The following includes the full study protocol for project
"Transitioning Together: Development of a Family-Based Transition Planning Program for Culturally-Diverse Youth on the Autism Spectrum" (NCT05965648)
Protocol most recently approved by the Boston University Charles River IRB on August 21, 2023

BU Charles River IRB
Application Form (Full Board and Expedited Review)

SECTION A: PROTOCOL AND CONTACT INFORMATION

Protocol Title:	Development of a new family-focused transition program
Principal Investigator **(Name, degrees, licenses, etc.):** ☐ Mr. ☒ Ms.	Kristin Long, PhD
Department/School:	Dept. of Psychological and Brain Sciences / CAS
BU Mailing Address:	900 Commonwealth Ave., 2nd Floor
Email:	kalong@bu.edu
Telephone:	617-358-4296
Additional Contact Person:	Marcella Mazzenga
Email:	mmazz@bu.edu
Telephone:	617-358-1633
☒ YES **(REQUIRED)**	I confirm that I qualify to serve as the Principal Investigator of this study and am in compliance with the following policies: http://www.bu.edu/researchsupport/compliance/human-subjects/

SECTION B: FUNDING

Provide information regarding **ALL** funding sources for this project, including existing funding, pending funding, and funding that has been applied for to support this research.

Please check all that apply:	
☒	This research is funded
☐	Funding has been requested Have you received Just In Time (JIT) Notification? ☒ Yes ☐ No NOTE: Once the funding has been awarded, submit an amendment to the IRB to add the funding source
☐	Research is not funded

If the research is funded or funding has been requested, it is REQUIRED that you complete the box below. If you don't have an award #, please state that in the box below. If you have multiple funding sources, add additional boxes as necessary.

Sponsor Name		Deborah Munroe Noonan Memorial Research Fund
Title of Grant/Proposal		Development of a Family-Based Transition Planning Program for Culturally-Diverse Youth on the Autism Spectrum
Sponsor Award # **(REQUIRED)*** *If Award is pending, put "pending".		(No award number given)
YES	**NO**	

☒	☐	Is Boston University the Prime Awardee of the grant?
☐	☒	Is Boston University receiving a sub-award? Name of Prime Recipient:
☐	☒	Is the research being supported by an Industry Contract or Clinical Trial Agreement?

***NOTES:**

- Provide a copy of the grant application, funding proposal, contract/agreement, scope of work, or sub-award agreement supporting the research. If an award is pending, once the funding has been awarded, submit an amendment to the IRB to add the funding source.
- If this research study is for your dissertation, provide a copy of your prospectus (if available).

SECTION C: CONFLCT OF INTEREST

☒ YES **(REQUIRED)**	I confirm that **ALL** those responsible for the design, conduct, or reporting of the proposed research, including at minimum, all Senior/key personnel in the grant application, have completed the financial interest disclosure forms, submitted them to the COI office, and completed training as dictated at: http://www.bu.edu/researchsupport/compliance/conflicts-of-interest/, and as provided under *the Boston University Investigator Conflicts of Interest Policy for Research.* **NOTE: You must attach a copy of the PI's COI submission confirmation email. COI submission confirmation emails for all other study staff should be maintained at the research site.**
Of the financial interest disclosure forms submitted, did you check "yes" to any of the questions on either the FIND1 or NONFIND1 form? ☐ Yes* ☒ No	

***If you checked "yes" to any of the questions on either the FIND1 or NONFIND1 form, the IRB Director will contact the COI office to obtain the disclosure information.**

SECTION D: TYPE OF REVIEW

For Guidance regarding Type of Review please refer to the CRC IRB website

I. **FULL BOARD** ☐
Please refer to the CRC IRB website for Full Board submission deadlines and meeting dates.

II. **EXPEDITED** ☒
In order to qualify for expedited review, the study must be no more than minimal risk* **AND** must fall into one of the categories below. Check all that apply:

1. ☐ Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases

the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. ☐ Collection of blood samples by finger stick, heel-stick, ear stick, or venipuncture as follows:
   a. From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or
   b. From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

3. ☐ Prospective collection of biological specimens for research purposes by noninvasive means. Examples include hair and nail clippings, saliva or cheek swabs, sweat, etc.

