 who are diagnosed with Disruptive, Impulse-Control, and Conduct disorders (DIC) on your caselist to make it easier to identify parents who may be eligible for the study. This step is optional and saying no will not keep you from participating in the study.

Yes, you have my permission to share my name with the Centerstone Research Institute

No, you do not have my permission to share my name with the Centerstone Research Institute

Modification and evaluation of the DECIDE intervention to improve parent-provider interactions in low-income parents of adolescents with Disruptive Impulse Control, and Conduct Disorders

NCT number: R21MD015150

Date: 10/12/2022

**INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR RESEARCH**

**Modification and evaluation of the DECIDE intervention to improve parent-provider interactions in low-income parents of adolescents with Disruptive Impulse Control, and Conduct Disorders**
**Midtown/Sandra Eskenazi Mental Health Healthcare Provider**
**IRB #1911897011**

## ABOUT THIS RESEARCH

You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

## TAKING PART IN THIS STUDY IS VOLUNTARY

You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with Midtown/Sandra Eskenazi Mental Health or Indiana University

## WHY IS THIS STUDY BEING DONE?

The purpose of this study is to compare two different programs utilized by healthcare providers and guardians (biological parent, adoptive parent, step parent, foster parent, or legal guardian) aged 21 years and older of children and adolescents aged 6 to 17 who are diagnosed with Disruptive, Impulse-Control, and Conduct disorders (DIC). This includes children with behavior problems, such as Oppositional Defiant disorder, Conduct disorders, or Intermittent Explosive disorders). We will be studying outcomes in guardians.

You were selected as a possible participant because you are a healthcare provider that provides mental health treatment at Midtown/Sandra Eskenazi Mental Health for children and adolescents aged 6 to 17 who are diagnosed with DIC.

The study is being conducted by Dr. Susan Perkins at Indiana University and Dr. Ukamaka Oruche at University of South Florida and their research team. It is funded by the National Institutes of Health.

## HOW MANY PEOPLE WILL TAKE PART?

If you agree to participate, you will be one of 101 people taking part in this study (21 behavioral healthcare providers and 80 parents).

**WHAT WILL HAPPEN DURING THE STUDY?**

If you agree to be in the study, you will do the following things:

**Healthcare Providers (e.g., administrator, nurse, social worker, case manager, physician, advanced practice provider)**

1. Complete demographic surveys or questionnaires about you including age, gender, race/ethnicity, education, and years of practice, and experiences with working with parents. These surveys will take about 10 minutes.
2. Complete a self-paced on-line training (about 2.5 hours). You will receive CEUs upon completion of this training.
3. Within 1-4 weeks of completing the on-line training, participate in a recorded individual interview via Zoom Health to share feedback about your participation/experiences. This will take about 20-30 minutes. At this time, you will also be asked to complete the final set of surveys about your experiences working with parents.
4. Invite parents that have children/adolescents from ages 6-17 who are diagnosed with Disruptive, Impulse-Control, and Conduct disorders (DIC) on your case list to participate in the Parent version of the DECIDE training.

You will participate in the DECIDE training, survey completion, and oral interview remotely (e.g., via phone, zoon, or similar HIPPA approved telemedicine platforms such as WebEx.)
You will be involved in the study for an estimated period of 2 to 10 weeks, depending on your availability.

**WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?**

While participating in the study, the risks, side effects, and/or discomforts include:

- Discomfort answering questions regarding your interactions with your patients and their parents
- Discomfort related to feedback
- Discomfort related to having the oral interview recorded
- A potential loss of confidentiality

Several things will be done to minimize yours risks of taking part in the study:

- While completing the training workshops or talking to the researcher, you can tell the researcher that you feel uncomfortable or that you do not want to answer a particular question or discuss a particular topic.
- You can stop the task(s) at any time
- Audio recordings will not be shared with anyone other than study staff unless required by law. Recordings will be stored in a secure, HIPPA compliant database.
- All information about you will be saved on password-protected computers

**WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THE STUDY?**

There will be no direct benefits to taking part in this study. We hope to learn things that will help scientists in the future.

**HOW WILL MY INFORMATION BE PROTECTED?**

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. No information which could identify you will be shared in publications about this study. Only investigators will have access to any recordings.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the Indiana University Institutional Review Board or its designees, Indiana University, and state or federal agencies who may need to access the research records (as allowed by law). State and federal agencies may include the "Office for Human Research Protections (OHRP)" for federally-funded research, and/or "National Institutes of Health (NIH)."

For the protection of your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers may not disclose or use any information, documents, or specimens that could identify you in any civil, criminal, administrative, legislative, or other legal proceeding, unless you consent to it. Information, documents, or specimens protected by this Certificate may be disclosed to someone who is not connected with the research:

(1) if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases);
(2) if you consent to the disclosure, including for your medical treatment;
(3) if it is used for other scientific research in a way that is allowed by the federal regulations that protect research subjects;
(4) for the purpose of auditing or program evaluation by the government or funding agency;

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself. 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.

**WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?**

Information for this study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, we will not ask for your

additional consent.

A description of this clinical trial will be available on 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.

**WILL I BE PAID FOR PARTICIPATION?**

We will offer continuing education units (CE) for the DECIDE training, and Midtown/Sandra Eskenazi Mental Health has offered to provide training credit for all study-related activities.

**WILL IT COST ME ANYTHING TO PARTICIPATE?**

There is no cost to you for taking part in this study.

**WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?**

For questions about the study or in the event of an emergency, you may contact either of the lead researchers, Dr. Susan Perkins (Indiana University) at (317) 274-2626 or Dr. Ukamaka Oruche (University of South Florida) at (813) 396-2524.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact the IU Human Subjects Office at 800-696-2949 or at irb@iu.edu.

**CAN I WITHDRAW FROM THE STUDY?**

If you decide to participate in this study, you can change your mind and decide to leave the study at any time in the future. The study team will help you withdraw from the study safely. If you decide to withdraw, notify one of the researchers.