Study Title: Health System Integration of Tools to Improve Primary Care for Autistic Adults

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OREGON HEALTH & SCIENCE UNIVERSITY

Information Sheet and Authorization

IRB#________

Information Sheet for Patient Participants

TITLE: AASPIRE Healthcare Toolkit Integration Study

PRINCIPAL INVESTIGATOR:	Christina Nicolaidis, MD, MPH nicolaid@ohsu.edu, (503) 494-9602
CO-INVESTIGATORS:	Dora Raymaker, PhD draymake@pdx.edu, (503) 725-9629
	Lisa Croen, PhD lisa.a.croen@kp.org, (510) 891-3463
	Junghee Lee, PhD jungl@pdx.edu, (503) 725-5374
	Jennifer Aengst, PhD jaengst@pdx.edu, (503) 725-9633

SPONSOR: National Institutes of Health

What is this Information Sheet about?

This sheet gives details about a research study being conducted by the Academic Autistic Spectrum Partnership in Research and Education (AASPIRE). After you read the details, you can decide whether or not you want to participate.

What is the study about?

AASPIRE has created a set of online resources to improve healthcare for patients on the autism spectrum and those with other communication disabilities. The goal of this study is to test these resources. We will see how best to use them in clinics in different health systems. We will also see how well they work for patients and providers.

We are comparing the healthcare experiences of patients in clinics that do or do not use these resources. The resources are available in an online healthcare toolkit. Your clinic will be using this toolkit to try to improve care.

What do I need to participate in this study?

You can participate in this study if:

- You are over 18
- You have a diagnosis on the autism spectrum (autism, Asperger's, PDD-NOS, childhood disintegrative disorder, or autism spectrum disorder) or another communication disorder
- You are currently receiving primary care at one of the following clinics: OHSU Gabriel Park, OHSU Scappoose, Legacy Emanuel Medical Center, Legacy Good Samaritan Medical Center, or Kaiser Permanent Northern California.

What can I expect if I do the study?

If you choose to participate in the study, you will do the following, with or without help from a supporter:

1. You will take a short online survey at the beginning of the study.
2. You will create a customized accommodations report for your healthcare provider, using the online toolkit.
3. After reviewing the report, you will be asked permission to have the report sent directly to your primary care provider.
4. You will use whichever resources you find helpful from the healthcare toolkit website.
5. Six months later, you will take another short online survey.
6. After you complete the survey, you may also be contacted to participate in an interview.
7. The research team will look at your electronic medical records. We want to see how often you have used healthcare services during the study. Examples of healthcare services include primary care visits, flu shots, Pap smears, emergency room visits, or other hospital stays. We also want to see how you and your providers have used the resources from the healthcare toolkit. For example, we will check to see if your accommodations report was entered into your medical record correctly and if your providers have looked at it.

Each survey should take about 20 minutes to complete. It will take another 20 minutes to create the customized accommodations report. You can spend as much time as you want to use the online toolkit.

What are the possible risks of participating in this study?

- You might get tired or overloaded, or find some of the questions frustrating.
- You might get frustrated if you experience computer problems while participating in the study.

- Though we will try to protect your privacy as described below, there is a risk of loss of privacy when using the internet.
- You may get upset if you remember previous negative experiences with healthcare.
- There is a chance that your provider may not use the information in the accommodations report.

What are the possible benefits of participating in this study?

Doing the study and using the resources in the toolkit may or may not be helpful to you. If you participate in this study, you will get to use the toolkit as part of your regular healthcare. Your experience using the toolkit may help you better prepare for your healthcare visits. It may also help your provider better understand what accommodations or supports may be useful to you. The results of this study may help improve the healthcare of other adults on the autism spectrum or people with other communication disabilities in the future.

How will my information be kept private?

We will protect your privacy in the following ways:

- We will not use your name or your identity for publication or publicity purposes.
- Your name and date of birth will be on the customized accommodations report you create for your provider. We will only send that report to your provider with your permission. We will not share the report with anyone other than your provider and their clinic staff.
- We will collect additional information about you in the two surveys. A code number will be assigned to you and your survey answers.
- We will also collect data from your medical record about your medical diagnoses and what healthcare services you have used.
- Only the research team will be able to connect your code number to your survey answers and the information from your medical records.
- Health information is private and is protected under federal law and Oregon law. By agreeing to be in this study, you are giving us permission (also called authorization) to use your health information as described above in this form ("What can I expect if I do the study?").
- If the Office for Human Research Protections, a federal agency that oversees research involving humans, requests it as part of an audit of our project, we could disclose your personal information to them. We will not release information about you to others not listed above, unless required or permitted by law.

Will I pay or get any money to participate?

No, you do not have to pay anything to participate. However, we encourage you to go over your accommodations report with your provider during a regular healthcare visit. You will be responsible for the costs of your healthcare visits.

You will receive $30 for completing both surveys. You can choose to be paid with an Amazon.com gift card or a check. If you start but do not finish the study, you will be paid 5 dollars with an Amazon.com gift card.

What are my rights as a research participant?

You do not have to be in this or any research study. You do not have to allow the use and disclosure of your health information in the study, but if you do not, you cannot be in the study. If you choose to do this study and then later change your mind, you may quit at any time. This includes the right to withdraw your authorization to use and disclose your health information. Contact the principal investigator, Christina Nicolaidis, if you want to withdraw from the study. If you choose not to do this study or if you choose to end the study early, you will not experience any bad consequences. Your healthcare will not be affected if you decide not to participate in this study. If you no longer want your health information to be used and disclosed as described in this form, you must send a written request or email stating that you are revoking your authorization to:

Christina Nicolaidis, MD, MPH
OHSU Division of General Internal Medicine
3181 SW Sam Jackson Park Road
Mailcode L475
Portland, OR 97239

If you have any questions regarding your rights as a research subject, you may contact the OHSU Research Integrity Office at (877) 733-8313 (toll free) or oioeduc@ohsu.edu.

If you have any questions regarding this study now or in the future, contact Christina Nicolaidis, MD, MPH by emailing nicolaid@ohsu.edu or by calling (503) 725-9603.

If you have read this information, understood it, and decided what you want to do, please click the circle next to your decision. If you choose "Yes, I want to participate," it means that you voluntarily agree to participate in the study.

___Yes, I want to participate.

Your name (if applicable, the patient's name, not the supporter's name):

________________ First ____________ Middle ________________ Last

___No, I do not want to participate.

<If yes>

We will generally use email to contact you during the study. For example, we will send you email reminders to let you know when it is time to take your follow-up survey.

What is your email address?
<write in>

We would like to have additional contact information in case there is a problem reaching you by email. Please let us know how else we can reach you, if need be:

Telephone number for voice calls: ________

Text number: _______________

Physical address: _______________

Fax number (if available): ______________

None of these

Would it be ok to reach you using contact information that has been updated in your medical record?

_ Yes
_ No

IRB Approved: 9/27/2017
Approval Expires: 7/11/2018

Information about the National Institute of Mental Health Data Archive (NDA)

What is this next section about?

This next section will help you decide if you want your information shared with other researchers using the National Institute of Mental Health Data Archive (NDA).

What is the National Institute of Mental Health Data Archive (NDA)?

The NDA is a "data repository" – that means it is a large database that stores information from different studies.

