Phase II 'Rural NODA' Progress Final Report

NIMHR44MH112470 - Accelerating the diagnosis of autism spectrum disorder in rural Idaho via evidence-based Smartphone technology -

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Summary:

Phase II NODA™ (Naturalistic Observation Diagnostic Assessment) study was carried out from January 1, 2017 to March 31st, 2018. Three autism research sites including Emory Autism Center (EAC), Southwest Autism Research and Resource Center (SARRC) and the University of Idaho ultimately participated, and a fourth site St. Luke's (Boise) advised on study design after failing to obtain its IRB approval as a fourth site. Each site recruited families from both surrounding urban and rural communities in their respective states who were seeking a developmental evaluation. Based on their assignment after informed consent, a child was evaluated through a traditional "In-person Assessment" (IPA) or through the smartphone-based NODA method, an evidence-supported telehealth application. A total of 57 families were included in this project, of which 11 were from rural communities. 28 families participated in the NODA program and 29 families utilized the traditional IPA method. Families were asked to complete a questionnaire after assessment data were collected, and then 3-months after receiving a diagnostic report.

The average total time associated with obtaining an ASD assessment using the IPA method was 118 days and 59 days using the NODA program. The disparity between the two methods was even more vast for Rural (n =11) vs urban groups (n=46) was 159 days and 60 days respectively. Re family social validity for both methods, there was no substantial differences were observed between the rural and urban families who either participated in the NODA program or the IPA method. The response to the 3-month "post project survey" indicated that families who participated in the NODA program had a slightly less favorable opinion about the diagnostic assessment process in comparison to the families who completed the autism assessment using the traditional IPA method. However, the results revealed that the NODA program shortened the overall time required to complete an ASD assessment while providing acceptable levels of satisfaction for the families involved.

Methods and Procedures:

The three autism research sites used the same protocol for placing families into either the NODA program or the In-Person Assessment (IPA) group. The following steps were included:

1. Study personnel at each site obtained informed consent from each family (Appendix A). The start date for the procedure was the day they signed consent.
2. The site provided BIS the client's date of birth, sex, and zip code and BIS assigned each family to either NODA or IPA method:
    a. Families were deemed rural or urban based on zip code and according to the US Census[1]
3. Each site tracked 1. follow-up with families, 2. drop outs and 3. records if assessment was positive or negative for autism.

NODA vs In-Person Assessment – Time Required

The following steps were used when a family was assigned to the **NODA (telehealth)** research method:

1. The family was sent a link to the NODA app for download and asked to register on the NODA assessment website.
2. The NODA app provided instructions to families to record and submit videos of their child in four different situations in the home, and complete a developmental history questionnaire (aka 'Evidence Submission')
    a. If no videos were submitted within one week, a follow-up e-mail was sent to offer assistance. Another email was sent if there was no response.
    b. If no videos were submitted in 3 weeks, the family was excluded from the study (see 'Drop Outs' below)
3. After a family submitted all four videos, they were reviewed by a rater and a psychologist (review of evidence).
4. When the evidence review was complete, each family was asked to complete the first satisfaction survey.

[1] USDA website, What is Rural for Health Programs? (Veteran Affairs definition) https://www.nal.usda.gov/ric/what-is-rural

5. The family received the diagnostic report and a conference call or face-to-face meeting was scheduled to discuss the results, questions, or recommendations
6. After 3 months, the family was then asked to respond to a second satisfaction survey (see Family Social Validity below).

The following steps were taken when a family was assigned to the traditional **IPA method**:

1. The family was notified that they were assigned to the IPA method. A tentative date for the IPA appointment was given and site-specific forms to be completed were sent to the family. On the day of the appointment, the child's developmental or cognitive functioning was assessed with either the PPVT-4 or MSEL (depending on site) or KBIT-2 (depending on age). ASD symptoms were assessed with the ADOS-2 and either the ADI-R, or an in-depth Autism Symptom Questionnaire.
2. Assessment results were used to inform clinical judgment, a DSM-5 ASD criteria checklist was completed, and a diagnostic report was written by the psychologist.
3. Before diagnostic assessment results are shared, family completed the first survey.
4. The diagnostic report was either given to family during the (final) appointment, or mailed to family.
5. Three months after the family received the diagnostic report, the site sent an email with a link to the second satisfaction survey.

Family Social Validity

Two online surveys were completed by all families regardless of location (rural or urban) or study group (IPA or NODA). The first survey was administered after families experienced the assessment methods and prior to getting a diagnostic report. The second survey was administered three months later. Families were asked to respond to a series of statements related to either the In-Person Assessment (IPA) or the NODA method they experienced. Using a five point Likert scale, the parent rated the degree to which they agreed with the following three statements:

1. This evaluation gathered important information about my child's challenges and strengths.
2. I think that this was an easy process to have my child assessed.
3. I think I will learn valuable information about my child from this evaluation.

The statements used in the second satisfaction survey results also included the following statements:

1. During the 3 months, I've been able to get extra supports or treatments to help with my child's development.
2. I would be willing to get additional therapy services from an expert using my computer or smartphone.

Families were invited to also provide open-ended responses regarding their experiences and recommendations. We tabulated and summarized those responses as well.

Results:

107 families were recruited into this study; 57 families completed assessments.

NODA vs In-Person - Time Required for Assessment

Combining the results obtained at Emory University, SARRC and the University of Idaho showed that the time to complete ASD symptom assessment using the NODA method required an average of 59 days while the traditional IPA process required an average of 118 days. In the NODA group, families took an average of 27 days to register, collect and share developmental history and video examples, and clinical time averaged 32 days to review, interact with families for more data if desired, and to authorize a final diagnostic opinion, and share a diagnostic report with the family. Figure 2 illustrates the average time-savings between the two methods.