4. ☐ Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. Examples:
   - Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy
   - Weighing or testing sensory acuity
   - Magnetic resonance imaging
   - Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography
   - Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual

5. ☐ Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis)

6. ☒ Collection of data from voice, video, digital, or image recordings made for research purposes.

7. ☒ Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Note: The IRB will make the final determination on the Type of Review

***Minimal risk** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

SECTION E: STUDY STAFF AND HUMAN SUBJECTS TRAINING

List **ALL** current members of the research team in the table below. Add more rows as necessary.

STUDENT RESEARCH:
The Faculty Advisor must be listed as a co-investigator in this section and must complete the Human Subjects training requirements. Faculty Advisors are responsible for reviewing the IRB application, agreeing to serve as the Co-PI for this study with the student and are responsible for the ethical conduct of this student's human subjects research. Faculty Advisors must sign this Application prior to it being submitted to the IRB.

BU CHARLES RIVER CAMPUS (CRC) INVESTIGATORS/STUDY STAFF
Note: Boston University Medical Campus (BUMC) investigators/study staff should be listed in the NON-BU INVESTIGATOR/STUDY STAFF section

Name, Degree, & Department/School	Study Role (e.g. co-investigator, research coordinator, research assistant, project manager, lab manager)	Human Subjects Training*
Kristin Long, PhD, Dept. Psychological and Brain Sciences/ College of Arts & Sciences	PI	☒ CITI ☐ Other**:_____ Most Recent Date Completed: 7/04/2020
Gael Orsmond, PhD, Dept. Occupational Therapy/Sargent College	Co-I	☒CITI ☐Other**: Most Recent Date Completed: 9/13/2020
Christina Amaro, PhD, CAS Department of Psychological and Brain Sciences	Post-doctoral Researcher	☒ CITI ☐ Other**: Most Recent Date Completed: 09/03/2020

Monica Gordillo, MA, CAS Department of Psychological and Brain Sciences	Graduate Student Researcher	☒ CITI ☐ Other**: Most Recent Date Completed: 5/24/2019
Jenna Eilenberg, MA, MPH, CAS Department of Psychological and Brain Sciences	Graduate Student Researcher	☒ CITI ☐ Other**: Most Recent Date Completed: 7/18/2020
Ariel Blakey, MA, CAS Department of Psychological and Brain Sciences	Graduate Student Researcher	☒ CITI ☐ Other**: Most Recent Date Completed: 09/04/2019
Kathryn Davis, MA, CAS Department of Psychological and Brain Sciences	Graduate Student Researcher	☒ CITI ☐ Other**: Most Recent Date Completed: 9/04/2019
John 'Jay' Wilson, MA, CAS Department of Psychological and Brain Sciences	Graduate Student Researcher	☒ CITI ☐ Other**: Most Recent Date Completed: 9/13/2020
Emily Wunder, BA, CAS Department of Psychological and Braine Sciences	Graduate Student Researcher	☒ CITI ☐ Other**: Most Recent Date Completed: 12/8/21
Marcella Mazzenga, BA, CAS Department of Psychological and Brain Sciences	Assistant Research Technician (Staff)	☒ CITI ☐ Other**: Most Recent Date Completed: 6/6/2020
Caroline Hollahan, BA, CAS Department of Psychological and Brain Sciences	Research Assistant (Staff)	☒ CITI ☐ Other**: Most Recent Date Completed: 2/7/2019
Huanrui 'Ben' Wei, CAS Department of Psychological and Brain Sciences	Undergraduate Researcher	☒ CITI ☐ Other**: Most Recent Date Completed: 10/20/2021
Shumin Guan, CAS Department of Psychological and Brain Sciences	Undergraduate Research (Staff)	☒ CITI ☐ Other**: Most Recent Date Completed: 10/25/2021

