

Randomized Comparison of Evidence-Based Protocols for Adolescents with ADHD in Specialty  
Care: Behavioral Only versus Integrated Behavioral and Medication Interventions

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12/5/2016

Institutional Review Board of The National Center on Addiction and Substance Abuse  
633 Third Avenue, 19<sup>th</sup> Floor  
New York, NY 10017-6706  
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## **ASSENT TO PARTICIPATE IN A BASELINE INTERVIEW: ADOLESCENT**

We are asking you to complete a research interview today. If you agree to participate, we would like to ask you to sign this Informed Consent document. Informed Consent is a written agreement that you sign to show that you are willing to participate in this research interview. This document will tell you about the purpose, risks and benefits of the research interview. You should consent only after you have been given all the necessary information. Your signature on this form is voluntary. By signing this form, you do not give up any legal rights and you will still receive any services and care that you are entitled to.

### **Why have I been asked to complete this interview?**

You are being asked to participate in a baseline interview for a clinical research study that is being conducted by The National Center on Addiction and Substance Abuse. The goal of this interview is to determine if your family is eligible for a treatment study called CASALEAP that is examining the best ways to treat teenagers with attention and behavior problems. You are being asked to participate in this interview because the person/agency who referred you believes you and your family might be eligible for the study and interested in participating.

### **How long will the interview last?**

This baseline interview will last about 90 minutes today. At the end of this interview, if you are eligible for the one-year follow-up research study, that study will be described to you.

### **How will the data be used?**

The interview data will be used only for research purposes.

### **What is involved in the interview process?**

You will be asked to give personal information about your family and yourself: how you feel about yourself, strengths and weaknesses of your family, and any problems your family may be having, including substance use and illegal activities. You will provide information in two ways: interview questions and computerized questionnaires.

You will be interviewed alone. Information you give will not be shared with your caregiver, and information given by your caregiver will not be shared with you.

You are also being asked to agree to allow project staff to disclose the following information to the person/agency that referred your family:

1. Whether or not your family is eligible for the follow-up research study.
2. Whether or not we provide your family with contact information for appropriate counseling.

By initialing here, you agree to allow project staff to disclose this information to the agency that referred your family. \_\_\_\_\_

**What are the risks of the interview?**

During this interview you may feel uncomfortable discussing personal matters. If you are uncomfortable, you may decide to skip questions or to end the interview. Also, if the interviewer is convinced that you will cause harm to yourself or another person, it may be necessary to report this information. Project staff voluntarily comply with state laws requiring reporting where there is reasonable cause to suspect a child has been abused, neglected, or maltreated.

**What are the benefits of participation?**

If you wish, your family will receive a referral for appropriate counseling upon completing the interview. Your participation will help researchers develop better treatment services for teenagers with attention and behavior problems.

**Will I receive any payment?**

As a thank you for participating in this interview, you will receive \$40 in gift vouchers.

**What other options are there?**

You can choose not to participate in this interview. Your participation is voluntary. You are free to not answer any question(s) or withdraw at any time. Leaving the interview will not result in any penalty or loss of benefits to you. In the event your family is determined to be eligible for the follow-up research study, your participation in that study also will be voluntary. You will be asked to agree to a separate Informed Consent document for the research study.

**What about confidentiality?**

The results of the interview may be published for scientific purposes but will not give your name or identify you in any way. However, any data from your participation may be inspected by the Patient-Centered Outcomes Research Institute (the funders of the research), by any relevant federal agency under the Department of Health and Human Services, by the Institutional Review Board of The National Center on Addiction and Substance Abuse, or by the researchers conducting the research study. Any person who inspects your data will also be required to keep your identity confidential.

While complete confidentiality cannot be guaranteed, everything possible will be done to protect your privacy. All study records are kept in locked cabinets or on secure computers. Where possible, your name will be separated from your records which will be assigned a number. Access to the list matching file numbers and names will be restricted. The only persons who can see information that identifies you and your family are the members of the The National Center on Addiction and Substance Abuse research team. Also, the Institutional Review Board of The National Center on Addiction and Substance Abuse may inspect the records to ensure that confidentiality is being maintained and that your privacy is being protected.