The NDA allows researchers to share "deidentified" information with each other.

"Deidentified" means that a person's identifying information—such as their name, date of birth, and place of birth—is removed from the data. A computer program replaces the information with a code number before we put data into the NDA. Researchers using the NDA would not be able to learn identifying data from the code number, but they can use the code number to link data from different studies.

Why do I have to make a choice about the NDA?

This study is funded by the National Institute of Mental Health (NIMH). The NIMH requires researchers take part in its NDA program.

However, it is up to you to decide whether you want AASPIRE to put *your own data* into the NDA.

What will happen if I agree to share my data with other researchers using the NDA?

If you agree, we will send some of the information we collect in this study to the NDA. Other researchers nationwide can then file an application with the NIMH to get access to your deidentified study data. This would include your survey answers and the information we collect from your medical record about how you use healthcare services. All personal information will be replaced with a code number. Other researchers can then use that data in their own research.

What are the risks of sharing my data with other researchers using the NDA?

- There is a small risk of loss of privacy.
- Other researchers may use your information in future studies. AASPIRE will not be involved in those studies. There is a chance that you may not agree with the goals or methods of those future studies.

What are the benefits of sharing my data with other researchers using the NDA?

You may not benefit directly from allowing us to share your information with the NDA. In the future, the NDA may help researchers around the world improve outcomes for people who have mental health conditions.

Can I still take part in this study even if I don't agree to share my information with the NDA?

Yes. You can take part in this study whether or not you agree to share your information with other researchers using the NDA.

What would happen if I changed my mind about the NDA in the future?

You may decide later that you do not want to share your information using the NDA. If so, contact the AASPIRE team, and they will tell the NDA. The NDA will then stop sharing your research information. However, the NDA cannot take back information that they shared before you changed your mind.

How do I get more information about the NDA?

More information about the NDA is available at: http://data-archive.nimh.gov.

Would you like to share your information with other researchers using the NDA?
(You can take part in the study whether or not you agree to share information using the NDA.)

____ Yes, I would like to share my information with other researchers using the NDA.
____ No, I do not wish to share my information.

<If yes>
Thank you for agreeing to participate in the NDA. If you provide the following information, your data from this study may be linked with your data from past and future studies that also use the NDA. The information you provide will be replaced by a code number so your identity will not be shared with other researchers. If you don't provide this information, you can still participate in the NDA, and researchers can still use your data from this study, but they will not be able to link your data across studies.

When and where were you born?
Month ___
Day ___
Year ___
City ____
State ____
Country _____
I do not wish to share this information with the NDA

Hotlink:

Deidentified: “Deidentified” means that a person’s identifying information—such as their name, date of birth, and place of birth—is removed from the data. A computer program replaces the information with a code number before we put data into the NDA.

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Information Sheet and Authorization

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Information Sheet for Patient Participants

TITLE: AASPIRE Healthcare Toolkit Integration Study

PRINCIPAL INVESTIGATOR: Christina Nicolaidis, MD, MPH
nicolaid@ohsu.edu, (503) 494-9602

CO-INVESTIGATORS: Dora Raymaker, PhD
draymake@pdx.edu, (503) 725-9629

Lisa Croen, PhD
lisa.a.croen@kp.org, (510) 891-3463

Junghee Lee, PhD
jungl@pdx.edu, (503) 725-5374

Jennifer Aengst, PhD
jaengst@pdx.edu, (503) 725-9633

SPONSOR: National Institutes of Health

What is this Information Sheet about?

This sheet gives details about a research study being conducted by AASPIRE (Academic Autistic Spectrum Partnership in Research and Education). After you read the details, you can decide whether or not you want to participate.

What is the study about?

AASPIRE has created a set of online resources to improve healthcare for patients on the autism spectrum and those with other communication disabilities. The goal of this study is to test these resources. We will see how best to use them in clinics in different health systems. We will also see how well they work for patients and providers.

We are comparing the healthcare experiences of patients in clinics that do or do not use these resources. Some clinics are using the new resources now. Your clinic is not using these resources now, however you will get a chance to use them after this study is completed.

What do I need to participate in this study?

You can participate in this study if:
- You are over 18
- You have a diagnosis on the autism spectrum (autism, Asperger's, PDD-NOS, childhood disintegrative disorder, or autism spectrum disorder) or another communication disorder.
- You are currently receiving primary care at: OHSU Gabriel Park, OHSU Scappoose, Legacy Emanuel Medical Center, Legacy Good Samaritan Medical Center, or Kaiser Permanent Northern California.

What can I expect if I do the study?

If you choose to participate in the study:

1. You will take a short online survey at the beginning of the study.
2. Six months later, you will take another short online survey.
3. After you complete the survey, you may be contacted to participate in an interview.
4. The research team will review your medical records. We want to see how often you have used healthcare services during the study. Examples of healthcare services include primary care visits, flu shots, Pap smears, emergency room visits, or other hospital stays.

Each survey should take about 20 minutes to complete.

What are the possible risks of participating in this study?

- You might get tired or overloaded, or find some of the questions frustrating.
- You might get frustrated if you experience computer problems while participating in the study.
- Though we will try to protect your privacy as described below, there is a risk of loss of privacy when using the internet.
- You may get upset if you remember previous negative experiences with healthcare.

What are the possible benefits of participating in this study?

Doing the study may or may not be helpful to you. The results of this study may help improve the healthcare of other adults on the autism spectrum and those with other communication disabilities in the future.

How will my information be kept private?

We will protect your privacy in the following ways:

- We will not use your name or your identity for publication or publicity purposes.
- We will collect additional information about you in the two surveys. A code number will be assigned to you and your survey answers.
- We will also collect data from your medical record about your medical diagnoses and what healthcare services you have used.
- Only the research team will be able to connect your code number to your survey answers and the information from your medical records.
- Health information is private and is protected under federal law and Oregon law. By agreeing to be in this study, you are giving us permission (also called authorization) to use your health information as described above in this form ("What can I expect if I do the study?").
- If the Office for Human Research Protections, a federal agency that oversees research involving humans, requests it as part of an audit of our project, we could disclose your personal information to them. We will not release information about you to others not listed above, unless required or permitted by law.

Will I pay or get any money to participate?

No, you do not have to pay anything to participate.

You will receive $30 for completing both surveys. You can choose to be paid with an Amazon.com gift card or a check. If you start but do not finish the study, you will be paid 5 dollars with an Amazon.com gift card.

What are my rights as a research participant?

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If you have read this information, understood it, and decided what you want to do, please click the circle next to your decision. If you choose "Yes, I want to participate," it means that you voluntarily agree to participate in the study.

___Yes, I want to participate.

Your name (if applicable, the patient's name, not the supporter's name):____
First Middle Last

___No, I do not want to participate.

<If yes>

We will generally use email to contact you during the study. For example, we will send you email reminders to let you know when it is time to take your follow-up survey.

What is your email address?
<write in>

We would like to have additional contact information in case there is a problem reaching you by email. Please let us know how else we can reach you, if need be:

Telephone number for voice calls: ________

Text number: _______________

Physical address: _______________

Fax number (if available): ______________

Would it be ok to reach you using contact information that has been updated in your medical record?

_ Yes
_ No

Information about the National Institute of Mental Health Data Archive (NDA)

What is this next section about?