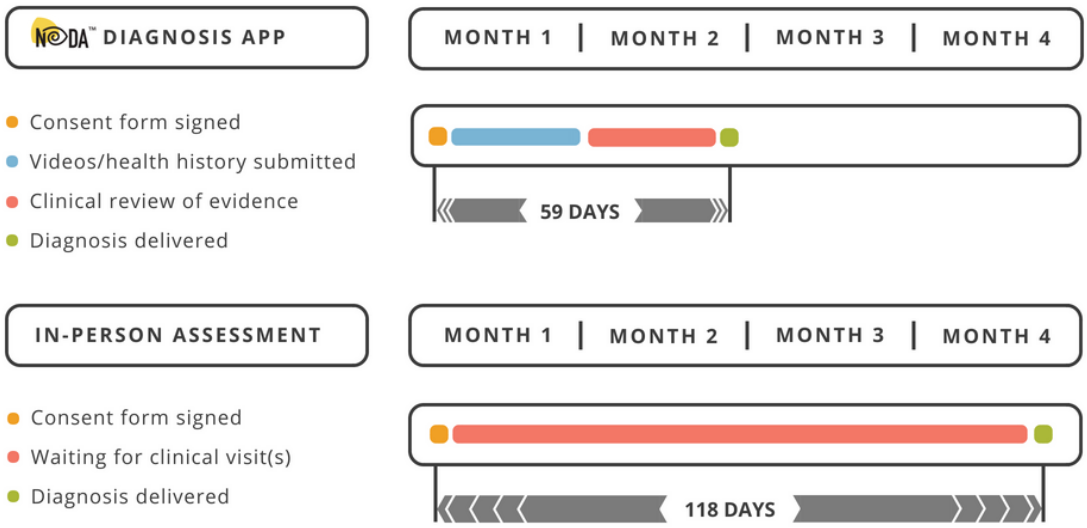
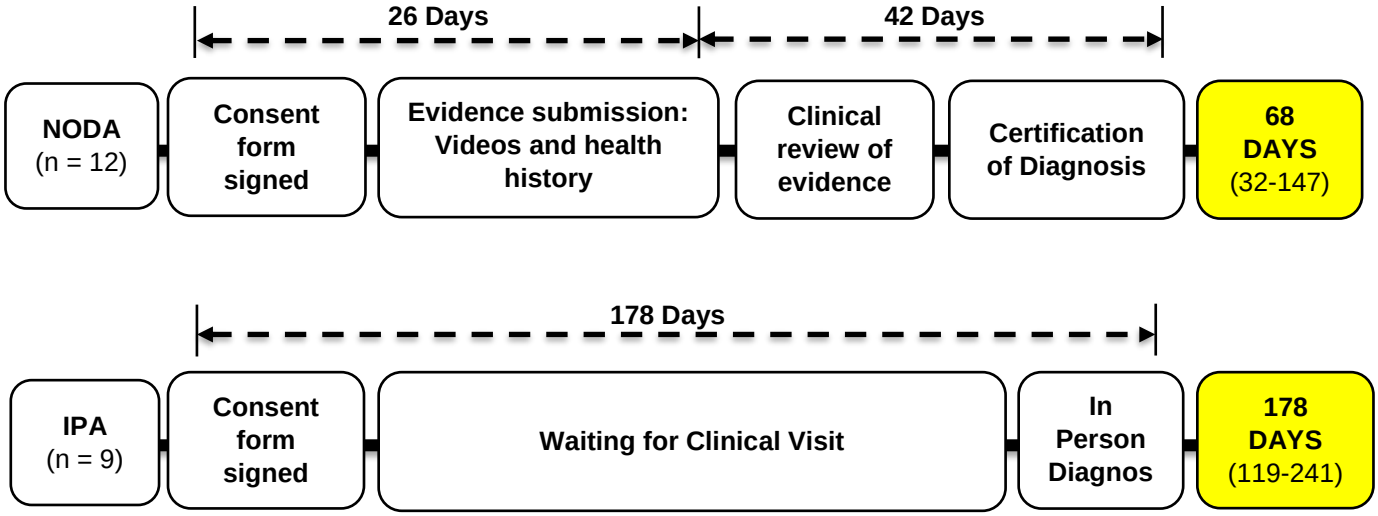


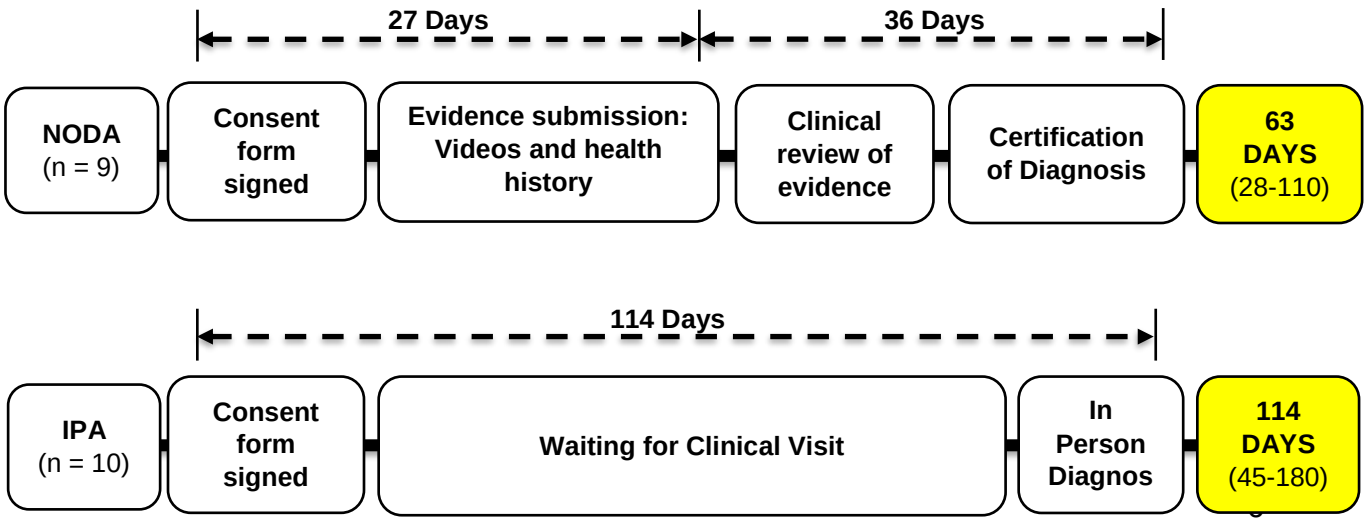
Figure 2 – Comparison of NODA vs IPA of timespan to provide diagnostic assessment report

At EAC, the NODA method required an average of 68 days and the IPA approach required on the average of 178 days. At SARRC, NODA required an average 63 days and IPA required an average 114 days. At the University of Idaho, NODA required on the average 36 days and IPA on the average 70 days. Figure 3 illustrates the NODA and IPA comparison separately for EAC, SARRC and University of Idaho.

EMORY UNIVERSITY SITE: (21 CLIENTS)



SARRC SITE: (19 CLIENTS)



University of Idaho Site: (17 Clients)

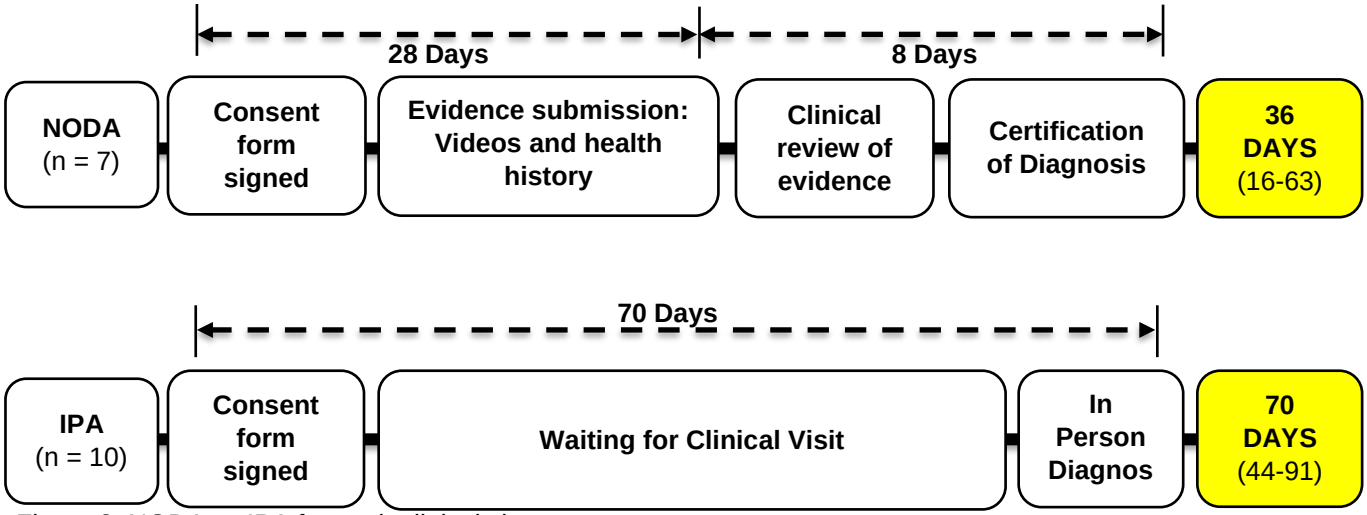


Figure 3: NODA vs IPA for each clinical site

Of the total sample of 57 families, 11 (19%) were from rural communities, which paralleled the national estimate (ie. 20% of population living in rural communities). Rural families are known to face additional challenges for obtaining assessments (eg. Long distances, child care).