Your consent to allow researchers to use your interview data for the research purposes stated above does not expire. This information will be maintained in a database. The National Center on Addiction and Substance Abuse's Institutional Review Board may

grant permission to other researchers to use your data for other, similar research purposes after ensuring confidentiality, that is, ensuring your interview data contain no identifying information.

**What are my rights as a research participant?**

You and your family may quit the interview at any time. If you quit, researchers may still use any interview data that has already been collected from your family if that information is necessary to the research study.

**Informed Consent Approval**

I have read the information in this form, which includes the interview procedures to be followed, its purpose, possible discomfort, and expected benefits. I have talked to the CASALEAP staff member who signed below, and she/he has answered my questions about the baseline research interview. At any time, I can ask about the research study or ask for a summary of results when available.

If I have further questions, I may ask the undersigned research staff member or the research study's Principal Investigator:

Aaron Hogue, Ph.D.  
Director, Adolescent and Family Research  
The National Center on Addiction and Substance Abuse  
633 Third Avenue  
New York, NY 10017  
(212) 841-5278

If I have any questions about my rights or privacy as a research participant, or to report a negative event related to this interview, I or my family may contact The National Center on Addiction and Substance Abuse Institutional Review Board Human Protections Administrator, Alana Ribowsky at (212) 841-5236.

I have read and understood this Assent Form and I volunteer to participate in this research interview. I give the CASALEAP research team permission to present the results of these interviews in written and oral form, without further permission from me. I understand that I will be given a copy of this form.

Adolescent Name (Print): \_\_\_\_\_

Adolescent Signature: \_\_\_\_\_

Date: \_\_\_\_\_

I have explained the purpose of the research interview described above and have explained any known risks and discomforts to the above participant. I have also assured the participant that I will answer any questions about the interview and follow-up research study and that participants are free to withdraw at any time without penalty.

Staff Signature: \_\_\_\_\_ Date: \_\_\_\_\_

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**IRB Official Use Only**

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Approved From: 12/5/2016 To: 12/4/2017  
The study expiration date applies for this form

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## **FOLLOW-UP STUDY ENROLLMENT ASSENT: ADOLESCENT**

### **What is the follow-up study?**

You have just completed a baseline interview for the CASALEAP research project. Your responses, along with those of your caregiver, indicate that your family is eligible to participate in a CASALEAP follow-up study. The goal of the follow-up research study is to help CASALEAP understand the best ways to treat teenagers with attention and behavior problems.

If you agree to participate in the CASALEAP follow-up study:

1. You and your family agree to enroll in a counseling program at a participating treatment clinic in a nearby location. The CASALEAP research team will be consulting with the clinic and therapist on the treatment you and your family receive. CASALEAP project staff will assist your family as needed in scheduling an intake appointment and attending the intake session at the designated clinic.
2. You and your family agree to enter a lottery at the counseling program. Half of families in the study will be assigned to therapists who will use research tools to educate their clients about attention problems in adolescents, and half will be assigned to therapists who will use their regular procedures to educate clients. All study families will receive the same access to all available services at the clinic.
3. After enrollment in the counseling program, you agree to be interviewed by CASALEAP staff and give personal information similar to the baseline interview you just completed. You will be interviewed alone. Information given by you will not be shared with your caregiver, and information given by your caregiver will not be shared with you. About 90 minutes will be needed at 3, 6, and 12 months from today to complete the follow-up interviews. You will receive \$50 in gift certificates for completing the 3-month interview, \$50 for the 6-month interview, and \$100 for the 12-month interview.

### **What research information will be collected from and given to the treatment clinic?**

During counseling sessions at the treatment site, and with your consent, you and your family will be audio-recorded by the therapist for supervision and research purposes, and these audiotapes will be given to CASALEAP staff. Also, CASALEAP staff will request the release of your and your family's treatment record from the clinic. No information that you or your caregiver give to CASALEAP staff during research interviews will be shared with the clinic without your written permission.

