PROTOCOL TITLE:

Autism Spectrum Disorder Behavior Study

PROTOCOL VERSION/AMENDMENT # AND DATE

December 3, 2024

PRINCIPAL INVESTIGATOR:

Hants Williams

1.0 Objectives

1.1 Describe the purpose of this research. Explain why it is important to do the study. If there are hypotheses, please list them here.

The objective of this study is to perform a systematic literature review on the impact of machine learning in relationship with ASD. This paper will analyze the current existing literature and expand on the research question on the impact of bio-wearable technologies and reported physiological indicators in predicting 'challenging' behaviors in the population with ASD as well as using wearable technologies to aid in diagnosing autism. By evaluating the current state of research, we aim to identify gaps and opportunities for future studies.

2.0 Background

2.1 Provide the scientific or scholarly background, rationale, and significance of the research based on the existing literature and how it will contribute/fill in gaps to existing knowledge. Include complete citations or references:

Autism Spectrum Disorder (ASD) is a disease that impacts individuals neurologically and developmentally. It can pose challenges for children in developing social and cognitive skills which results in communication problems, restricted interest, difficulty in social interactions, and long-term effects [1,2,3]. Oftentimes, individuals with autism will have unusual behavior patterns or display stereotypic behaviors therefore, it is essential to be able to understand their behaviors and predict when these behaviors will come up so that people around them can better prepare and help them [5]. It is also important for individuals to be detected for ASD early because early diagnosis can allow individuals to get treatment early which is beneficial for prognosis [2]. Limited studies have been done to address technologies that can be used to improve diagnosing individuals with ASD as well using these technologies to enhance the prediction of behaviors in individuals [1,4].

According to studies, the current types of diagnosis for ASD is lengthy, time consuming, and not as cost effective because it takes a lot of time to observe an individual to be able to diagnose them with ASD. In addition, sometimes misdiagnosis can also happen with the current forms of diagnosing ASD resulting in individuals not getting the right treatments [6]. Studies have shown however, that machine learning can make diagnosing ASD more efficient and more accurate. They developed different devices that may be able to help detect autism and may even be able to help people in predicting when autism 'challenging' behaviors will happen. For example, the use of facial detection technology like motion capture and computer vision, mood detection technology, and passive technologies which include smart wearable shirts and vests.

3.0 Study Design

3.1 Describe the study design (e.g., case-control, cross-sectional, ethnographic, longitudinal, and observational).

This study design is an ethnographic quantitative research study which includes observation of participants, field notes, and data collection.

4.0 Local Number of Participants

4.1 Indicate the total number of participants who will be enrolled or records that will be reviewed.

The total number of participants who will be enrolled is undetermined as of this moment.

4.2 Indicate whether you are specifically recruiting or targeting any of the following special populations in your study using the checkboxes below.

- ☒ *Adults unable to consent*
- ☐ *Minors (under 18 years old)*
- ☒ *Pregnant women*
- ☐ *Prisoners*

4.3 Indicate if you will include minorities (American Indians, Alaskan Native, Asian, Native Hawaiian, Pacific Islander, Black [not of Hispanic origin] and Hispanic) as Federal mandates require that you include minorities unless you can justify their exclusion

Minorities are included in this study.

4.4 Indicate whether you will include non-English speaking individuals in your study. Provide justification if you will specifically exclude non-English speaking individuals. Following approval of the English versions, you must submit the translated materials (consent and assent forms, questionnaires, etc) with the translation attestation for approval.

Non-English-speaking individuals are included in the study.

5.0 Recruitment and Screening Methods

5.1 Describe source of participants: when, where, and how potential participants will be recruited. Include age range of participants as well as other inclusion/exclusion criteria. NOTE: Recruitment can include, but is not limited to: West Campus departmental pools, research participant groups/help groups, advertising companies, call centers, in person announcements / presentations. If you are using a recruitment or screening tool, upload the tool. These can include flyers, questionnaires, posters, letters or written material to be sent or emailed, pamphlets, posted advertisements, email invitations, etc.

The participants will be from the Nicholas Center which is a non-profit organization located in Port Washington. The age range of the participants are adults 21 years of age and older. Inclusion criteria includes individuals who are currently in the Nicholas Center for ASD treatment and individuals who are employed by the Nicholas Center . Exclusion criteria includes individuals outside of the Nicholas Center.

5.2 Describe how you will protect the privacy interests of prospective participants during the recruitment and screening process).