Completed Assessments – Urban vs Rural

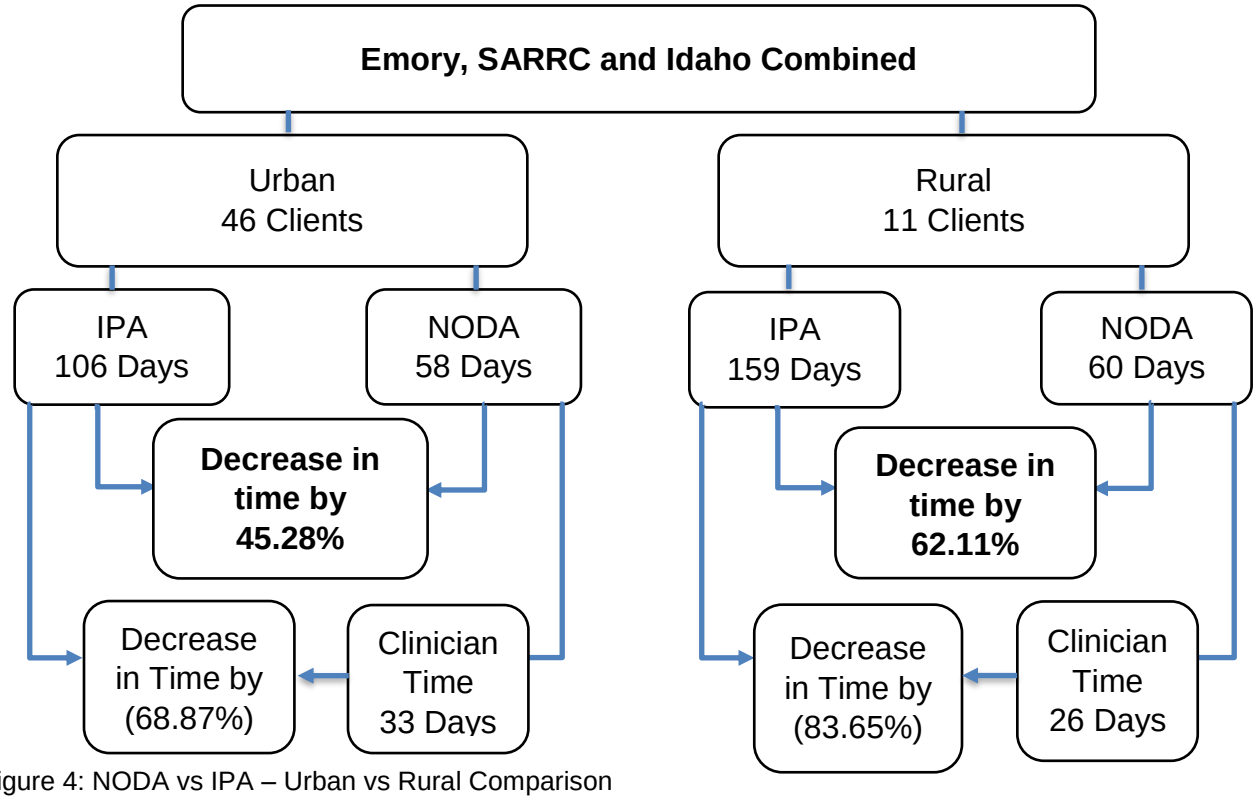


Figure 4: NODA vs IPA – Urban vs Rural Comparison

Drop-outs

St. Luke's dropped out as a 4th clinical site, having internal issues to obtain IRB approval in a timely manner (3 sites were already underway). St. Luke's Developmental Pediatrician Dr. Tim Leavell was retained as a consultant to other sites, and to give feedback to DSMB committee.

Rate for drop-out was 47%, initially a concern to the PI. It was suggested by the Research team that this is not atypical for this type of study protocol, in that families will simply prioritize an alternative center for diagnostic assessment. We did not formally track reasons for drop-outs, but several families provided reasons including:

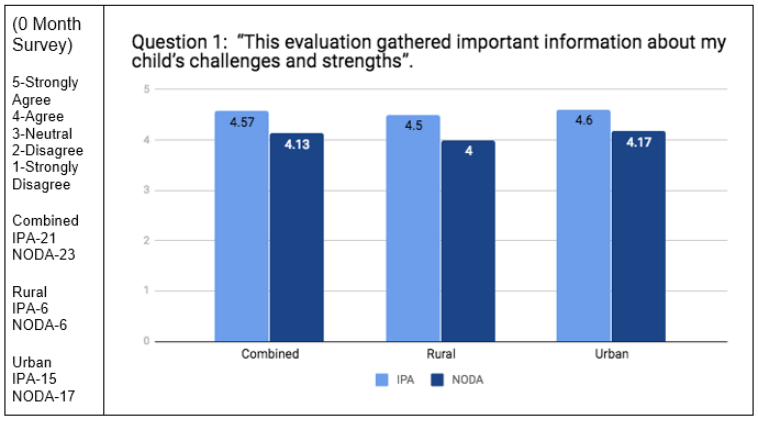
- they no longer wished to get their child assessed for autism
- they ended up getting their child assessed at another center while this process unfolded
- 'they were hoping they'd be put in the IPA group'; decided to not continue when they were put into the 'smartphone' group

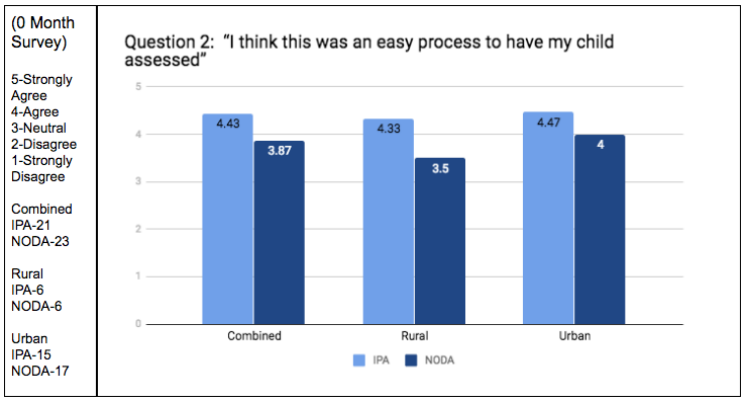
Family Social Validity / Survey

We were able to collect 32 satisfaction surveys from families from time zero (aka First Satisfaction survey) from both IPA and NODA groups. We collected 15 survey responses from families for both IPA and NODA groups.

First Satisfaction Survey

After the assessment was completed and prior to being given results, families indicated that the IPA approach provided slightly more information, more value, and more simplicity than NODA. This difference was seen for both the rural families and the urban families. The results of the survey are summarized in Figure 5.





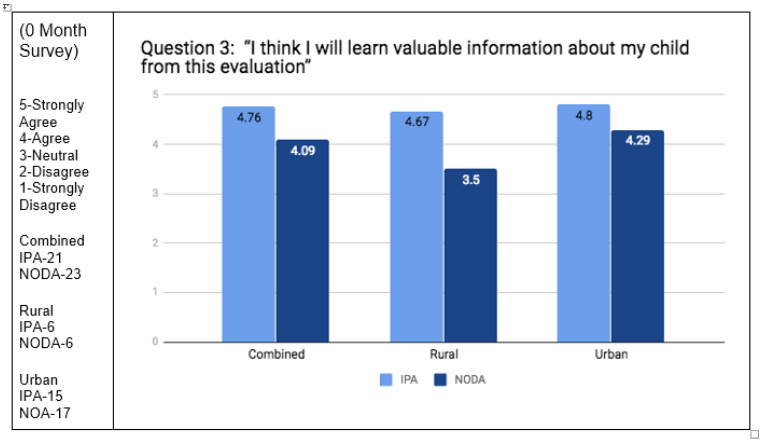


Figure 5. Summary of pre-participation questionnaire responses addressing importance and value of information expected and expected simplicity of process.