### **What about confidentiality?**

The results of the research study may be published for scientific purposes but will not give your name or identify you in any way. However, any data from your participation may be inspected by the Patient-Centered Outcomes Research Institute (the funders of the research), by any relevant federal agency under the Department of Health and Human Services, by the Institutional Review Board of The National Center on Addiction and Substance Abuse, or by the researchers conducting the research study. Any person who inspects your data will also be required to keep your identity confidential.

While complete confidentiality cannot be guaranteed, everything possible will be done to protect your privacy. All study records are kept in locked cabinets or on secure computers. Where possible, your name will be separated from your records which will be assigned a number. Access to the list matching file numbers and names will be restricted. The only persons who can see information that identifies you and your family are the members of the The National Center on Addiction and Substance Abuse research team. Also, the Institutional Review Board of The National Center on Addiction and Substance Abuse may inspect the records to ensure that confidentiality is being maintained and that your privacy is being protected.

Your consent to allow researchers to use your interview data for the research purposes stated above does not expire. This information will be maintained in a database. The National Center on Addiction and Substance Abuse's Institutional Review Board may grant permission to other researchers to use your data for other, similar research purposes after ensuring confidentiality, that is, ensuring your interview data contain no identifying information.

### **How will CASALEAP refer my family to the clinic?**

You are now being asked to allow CASALEAP staff to disclose the following standard referral information to the selected treatment clinic: *[NOTE TO INTERVIEWER: if referral is to substance use specific clinic or substance use information is being disclosed to the clinic, written Part 2 specific consent must be obtained\* and redisclosure prohibition notice must be used\*\*]*

1. Your first and last name
2. Your age and date of birth
3. Your contact information (telephone number, address)
4. Your insurance plan information (name, type)
5. The name of the agency or site that referred your family to CASALEAP
6. The original reason for referral to CASALEAP from the referral source
7. The fact that your family is interested in services

By initialing here, you agree to allow CASALEAP to give this information to the clinic:

\_\_\_\_\_

### **What if we talk about alcohol and drug use?**

Because the CASALEAP Program asks questions about alcohol and drug use and may, in referring you to a treatment clinic, disclose some of your answers to these questions, we are required by law to provide you with the following notice. However, please note that before making any of these disclosures, we will obtain your express consent as required by law.

#### **PARTICIPANT NOTICE CONFIDENTIALITY OF ALCOHOL AND DRUG ABUSE RECORDS**

The confidentiality of alcohol and drug abuse records maintained by this program is protected by Federal law and regulations. Generally, the program may not say to a person outside the program that a participant attends the program, or disclose any information identifying a participant as an alcohol or drug abuser unless:

- (1) The participant consents in writing;
- (2) The disclosure is allowed by a court order; or
- (3) The disclosure is made to medical personnel in a medical emergency or to qualified personnel for research, audit, or program evaluation.

Violation of the Federal law and regulations by a program is a crime. Suspected violations may be reported to appropriate authorities in accordance with Federal regulations.

Federal law and regulations do not protect any information about a crime committed by a participant either at the program or against any person who works for the program or about any threat to commit such a crime. Federal laws and regulations do not protect any information about suspected child abuse or neglect from being reported under State law to appropriate State or local authorities.

### **What are the risks of the follow-up study?**

During the follow-up interviews you may feel uncomfortable discussing personal matters. If you are uncomfortable, you may decide to skip questions or to end the interview. Also, if the interviewer is convinced that you will cause harm to yourself or another person, it may be necessary to report this information. Project staff voluntarily comply with state laws requiring reporting where there is reasonable cause to suspect a child has been abused, neglected, or maltreated.

### **What are the benefits of participation?**

Your participation will help researchers develop better treatment services for teenagers with attention and behavior problems.



**What are my rights as a participant?**

You and your family may quit the study at any time by contacting the research team by phone or in writing, using the address below. If you quit, researchers may still use data that have already been collected from you and your family if those data are necessary to the research study.

**Informed Consent Approval**

I have read the information in this form. I have talked to the CASALEAP staff member who signed below, and she/he has answered my questions about the follow-up study. At any time, I can ask about the research or ask for a summary of results when available.