This next section will help you decide if you want your information shared with other researchers using the National Institute of Mental Health Data Archive (NDA).

What is the National Institute of Mental Health Data Archive (NDA)?

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The NDA allows researchers to share "deidentified" information with each other.

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Why do I have to make a choice about the NDA?

This study is funded by the National Institute of Mental Health (NIMH). The NIMH requires researchers take part in its NDA program.

However, it is up to you to decide whether you want AASPIRE to put *your own data* into the NDA.

What will happen if I agree to share my data with other researchers using the NDA?

If you agree, we will send some of the information we collect in this study to the NDA. Other researchers nationwide can then file an application with the NIMH to get access to your deidentified study data. This would include your survey answers and the information we collect from your medical record about how you use healthcare services. All personal information will be replaced with a code number. Other researchers can then use that data in their own research.

What are the risks of sharing my data with other researchers using the NDA?

- There is a small risk of loss of privacy.
- Other researchers may use your information in future studies. AASPIRE will not be involved in those studies. There is a chance that you may not agree with the goals or methods of those future studies.

What are the benefits of sharing my data with other researchers using the NDA?

You may not benefit directly from allowing us to share your information with the NDA. In the future, the NDA may help researchers around the world improve outcomes for people who have mental health conditions.

Can I still take part in this study even if I don't agree to share my information with the NDA?

Yes. You can take part in this study whether or not you agree to share your information with other researchers using the NDA.

What would happen if I changed my mind about the NDA in the future?

You may decide later that you do not want to share your information using the NDA. If so, contact the AASPIRE team, and they will tell the NDA. The NDA will then stop sharing your research information. However, the NDA cannot take back information that they shared before you changed your mind.

How do I get more information about the NDA?

More information about the NDA is available at: http://data-archive.nimh.gov.

Would you like to share your information with other researchers using the NDA?
(You can take part in the study whether or not you agree to share information using NDA.)

_____ Yes, I would like to share my information with other researchers using the NDA.
_____ No, I do not wish to share my information.

<If yes>
Thank you for agreeing to participate in the NDA. If you provide the following information, your data from this study may be linked with your data from past and future studies that also use the NDA. The information you provide will be replaced by a code number so your identity will not be shared with other researchers. If you don't provide this information, you can still participate in the NDA, and researchers can still use your data from this study, but they will not be able to link your data across studies.

When were you born?
Month ___
Day ___
Year ___

Where were you born?
City ____
State ____
Country _____

Hotlink:

Deidentified: “Deidentified” means that a person’s identifying information—such as their name, date of birth, and place of birth—is removed from the data. A computer program replaces the information with a code number before we put data into the NDA.

IRB Approved: 9/27/2017
Approval Expires: 7/11/2018

Information Sheet and Authorization

IRB#________

Information Sheet for Legally Authorized Representative

TITLE: AASPIRE Healthcare Toolkit Integration Study

PRINCIPAL INVESTIGATOR:	Christina Nicolaidis, MD, MPH nicolaid@ohsu.edu, (503) 494-9602
CO-INVESTIGATORS:	Dora Raymaker, PhD draymake@pdx.edu, (503) 725-9629
	Lisa Croen, PhD lisa.a.croen@kp.org, (510) 891-3463
	Junghee Lee, PhD jungl@pdx.edu, (503) 725-5374
	Jennifer Aengst, PhD jaengst@pdx.edu, (503) 725-9633

SPONSOR: National Institutes of Health

What is this Information Sheet about?

This sheet gives details about a research study being conducted by the Academic Autistic Spectrum Partnership in Research and Education (AASPIRE). After you read the details, you can decide whether or not you give consent for the Supporter to participate on behalf of the patient.

What is the study about?

AASPIRE has created a set of online resources to improve healthcare for patients on the autism spectrum and those with other communication disabilities. The goal of this study is to test these resources. We will see how best to use them in clinics in different health systems. We will also see how well they work for patients and providers.

We are comparing the healthcare experiences of patients in clinics that do or do not use these resources. The resources are available in an online healthcare toolkit. The patient's clinic will be using this toolkit to try to improve care.

What do the patient and the Supporter need to participate in this study?

The patient can participate in this study if:

- The patient is over 18.
- The patient has a diagnosis on the autism spectrum (autism, Asperger's, PDD-NOS, childhood disintegrative disorder, or autism spectrum disorder) or another communication disorder.
- The patient is currently receiving primary care at one of the following clinics: OHSU Gabriel Park, OHSU Scappoose, Legacy Emanuel Medical Center, Legacy Good Samaritan Medical Center, or Kaiser Permanente Northern California.

The patient will be participating via a Supporter. The Supporter can participate in this study if:

- They are over 18.
- They know the patient well and have experience supporting them in healthcare settings.

What can the patient and the Supporter expect if they do the study?

If you give consent for the patient to participate in the study via the Supporter, the following will happen:

1. The Supporter will take a short online survey at the beginning of the study.
2. The Supporter will create a customized accommodations report for the patient's healthcare provider, using the online toolkit.
3. After reviewing the report, the Supporter will be asked permission to have the report sent directly to the patient's primary care provider.
4. The Supporter will use whichever resources they find helpful from the healthcare toolkit website.
5. Six months later, the Supporter will take another short online survey.
6. After the Supporter completes the survey, the Supporter may also be contacted to participate in an interview.
7. The research team will look at the patient's electronic medical records. We want to see how often the patient has used healthcare services during the study. Examples of healthcare services include primary care visits, flu shots, Pap smears, emergency room visits, or other hospital stays. We also want to see how the Supporter and the patient's providers have used the resources from the healthcare toolkit. For example, we will check to see if the patient's accommodations report was entered into their medical record correctly and if their providers have looked at it.

Each survey should take about 20 minutes to complete. It will take another 20 minutes to create the customized accommodations report. The Supporter can spend as much time as they want to use the online toolkit.

What are the possible risks of participating in this study?

- The Supporter might get tired or overloaded, or find some of the questions frustrating.
- The Supporter might get frustrated if they experience computer problems while participating in the study.
- Though we will try to protect the patient's privacy as described below, there is a risk of loss of privacy when using the internet.
- There is a chance that the patient's provider may not use the information in the accommodations report.

What are the possible benefits of participating in this study?

Doing the study and using the resources in the toolkit may or may not be helpful to the patient. If the Supporter participates in this study, the patient will get to use the toolkit as part of their regular healthcare. The patient's experience using the toolkit may help them better prepare for their healthcare visits. It may also help their provider better understand what accommodations or supports may be useful to the patient. The results of this study may help improve the healthcare of other adults on the autism spectrum or people with other communication disabilities in the future.

How will the patient's information be kept private?

We will protect the privacy of the patient in the following ways:

- We will not use the patient's name or identity for publication or publicity purposes.
- The patient's name and date of birth will be on the customized accommodations report that will be sent to the patient's provider. We will only send that report to the provider with permission from the Supporter. We will not share the report with anyone other than the patient's provider and their clinic staff.
- We will collect additional information about the patient in the two surveys. A code number will be assigned to the patient and the survey answers.
- We will also collect data from the patient's medical record about the patient's medical diagnoses and what healthcare services the patient has used.
- Only the research team will be able to connect the patient's code number to the survey answers and the information from the patient's medical records.
- Health information is private and is protected under federal law and Oregon law. By agreeing to be in this study, you are giving us permission (also called authorization) to use the patient's health information as described above in this form ("What can the patient and Supporter expect if they do the study?").
- If the Office for Human Research Protections, a federal agency that oversees research involving humans, requests it as part of an audit of our project, we could disclose the patient's personal information to them. We will not release information about the patient to others not listed above, unless required or permitted by law.