Second Satisfaction Survey (3 month)

The 3-month post-participation survey responses, families indicated the IPA and NODA methods were similar with regard to the simplicity and value of the information gained based on their experience. This is summarized in Figure 6.

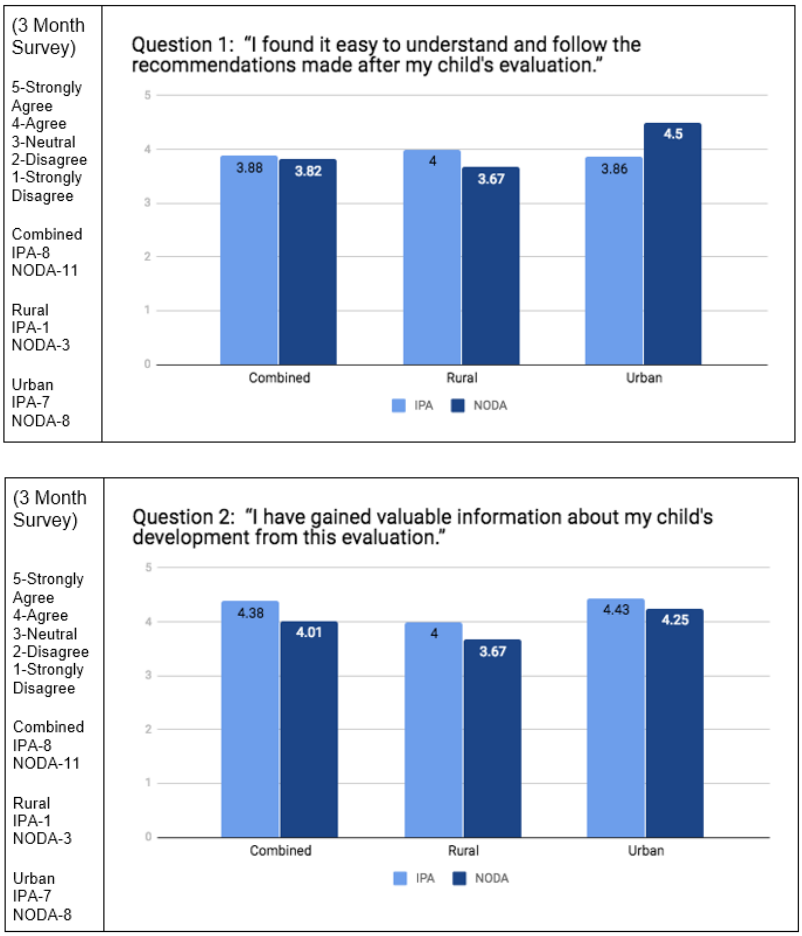
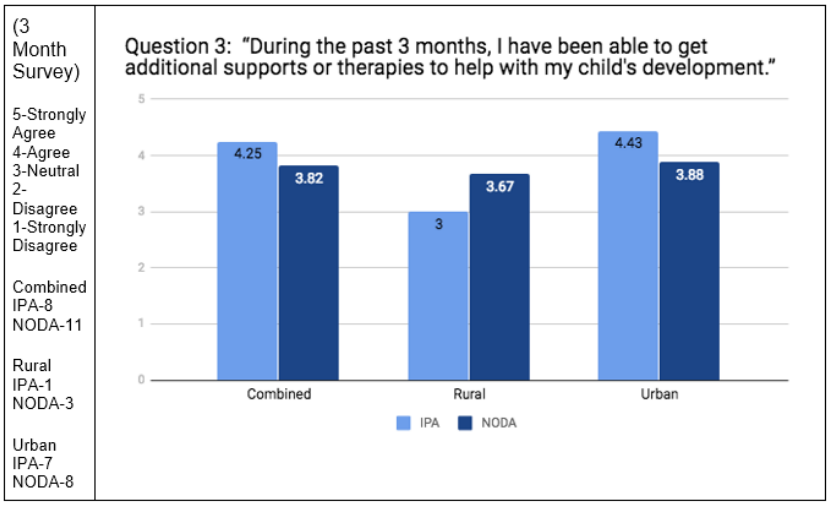


Figure 6. Summary of post-participation questionnaire responses addressing the recommendations received and the value of information received as a result of the diagnosis.

The 3-month post-participation survey responses also indicated that, with regards to additional support and therapy in the future, parents who received a diagnosis using the IPA approach expressed slightly higher satisfaction than the parents who experienced the NODA method. This is summarized in Figure 7.



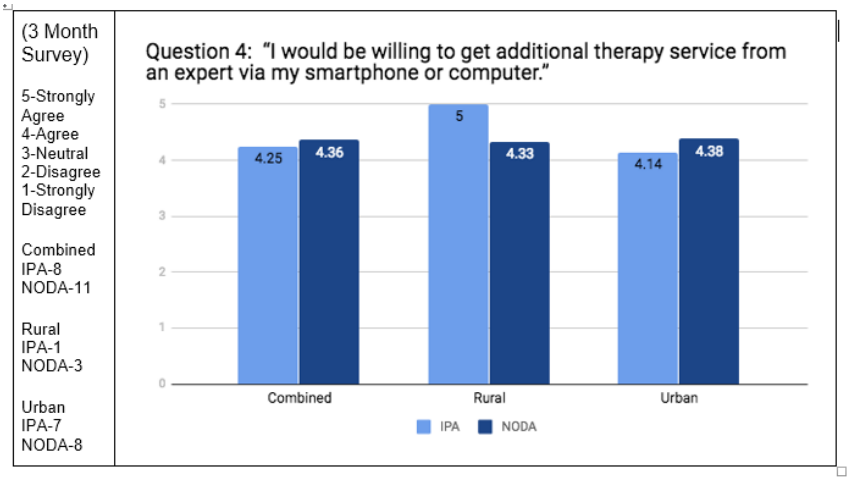


Figure 7. Summary of post-participation questionnaire responses addressing additional support or therapies and willingness to obtain additional services via smartphone or computer.

1. Post-Participation Written Comments

The post-participation survey provided an opportunity for families to comment in written form. The comments were grouped into “positive” and “negative” response categories as shown in Figure 8 and Figure 9.

Positive Comments

NODA (Month-3 Survey)

#	Statement	Frequency
1	Got the "ball" rolling	1
2	This is a very useful tool	2
3	Liked the assistance I received	1
4		

IPA (Month-3 Survey)

#	Statement	Frequency
1	Good experience	2
2	Received helpful feedback	1
3	Diagnosis allowed us to obtain additional therapies	1
4		

Figure 8. Positive written comments received regarding the NODA and IPA methods

Negative Comments

NODA (Month-3 Survey)

#	Statement	Frequency
1	Video system did not allow presentation of important concerns	2
2		
3		
4		

IPA (Month-3 Survey)

#	Statement	Frequency
1	Still confused about getting the appropriate assessment done	1
2	Not sure what to do in the future	1
3		
4		

Figure 9. Negative written comments received regarding the NODA and IPA methods

The positive written survey responses from both the NODA and IPA families confirmed the importance family engagement in the assessment process. The negative responses indicated the need for technology support and guidance beyond the diagnosis.