If I have further questions, I may ask the undersigned research staff member or the study's Principal Investigator:

Aaron Hogue, Ph.D.  
Director, Adolescent and Family Research  
The National Center on Addiction and Substance Abuse  
633 Third Avenue,  
New York, NY 10017  
(212) 841-5278

If I have any questions about my rights or privacy as research participants, or to report a negative event related to this study, I may contact the The National Center on Addiction and Substance Abuse Institutional Review Board Human Protections Administrator, Alana Ribowsky at (212) 841-5236.

I have read and understood this Consent Form and I volunteer to participate in this research study. I give the CASALEAP research team permission to present information relating to the study and my participation in it in written and oral form, without identifying me or my family, without further permission from me. I understand that I will be given a copy of this form.

Adolescent Name (Print): \_\_\_\_\_

Adolescent Signature: \_\_\_\_\_

Date: \_\_\_\_\_

I have explained the purpose of the study described above and have explained any known risks and discomforts to the above participant. I have also assured the participant that I will answer any questions about the study and that participants are free to withdraw at any time without penalty.

Staff Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**\*PARTICIPANT CONSENT  
RELEASE OF ALCOHOL AND DRUG ABUSE RECORDS**

I (name of adolescent) \_\_\_\_\_, authorize the CASALEAP Program to:

Disclose to the program to which CASALEAP is referring me and my family for counseling, \_\_\_\_\_, the details collected about my alcohol and drug use, including any diagnosis made by the CASALEAP staff, for the purpose of obtaining counseling for me and my family as part of a research study being conducted by CASALEAP staff. I understand that the referral process may result in my family becoming aware that I have been using alcohol or drugs.

I also understand that if I do not consent to details about my alcohol and drug use being disclosed to the program to which CASALEAP is referring me and my family, I will still be referred for counseling but CASALEAP will not disclose to that program any information about my alcohol or drug use and will not refer me and my family to any program where my participation alone would identify me as someone who abuses drugs and alcohol.

\_\_\_\_\_  
Signature of adolescent

\_\_\_\_\_  
Date

This consent may be withdrawn by you at any time except to the extent that the CASALEAP Program has already taken action in reliance on it. If not withdrawn by you, this consent will terminate 30 days after your final (12-month) follow-up interview.

**\*\*FAX WITH REFERRAL CONTAINING SUD INFO OR TO SUD SPECIFIC CLINIC**

Each disclosure made with the participant's written consent must be accompanied by the following written statement:

**PROHIBITION ON REDISCLOSURE**

This information has been disclosed to you from records protected by Federal confidentiality rules (42 CFR Part 2). The Federal rules prohibit you from making any further disclosure of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by 42 CFR Part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose. The Federal rules restrict any use of the information to criminally investigate or prosecute any alcohol or drug abuse patient.

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**Approved From:** 12/5/2016 **To:** 12/4/2017  
The study expiration date applies for this form

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## **CONSENT TO PARTICIPATE IN A BASELINE INTERVIEW: CAREGIVER**

We are asking you to complete a research interview today. If you agree to participate, we would like to ask you to sign this Informed Consent document. Informed Consent is a written agreement that you sign to show that you are willing to participate in this research interview. This document will tell you about the purpose, risks and benefits of the research interview. You should consent only after you have been given all the necessary information. Your signature on this form is voluntary. By signing this form, you do not give up any legal rights and you will still receive any services and care that you are entitled to.

### **Why have I been asked to complete this interview?**

You are being asked to participate in a baseline interview for a clinical research study that is being conducted by The National Center on Addiction and Substance Abuse. The goal of this interview is to determine if your family is eligible for a treatment study called CASALEAP that is examining the best ways to treat teenagers with attention and behavior problems. You are being asked to participate in this interview because the person/agency who referred you believes your family might be eligible for the study and interested in participating.

### **How long will the interview last?**

This baseline interview will last about 90 minutes today. At the end of this interview, if you are eligible for the one-year follow-up research study, that study will be described to you.

### **How will the data be used?**

The interview data will be used only for research purposes.

### **What is involved in the interview process?**

You will be asked to give personal information about your family and yourself similar to the family needs assessment you already completed by phone: how you feel about yourself, strengths and weaknesses of your family, and any problems your family may be having, including substance use and illegal activities. You will provide information in two ways: interview questions and computerized questionnaires. Your teenager will be asked to provide similar information. You will be interviewed alone. Information you give will not be shared with your teenager, and information given by your teenager will not be shared with you, unless he or she states an intention to harm self or others.