Will the patient pay or get any money to participate?

No, the patient does not have to pay anything to participate. However, we encourage the Supporter to go over the accommodations report with the patient's provider during a regular healthcare visit. The patient will be responsible for the costs of their healthcare visits.

The Supporter will receive $30 for completing both surveys. The Supporter can choose to be paid with an Amazon.com gift card or a check. If the Supporter starts but does not finish the study, the Supporter will be paid 5 dollars with an Amazon.com gift card.

What are the rights of the patient as a research participant?

The patient and the Supporter do not have to be in this or any research study. You do not have to allow the use and disclosure of the patient's health information in the study, but if you do not, the patient cannot be in the study. If you give consent for the Supporter to participate in this study on behalf of the patient and you or the Supporter later change your mind, you may quit at any time. This includes the right to withdraw your authorization to use and disclose the patient's health information. Contract the principal investigator, Christina Nicolaidis, if you want to withdraw from the study. If you choose not to do this study or if you choose to end the study early, the patient will not experience any bad consequences. The patient's healthcare will not be affected if you decide not to participate in this study. If you no longer want the patient's health information to be used and disclosed as described in this form, you must send a written request or email stating that you are revoking your authorization to:

Christina Nicolaidis, MD, MPH
OHSU Division of General Internal Medicine
3181 SW Sam Jackson Park Road
Mailcode L475
Portland, OR 97239

If you have any questions regarding the patient's rights as a research subject, you may contact the OHSU Research Integrity Office at (877) 733-8313 (toll free) or oioeduc@ohsu.edu.

If you have any questions regarding this study now or in the future, contact Christina Nicolaidis, MD, MPH by emailing nicolaid@ohsu.edu or by calling (503) 725-9603.

If you have read this information, understood it, and decided what you want to do, please click the circle next to your decision. If you choose "Yes, I want to participate," it means that you are voluntarily giving consent for the Supporter to participate in the study.

___Yes, I want to participate.

Name of patient: ____
First Middle Last

Name of Legally Authorized Representative: ______________________________
First Middle Last

___No, I do not want to participate.

<If yes>

We may need to contact you (the Legally Authorized Representative) during the study. If so, we will likely use email as a way to contact you. However, we would like to have additional ways to reach you just in case there is a problem with email.

Email address: _________________________________

Telephone number for voice calls: ________

Text number: ________________

Physical address: ________________

Fax number (if available): _______________

Would it be ok to reach you using contact information that has been updated in the patient's medical record?

_ Yes
_ No

Information about the National Institute of Mental Health Data Archive (NDA)

What is this next section about?

This next section will help you decide if you want the patient's information shared with other researchers using the National Institute of Mental Health Data Archive (NDA).

What is the National Institute of Mental Health Data Archive (NDA)?

The NDA is a "data repository" – that means it is a large database that stores information from different studies.

The NDA allows researchers to share "deidentified" information with each other.

"Deidentified" means that a person's identifying information—such as their name, date of birth, and place of birth—is removed from the data. A computer program replaces the information with a code number before we put data into the NDA. Researchers using the NDA would not be able to learn identifying data from the code number, but they can use the code number to link data from different studies.

Why do I have to make a choice about the NDA?

This study is funded by the National Institute of Mental Health (NIMH). The NIMH requires researchers take part in its NDA program.

However, it is up to you to decide whether you want AASPIRE to put *the patient's data* into the NDA.

What will happen if I agree to share data with other researchers using the NDA?

If you agree, we will send some of the information we collect in this study to the NDA. Other researchers nationwide can then file an application with the NIMH to get access to the deidentified study data. This would include the patient's survey answers and the information we collect from their medical record about how the patient uses healthcare services. All personal information will be replaced with a code number. Other researchers can then use that data in their own research.

What are the risks of sharing the patient's data with other researchers using the NDA?

- There is a small risk of loss of privacy.
- Other researchers may use the patient's information in future studies. AASPIRE will not be involved in those studies. There is a chance that you may not agree with the goals or methods of those future studies.

What are the benefits of sharing data with other researchers using the NDA?

You may not benefit directly from allowing us to share information with the NDA. In the future, the NDA may help researchers around the world improve outcomes for people who have mental health conditions.

Can the patient and their Supporter still take part in this study even if I don't agree to share information with the NDA?

Yes. The patient and their Supporter can take part in this study whether or not you agree to share information with other researchers using the NDA.

What would happen if I changed my mind about the NDA in the future?

You may decide later that you do not want to share the patient's information using the NDA. If so, contact the AASPIRE team, and they will tell the NDA. The NDA will then stop sharing the patient's research information. However, the NDA cannot take back information that they shared before you changed your mind.

How do I get more information about the NDA?

More information about the NDA is available at: http://data-archive.nimh.gov.

Would you like to share the patient's information with other researchers using the NDA?
(The patient and their Supporter can take part in the study whether or not you agree to share information using the NDA.)

_____ Yes, I would like to share the patient's information with other researchers using the NDA.
_____ No, I do not wish to share the patient's information.

<If yes>
Thank you for agreeing to participate in the NDA. If you provide the following information, the patient's data from this study may be linked with the patient's data from past and future studies that also use the NDA. The information you provide will be replaced by a code number so the patient's identity will not be shared with other researchers. If you don't provide this information, the patient can still participate in the NDA, and researchers can still use the patient's data from this study, but they will not be able to link the patient's data across studies.

When and where was the patient born?
Month ___
Day ___
Year ___
City ____
State ____
Country _____

Hotlink:

Deidentified: “Deidentified” means that a person’s identifying information—such as their name, date of birth, and place of birth—is removed from the data. A computer program replaces the information with a code number before we put data into the NDA.

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Information Sheet and Authorization

IRB#________

Information Sheet for Legally Authorized Representative

TITLE: AASPIRE Healthcare Toolkit Integration Study

PRINCIPAL INVESTIGATOR: Christina Nicolaidis, MD, MPH
nicolaid@ohsu.edu, (503) 494-9602

CO-INVESTIGATORS: Dora Raymaker, PhD
draymake@pdx.edu, (503) 725-9629

Lisa Croen, PhD
lisa.a.croen@kp.org, (510) 891-3463

Junghee Lee, PhD
jungl@pdx.edu, (503) 725-5374

Jennifer Aengst, PhD
jaengst@pdx.edu, (503) 725-9633

SPONSOR: National Institutes of Health

What is this Information Sheet about?

This sheet gives details about a research study being conducted by the Academic Autistic Spectrum Partnership in Research and Education (AASPIRE). After you read the details, you can decide whether or not you give consent for the Supporter to participate on behalf of the patient.

What is the study about?

AASPIRE has created a set of online resources to improve healthcare for patients on the autism spectrum and those with other communication disabilities. The goal of this study is to test these resources. We will see how best to use them in clinics in different health systems. We will also see how well they work for patients and providers.