Analysis:

Time Required for ASD Assessment:

The time differences between the IPA process and NODA method to achieve an ASD assessment demonstrates an advantage offered by the NODA approach in comparison to the IPA method. The NODA clinician's ability to review developmental history and directly observe behaviors exhibited by a child from the child's naturalistic (home) setting, captured and transmitted remotely by families, provides a clinician earlier access to meaningful contextual data of a child that legitimizes a confident assessment of autism when present. Therefore, observation of atypical behaviors at home is a valuable tool in conducting an ASD assessment. This not only adds simplicity to the assessment process but shortens the time required to complete an assessment remotely. This time advantage was clearly demonstrated in this study.

To study specifically the critical path of 'clinician time' to perform diagnostic evaluations, we also calculated the average time taken by the family to register with the NODA app, complete the developmental questionnaire, collect and transmit their video samples (see Figure 2: Videos/Health history submitted). This allows an even more dramatic comparison of Time to Diagnosis, if future studies justify that 'wait time' is better analyzed starting from the time families share their behavior examples and developmental history.

Other Clinician Findings / Feedback:

One unexpected finding was that the clinicians appreciated the NODA clinical-tagging system enough - that Emory recommended that BIS adopt the CDC-related tagging system (used in ADDM) for autism surveillance. NODA 2.0 will incorporate the CDC / ADDM specific tags in future commercialized versions of NODA to offer additional evidence-supported clinical decision support tools.

Survey Responses:

Regarding family's social validity, the first survey responses indicated that for the three questions presented, the families choosing the IPA approach anticipated slightly more information, more value and more simplicity from the IPA approach than did the families assigned to the NODA method. This difference was seen for both the rural families and the urban families.

The 3-month post-participation survey responses indicated that, for the four questions presented, the families assigned to the IPA approach and the NODA method had similar opinions with regards to the simplicity and value of the information gained based on their experience with either the IPA process or the NODA method.

The 3-month survey responses also indicated that although small completed surveys can't substantiate this statistically, with regards to additional support and therapy in the future, parents had slightly higher correlation with getting services who were in the NODA group. However, parents who received a diagnosis using the IPA approach expressed slightly higher satisfaction than the parents who experienced the NODA method.

The positive written survey responses from both the NODA and IPA families confirmed the importance of family engagement in the assessment process. The negative responses indicated the need for technology support and guidance beyond the diagnosis.

Biostatistical Observations

Time Required for ASD Assessment:

We consider these data to be highly reliable since they rely only on recording the day of entering into the study and the day on which a first diagnosis was made. We assume data are normally distributed. Our data indicate that Standard Deviation (SD) for both IPA and NODA procedures is about 3/4 of the mean. We can use the t-test of difference between two means to estimate the level of confidence in results. With n = 28, we achieve a level of confidence of 99% and a power of 99%.

Thus, we conclude with very high confidence that the NODA procedure provides the important benefit of a shorter time to obtain a diagnosis as compared with the traditional IPA procedure.

Survey Responses:

In general, survey responses are often based upon personal biases instead of hard numbers. Statistically-valid conclusions of our data were not possible because of (1) number of responses, and (2) similarity of responses, i.e., mean and SD of responses of IPA families were closely similar to those of NODA families. We conclude that findings cannot be regarded with reasonable confidence levels. Based on rural (n=11) families who completed assessments, we acknowledge that it is not possible to make statistically-based comparisons unless many more responses were to be obtained. That said, the findings learned from this group still suggests increased barriers to this group, and how NODA is a viable method to overcome these barriers.

Conclusion:

The data obtained in the Phase II study showed that the NODA program offered a notable time advantage over the traditional IPA method. This is important because NODA was conducted remotely which allowed families to access clinical ASD diagnostic assessment services outside of their geographic locations. Furthermore, the post-study survey indicated that the level of satisfaction expressed by families using the NODA program was similar to the satisfaction expressed by families who completed the assessment using the traditional IPA method. The positive outcome indicates that the use of the NODA program in the future should be able to benefit autism families regionally or nationally, and potentially internationally.

Appendix 1 – Informed Consent Sample

Emory Autism Center – Emory University

Title: Evaluating technologies for clinician-directed in-home capture to support clinical assessments

Principal Investigator: Michael J Morrier, PhD, BCBA-D, Emory Autism Center, Department of Psychiatry & Behavioral Sciences, Emory University School of Medicine

Funding Source: Behavior Imaging Solutions Inc. through funds received from National Institutes of Health

Introduction
You are being asked to be in a research study. This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study. It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.
This study is a collaboration between researchers at the Emory Autism Center (EAC), Department of Psychiatry & Behavioral Sciences, Emory University School of Medicine (Georgia), Behavior Imaging Solutions Inc. (BIS) (Idaho), a company that develops technology to help support children with disabilities and their families, the Southwest Autism Research and Resource Center (SARRC) (Arizona), St. Luke's Medical Center (Idaho), and University of Idaho (Idaho).

Before making your decision:
Please carefully read this form or have it read to you
Please ask questions about anything that is not clear

Things to know before deciding to take part in a research study:
The main goal of a research study is to learn things to help patients in the future.
Your participation in this study is voluntary. You do not have to be in this study if you don't want to be.
You have the right to change your mind and leave the study at any time without giving any reason and without penalty.
Any new information that may make you change your mind about being in this study will be given to you.
You do not waive any of your legal rights by signing this consent form.

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. By signing this form you will not give up any legal rights.

Study Overview
Twenty subjects will be recruited from the Emory site, with 10 subjects from rural areas and 10 subjects from urban areas of Georgia. A total of 80 subjects will be recruited from the four clinical sites participating in this study. Half the subjects will be from rural areas and half from urban areas. Participants will be expected to participate for the length of the assessment protocol assigned, plus three months in order to determine effects of assessment process on beginning treatment.

Understanding behavior in its natural environment is valuable for clinical assessment. BIS and SARRC designed a system that parents can use at home to record their child's behaviors and share the recordings with professionals who assess and diagnose autism. The professionals will log on to a special secure website to view the recordings and note behaviors that may suggest autism. The goal of this study is to see if this method of diagnosis can make the diagnostic process for autism spectrum disorder (ASD) more efficient when compared to the in-person assessment.

Procedures
If you agree to be in this study, you will be assigned to one of two study groups. Group assignment will be determined by randomization completed by BIS based on your child's age, gender, and rural/urban status. One group will complete the procedures for the in-person assessment at the EAC, and the other group will complete the diagnostic procedures for the remote diagnostic assessment.

Group 1: Remote Diagnostic Assessment

The remote diagnostic assessment group will follow these procedures:
use our video recording system installed on a smart phone in your home, over a period of 2-3 days.
record your answers to brief questions about your child's development.
record four 10-minute video clips of your child. These include: family meal time, your child playing with his or her sibling (or with you, if there are no siblings), your child playing alone, and any behavior or situation that is of concern to you about your child. In each scenario there will be simple instructions for you to follow.
When you are finished recording a scenario, the system will prompt you to upload the video so a clinician can review it. You can choose to delete the video and record it again.

Study staff at EAC or any of the other sites in this project will review the video clips you record and upload. They will use a special secure website to watch the videos and to mark behaviors that are associated with autism. These professionals will not know your name or location unless you say it on the video, but they will see you and your child on the video. These clinicians may message you through the smart phone system and ask you for more information or additional videos.

After the videos are reviewed, a staff member will call you to review the results with you and discuss your next steps. You will receive a final report that summarizes the results of the evaluation.