The privacy of the prospective participants will be protected under the Health Insurance Portability and Accountability law which protects the privacy of an individuals' health information under the privacy and security rules. Prior to starting the investigation members of our team went through HIPAA training to ensure the importance of protecting participants' information and signed a consent form.

6.0 Research Procedures

6.1 Provide a detailed description of all research procedures or activities being performed on/by the research participants (what will occur, where each activity will occur, etc.). This should include enough detail so that another investigator could pick up your protocol and replicate the research. If the study includes an intervention, please describe the intervention (e.g., subjects play an on-line game, solve puzzles under various noise conditions, etc.).

Behavioral therapists will be recording the participants' actions and speech throughout their 8 hour day doing many different tasks and activities.

6.2 Describe what data will be collected.
List, and upload, any instruments or measurement tools used to collect data (e.g., surveys, scripts, questionnaires, interview guides, validated instruments, data collection forms).

The data being collected include scripts, recording, data collection forms, and google appsheet.

6.3 Describe any source records that will be used to collect data about participants (e.g. school records, electronic medical records) and include the date range for records that will be accessed.

Source records that are collected include participants' previous notes taken by the behavioral clinicians during their past visits and data from google appsheets.

6.4 Indicate if subjects will be deceived regarding the nature or purpose of the research.

☒ *No*
☐ *Yes*

7.0 Study Timelines

7.1 Describe the duration of an individual participant's participation in the study. Include length of study visits.

Each participant will be at the Nicholas Center for 8 hours a day from 9am to 5pm Monday through Friday. It is an ad hoc process as it is non-standardized and designed to address specific issues as needed.

8.0 Other Approvals

8.1 List approvals that will be obtained prior to commencing the research (e.g., school, external site, funding agencies, laboratory, University Hospital, Cancer Center).

Approvals that will be obtained prior to commencing the research would be from the Nicholas Center which is an external site and Stony Brook University.

9.0 Data Management and Analysis

9.1 Describe the data analysis plan, including any statistical procedures. This section applies to both quantitative and qualitative analysis.

Data will be provided to us by Tom Forth, who volunteered as an information technology consultant for the Nicholas center and helped build current quality of life applications. Ethnographic data will be collected during the field visit and research will be implemented through pubmed articles.

10.0 Confidentiality

Data

10.1 Where and how will all data and records be stored? If the research involves the access, use, or disclosure of Protected Health Information (PHI), please indicate. Include information about password protection, encryption, physical controls, authorization of access, certificates of confidentiality, and separation of identifiers and data, as applicable for both paper and electronic files.

All data and records will be stored electronically in the quality of life app and google appsheets.

10.2 Who will have access to the data?

Staff at the Nicholas Center including the behavioral specialist, Jeremy Scalchunes the associate executive director of programs at the Nicholas Center, Tom Forth an outside consultant who volunteered at the Nicholas Center, members of our team, and our lead investigator Hants Williams will have access to the data.

10.3 How will the data be transported/transmitted?

Data will be transported through the quality of life app and google appsheets.

*10.4 Describe the procedures for maintenance of security and confidentiality of **patient records** that will be reviewed for data collection.*

Patient records are stored in the Nicholas Center's secure computer which requires a Duo login for the quality of life app. The patient records are protected under the HIPAA complaint and a consent form is filled out.

10.5 Will a waiver, partial waiver, or alteration of HIPAA authorization be needed?

Waiver, partial waivers, or alteration of HIPAA authorization will not be needed in this research.

If requesting a waiver or alteration of HIPAA authorization, please confirm the following

- ☐ *There is an adequate plan to protect the identifiers from improper use and disclosure*
- ☐ *There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.*
- ☐ *There is adequate written assurance that the PHI will not be reused or disclosed to any other person or entity, except as required by law for authorized oversight of the research project, or for other research for which the use or disclosure of PHI would be permitted*
- ☐ *The research could not practicably be conducted without the waiver or alteration*
- ☐ *The research could not practicably be conducts without access to and use of the*

Specimens

☒ **No specimens will be collected or analyzed in this research.**

10.6 Where and how will all specimens be stored? Include information about physical controls, authorization of access, separation of identifiers and specimens and labeling of specimens, as applicable.

No specimen will be collected in this study.

10.7 How long will the specimens be stored?

No specimen will be stored in this study.

10.8 Who will have access to the specimens?

No specimen will be used in this study.

11.0 Compensation for Participation

11.1 Describe the amount/nature and timing/scheduling of any compensation to participants, including monetary, course credit, or gift card compensation.