Pamela Ruiz, CAS Department of Psychological and Brain Sciences	Undergraduate Researcher (Staff)	☒ CITI ☐ Other**: Most Recent Date Completed: 10/16/2021
Freya Zhu, CAS Department of Psychological and Brain Sciences	Undergraduate Researcher	☒ CITI ☐ Other**: Most Recent Date Completed: 11/17/2021
Oksana Litardo, Sargent College	Graduate Student Researcher	☒ CITI ☐ Other**: Most Recent Date Completed: 9/2/2019
Yeook Kim Sargent College	PhD student	☒ CITI ☐ Other**: Most Recent Date Completed: 9/3/2021
Sharada Krishnan Sargent College	PhD student	☒ CITI ☐ Other**: Most Recent Date Completed: 9/3/2021
Anuoluwa Ayannusi, Sargent College	Undergraduate Researcher	☒ CITI ☐ Other**: Most Recent Date Completed: 10/9/2021
Carissa Mastrangelo, CAS Department of Psychological and Brain Sciences	Undergraduate Researcher	☒ CITI ☐ Other**: Most Recent Date Completed: 1/11/2022
Julia Duda	Undergraduate Researcher	☒ CITI ☐ Other**: Most Recent Date Completed: 6/6/2021
Rachel Meyer	Undergraduate Researcher	☒ CITI ☐ Other**: Most Recent Date Completed: 6/2/2021

TBA	Program Facilitator (Based at the Arc)	☐ CITI ☐ Other**: Most Recent Date Completed:

- *For more information regarding the Human Subjects Training Policy, refer to the 'Training' section of the Policies & Guidance section IRB website.
- **If the investigator/study staff did not complete CITI, you must submit a copy of his/her training certificate.

NON-BU INVESTIGATORS/STUDY STAFF* ☐ **N/A**

Note: BUMC and BMC staff are considered non-BU staff and should be listed in this section. Add more rows as necessary. All the columns in the box below must be completed. In addition, you must complete the box that follows with a description of the activities for each staff member.

Name, Degree, Institution	Study Role	Staff Information	Will IRB Approval be Obtained from Non-BU Institution?
Amanda Brandone, PhD	Lehigh University	1. Will this staff interact with subjects? ☒ Yes ☐ No 2.Will this staff have access to identifiable information? ☒ Yes ☐ No 3.Is the work that the staff will complete related to his/her role or coursework at his/her affiliate institution.? ☐ Yes ☒ No	☐ Yes: Provide copy of IRB approval letter when available: ☒ No (provide reason): Lehigh has ceded review to BU IRB
Wenyan Feng, MA	Lehigh University	1. Will this staff interact with subjects? ☒ Yes ☐ No 2. Will this staff have access to identifiable information? ☒ Yes ☐ No	☐ Yes; provide copy of IRB approval letter ☒ No (provide reason): Lehigh has ceded review to BU IRB

		3. Is the work that the staff will complete related to their role or coursework at their institution? ☐ Yes ☒ No	

*If IRB approval will be obtained from the affiliate site, only list the lead investigator from the affiliate on this form.

The box below must be completed. Include a summary for each staff listed in the above box. If any of the investigators listed on this form are not affiliated with BU, provide a summary of the study activities that he/she will conduct. If IRB approval is not being obtained at the affiliate institution, provide an explanation. **NOTE: Non-BU staff may be required to complete an Individual Investigator Agreement (IIA). The IRB will notify you if this form is required.**

Dr. Amanda Brandone and Ms. Wenyan Feng at Lehigh University will contribute to recruitment, consenting, data collection, and data analysis for Phase 1 of the study. This will include – but may not be limited to – working with families who speak Mandarin or Cantonese as their primary language.

REQUIRED GOOD CLINICAL PRACTICE TRAINING FOR NIH-FUNDED CLINICAL TRIALS

YES*	NO	NIH-FUNDED CLINICAL TRIALS
☐	☒	Is your study NIH-Funded AND meet the definition of a clinical trial as defined in the NIH policy?

