Advocating for Supports to Improve Service Transitions (*ASSIST*)

NCT#: NCT04173663

Global Parent, Youth/Adult, and Local Expert Consent Forms

Study Title: Project ASSIST: Advocating for Supports to Improve Service Transitions
Version Date: September 11, 2019

PARENT CONSENT
Part 1 of 2: MASTER CONSENT

Name of parent participant: _____ Age: _____

You are invited to take part in a research study. This study will take place in three states. Because the study takes place in three states, this consent form includes two parts. Part 1 of this consent form is the Master Consent and includes information that applies to all states. Part 2 of the consent form includes information specific to the state where you are being asked to participate. Both parts together are the legal consent form and must be provided to you.

We want to tell you about this research project and your participation in it. Please read this form carefully and feel free to ask any questions you have about this study or what it says in this form. You should ask questions any time, and as many questions as you want, and your questions will be answered. Your participation in this study is voluntary. That means you are free to stop, or withdraw from, this study at any time for any reason.

What is the purpose of this study?

The purpose of this study is to test a 12-week long parent advocacy program (called ASSIST) to improve parents' knowledge about the adult service system, their advocacy and empowerment, and ultimately service access and other outcomes for their adult children. You are being asked to take part in this research study because you have a son or daughter with an autism spectrum disorder (ASD) diagnosis who is a teenager or young adult.

We are asking you to participate in a parent advocacy program designed to improve your ability to get services that can support your son or daughter in adulthood. If you participate in this study, you and your son or daughter will come to one of the project sites (Nashville, TN; Madison or Milwaukee, WI; Chicagoland, IL) for a data collection visit that includes interviews and questionnaires for you, and a brief psychological assessment for your son or daughter. Either as part of this visit or after (depending on your preference), we will ask you to participate with your son or daughter in a discussion about his/her future. Overall, we are also asking you to participate in data collection for up to 3.5 years, including follow-up data collections (including research interviews and surveys) at multiple times. Potential risks associated with this study are minimal, and may include: feeling uncomfortable, a slight chance of breach of confidentiality, and/or becoming tired, bored, or frustrated while participating in the study.

You do not have to be in this research study. Participation or lack of participation in this study will not affect any services and healthcare that you or your son/daughter receive (other than access to the ASSIST program, which is being tested in this study). You and your son or daughter can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you and your son or daughter can decide whether or not you still want to be in this study.

Risks that can be reasonable expected if you take part in this study

This study is very low risk.

- Participation in the ASSIST program. There is some risk to you and to your son or daughter of discussing confidential information in a group setting. It is also possible that participating in ASSIST might increase the strain between you and your son or daughter with ASD, particularly if information gained from the ASSIST program is being used to advocate for goals that do not align well with the goals of your son/daughter. If you are assigned to the control group and have to wait to start the program, this might be stressful. We will provide you with the written documents that the treatment group receives, so that you will have some resources until the time that you take the ASSIST program.

- Data collection. The baseline diagnostic evaluation will take 3-4 hours. Your son/daughter might get tired or frustrated with the activities. If so, s/he can take a break. Of course, you can take breaks as well. You might feel uncomfortable being audiotaped, and your son/daughter might feel uncomfortable being videotaped. Further, some questions in the interview and questionnaires may deal with personal or emotional matters that may be stressful or upsetting. You may refuse to answer any questions that make you too uncomfortable.

- Breach of confidentiality. Another possible risk of this study is a breach of confidentiality: that means that there is a very slight chance that someone outside of study team members could see the personal information you give us. The study team takes many steps to make sure this will not happen: We will keep the forms you fill out in a locked cabinet inside a locked office, and we will enter your information in password-protected computer files.

- Other small risks. This study requires several hours of your time, which may not be convenient for you and your family. Finally, there may be uncommon or unknown risks. You should feel free to talk to the study team members about any problems that come up as part of this study.

Good effects that might result from this study

There is no guarantee that you or your child may benefit personally from participating in this study. The goal of this study is to increase service access and improve outcomes for youth and young adults with ASD. There are very few programs that try to help youth with ASD transition to adulthood. If successful, the ASSIST program might help many people with ASD across the country as they transition to adulthood.