You will complete a brief questionnaire about your experience using the system.

You will be contacted by phone three months after you receive the report and will be asked a few questions about your experiences since the evaluation.

At the end of the remote diagnostic procedure you may also participate in the in-person assessment procedures if you choose.

Group 2: In-person Assessment Group

If you are in the in-person assessment group, you (and your child) will visit EAC and complete the following procedures:

Prior to the assessment
complete a form detailing your child's developmental history
complete rating scales on behaviors that your child may be showing (30-45 minutes)

On the day of the assessment
a direct observation of your child interacting with a staff member to play with toys, books, and puzzles, and answer some questions (45 minutes)
a receptive language assessment completed with your child (20 minutes)
direct observation of your child with same-aged un familiar children at an on-site early childhood center (15-20 minutes)
an interview about your about your child's development (1.5 hours)
a questionnaire about your child's adaptive behavior in communication, daily living skills, socialization, and motor skills completed by you (approximately 30-45 minutes)

Finally, we may ask you to give us copies of any diagnostic records you have for your child or to authorize your clinician to release a copy of your child's diagnostic records to us. Separate from this consent form, we will ask you to sign a HIPAA Authorization Form to allow any outside physicians or clinicians to release this information to us.

After the assessment is completed, a report will be provided to you and/or your pediatrician. A staff member will review the report with you.

You will be asked to complete a brief questionnaire about your experience using the system.

You will be contacted by phone three months after you receive the report and will be asked a few questions about your experiences since the evaluation.

Risks and Discomforts
The risks involved are no greater than those involved in daily activities at home, such as playing and watching TV, and those associated with a routine developmental evaluation

Potential emotional risks include:
your child becomes uncomfortable or self-conscious about being recorded on video, or
accidental recording of something the family doesn't want others to see, or
parents may become distressed when they find out their child meets criteria for ASD.

You can delay/stop recordings if your child becomes uncomfortable during the video recording. Additionally, you will have the option to delete the video if it includes something that makes you or your child uncomfortable.

There is a risk of loss of confidentiality from your participation in this research study.

New Information
It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Benefits
This study is designed to benefit you directly by providing information on if your child meets the diagnostic criteria for autism spectrum disorder as specified by the DSM-5. This study is designed to learn more about the quickest way to help families receive a diagnosis of ASD. The study results may be used to help others in the future.

In addition, an experienced clinician with expertise in ASD will fully explain the results of the evaluation and provide you with guidelines about your next steps to take for seeking appropriate treatment. Ask your study doctor how long it will take to receive your evaluation.
However, there is no guarantee you or your child will benefit by participating in this study.

You will be assisting in the development of a system that will help parents to record their child's behaviors of concern and share it with clinicians for assessment purposes.
Compensation
You will not be offered payment for being in this study. There will be no cost to you to participate in this study.

For those in the remote diagnostic assessment group, you may complete an additional in-person assessment if you wish after the remote assessments have been completed. The cost would be $1,500 to be paid by you and the EAC will assist with getting you reimbursed by your insurance provider, although reimbursement cannot be guaranteed.
Other Options Outside this Study
If you decide not to enter this study, there is care available to you outside of this research. The EAC will provide you with a list of outside agencies and individual providers that are able to provide comprehensive diagnostic assessments for ASD. We will discuss these with you. You do not have to be in this study to be treated for ASD OR to get an assessment for potential ASD or to receive services through any of the EAC clinical programs.
Confidentiality
Certain offices and people other than the researchers may look at study records. Government agencies and Emory employees overseeing proper study conduct may look at your study records. These offices include the Office for Human Research Protections, the funder(s), the Emory Institutional Review Board, the Emory Office of Research Compliance. Study funders may also look at your study records. Emory will keep any research records we create private to the extent we are required to do so by law. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might point to you will not appear when we present this study or publish its results.

The data collected in this study will be shared among researchers at EAC, BIS, SARRC, St. Luke's Hospital, and the University of Idaho. Hard copy data with names, ages, and dates of birth will be stored in locked filing cabinets in locked rooms at EAC. Each family will be issued a unique identification number that is not based on any of their family information. Family background information and data from diagnostic assessments will be entered into password-protected electronic data files, with only the ID number. All video/audio recordings will be saved under the ID number only. At EAC, electronic data and video/audio recordings will be saved on a password protected limited

access drive on a password-protected computer. Your home video recordings will be viewed by clinicians or other health professionals who are participating in this study. These clinicians will be able to watch the videos by logging into a secure online portal maintained by Behavior Imaging Solutions (BIS). The videos will be stored on a HIPAA-conforming server at BIS. Clinicians will not be able to download the videos, only to view them.

Absolute confidentiality cannot be guaranteed because of the need to give information to these parties. The results of this research study may be presented at meetings or in publications. Your identity will not be disclosed in those presentations.

Sharing Your Videos in Public
When we present the results of this research, it may be important for us to share the videos we collect from you or your family during presentations in classrooms or conferences or training meetings. We will not share your name or associated identifying information, but we may share your videos which does include identifying information.

If you want to give your permission to show your videos at these meetings, please initial below. If you do not initial, we will not use your videos for any other purpose other than the research study. We will still share your videos with other researchers in this study.

I give permission for the researchers to use my videos recorded for this study for presentations and trainings.

Please initial your choice: YES_____

NO_____

Additional Consent to Share Data for Research Purposes
We will keep all the recordings as long as we think they can be used in research and training. When the study is over, we will save the recordings indefinitely. We may need to share data from this project with other collaborating researchers.

I give permission for the researchers to share my video and audio recordings and any associated data with other researchers who are interested in collaborating on this study.

Please initial your choice: YES_____

NO_____

Study records can be opened by court order. They may also be produced in response to a subpoena or a request for production of documents.

Authorization to Use and Disclose Protected Health Information
The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the study.

PHI that Will be Used/Disclosed:
The PHI that we will use or share for the main research study includes:
Medical information about you including your medical history and present/past medications.
Results of exams, procedures and tests you have before and during the study.
Diagnostic test results.

Purposes for Which Your PHI Will be Used/Disclosed:
We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information. We will use and disclose your PHI for the administration and payment of any costs relating to subject injury from the study.

Use and Disclosure of Your Information That is Required by Law:
We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

Authorization to Use PHI is Required to Participate:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not sign this form, then you may not participate in the research study or receive research-related treatment. You may still receive non-research related treatment.

People Who will Use/Disclose Your PHI:
The following people and groups will use and disclose your PHI in connection with the research study:
The Principal Investigator and the research staff will use and disclose your PHI to conduct the study and give you study related treatment.
Emory may use and disclose your PHI to get payment for study related treatment and to run normal business operations.
The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
Behavior Imaging Solutions Inc. and NIH are the Sponsors of the study. The Sponsors may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
The following people and groups will use your PHI to make sure the research is done correctly and safely:
Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
Government agencies that regulate the research including: Office for Human Research Protections.
Public health agencies.
Research monitors and reviewer.
Accreditation agencies.

Expiration of Your Authorization
Your PHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at: (404) 727-8350 or assessment.eac@emory.edu.

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them. The Sponsor, and people and companies working with the Sponsor on this study are not covered by the Privacy Rules. They will only use and disclose your information as described in this Consent and Authorization.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Voluntary Participation and Withdrawal from the Study
Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

The researchers and funder also have the right to stop your participation in this study without your consent if:
They believe it is in your best interest;
You were to object to any future changes that may be made in the study plan;
or for any other reason.