We are comparing the healthcare experiences of patients in clinics that do or do not use these resources. Some clinics are using the new resources now. The patient’s clinic is not using these resources now, however the patient will get a chance to use them after this study is completed.

What do the patient and the Supporter need to participate in this study?

The patient can participate in this study if:

- The patient is over 18.
- The patient has a diagnosis on the autism spectrum (autism, Asperger's, PDD-NOS, childhood disintegrative disorder, or autism spectrum disorder) or another communication disorder.
- The patient is currently receiving primary care at one of the following clinics: OHSU Gabriel Park, OHSU Scappoose, Legacy Emanuel Medical Center, Legacy Good Samaritan Medical Center, or Kaiser Permanente Northern California.

The patient will be participating via a Supporter. The Supporter can participate in this study if:

- They are over 18.
- They know the patient well and have experience supporting them in healthcare settings.

What can the patient and the Supporter expect if they do the study?

If you give consent for the patient to participate in the study via the Supporter, the following will happen:

1. The Supporter will take a short online survey at the beginning of the study.
2. Six months later, the Supporter will take another short online survey.
3. After the Supporter completes the survey, the Supporter may also be contacted to participate in an interview.
4. The research team will look at the patient's electronic medical records. We want to see how often the patient has used healthcare services during the study. Examples of healthcare services include primary care visits, flu shots, Pap smears, emergency room visits, or other hospital stays.

Each survey should take about 20 minutes to complete.

What are the possible risks of participating in this study?

- The Supporter might get tired or overloaded, or find some of the questions frustrating.
- The Supporter might get frustrated if they experience computer problems while participating in the study.
- Though we will try to protect the patient's privacy as described below, there is a risk of loss of privacy when using the internet.
- The Supporter may get upset if you remember previous negative experiences with healthcare.

What are the possible benefits of participating in this study?

Doing the study may or may not be helpful to the patient. The results of this study may help improve the healthcare of other adults on the autism spectrum or people with other communication disabilities in the future.

How will the patient's information be kept private?

We will protect the privacy of the patient in the following ways:

- We will not use the patient's name or identity for publication or publicity purposes.
- We will collect additional information about the patient in the two surveys. A code number will be assigned to the patient and the survey answers.
- We will also collect data from the patient's medical record about the patient's medical diagnoses and what healthcare services they have used.
- Only the research team will be able to connect the patient's code number to the survey answers and the information from the patient's medical records.
- Health information is private and is protected under federal law and Oregon law. By agreeing to be in this study, you are giving us permission (also called authorization) to use the patient's health information as described above in this form ("What can the patient and Supporter expect if they do the study?").
- If the Office for Human Research Protections, a federal agency that oversees research involving humans, requests it as part of an audit of our project, we could disclose the patient's personal information to them. We will not release information about the patient to others not listed above, unless required or permitted by law.

Will the patient pay or get any money to participate?

No, the patient does not have to pay anything to participate.

The Supporter will receive $30 for completing both surveys. The Supporter can choose to be paid with an Amazon.com gift card or a check. If the Supporter starts but does not finish the study, the Supporter will be paid 5 dollars with an Amazon.com gift card.

What are the rights of the patient as a research participant?

The patient and the Supporter do not have to be in this or any research study. You do not have to allow the use and disclosure of the patient's health information in the study, but if you do not, the patient cannot be in the study. If you give consent for the Supporter to participate in this study on behalf of the patient and you or the Supporter later change your mind, you may quit at any time. This includes the right to withdraw your authorization to use and disclose the patient's health information. Contact the principal investigator, Christina Nicolaidis, if you want to withdraw the patient from the study. If you choose not to do this study or if you choose to end the study early, the patient will not experience any bad consequences. The patient's healthcare will not be affected if you decide not to participate in this study. If you no longer want the patient's health information to be used and disclosed as described in this form, you must send a written request or email stating that you are revoking your authorization to:

Christina Nicolaidis, MD, MPH
OHSU Division of General Internal Medicine
3181 SW Sam Jackson Park Road
Mailcode L475
Portland, OR 97239

If you have any questions regarding the patient's rights as a research subject, you may contact the OHSU Research Integrity Office at (877) 733-8313 (toll free) or oioeduc@ohsu.edu.

If you have any questions regarding this study now or in the future, contact Christina Nicolaidis, MD, MPH by emailing nicolaid@ohsu.edu or by calling (503) 725-9603.

If you have read this information, understood it, and decided what you want to do, please click the circle next to your decision. If you choose "Yes, I want to participate," it means that you are voluntarily giving consent for the Supporter to participate in the study.

___Yes, I want to participate.

Name of patient: ____
First Middle Last

Name of Legally Authorized Representative: ______________________________
First Middle Last

___No, I do not want to participate.

<If yes>

We may need to contact you (the Legally Authorized Representative) during the study. If so, we will likely use email as a way to contact you. However, we would like to have additional ways to reach you just in case there is a problem with email.

Email address: ______________________________

Telephone number for voice calls: ________

Text number: _______________

Physical address: _______________

Fax number (if available): ______________

Would it be ok to reach you using contact information that has been updated in the patient's medical record?

_ Yes
_ No

Information about the National Institute of Mental Health Data Archive (NDA)

What is this next section about?

This next section will help you decide if you want the patient's information shared with other researchers using the National Institute of Mental Health Data Archive (NDA).

What is the National Institute of Mental Health Data Archive (NDA)?

The NDA is a "data repository" – that means it is a large database that stores information from different studies.

The NDA allows researchers to share "deidentified" information with each other.

"Deidentified" means that a person's identifying information—such as their name, date of birth, and place of birth—is removed from the data. A computer program replaces the information with a code number before we put data into the NDA. Researchers using the NDA would not be able to learn identifying data from the code number, but they can use the code number to link data from different studies.

Why do I have to make a choice about the NDA?

This study is funded by the National Institute of Mental Health (NIMH). The NIMH requires researchers take part in its NDA program.

However, it is up to you to decide whether you want AASPIRE to put *the patient's data* into the NDA.

What will happen if I agree to share data with other researchers using the NDA?

If you agree, we will send the information we collect in this study to the NDA. Other researchers nationwide can then file an application with the NIMH to get access to the deidentified study data. This would include the patient's survey answers and the information we collect from their medical record about how the patient uses healthcare services. All personal information will be replaced with a code number. Other researchers can then use that data in their own research.

What are the risks of sharing the patient's data with other researchers using the NDA?

- There is a small risk of loss of privacy.
- Other researchers may use the patient's information in future studies. AASPIRE will not be involved in those studies. There is a chance that you may not agree with the goals or methods of those future studies.

What are the benefits of sharing data with other researchers using the NDA?

You may not benefit directly from allowing us to share information with the NDA. In the future, the NDA may help researchers around the world improve outcomes for people who have mental health conditions.

Can the patient and their Supporter still take part in this study even if I don't agree to share information with the NDA?

Yes. The patient and their Supporter can take part in this study whether or not you agree to share information with other researchers using the NDA.

What would happen if I changed my mind about the NDA in the future?

You may decide later that you do not want to share the patient's information using the NDA. If so, contact the AASPIRE team, and they will tell the NDA. The NDA will then stop sharing the patient's research information. However, the NDA cannot take back information that they shared before you changed your mind.

How do I get more information about the NDA?