Your participation may include the following

- First data collection. One parent or Legally authorized representative (LAR) and the youth with ASD will travel to a study site for the baseline data collection and psychological assessment. It will last 3-4 hours. During this visit, we will ask you questions about what your son or daughter was like when he/she was young and what he/she is like now. This will be audio and/or video-recorded. We will ask your son or daughter to answer some questions and complete some tasks. This will help us get an estimate of his/her behavior and cognitive abilities. Your son or daughter will receive an IQ test, and a test of symptoms of ASD. This will be audio and video-recorded. Before or during this visit, we will also ask you to complete a questionnaire that includes information about you and your family. We will also ask you to share with us copies of your son/daughter's Individualized Education Plan from school and/or results of previous autism-related testing.

- Discussion about your son or daughter's future. During or after the first data collection visit, you and your son/daughter will participate in a conversation with our team about his/her future hopes, dreams, and goals. We will record this meeting.

- Assignment to treatment group. Next, we will randomly assign you to one of the study groups; either the treatment group who will start the ASSIST program soon after randomization, or the control group who will start the ASSIST program one year after the treatment group finishes the program. Although the control group will wait to take the full ASSIST program, we will send each control family the full binder of written materials being used in the ASSIST program, which will be a helpful resource during the interim.

- Post-test. After the treatment group finishes the ASSIST program, we will ask you (regardless of group) to fill out a questionnaire about your ability to find services for your son or daughter with ASD. We will ask you to fill out he questionnaire again after control group participants have taken the full ASSIST program.

- Follow-up data collection. About 6 months, 12 months, 18 months, 24 months, and 30 months after the treatment group has taken the ASSIST program, we will ask you questions by interview and by questionnaire about your advocacy activities and how your son or daughter is doing. If your son of daughter has left high school, we will ask you more questions about that transition. We will also do interviews and collect questionnaires from your son or daughter with ASD if he/she is able and willing to participate. All of the interviews will be audio- and/or video-recorded. You may continue in the study regardless of whether your son or daughters is able or interested in participating in the follow-up data collection.

Privacy

To make sure that nobody knows you are in this study (unless you choose to tell them), we will keep you and your son/daughter's names separate from the information we collect in this study including test records, questionnaires, interviews, and media files. There will be a code (a participant ID number) but no name on your records, questionnaires, and interviews. Your name and contact information will be kept at a separate location. Your information will be kept in locked filing cabinets or in computer files that are protected by a key or password.

The information collected in this study will be shared across all study sites (Vanderbilt University Medical Center, University of Wisconsin, University of Illinois Urbana-Champaign). To keep your information private, information will only be shared using secure channels and platforms that are approved by the Universities. To help protect your privacy, people outside of the research team will not have access to any information collected.

There is an important exception to your expectation of privacy. During the research, if we learn that you are having thoughts about hurting yourself or others, the research staff will ask you more questions about your thoughts. Based on your response, the staff may provide your family with ways to get help. This may include:

- Working with you to contact your family doctor, a trusted family member, or a therapist to discuss these thoughts
- Working with you on a plan that may include getting you to a hospital for safety

The same procedures will apply if we learn that your son or daughter is having thoughts about hurting him/herself or others.

As with any research study, there might be other people involved in the research process who might need to look at your information. Organizations that may inspect and copy your information include the IRB

and other university representatives responsible for the management or oversight of this study. Efforts will be made to limit use or disclosure of your personal information, including research study and medical records, to only those people who have a need to review this information. We cannot promise complete confidentiality.

Reasons why the Principle Investigator may take you out of this study

The person in charge of the research study or the sponsor can remove you from the research study without your approval. There are no known reasons at the time for why you might be removed from the study. If you are removed from the study, you will be given the reason and compensated for your time spent in the study.

Clinical Trials Registry

Because we are testing a new program, this study is considered a clinical trial. A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

National Database for Autism Research

Data from this study will be submitted to the National Database for Autism Research (NDAR). NDAR is a computer system run by the National Institutes of Health (NIH) that allows researchers studying autism to collect and share information with each other. With this database, researchers hope to learn new and important things about autism more quickly than before. During and after the study, we will send information about your health and behavior to NDAR. However, before that, we will remove information that could identify you such as your name, address, and phone number, and replace that information with a code number. Other researchers nationwide can then file an application with NIH to obtain access to a dataset that could include your study data for research purposes. Experts at NIH who know how to protect health and science information will look at every request carefully to minimize risks to your privacy.