SECTION F: LOCATION OF THE RESEARCH

YES*	NO	
☒	☐	Will this research take place at sites/locations other than Boston University? **Note:** If the research will take place at Boston University, state the location (Building and Room number):

*If **YES,** please complete the boxes below

NOTE: You are responsible for obtaining permission/letters of support for research conducted off-site. This may include locations such as schools, workplaces, community organizations, etc. You must submit the letters/documentation of support with this application.

Institution Name and Address (if known)	**Describe Involvement (recruiting, consenting, data analysis, etc.) of the site. If the site or the site staff is not involved (engaged)[1] in research procedures, state NONE.**	**IRB/Ethics Approval/Site Permission Attached? If no[2], explain the plan to obtain this approval. If the site is not engaged in the research, you do not need to complete the box.**
Northeast Arc 6 Southside Rd. Danvers, MA 01923	Site will serve as recruitment source as well as intervention site. Staff at the Arc site will	No - Site is not engaged in research.

	conduct the telehealth program with participants. BU research staff will supervise, consent, and conduct all data collection.	
Brockton Area Arc 1250 West Chestnut St. Brockton, MA 02301	Site will serve as recruitment source as well as intervention site. Staff at the Arc site will conduct the telehealth program with participants. BU research staff will supervise, consent, and conduct all data collection.	No - Site is not engaged in research.
Communitas (Arc) 60-D Audubon Rd, Wakefield, MA 01880	Site will serve as recruitment source as well as intervention site. Staff at the Arc site will conduct the telehealth program with participants. BU research staff will supervise, consent, and conduct all data collection.	No - Site is not engaged in research.
Lehigh University	Collaborators at Lehigh University will contribute to recruiting, consenting, data collection, and analysis.	No - Submitted a single IRB request (BU = reviewing IRB; Lehigh = relying IRB)
[1]Guidance on Engagement of Institutions in Human Subjects Research [2]If IRB approval will not be obtained at the site, describe the IRB oversight arrangements here:		

YES*	NO	
☒	☐	Is the off-site location requesting that the Boston University IRB review the protocol in place of local IRB review? If **YES**, complete the Single IRB Review Form "Boston University is Institution A"

YES*	NO	
☒	☐	Is the BU PI the lead investigator **OR** is BU the lead site for this research? **Note: This box only needs to be completed if the off-site location is engaged in the research.**

***If YES**, provide the following information in this box:

- The plan for collection and management of data from all the sites
- The plan for reporting and evaluating:
- Unanticipated problems
- Serious and/or continuing non-compliance
- Suspensions and terminations of research
- Interim results
- Protocol modifications
- The name of the Principal Investigator from each site

- If IRB approval will be obtained at the site, confirmation that you have a copy (or will obtain a copy) of the IRB approval letters and the IRB-approved protocols from each site
- If IRB approval will be obtained at the site, confirmation that the site IRB has a FederalWide assurance (FWA)

The Lehigh team will be involved in consenting and data collection for Phase 1 of the study. The site PI at Lehigh is Dr. Amanda Brandone; Dr. Brandone will oversee the work done by her graduate student, Ms. Wenyan Feng. We will use a secure SharePoint site for the secure exchange of research information (consent forms, interview recordings and transcripts), as this site can be accessed from research personnel across both universities. The Sharepoint site will be created and maintained by research staff at BU. The Lehigh team also will be involved with coding qualitative data.
Dr. Long (PI) will have regular contact with the Lehigh team. If any unanticipated problems occur, Dr. Long will take responsibility for reporting this to the IRB at BU. If any serious and/or continuing instances of non-compliance occur, Dr. Long will reevaluate the collaboration, and if necessary, move all research activities to BU.
IRB approval will not be obtained at Lehigh, as they will cede review to BU's IRB. (Lehigh does have a FWA).

YES*	NO	
☐	☒	Will this research be conducted outside of the United States? If **YES**, complete the International Research Form.