You are also being asked to agree to allow project staff to disclose the following information to the person/agency that referred your family:

1. Whether or not your family is eligible for the follow-up research study.
2. Whether or not we provide you with contact information for appropriate counseling.

By initialing here, you agree to allow project staff to disclose this information to the agency that referred your family. \_\_\_\_\_

### **What are the risks of the interview?**

During this interview you may feel uncomfortable discussing personal matters. If you are uncomfortable, you may decide to skip questions or to end the interview. Also, if the interviewer is convinced that you will cause harm to yourself or another person, it may be necessary to report this information. Project staff voluntarily comply with state laws requiring reporting where there is reasonable cause to suspect a child has been abused, neglected, or maltreated.

### **What are the benefits of participation?**

If you wish, you will receive a referral for appropriate counseling upon completing the interview. Your participation will help researchers develop better treatment services for teenagers with attention and behavior problems.

### **Will I receive any payment?**

As a thank you for participating in this interview, you will receive \$40 in gift vouchers. Your teenager will receive the same amount for completing his/her interview. Gift certificates earned by your teenager will be given directly to him/her, unless you prefer that they be given to you for distribution to your teenager.

### **What other options are there?**

You can choose not to participate in this interview. Your participation is voluntary. You are free to not answer any question(s) or withdraw at any time. Leaving the interview will not result in any penalty or loss of benefits to you. In the event you and your family are determined to be eligible for the follow-up research study, your participation in that study also will be voluntary. You will be asked to agree to a separate Informed Consent document for the research study.

### **What about confidentiality?**

The results of the interview may be published for scientific purposes but will not give your name or identify you in any way. However, any data from your participation may be inspected by the Patient-Centered Outcomes Research Institute (the funders of the research), by any relevant federal agency under the Department of Health and Human Services, by the Institutional Review Board of The National Center on Addiction and Substance Abuse, or by the researchers conducting the research study. Any person who inspects your data will also be required to keep your identity confidential.

While complete confidentiality cannot be guaranteed, everything possible will be done to protect your privacy. All study records are kept in locked cabinets or on secure computers. Where possible, your name will be separated from your records which will be assigned a number. Access to the list matching file numbers and names will be restricted. The only persons who can see information that identifies your family are the members of The National Center on Addiction and Substance Abuse research team. Also, the Institutional Review Board of The National Center on Addiction and Substance Abuse may inspect the records to ensure that confidentiality is being maintained and that your privacy is being protected.

Your consent to allow researchers to use your interview data for the research purposes stated above does not expire. This information will be maintained in a database. The National Center on Addiction and Substance Abuse's Institutional Review Board may grant permission to other researchers to use your data for other, similar research purposes after ensuring confidentiality, that is, ensuring your interview data contain no identifying information.

**What are my rights as a research participant?**

You may quit the interview at any time. If you quit, researchers may still use any interview data that has already been collected from your family if that information is necessary to the research study.

**Informed Consent Approval**

I have read the information in this form, which includes the interview procedures to be followed, its purpose, possible discomfort, and expected benefits. I have talked to the CASALEAP staff member who signed below, and she/he has answered my questions about the baseline research interview. At any time, I can ask about the research study or ask for a summary of results when available.

If I have further questions, I may ask the undersigned research staff member or the research study's Principal Investigator:

Aaron Hogue, Ph.D.  
Director, Adolescent and Family Research  
The National Center on Addiction and Substance Abuse  
633 Third Avenue  
New York, NY 10017  
(212) 841-5278

If I have any questions about my family's rights or privacy as research participants, or to report a negative event related to this interview, I may contact The National Center on Addiction and Substance Abuse Institutional Review Board Human Protections Administrator, Alana Ribowsky, at (212) 841-5236.

I have read and understood this Consent Form and I volunteer to participate in this research interview. I also allow my teenager to participate if he or she consents during a separate interview. I give the CASALEAP research team permission to present the results of these interviews in written and oral form, without further permission from me. I understand that I will be given a copy of this form.