You may not benefit directly from allowing your information to be shared with NDAR. The information provided to NDAR might help researchers around the world develop services and supports for other children and adults on the autism spectrum. NDAR will report to Congress and on its website about the different studies that researchers are conducting using NDAR data; however, NDAR will not be able to contact you individually about specific studies.

You may decide now or later that you do not want to share your information using NDAR. If so, contact the researchers who conducted this study, and they will tell NDAR, which can stop sharing the research information. However, NDAR cannot take back information that was shared before you changed your mind. If you would like more information about NDAR, this is available on-line at http://ndar.nih.gov.

Sharing recordings

You and your son/daughter will be audio and/or video-recorded during the first data collection visit and follow-up data collection. You will also be audio and/or video-recorded at follow-up interviews and/or during ASSIST group sessions. It is necessary to audio/video-record these activities to ensure that the data we collect is accurate and consistent across study sites, and to ensure that ASSIST is being delivered similar across the different states. With your permission, we may also share these audio/video-recordings at professional conferences or use them for training purposes.

Please initial one of the choices below regarding use of your audio/video recordings for this study:

_____(initials) Yes, the audio/video recordings from this study may be used for training purposes or professional conferences beyond the study specific purposes.

_____(initials) No, the audio/video recordings from this study may not be used for training purposes or professional conferences beyond the study specific use.

If you are your son/daughters Legally Authorized Representative (LAR) and/or he/she cannot consent for themselves, please initial one of the choices below regarding use of your son/daughter's audio/video recordings for this study:

_____(initials) Yes, the audio/video recordings from this study may be used for training purposes or professional conferences beyond the study specific purposes.

_____(initials) No, the audio/video recordings from this study may not be used for training purposes or professional conferences beyond the study specific use.

Study Title: Project ASSIST: Advocating for Supports to Improve Service Transitions
Version Date: September 11, 2019

Adult with an Autism Spectrum Disorder CONSENT
Part 1 of 2: MASTER CONSENT

Name of youth participant: _____ Age: _____

You are invited to take part in a research study. This study will take place in three states. Because the study takes place in three states, this consent form includes two parts. Part 1 of this consent form is the Master Consent and includes information that applies to all states. Part 2 of the consent form includes information specific to the state where you are being asked to participate. Both parts together are the legal consent form and must be provided to you.

We want to tell you about this research project and your participation in it. Please read this form carefully and feel free to ask any questions you have about this study or what it says in this form. You should ask questions any time, and as many questions as you want, and your questions will be answered. Your participation in this study is voluntary. That means you are free to stop, or withdraw from, this study at any time for any reason.

What is the purpose of this study?

The purpose of this study is to test a parent advocacy program (called ASSIST) to improve parents' knowledge about the adult service system, their advocacy and empowerment, and ultimately service access and other outcomes for their adult children. You are being asked to take part in this research study because you have been diagnosed with an autism spectrum disorder (ASD) and you are 18 or older. Your parent will participate in a parent advocacy program designed to improve their ability to get services that can support you in adulthood.

If you participate in this study, you and your parent will come to one of the project sites (Nashville, TN; Madison or Milwaukee, WI; Chicagoland, IL) for a 3-4-hour data collection visit that includes activities and interviews, and a discussion about your future. We are also asking you to participate in follow-up data collections during which you and your parent will be given the option to complete interviews and surveys at multiple times for up to 3.5 years. Potential risks associated with this study are minimal, and may include: feeling uncomfortable, a slight chance of breach of confidentiality, and/or becoming tired, bored, or frustrated while participating in the study.

You do not have to be in this research study. You may choose not to be in this study without changing your healthcare, services or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study.

Potential risks if you take part in this study

This study is very low risk.

- Participation in the ASSIST program. ASSIST is a group program. This means your parents will be in a group with other parents. It is possible that your parent might discuss something about you with the other parents. It is also possible that your parent's attendance might increase the strain between you and your parent. This may happen if information gained from the ASSIST program is used to advocate for goals that are not the same as your goals.

- Data collection. The first data collection visit will take 3-4 hours. You might get tired or frustrated with the activities. If so, you can take a break. You might feel uncomfortable being videotaped. Some questions in the interview and questionnaires may deal with personal or emotional matters that may be stressful or upsetting. You may refuse to answer any questions that make you uncomfortable.