Contact Information
Contact Dr. Michael J Morrier at (404) 727-8350 or assessment.eac@emory.edu:
if you have any questions about this study or your part in it,
if you feel you have had a research-related injury, or
if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:
if you have questions about your rights as a research participant.
if you have questions, concerns or complaints about the research.
You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

Consent & Authorization
I have read this consent form (or it has been read to me). Please, print your name and sign below if you agree to be in this study. By signing this consent form, you will not give up any of your legal rights. We will give you a copy of the signed consent, to keep.

_____
Name of Subject

_____ _____
Signature of Subject Date Time

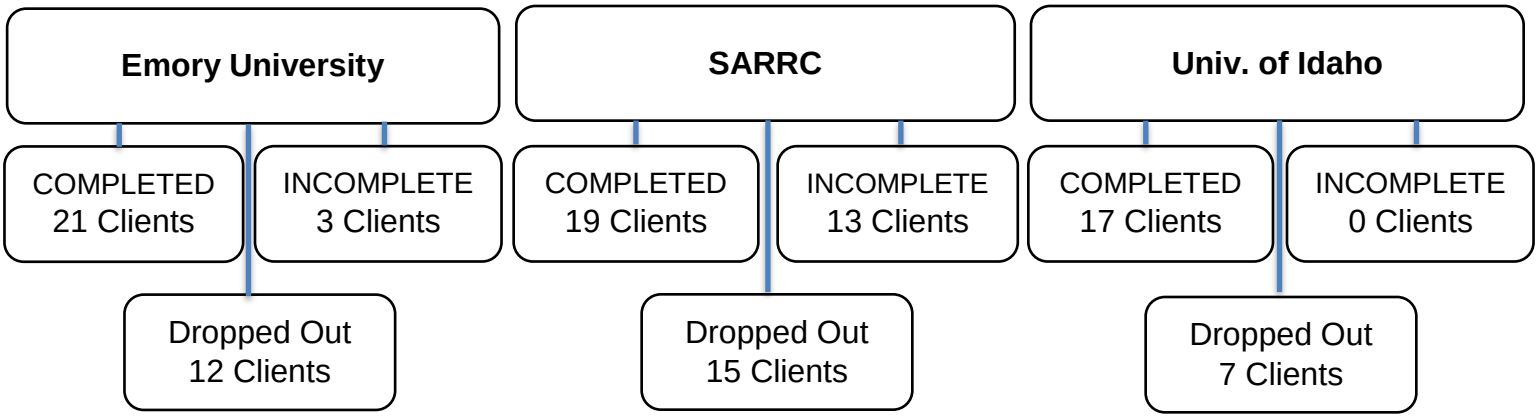
_____ _____
Signature of Person Conducting Informed Consent Discussion Date Time

_____ _____
Signature of Legally Authorized Representative Date Time

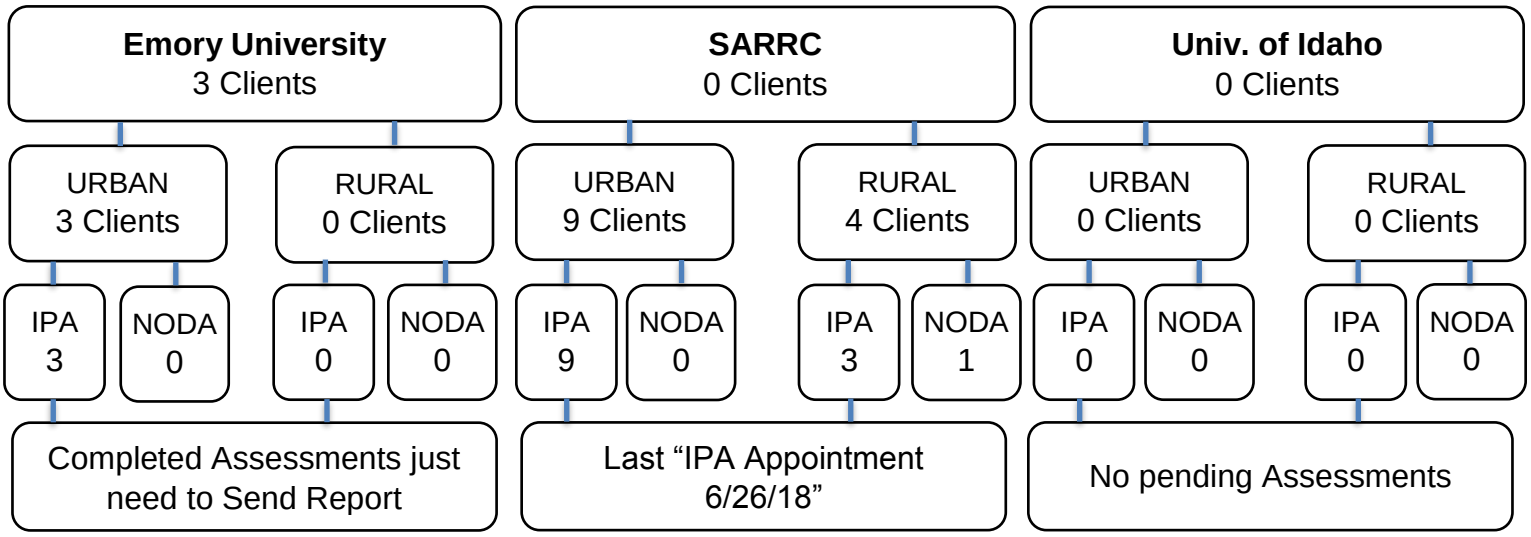
_____
Authority of Legally Authorized Representative or Relationship to Subject