Caregiver Name (Print): \_\_\_\_\_

Caregiver Signature: \_\_\_\_\_

Date: \_\_\_\_\_

I have explained the purpose of the research interview described above and have explained any known risks and discomforts to the above participant. I have also assured the participant that I will answer any questions about the interview and follow-up research study and that participants are free to withdraw at any time without penalty.

Staff Signature: \_\_\_\_\_ Date: \_\_\_\_\_

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## **FOLLOW-UP STUDY ENROLLMENT CONSENT: CAREGIVER**

### **What is the follow-up study?**

You have just completed a baseline interview for the CASALEAP research project. Your responses, along with those of your teen, indicate that your family is eligible to participate in a CASALEAP follow-up study. The goal of the follow-up research study is to help CASALEAP understand the best ways to treat teenagers with attention and behavior problems.

If you agree to participate in the CASALEAP follow-up study:

1. You and your teen agree to enroll in a counseling program at a participating treatment clinic in a nearby location. The CASALEAP research team will be consulting with the clinic and therapist on the treatment your family receives. CASALEAP project staff will assist your family as needed in scheduling an intake appointment and attending the intake session at the designated clinic.
2. You and your teen agree to enter a lottery at the counseling program. Half of families in the study will be assigned to therapists who will use research tools to educate their clients about attention problems in adolescents, and half will be assigned to therapists who will use their regular procedures to educate clients. All study families will receive the same access to all available services at the clinic.
3. After enrollment in the counseling program, you and your teen agree to be interviewed by CASALEAP staff and give personal information similar to the baseline interview you just completed. You will be interviewed alone. Information given by you will not be shared with your teen, and information given by your teen will not be shared with you, unless he or she states an intention to harm self or others. About 90 minutes will be needed at 3, 6, and 12 months from today to complete the follow-up interviews. You will receive \$50 in gift certificates for completing the 3-month interview, \$50 for the 6-month interview, and \$100 for the 12-month interview.. Your teen will receive gift certificates in the same amounts.

If your teen is held in detention at any time during the next year, project staff may not interview him/her. If your teenager later becomes involved in foster care or residential



care, project staff will seek permission from the appropriate authority to continue the interviews.

### **What research information will be collected from and given to the treatment clinic?**

During counseling sessions at the treatment site, and with your consent, your family will be audio-recorded by the therapist for supervision and research purposes, and these audiotapes will be given to CASALEAP staff. Also, CASALEAP staff will request the release of your family's treatment record from the clinic. No information that you or your teen give to CASALEAP staff during research interviews will be shared with the clinic without your written permission.

### **What about confidentiality?**

The results of the research study may be published for scientific purposes but will not give your name or identify you in any way. However, any data from your participation may be inspected by the Patient-Centered Outcomes Research Institute (the funders of the research), by any relevant federal agency under the Department of Health and Human Services, by the Institutional Review Board of The National Center on Addiction and Substance Abuse, or by the researchers conducting the research study. Any person who inspects your data will also be required to keep your identity confidential.

While complete confidentiality cannot be guaranteed, everything possible will be done to protect your privacy. All study records are kept in locked cabinets or on secure computers. Where possible, your name will be separated from your records which will be assigned a number. Access to the list matching file numbers and names will be restricted. The only persons who can see information that identifies your family are the members of The National Center on Addiction and Substance Abuse research team. Also, the Institutional Review Board of The National Center on Addiction and Substance Abuse may inspect the records to ensure that confidentiality is being maintained and that your privacy is being protected.

Your consent to allow researchers to use your interview data for the research purposes stated above does not expire. This information will be maintained in a database. The National Center on Addiction and Substance Abuse's Institutional Review Board may grant permission to other researchers to use your data for other, similar research purposes after ensuring confidentiality, that is, ensuring your interview data contain no identifying information.