- Breach of confidentiality. Another possible risk of this study is a breach of confidentiality: that means that there is a very slight chance that someone outside of study team members could see the personal information you give us. The study team take many steps to make sure this will not happen: We will keep the forms you fill out in a locked cabinet inside a locked office, and we will enter your information in password-protected computer files.

- Other small risks. This study requires several hours of your time, which may not be convenient for you and your family. Finally, there may be uncommon or unknown risks. You should feel free to talk to the study team members about any problems that come up as part of this study.

Good effects that might result from this study

There is no guarantee that you will benefit from participation in this study. The goal of this study is to increase service access and improve outcomes for young adults on the autism spectrum. There are very few programs that try to help autistic youth transition to adulthood. If successful, the ASSIST program might help many people on the autism spectrum across the country as they transition to adulthood.

Your participation may include the following

- First data collection visit. You and at least one parent will travel to a study site for the first data collection visit. It will last 3-4 hours. During this visit, we will ask you to answer some questions and complete some tasks. This will help us get an estimate of your behavior and abilities. This will be video-recorded. We will also ask your parents to share with us copies of your Individualized Education Plan from school and/or results of previous autism-related testing.

- Discussion about your future. During or after the first data collection visit, you and your parents can participate in a conversation with our team about your future hopes, dreams, and goals. We will record this meeting.

- Follow-up data collection. About 12 months, 18 months, 30 months, and 36 months after your first data collection visit, we will ask you questions by interview and by questionnaire about your life, happiness, and current activities. Those interviews might be over the phone, in person and/or via computer chat. All of the interviews will be audio- and/or video-recorded. Your parent may continue in the study regardless of whether you are interested in participating in this follow-up data collection.

Privacy

To make sure that nobody knows you are in this study (unless you choose to tell them), we will keep your name separate from the information we collect in this study including test records, questionnaires, interviews, and media files. There will be a code (a participant ID number) but no name on your records, questionnaires, and interviews. Your name and contact information will be kept at a separate location. Your information will be kept in locked filing cabinets or in computer files that are protected by a password.

The information collected in this study will be shared across all study sites (Vanderbilt University Medical Center, University of Wisconsin, University of Illinois Urbana-Champaign). To keep your information private, information will only be shared using secure channels and platforms that are approved by the Universities. To help protect your privacy, people outside of the research team will not have access to any information collected.

There is an important exception to your expectation of privacy. During the research, if we learn that you are having thoughts about hurting yourself or others, the research staff will ask you more questions about your thoughts. Based on your response, the staff may provide your family with ways to get help. This may include:

- Working with you and/or your parent to contact your family doctor, a trusted family member, or a therapist to discuss these thoughts
- Working with you and/or your parent on a plan that may include getting you to a hospital for safety

As with any research study, there might be other people involved in the research process who might need to look at your information. Organizations that may inspect and copy your information include the IRB and other university representatives responsible for the management or oversight of this study. Efforts will be made to limit use or disclosure of your personal information, including research study and medical

records, to only those people who have a need to review this information. We cannot promise complete confidentiality.

Reasons why the Principle Investigator may take you out of this study

The person in charge of the research study or the sponsor can remove you from the research study without your approval. There are no known reasons at the time for why you might be removed from the study. If you are removed from the study, you will be given the reason and compensated for your time spent in the study.

Clinical Trials Registry

Because we are testing a new program, this study is considered a clinical trial. A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

National Database for Autism Research

Data from this study will be submitted to the National Database for Autism Research (NDAR). NDAR is a computer system run by the National Institutes of Health (NIH) that allows researchers studying autism to collect and share information with each other. With this database, researchers hope to learn new and important things about autism more quickly than before. During and after the study, we will send information about your health and behavior to NDAR. However, before that, we will remove information that could identify you such as your name, address, and phone number, and replace that information with a code number. Other researchers nationwide can then file an application with NIH to obtain access to a dataset that could include your study data for research purposes. Experts at the NIH who know how to protect health and science information will look at every request carefully to minimize risks to your privacy.

You may not benefit directly from allowing your information to be shared with NDAR. The information provided to NDAR might help researchers around the world develop services and supports for other children and adults on the autism spectrum. NDAR will report to Congress and on its website about the different studies that researchers are conducting using NDAR data; however, NDAR will not be able to contact you individually about specific studies.