More information about the NDA is available at: http://data-archive.nimh.gov.

Would you like to share the patient's information with other researchers using the NDA?
(The patient and their Supporter can take part in the study whether or not you agree to share information using the NDA.)

_____ Yes, I would like to share the patient's information with other researchers using the NDA.
_____ No, I do not wish to share the patient's information.

<If yes>
Thank you for agreeing to participate in the NDA. If you provide the following information, the patient's data from this study may be linked with the patient's data from past and future studies that also use the NDA. The information you provide will be replaced by a code number so the patient's identity will not be shared with other researchers. If you don't provide this information, the patient can still participate in the NDA, and researchers can still use the patient's data from this study, but they will not be able to link the patient's data across studies.

When was the patient born?
Month ___
Day ___
Year ___

Where was the patient born?
City ____
State ____
Country _____

Hotlink:

Deidentified: “Deidentified” means that a person’s identifying information—such as their name, date of birth, and place of birth—is removed from the data. A computer program replaces the information with a code number before we put data into the NDA.

IRB Approved: 9/27/2017
Approval Expires: 7/11/2018

OREGON HEALTH & SCIENCE UNIVERSITY

Information Sheet and Authorization

IRB#________

Information Sheet for Supporter Participant

TITLE: AASPIRE Healthcare Toolkit Integration Study

PRINCIPAL INVESTIGATOR: Christina Nicolaidis, MD, MPH
nicolaid@ohsu.edu, (503) 494-9602

CO-INVESTIGATORS: Dora Raymaker, PhD
draymake@pdx.edu, (503) 725-9629

Lisa Croen, PhD
lisa.a.croen@kp.org, (510) 891-3463

Junghee Lee, PhD
jungl@pdx.edu, (503) 725-5374

Jennifer Aengst, PhD
jaengst@pdx.edu, (503) 725-9633

SPONSOR: National Institutes of Health

What is this Information Sheet about?

This sheet gives details about a research study being conducted by the Academic Autistic Spectrum Partnership in Research and Education (AASPIRE). After you read the details, you can decide whether or not you want to participate.

This form is intended for Supporters of patients who have been invited to participate in the study. A Supporter is someone who knows the patient well and has experience supporting them in healthcare settings.

What is the study about?

AASPIRE has created a set of online resources to improve healthcare for patients on the autism spectrum and those with other communication disabilities. The goal of this study is to test these resources. We will see how best to use them in clinics in different health systems. We will also see how well they work for patients and providers.

We are comparing the healthcare experiences of patients in clinics that do or do not use these resources. The resources are available in an online healthcare toolkit. The patient's clinic will be using this toolkit to try to improve care.

What do I need to participate in this study?

The patient can participate in this study if:

- The patient is over 18
- The patient has a diagnosis on the autism spectrum (autism, Asperger's, PDD-NOS, childhood disintegrative disorder, or autism spectrum disorder) or another communication disorder
- The patient is currently receiving primary care at one of the following clinics: OHSU Gabriel Park, OHSU Scappoose, Legacy Emanuel Medical Center, Legacy Good Samaritan Medical Center, or Kaiser Permanente Northern California.

You can participate in this study if:

You are over 18
You know the patient well and have experience supporting them in healthcare settings.

What can I expect if I do the study?

If you choose to participate in the study, you will do the following. Whenever possible, please obtain as much information as possible from the patient themselves.

1. You will take a short online survey at the beginning of the study.
2. You will create a customized accommodations report for the patient's healthcare provider, using the online toolkit.
3. After reviewing the report, you will be asked permission to have the report sent directly to the patient's primary care provider.
4. You will use whichever resources you find helpful from the healthcare toolkit website.
5. Six months later, you will take another short online survey.
6. After you complete the survey, you may also be contacted to participate in an interview.
7. The research team will look at the patient's electronic medical records. We want to see how often the patient has used healthcare services during the study. Examples of healthcare services include primary care visits, flu shots, Pap smears, emergency room visits, or other hospital stays. We also want to see how you and the patient's providers have used the resources from the healthcare toolkit. For example, we will check to see if the patient's accommodations report was entered into their medical record correctly and if the patient's providers have looked at it.

Each survey should take about 20 minutes to complete. It will take another 20 minutes to create the customized accommodations report. You can spend as much time as you want to use the online toolkit.

What are the possible risks of participating in this study?

- You might get tired or overloaded, or find some of the questions frustrating.
- You might get frustrated if you experience computer problems while participating in the study.
- Though we will try to protect your privacy and the patient's privacy as described below, there is a risk of loss of privacy when using the internet.
- You may get upset if you remember previous negative experiences with healthcare.
- There is a chance that the patient's provider may not use the information in the accommodations report.

What are the possible benefits of participating in this study?

Doing the study and using the resources in the toolkit may or may not be helpful to you or the patient. If you participate in this study, the patient will get to use the toolkit as part of their regular healthcare. Your experience using the toolkit may help you better prepare for the patient's healthcare visits. It may also help the patient's provider better understand what accommodations or supports may be useful to the patient. The results of this study may help improve the healthcare of other adults on the autism spectrum or people with other communication disabilities in the future.

How will the patient's information be kept private?

We will protect the privacy of the patient in the following ways:

- We will not use your or the patient's name or identity for publication or publicity purposes.
- The patient's name and date of birth will be on the customized accommodations report you create for the patient's provider. We will only send that report to the patient's provider with your permission. We will not share the report with anyone other than the patient's provider and their clinic staff.
- We will collect additional information about you and the patient in the two surveys. A code number will be assigned to your survey answers.
- We will also collect data from the patient's medical record about the patient's medical diagnoses and what healthcare services the patient has used.
- Only the research team will be able to connect the code number to your survey answers and the information from the patient's medical records.
- Health information is private and is protected under federal law and Oregon law. By agreeing to be in this study, you are giving us permission (also called authorization) to use the patient's health information as described above in this form ("What can I expect if I do the study?").

- If the Office for Human Research Protections, a federal agency that oversees research involving humans, requests it as part of an audit project, we could disclose the patient’s personal information to them. We will not release information about the patient to others not listed above, unless required or permitted by law.

Will I pay or get any money to participate?

No, you do not have to pay anything to participate. However, we encourage you to go over the patient’s accommodations report with their provider during a regular healthcare visit. The patient will be responsible for the costs of their healthcare visits.

You will receive $30 for completing both surveys. You can choose to be paid with an Amazon.com gift card or a check. If you start but do not finish the study, you will be paid 5 dollars with an Amazon.com gift card.

What are the rights of the patient as a research participant?

The patient does not have to be in this or any research study. You do not have to allow the use and disclosure of the patient’s health information in the study, but if you do not, the patient cannot be in the study. If you choose to do this study and then later change your mind, you may quit at any time. This includes the right to withdraw your authorization to use and disclose the patient’s health information. Contract the principal investigator, Christina Nicolaidis, if you want to withdraw from the study. If you choose not to do this study or if you choose to end the study early, the patient will not experience any bad consequences. The patient’s healthcare will not be affected if you decide not to participate in this study. If you no longer want the patient’s health information to be used and disclosed as described in this form, you must send a written request or email stating that you are revoking your authorization to:

Christina Nicolaidis, MD, MPH
OHSU Division of General Internal Medicine
3181 SW Sam Jackson Park Road
Mailcode L475
Portland, OR 97239

If you have any questions regarding your rights as a research subject, you may contact the OHSU Research Integrity Office at (877) 733-8313 (toll free) or oioeduc@ohsu.edu.