There will not be any compensation for participating in this research.

11.2 Participation in studies may be offered for credit in class but students MUST be given other options for fulfilling the research component that are comparable in terms of time, effort,

and education benefit. List alternative activities and who to contact about completing alternative activities below and in the consent document.

There will not be any compensation for participating in this research.

12.0 Informed Consent

12.1 Describe the consent process that will be conducted to ensure that participant is fully informed regarding study details and participant rights. Include where the consent process will take place with consideration of the need to protect the subject's right to privacy.

Participants will sign a document before their session with their clinician regarding what types of data will be collected from them and how the data will be collected. The document will include any risk associated with the study.

12.2 Describe how you will ensure that participants are provided with sufficient time to consider taking part in the research study. Detail if there is an expected time period between informing the prospective participant and obtaining the consent. If participants who do not speak English will be enrolled, describe the process to consent the participants, as well as the process to be used to ensure their understanding of the research

Participants will be allowed one week to consider and talk to friends and family if they want to take part in this research study to ensure they have sufficient time to decide. If participants who do not speak English are to be enrolled, a translator will be present to translate and describe the process to ensure that they understand this research before they consent to participating.

13.0 Consent Waiver Request for Secondary Research

Note: *This section is not applicable if the secondary research plan involves only the collection of* ***retrospective*** *(already available as of the date of initial IRB submission) data and/or biospecimens.*

For studies that involve collection of prospective data and/or biospecimens, please fully address each criterion below (ALL must be met for exemption of secondary research):

Have yet to be determined at this point.

☐ *The research involves no more than minimal risk.*

Please explain: N/A

☐ *The waiver will not adversely affect the rights and welfare of the subjects.*

Please explain: N/A

☐ *The research could not practicably be carried out without the waiver.*

Please explain: N/A

☐ *If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.*

Please explain: N/A

☐ *Whenever appropriate, the subjects will be provided with additional pertinent information after participation.*

Please explain: N/A

14.0 Multi-Site Research (Multisite/Multicenter Only)

14.1 If this is a multi-site study where SBU is the lead site and/or the IRB of record, describe the processes to ensure communication among sites. Include:

- *All sites have the most current version of the IRB documents, including the protocol, consent document, and HIPAA authorization.*
- *All required approvals have been obtained at each site (including approval by the site's IRB of record).*
- *All modifications have been communicated to sites, and approved (including approval by the site's IRB of record) before the modification is implemented.*
- *All engaged participating sites will safeguard data as required by local information security policies.*
- *All local site investigators conduct the study appropriately.*

All sites have the most current version of the IRB documents which includes the protocol consent document and HIPAA authorization.

References:

[1] Alcaniz, M., Chicchi-Giglioli, I. A., Carrasco-Ribelles, L. A., Marin-Morales, J., Teruel-Garcia, G., Sirera, M., & Abad, L. (2021). Eye gaze as a biomarker in the recognition of autism spectrum disorder using virtual reality and machine learning: A proof of concept for diagnosis. *PubMed Central*. 10.1002

[2] Banos, O., Comes-Gonzalez, Z., Medina, J., Polo-Rodriguez, A., Gil, D., Peral, J., Amador, S., & Villalonga, C. (2024). Sensing technologies and machine learning methods for emotion recognition in autism: Systematic review. *International Journal of Medical Informatics*, *187*. ScienceDirect. 10.1016

[3] Farooq, M. S., Tehseen, R., Sabir, M., & Atal, Z. (2023, June 13). Detection of autism spectrum disorder (ASD) in children and adults using machine learning. *PubMed Central*. 10.1038/s41598-023-35910-1

[4] Nabil, M. A., Akram, A., & Fathalla, K. M. (2021). Applying machine learning on home videos for remote autism diagnosis: Further study and analysis. *Health Informatics Journal*. sagepub. 10.11771460458221991882

[5] Siddiqui, U. A., Ullah, F., Iqbal, A., Khan, A., Ullah, R., Paracha, S., Shahzad, H., & Kwak, K.-S. (2021, May 11). Wearable-Sensors-Based Platform for Gesture Recognition of Autism Spectrum Disorder Children Using Machine Learning Algorithms. *PubMed Central*. 10.3390/s21103319

[6] Thabtah, F. (2019). An accessible and efficient autism screening method for behavioural data and predictive analyses. *Health Informatics Journal*, *25*. sagepub. 10.1177/1460458218796636