You may decide now or later that you do not want to share your information using NDAR. If so, contact the researchers who conducted this study, and they will tell NDAR, which can stop sharing the research

information. However, NDAR cannot take back information that was shared before you changed your mind. If you would like more information about NDAR, this is available on-line at http://ndar.nih.gov.

Sharing recordings

You will be video and audio-recorded during the first data collection visit. You will also be audio and/or video-recorded at follow-up interviews. It is necessary to audio/video-record these activities to ensure that the data we collect is accurate and consistent across study sites. With your permission, we may also share these audio/video-recordings at professional conferences or use them for training purposes.

Please initial one of the choices below regarding use of your audio/video recordings for this study:

_____(initials) Yes, the audio/video recordings from this study may be used for training purposes or professional conferences beyond the study specific purposes.

_____(initials) No, the audio/video recordings from this study may not be used for training purposes or professional conferences beyond the study specific use.

Study Title: Project ASSIST: Advocating for Supports to Improve Service Transitions
Version Date: September 11th, 2019

LOCAL EXPERT CONSENT
Part 1 of 2: MASTER CONSENT

Name of Local Expert / Facilitator participant: _____ Age: _____

You are invited to take part in a research study. This study will take place in three states. Because the study takes place in three states, this consent form includes two parts. Part 1 of this consent form is the Master Consent and includes information that applies to all states. Part 2 of the consent form includes information specific to the state where you are being asked to participate. Both parts together are the legal consent form and must be provided to you.

We want to tell you about this research project and your participation in it. Please read this form carefully and feel free to ask any questions you have about this study or what it says in this form. You should ask questions any time, and as many questions as you want, and your questions will be answered. Your participation in this study is voluntary. That means you are free to stop, or withdraw from, this study at any time for any reason.

What is the purpose of this study?

We are asking you to participate as a facilitator (under the study team direction) in one session of our parent advocacy program, designed to improve parents' ability to get services that can support their son or daughter with Autism Spectrum Disorder (ASD) in their transition to adulthood. You are being asked to take part in this research study because you are an expert in one of the topics that the parent advocacy program will focus one of its sessions on. We are also asking you to answer some questionnaires after facilitating the session. Your participation in this study will take 3-4 hours. This includes the time you will spend working on presentation slides for the session (1-2 hours), and the time facilitating the session (2 hours). If interested, we may ask you to facilitate this same session at future times when we deliver the parent advocacy program.

The purpose of this study is to test a parent advocacy program (called ASSIST) to improve parents' knowledge about the adult service system, parents' advocacy and empowerment, and ultimately service access and other outcomes for their adult children with ASD. If you participate in this study, you will come to one of the project sites (Nashville, TN; Madison or Milwaukee, WI; Chicagoland, IL) and deliver one or more of the ASSIST session/s. With support and direction from the research team, you will be asked to prepare a presentation to facilitate the session/s. Participating parents who attend the session/s will have the possibility to ask you questions and ask for clarification. The research study team will provide you with a list of learning objectives for your session/s and information that the parents will receive during the first

ten minutes of the session. The session/s will be audio and video recorded to share with any of the participants who could not attend in person, and to assess treatment fidelity. After the session/s, we will ask you to complete a brief online questionnaire. In total, your participation in the study will last about up to 3 years (from 2020 to 2022, if you present in ASSIST sessions through the research period). More details about the project are described below.

You do not have to be in this research study. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study.

Risks that can be reasonable expected if you take part in this study

This study is very low risk.

- Participation in the ASSIST program as a facilitator / local expert. There is some risk to you of discussing confidential information in a group setting, if you decide to use personal examples to illustrate or help parents understand the session you are facilitating.

- The ASSIST session. The estimated time for preparing the presentation (PowerPoint slides and topic discussion questions) should take no longer than 1-2 hours. You might get tired while working on these materials. Additionally, the research team members may provide feedback that you find frustrating. You might feel uncomfortable being video and audiotaped. Further, we cannot anticipate all questions or comments that parent participants share during the session, which you may find stressful.

- Breach of confidentiality. Another possible risk of this study is a breach of confidentiality: that means that there is a very slight chance that someone outside of study team members could see the personal information you give us. The study team take many steps to make sure this will not happen: We will keep the forms you fill out in a locked cabinet inside a locked office, and we will enter your information in password-protected computer files.