If you have any questions regarding this study now or in the future, contact Christina Nicolaidis, MD, MPH by emailing nicolaid@ohsu.edu or by calling (503) 725-9603.

If you have read this information, understood it, and decided what you want to do, please click the circle next to your decision. If you choose "Yes, I want to participate," it means that you voluntarily agree to participate in the study on behalf of the patient.

___Yes, I want to participate.

Name of patient:____
First Middle Last

Name of Supporter: ____
First Middle Last

___No, I do not want to participate.

<If yes>

We will generally use email to contact you (the Supporter) during the study. For example, we will send you email reminders to let you know when it is time to take your follow-up survey.

What is your email address?
<write in>

We would like to have additional contact information in case there is a problem reaching you by email. Please let us know how else we can reach you, if need be:

Telephone number for voice calls: ________

Text number: _______________

Physical address: _______________

Fax number (if available): ______________

Would it be ok to reach you using contact information that has been updated in the patient's medical record?

_ Yes
_ No

<If Supporter is also LAR, continue>

Information about the National Institute of Mental Health Data Archive (NDA)

What is this next section about?

This next section will help you decide if you want the patient's information shared with other researchers using the National Institute of Mental Health Data Archive (NDA).

What is the National Institute of Mental Health Data Archive (NDA)?

The NDA is a "data repository" – that means it is a large database that stores information from different studies.

The NDA allows researchers to share "deidentified" information with each other.

"Deidentified" means that a person's identifying information—such as their name, date of birth, and place of birth—is removed from the data. A computer program replaces the information with a code number before we put data into the NDA. Researchers using the NDA would not be able to learn identifying data from the code number, but they can use the code number to link data from different studies.

Why do I have to make a choice about the NDA?

This study is funded by the National Institute of Mental Health (NIMH). The NIMH requires researchers take part in its NDA program.

However, it is up to you to decide whether you want AASPIRE to put *the patient's data* into the NDA.

What will happen if I agree to share data with other researchers using the NDA?

If you agree, we will send some of the information we collect in this study to the NDA. Other researchers nationwide can then file an application with the NIMH to get access to the deidentified study data. This would include the patient's survey answers and the information we collect from their medical record about how the patient uses healthcare services. All personal information will be replaced with a code number. Other researchers can then use that data in their own research.

What are the risks of sharing the patient's data with other researchers using the NDA?

- There is a small risk of loss of privacy.
- Other researchers may use the patient's information in future studies. AASPIRE will not be involved in those studies. There is a chance that you may not agree with the goals or methods of those future studies.

What are the benefits of sharing data with other researchers using the NDA?

You may not benefit directly from allowing us to share information with the NDA. In the future, the NDA may help researchers around the world improve outcomes for people who have mental health conditions.

Can the patient and their Supporter still take part in this study even if I don't agree to share information with the NDA?

Yes. The patient and their Supporter can take part in this study whether or not you agree to share information with other researchers using the NDA.

What would happen if I changed my mind about the NDA in the future?

You may decide later that you do not want to share the patient's information using the NDA. If so, contact the AASPIRE team, and they will tell the NDA. The NDA will then stop sharing the patient's research information. However, the NDA cannot take back information that they shared before you changed your mind.

How do I get more information about the NDA?

More information about the NDA is available at: http://data-archive.nimh.gov.

Would you like to share the patient's information with other researchers using the NDA?
(The patient and their Supporter can take part in the study whether or not you agree to share information using the NDA.)

_____ Yes, I would like to share the patient's information with other researchers using the NDA.
_____ No, I do not wish to share the patient's information.

<If yes>
Thank you for agreeing to participate in the NDA. If you provide the following information, the patient's data from this study may be linked with the patient's data from past and future studies that also use the NDA. The information you provide will be replaced by a code number so the patient's identity will not be shared with other researchers. If you don't

provide this information, the patient can still participate in the NDA, and researchers can still use the patient's data from this study, but they will not be able to link the patient's data across studies.

When was the patient born?
Month ___
Day ___
Year ___

Where was the patient born?
City ____
State ____
Country _____

Hotlink:

Deidentified: "Deidentified" means that a person's identifying information—such as their name, date of birth, and place of birth—is removed from the data. A computer program replaces the information with a code number before we put data into the NDA.

IRB Approved: 9/27/2017
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Information Sheet and Authorization

IRB#________

Information Sheet for Supporter Participant

TITLE: AASPIRE Healthcare Toolkit Integration Study

PRINCIPAL INVESTIGATOR:	Christina Nicolaidis, MD, MPH nicolaid@ohsu.edu, (503) 494-9602
CO-INVESTIGATORS:	Dora Raymaker, PhD draymake@pdx.edu, (503) 725-9629
	Lisa Croen, PhD lisa.a.croen@kp.org, (510) 891-3463
	Junghee Lee, PhD jungl@pdx.edu, (503) 725-5374
	Jennifer Aengst, PhD jaengst@pdx.edu, (503) 725-9633

SPONSOR: National Institutes of Health

What is this Information Sheet about?

This sheet gives details about a research study being conducted by the Academic Autistic Spectrum Partnership in Research and Education (AASPIRE). After you read the details, you can decide whether or not you want to participate.

This form is intended for Supporters of patients who have been invited to participate in the study. A Supporter is someone who knows the patient well and has experience supporting them in healthcare settings.

What is the study about?

AASPIRE has created a set of online resources to improve healthcare for patients on the autism spectrum and those with other communication disabilities. The goal of this study is to test these resources. We will see how best to use them in clinics in different health systems. We will also see how well they work for patients and providers.

We are comparing the healthcare experiences of patients in clinics that do or do not use these resources. Some clinics are using the new resources now. The patient's clinic is not using these resources now, however the patient will get a chance to use them after the study is completed.

What do I need to participate in this study?

The patient can participate in this study if:

- The patient is over 18
- The patient has a diagnosis on the autism spectrum (autism, Asperger's, PDD-NOS, childhood disintegrative disorder, or autism spectrum disorder) or another communication disorder
- The patient is currently receiving primary care at one of the following clinics: OHSU Gabriel Park, OHSU Scappoose, Legacy Emanuel Medical Center, Legacy Good Samaritan Medical Center, or Kaiser Permanente Northern California.

You can participate in this study if:

You are over 18
You know the patient well and have experience supporting them in healthcare settings.

What can I expect if I do the study?

If you choose to participate in the study, you will do the following. Whenever possible, please obtain as much information as possible from the patient themselves.

1. You will take a short online survey at the beginning of the study.
2. Six months later, you will take another short online survey.
3. After you complete the survey, you may also be contacted to participate in an interview.
4. The research team will look at the patient's electronic medical records. We want to see how often the patient has used healthcare services during the study. Examples of healthcare services include primary care visits, flu shots, Pap smears, emergency room visits, or other hospital stays.

Each survey should take about 20 minutes to complete.

What are the possible risks of participating in this study?

- You might get tired or overloaded, or find some of the questions frustrating.
- You might get frustrated if you experience computer problems while participating in the study.
- Though we will try to protect your privacy and the patient's privacy as described below, there is a risk of loss of privacy when using the internet.
- You may get upset if you remember previous negative experiences with healthcare.