### **How will CASALEAP refer my family to the clinic?**

You are now being asked to allow CASALEAP staff to disclose the following standard referral information to the selected treatment clinic:

1. Your first and last name
2. Your teenager's first and last name, age and date of birth

3. Your contact information (telephone number, address)
4. Your insurance plan information (name, type)
5. The name of the agency or site that referred your family to CASALEAP
6. The original reason for referral to CASALEAP from the referral source
7. The fact that your family is interested in services

By initialing here, you agree to allow CASALEAP to give this information to the clinic:

\_\_\_\_\_

### **Who will pay for treatment?**

You, or your insurance carrier, will be responsible for the costs of treatment at the selected clinic. As stated above, project staff will provide you with gift certificates for completing the follow-up research interviews.

### **What about ADHD treatment, including medication?**

If your teen receives a diagnosis of ADHD at the clinic, your therapist will devote time in several sessions to discussing ADHD symptoms, the impact of ADHD on family relations and school performance, and strategies that can be used in the home to support your teen's school achievement. Also, your therapist may discuss with you the option of starting medication. Your teen will not have to start medication if you don't want them to.

### **What are the risks of the follow-up study?**

During the follow-up interviews you may feel uncomfortable discussing personal matters. If you are uncomfortable, you may decide to skip questions or to end the interview. Also, if the interviewer is convinced that you will cause harm to yourself or another person, it may be necessary to report this information. Project staff voluntarily comply with state laws requiring reporting where there is reasonable cause to suspect a child has been abused, neglected, or maltreated.

### **What are the benefits of participation?**

Your participation will help researchers develop better treatment services for teenagers with attention and behavior problems.

### **What are my rights as a participant?**

Your family may quit the study at any time by contacting the research team by phone or in writing, using the address below. If you quit, researchers may still use data that have already been collected from your family if those data are necessary to the research study.

**Informed Consent Approval**

I have read the information in this form. I have talked to the CASALEAP staff member who signed below, and she/he has answered my questions about the follow-up study. At any time, I can ask about the research or ask for a summary of results when available.

If I have further questions, I may ask the undersigned research staff member or the study's Principal Investigator:

Aaron Hogue, Ph.D.  
Director, Adolescent and Family Research  
The National Center on Addiction and Substance Abuse  
633 Third Avenue  
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If I have any questions about my family's rights or privacy as research participants, or to report a negative event related to this study, I may contact The National Center on Addiction and Substance Abuse Institutional Review Board Human Protections Administrator, Alana Ribowsky at (212) 841-5236.

I have read and understood this Consent Form and I volunteer to participate in this research study. I also allow my teenager to participate if he or she consents during a separate interview. I give the CASALEAP research team permission to present information relating to the study and my family's participation in it in written and oral form, without identifying me or my family, without further permission from me. I understand that I will be given a copy of this form.

Caregiver Name (Print): \_\_\_\_\_

Caregiver Signature: \_\_\_\_\_

Date: \_\_\_\_\_

I have explained the purpose of the study described above and have explained any known risks and discomforts to the above participant. I have also assured the participant that I will answer any questions about the study and that participants are free to withdraw at any time without penalty.

Staff Signature: \_\_\_\_\_ Date: \_\_\_\_\_

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Approved From: 12/5/2016 To: 12/4/2017

The study expiration date applies for this form

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Institutional Review Board of The National Center on Addiction and Substance Abuse  
633 Third Avenue, 19<sup>th</sup> Floor  
New York, NY 10017-6706  
Phone: 212/841-5200 Fax: 212/956-8020

**ASSENT/CONSENT FOR RELEASE OF CONFIDENTIAL INFORMATION**

Youth Name: \_\_\_\_\_ DOB: \_\_\_\_\_ SS/Case#: \_\_\_\_\_

Parent Name: \_\_\_\_\_ DOB: \_\_\_\_\_ SS/Case#: \_\_\_\_\_

We hereby authorize The National Center on Addiction and Substance Abuse (the Center) to:

OBTAIN FROM: \_\_\_\_\_

The following records pertaining to the above named youth:

\_\_\_\_\_ Treatment/Discharge Summary

\_\_\_\_\_ Therapist Treatment Logs

We agree to release this information for the purpose of a confidential research study being conducted by the Center. The goal of this confidential research is to help the Center better understand how successful various behavioral health treatment programs are in serving the needs of adolescents and families.