- Other small risks. This study requires several hours of your time, which may not be convenient for you. Finally, there may be uncommon or unknown risks. You should feel free to talk to the study team members about any problems that come up as part of this study.

Good effects that might result from this study

You may not benefit personally from participation in this project. The goal of this study is to increase service access and improve outcomes for youth and young adults with ASD. There are very few programs that try to help youth with ASD transition to adulthood. If successful, the ASSIST program might help many people with ASD across the country as they transition to adulthood.

Your participation may include the following

- First contact with the research team. You will meet with the research team in person or during video or telephone conference (depending on your preference). This meeting will last 10-15 minutes. One of the research team members will go over the consent form, the topic of the ASSIST session/s you will be facilitating as a participant in this study, and the objectives your presentation/s should cover. During this meeting, if you decide to participate in the study, we will ask you to sign the consent form (in person, whenever possible, or electronically).

- Materials for the ASSSIST session you will be facilitating. Next, you will receive an email with written instructions and learning objectives for your presentation. This email will also include the ASSIST materials that the parent participants will access during the first ten minutes of the session (this is done to avoid any overlapping between that content and the content you will prepare). You will be asked to work on your presentation on your own, and send it to the study team at least two weeks before the date of the session. During this process, you are encouraged to ask as many questions as needed to the research team. After reviewing your presentation, a member of the team will provide feedback and/or modifications to your presentation.

- Facilitating the ASSIST session. We will ask you to attend the ASSIST session/s and facilitate it with assistance from the study team. Your role as a participant in this study is to be the local expert who will explain how services work in your region. A study team member will attend the session and take care of setting up the room, checking attendance, supplying snacks and beverages (whenever possible), and/or managing the technology in that room (projectors, computers, internet connection, etc.). The study team member will introduce you to the parents after the first ten minutes of the session. At this point, you will take the lead in presenting your materials and facilitating the session. Your presentation should last no less than 60 minutes and no longer than 90 minutes. Questions from parents and an open discussion will be encouraged after your presentation, for the last 20-30 minutes of the 2 hour session.

- Post-session data collection. The day after you facilitate the question, you will receive an online questionnaire about your opinions and suggestions about the ASSIST session that you facilitated. You will have two weeks to respond to this survey.

Privacy

To make sure that nobody knows you are in this study (unless you choose to tell them), we will keep your name separate from the information we collect in this study including questionnaires, interviews, and media files. There will be a code (a participant ID number) but no name on your questionnaires, media files and interviews. Your name and contact information will be kept at a separate location. Your information will be kept in locked filing cabinets or in computer files that are protected by a key or password.

The information collected in this study will be shared across all study sites (Vanderbilt University Medical Center, University of Wisconsin, University of Illinois Urbana-Champaign). To keep your information private, information will only be shared using secure channels and platforms that are approved by the Universities. To help protect your privacy, people outside of the research team will not have access to any information collected.

As with any research study, there might be other people involved in the research process who might need to look at your information. Organizations that may inspect and copy your information include the IRB and other university representatives responsible for the management or oversight of this study. Efforts will be made to limit use or disclosure of your personal information, including research study and medical records, to only those people who have a need to review this information. We cannot promise complete confidentiality.

Any information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of your participation (other than the money for participating). These data may help us or other researchers learn more about services that may benefit youth with ASD and their families.

Reasons why the Principle Investigator may take you out of this study

The person in charge of the research study or the sponsor can remove you from the research study without your approval. There are no known reasons at the time for why you might be removed from the study. If you are removed from the study, you will be given the reason and compensated for your time spent in the study.

Clinical Trials Registry

Because we are testing a new program, this study is considered a clinical trial. A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Sharing recordings

You may be audio and/or video-recorded during the ASSIST group session. It is necessary to audio/video-record these activities to ensure that the data we collect is accurate and consistent across study sites, and to ensure that ASSIST is being delivered similar across the different states. With your permission, we may also share these audio/video-recordings at professional conferences or use them for training purposes.

Please initial one of the choices below regarding use of your audio/video recordings for this study:

_____(initials) Yes, the audio/video recordings from this study may be used for training purposes or professional conferences beyond the study specific purposes.

_____(initials) No, the audio/video recordings from this study may not be used for training purposes or professional conferences beyond the study specific use.