What are the possible benefits of participating in this study?

Doing the study may or may not be helpful to you or the patient. The results of this study may help improve the healthcare of other adults on the autism spectrum or people with other communication disabilities in the future.

How will the patient's information be kept private?

We will protect the privacy of the patient in the following ways:

- We will not use your or the patient's name or identity for publication or publicity purposes.
- We will collect additional information about you and the patient in the two surveys. A code number will be assigned to your survey answers.
- We will also collect data from the patient's medical record about the patient's medical diagnoses and what healthcare services the patient has used.
- Only the research team will be able to connect the code number to your survey answers and the information from the patient's medical records.
- Health information is private and is protected under federal law and Oregon law. By agreeing to be in this study, you are giving us permission (also called authorization) to use the patient's health information as described above in this form ("What can I expect if I do the study?").
- If the Office for Human Research Protections, a federal agency that oversees research involving humans, requests it as part of an audit of our project, we could disclose the patient's personal information to them. We will not release information about the patient to others not listed above, unless required or permitted by law.

Will I pay or get any money to participate?

No, you do not have to pay anything to participate.

You will receive $30 for completing both surveys. You can choose to be paid with an Amazon.com gift card or a check. If you start but do not finish the study, you will be paid 5 dollars with an Amazon.com gift card.

What are the rights of the patient as a research participant?

The patient does not have to be in this or any research study. You do not have to allow the use and disclosure of the patient's health information in the study, but if you do not, the patient cannot be in the study. If you choose to do this study and then later change your mind, you may quit at any time. This includes the right to withdraw your authorization to use and disclose the patient's health information. Contact the principal investigator, Christina Nicolaidis, if you want to withdraw from the study. If you choose not to do this study or if you choose to end the study early, the patient will not experience any bad consequences. The patient's healthcare will not be affected if you decide not to participate in this study. If you no longer want the patient's health information to be used and disclosed as described in this form, you must send a written request or email stating that you are revoking your authorization to:

Christina Nicolaidis, MD, MPH
OHSU Division of General Internal Medicine
3181 SW Sam Jackson Park Road
Mailcode L475
Portland, OR 97239

If you have any questions regarding your rights as a research subject, you may contact the OHSU Research Integrity Office at (877) 733-8313 (toll free) or oioeduc@ohsu.edu.

If you have any questions regarding this study now or in the future, contact Christina Nicolaidis, MD, MPH by emailing nicolaid@ohsu.edu or by calling (503) 725-9603.

If you have read this information, understood it, and decided what you want to do, please click the circle next to your decision. If you choose "Yes, I want to participate," it means that you voluntarily agree to participate in the study on behalf of the patient.

___Yes, I want to participate.

Name of patient:____
First Middle Last

Name of Supporter: ____
First Middle Last

___No, I do not want to participate.

<If yes>

We will generally use email to contact you (the Supporter) during the study. For example, we will send you email reminders to let you know when it is time to take your follow-up survey.

What is your email address?
<write in>

We would like to have additional contact information in case there is a problem reaching you by email. Please let us know how else we can reach you, if need be:

Telephone number for voice calls: ________

Text number: ________________

Physical address: ________________

Fax number (if available): _______________

Would it be ok to reach you using contact information that has been updated in the patient's medical record?

_ Yes
_ No

<If Supporter is also LAR, continue>

Information about the National Institute of Mental Health Data Archive (NDA)

What is this next section about?

This next section will help you decide if you want the patient's information shared with other researchers using the National Institute of Mental Health Data Archive (NDA).

What is the National Institute of Mental Health Data Archive (NDA)?

The NDA is a "data repository" – that means it is a large database that stores information from different studies.

The NDA allows researchers to share "deidentified" information with each other.

"Deidentified" means that a person's identifying information—such as their name, date of birth, and place of birth—is removed from the data. A computer program replaces the information with a code number before we put data into the NDA. Researchers using the NDA would not be able to learn identifying data from the code number, but they can use the code number to link data from different studies.

Why do I have to make a choice about the NDA?

This study is funded by the National Institute of Mental Health (NIMH). The NIMH requires researchers take part in its NDA program.

However, it is up to you to decide whether you want AASPIRE to put *the patient's data* into the NDA.

What will happen if I agree to share data with other researchers using the NDA?

If you agree, we will send some of the information we collect in this study to the NDA. Other researchers nationwide can then file an application with the NIMH to get access to the deidentified study data. This would include the patient's survey answers and the information we collect from their medical record about how they patient uses healthcare services. All personal information will be replaced with a code number. Other researchers can then use that data in their own research.

What are the risks of sharing the patient's data with other researchers using the NDA?

- There is a small risk of loss of privacy.
- Other researchers may use the patient's information in future studies. AASPIRE will not be involved in those studies. There is a chance that you may not agree with the goals or methods of those future studies.

What are the benefits of sharing data with other researchers using the NDA?

You may not benefit directly from allowing us to share information with the NDA. In the future, the NDA may help researchers around the world improve outcomes for people who have mental health conditions.

Can the patient and their Supporter still take part in this study even if I don't agree to share information with the NDA?

Yes. The patient and their Supporter can take part in this study whether or not you agree to share information with other researchers using the NDA.

What would happen if I changed my mind about the NDA in the future?

You may decide later that you do not want to share the patient's information using the NDA. If so, contact the AASPIRE team, and they will tell the NDA. The NDA will then stop sharing the patient's research information. However, the NDA cannot take back information that they shared before you changed your mind.

How do I get more information about the NDA?

More information about the NDA is available at: http://data-archive.nimh.gov.

Would you like to share the patient's information with other researchers using the NDA?
(The patient and their Supporter can take part in the study whether or not you agree to share information using the NDA.)

_____ Yes, I would like to share the patient's information with other researchers using the NDA.
_____ No, I do not wish to share the patient's information.

<If yes>
Thank you for agreeing to participate in the NDA. If you provide the following information, the patient's data from this study may be linked with the patient's data from past and future studies that also use the NDA. The information you provide will be replaced by a code number so the patient's identity will not be shared with other researchers. If you don't provide this information, the patient can still participate in the NDA, and researchers can

still use the patient's data from this study, but they will not be able to link the patient's data across studies.

When was the patient born?
Month ___
Day ___
Year ___

Where was the patient born?
City ____
State ____
Country _____

Hotlink:

Deidentified: "Deidentified" means that a person's identifying information—such as their name, date of birth, and place of birth—is removed from the data. A computer program replaces the information with a code number before we put data into the NDA.

To: <Provider name>
From: <Clinic Director name>
Date: <Date>

Our clinic is collaborating with the Academic Autistic Spectrum Partnership in Research and Education (AASPIRE) on a NIH-funded research study to improve care for adults on the autism spectrum and patients with other communication disabilities.

If you agree to participate in this study, you will take the attached survey now and another one in about 6-9 months. Each survey should take less than 5 minutes to complete. Your participation in this survey is voluntary and your information will be kept confidential. We will use an ID number to link your answers to the two surveys.

If you have any questions regarding this study, contact Christina Nicolaidis, MD, MPH by emailing nicolaid@ohsu.edu or by calling (503) 725-9603. Thanks for your participation in this important study!