Appendix 2 – NODA vs IPA Recruitment Data per Site

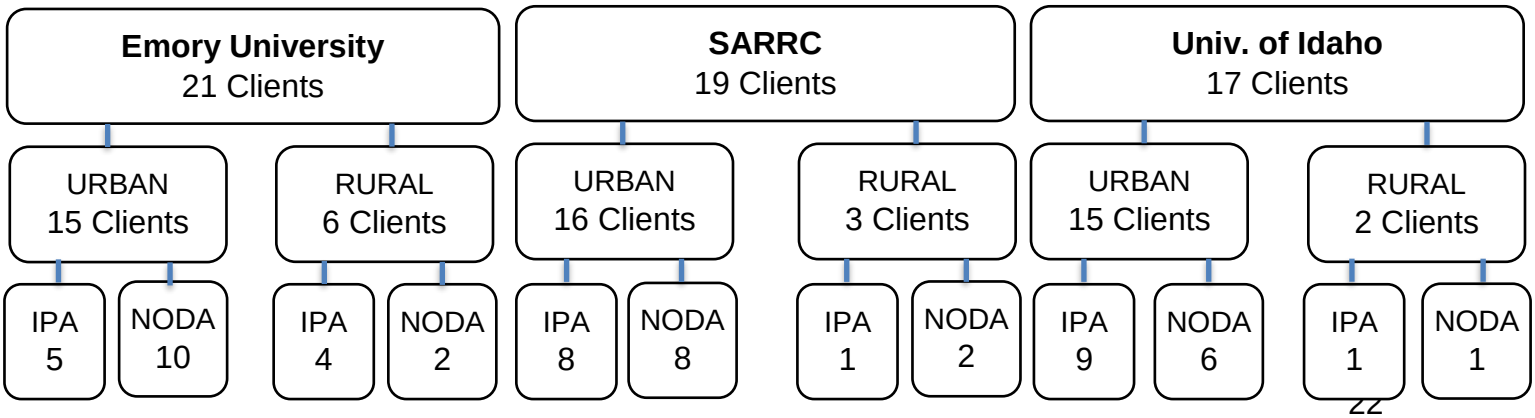
Summary of Client Recruitment per Site



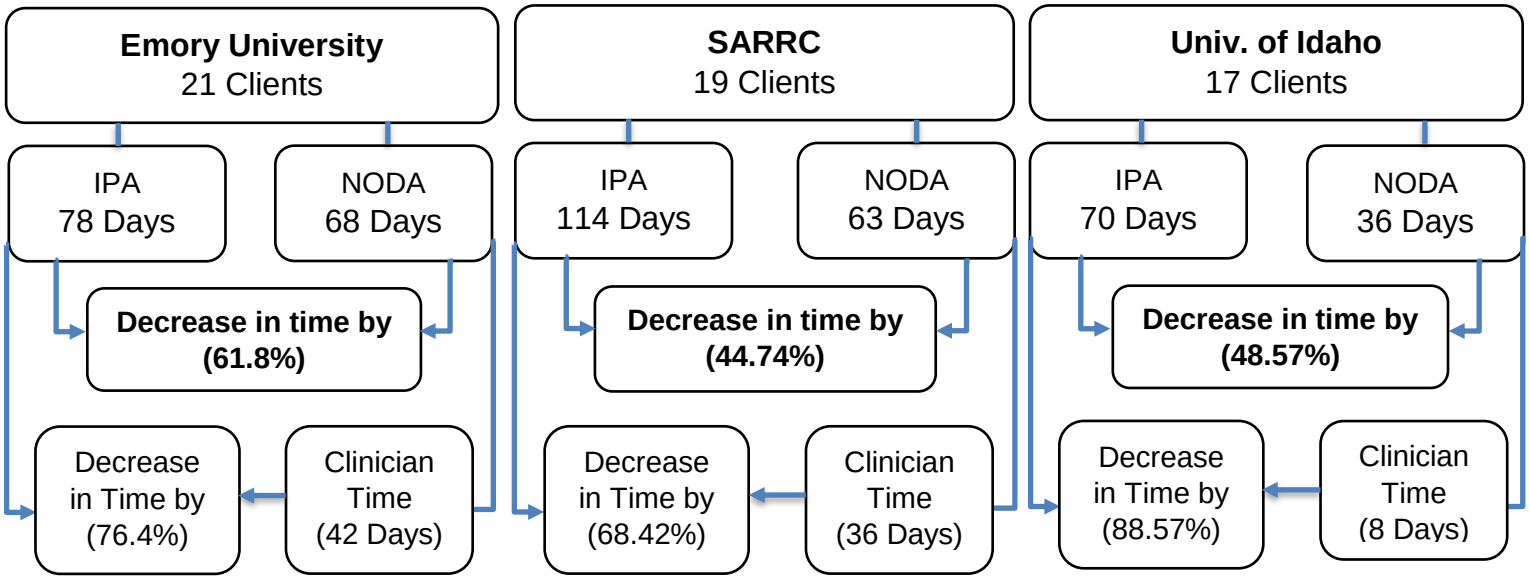
Incomplete Client Assessments per Site

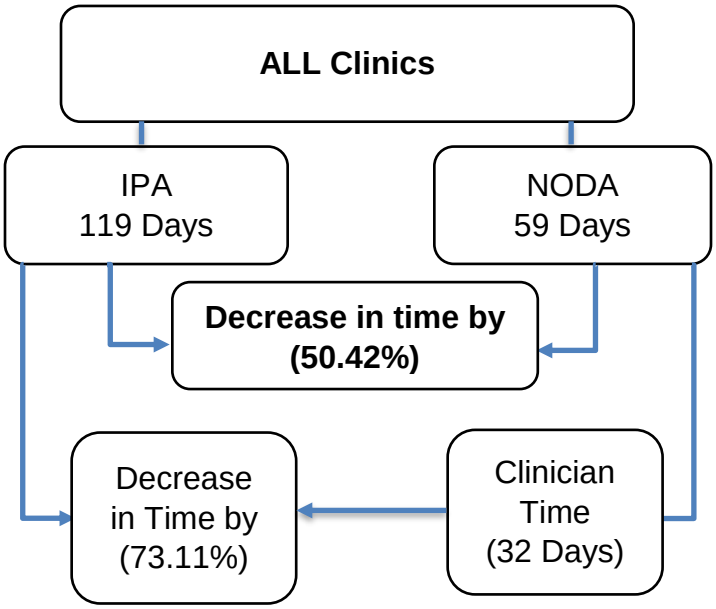


Completed Assessments – Urban vs Rural per Site



Completed Assessments – Time difference per Site





Appendix 3 - Presentations / Publications

Proposed Publications

- Comparing InPerson and NODA Autism Diagnostic Assessments for Urban and Rural Families with At-risk Children for Autism – Oberleitner et al., TBD
- Receptivity of InPerson vs. SmartPhone-enabled approaches for Autism Diagnostic Assessments – Univ of Idaho and Co-authors, TBD

Presentations / Distinctions

- Oberleitner, R, Pre-IMFAR Meaningful Outcomes Symposium : 'Earlier and Cost-Effective Diagnostic Assessments', San Francisco, CA, May 12, 2017
- Smith, Christopher J., Arizona ACCSS (Medicaid) Medical Directors – 'NODA as a Methodology for Diagnosis in Arizona', Phoenix, AZ, October 4th, 2017
- Mitchell, Gwen, Fodor, Julie, PacRim Disability Conference: ""Autism Diagnosis in the Child's Natural Setting" Gwen Mitchell, Julie Fodor, Honolulu, HI October 10, 2017
- Mitchell, Gwen, Fodor, Julie, Association of University Centers on Disability Annual Meeting: ""Autism Diagnosis in the Child's Natural Setting" Gwen Mitchell, Julie Fodor, Washington DC, November __, 2017
- Rice, C., Morrier, M. – 'APA (Psychology) Technology for Future' APA, Washington DC, April 2018 (not accepted)
- Smith, C., NODA Initial Validation Study, Implications for International Use, Riyhad, Saudi Arabia
- Behavior Imaging / NODA named 'Best Patient Engagement Solutions 2017' HealthTech Magazine Fall, 2017
- Comparing InPerson and NODA Autism Diagnostic Assessments for Urban and Rural Families with At-risk Children for Autism (poster) – Oberleitner et al., Telemedicine & Telehealth Service Provider Summit (SPS), Glendale, AZ, October 8-9, 2018

Appendix 4 – Enrollment Report Summary

View Burden Statement

PHS Inclusion Enrollment Report

This report format should NOT be used for collecting data from study participants.

OMB Number: 0925-0001 and 0925-0002
Expiration Date: 10/31/2018

***Study Title (must be unique):** Rural NODA Phase II

* Delayed Onset Study? ☐ Yes ☒ No

If study is not delayed onset, the following selections are required:

Enrollment Type	☐ Planned	☒ Cumulative (Actual)
Using an Existing Dataset or Resource	☒ Yes	☐ No
Enrollment Location	☒ Domestic	☐ Foreign
Clinical Trial	☐ Yes	☒ No

NIH-Defined Phase III Clinical Trial ☐ Yes ☒ No

Comments: This table is for caregivers and research subject combined for all 3 research sites

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	5	6	0	0	0	0	0	0	0	11
Asian	2	1	0	0	0	0	0	0	0	3
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	17	17	0	0	1	0	0	0	0	35
White	48	51	0	22	10	0	0	0	0	131
More than One Race	3	9	0	0	1	0	0	0	0	13
Unknown or Not Reported	0	0	0	0	0	0	18	12	0	30
Total	75	84	0	22	12	0	18	12	0	223

Report 1 of 1

< Previous Report | Delete Report | Next Report >

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