We understand that the confidentiality of these records and the information is protected by Federal and state laws and regulations and that they cannot be released without written consent except in special circumstances as provided by the same laws and regulations.

We also understand that this consent is valid for no more than 5 years from the date signed and that I may revoke this consent at any time (except to the extent that action has been taken in reliance on it) by written request to the Center. I have been offered a copy of this signed consent. If we have further questions, we may contact Dr. Hogue at the Center (212-841-5278), or call collect to the Center's Institutional Review Board Human Protections Administrator, Alana Ribowsky, at (212) 841-5200.

This consent is freely given this \_\_\_ day of \_\_\_\_\_, 20\_\_\_ and will expire on \_\_\_/\_\_\_/\_\_\_.

\_\_\_\_\_  
Youth Signature and Date

\_\_\_\_\_  
Caregiver Signature and Date

\_\_\_\_\_  
The Center Staff Signature and Date

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**FAMILY AUDIO RECORDING ASSENT/CONSENT FORM**

I agree to allow all treatment sessions conducted at my designated treatment site, in conjunction with the CASALEAP follow-up research study, to be audio-recorded by the therapist.

I authorize The National Center on Addiction on Substance Abuse to use any audio-recordings of myself and my family made during the course of counseling for the purposes of review by CASALEAP staff and their research partners (1) to evaluate the therapy for research purposes and/or (2) for on-site therapist training and monitoring purposes. I also agree that The National Center on Addiction and Substance Abuse Institutional Review Board may grant permission to other researchers to use the recordings for other, similar research purposes after ensuring that such recordings will not be marked with my name or other identifying information.

My consent for use of audio-recordings as stated above does not expire. However, in writing or by phone, I can request that any or all recordings be destroyed, and/or restrict their use to only one of the above purposes. All recordings will be copied from the recording device to a secure, encrypted computer file maintained by CASALEAP staff and after this transfer, recordings will be erased from the recording device. I understand that only CASALEAP staff and research partners, and staff at the treatment site, will have access to the recordings.

No personal identifying information will be attached to the recordings. Researchers and treatment clinic staff who listen to the recording will be subject to confidentiality with regard to all aspects of the recorded session.

If I have questions, I may contact the therapist or director of the treatment site; call Dr. Hogue at The National Center on Addiction and Substance Abuse (212-841-5278); or call The National Center on Addiction and Substance Abuse Institutional Review Board Human Protections Administrator, Alana Ribowsky, at (212) 841-5236.

Caregiver Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Adolescent Signature: \_\_\_\_\_

Date: \_\_\_\_\_

CASALEAP Staff signature: \_\_\_\_\_

Date: \_\_\_\_\_

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**NYCDOE DATA RELEASE CONSENT FORM**

Dear Parent/Legal Guardian of: \_\_\_\_\_

OSIS# \_\_\_\_\_

Your child has been selected to participate in CASALEAP, a study that is examining the best ways to treat teenagers with attention and behavior problems. As part of this study, The National Center on Addiction and Substance Abuse is requesting your consent to access identifiable student-level data from the New York City Department of Education for the academic years of 2014-2015 through 2019-2020, including:

- **Class grades**
- **Attendance records**
- **Disciplinary records (including enforced absences)**
- **Enrollment in any individualized education plan (IEP) or 504 plan**

Your participation in this study will help researchers develop better treatment services for teenagers with attention and behavior problems. It is very unlikely that this study could pose any unknown risks. Consent is completely voluntary. If you do not provide consent for The National Center on Addiction and Substance Abuse to access these data, there will be no effect on your child's grades or eligibility to participate in the CASALEAP treatment study.

If you have questions about participating in this study, you may contact the study's Principal Investigator:

Dr. Aaron Hogue, Ph.D.  
Director, Adolescent and Family Research  
The National Center on Addiction and Substance Abuse  
633 Third Avenue  
New York, NY 10017  
(212) 841-5278

If you consent to allowing The National Center on Addiction and Substance Abuse to collect your student's data, please sign below and return the consent form to the researcher.

Print Parent/Legal Guardian Name: \_\_\_\_\_

Parent/Legal Guardian Signature: \_\_\_\_\_ Date: \_\_\_\_\_

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