SECTION G: STUDY SUMMARY

Summarize the study in lay language (do not copy from the grant/scope of work/proposal, etc.). This summary should include the research design, purpose, objectives, research question, hypothesis, and any relevant background information.

Do not include a list of citations in this section. Please limit this section to no more than 300 words.

For youth on the autism spectrum, the transition to adulthood has been described as "falling off a cliff" due to the lack of available adult services and families feeling overwhelmed and unsupported. Although the transition to adulthood is universally challenging for families, it is also a time of increasing race/ethnicity-based service use disparities. No existing family-based programs focus on skills to navigate transition, are broad enough to include families of youth with a wide range of autism presentations, and consider cultural influences on transition processes or post-transition goals. We plan to develop a family-based transition planning program that addresses these gaps.

We will develop a program to increase family members' involvement in autism-related transition planning, with a focus on ensuring cultural relevance. The **Families FORWARD** (**F**ocusing **o**n **R**elationships, **W**ell-being, **a**nd **R**esponsibility ahea**D**) program will be delivered collaboratively with community organizations that support individuals on the autism spectrum. Parents/primary caregivers will participate in individual, personalized telehealth modules that incorporate aspects of motivational interviewing, skill-building (problem-solving; communication), and psychoeducation about services. Transition-aged youth on the autism spectrum will be

incorporated into the program to maximize their input in collaborative planning. A community advisory board (CAB) of key stakeholders will actively shape all stages of the research. CAB members will not have access to data or identifiable information.

The project aims to:
(1) develop the 6- to 7-session Families FORWARD program with culturally-diverse families and service providers. Parents/primary caregivers, youth on the autism spectrum (ages 14-21), and community providers will participate in individual interviews. Feedback will be used to refine the program's goals, format, and content.

(2) conduct proof-of-concept testing with a stratified sample of families who identify as Black, Latinx of any race, Asian, and non-Latinx White. Twenty families will participate in Families FORWARD and will provide feedback on the program and the research procedures.

SECTION H: RESEARCH METHODS AND ACTIVITIES (Check all that apply)

☒	Collection of audio, video, digital, or image recordings
☐	Biological samples → Complete Biological Samples Form Examples: blood, hair, cheek swab, urine, tears, saliva, etc.
☐	Collection of data that may be sensitive and if disclosed could put subjects at risk for legal or social harms. (e.g. Illegal behaviors, HIV status, psychiatric illness, information related to sexual behaviors, etc.
☐	Coordinating Center/Lead Site
☐	Deception
☐	Devices → Complete Devices Form
☐	Drugs → Complete Drugs Form
☒	Ethnographic: The study of people in their own environment through the use of methods such as participant observation and face-to-face interviewing
☐	Focus Groups
☐	Genetics Testing → Complete Genetics Form
☐	MRI
☐	Placebo
☐	Pregnancy Testing

☐	Randomization
☒	Surveys, interviews, questionnaires
☐	Secondary Data Analysis
☐	Other (please describe):

SECTION I: PARTICIPANT POPULATION

Provide the Number of Participants to be Enrolled. If you have sub-groups or more than one arm, please separate out these enrollment numbers. Note: Please account for participants who may drop out or be withdrawn from the study. Anyone who signs a consent form is considered to be enrolled in the research regardless of whether they complete any study procedures.

Individual interviews:

1. 15 service providers
2. 35 parents / caregivers
3. 25 transition-aged youth on the autism spectrum (ages 14-21)

Proof of concept trial:

1. 20 families, including parents/caregivers and (when possible) transition-aged youth
2. 4 program facilitators

Notes:

- *Families can participate in EITHER Phase 1 (interviews) OR Phase 2 (proof-of-concept trial), but not both.*
- *Parent participants: In both phases of the study, we anticipate enrolling one parent per family. However, a second parent / primary caregiver will be eligible to enroll, if warranted. The enrollment numbers above account for the possibility of >1 parent per family.*
- *Autistic youth / young adult participants: For Phase 1, multiple individuals from the same family may enroll if they meet inclusion criteria. The enrollment numbers above account for the possibility of >1 autistic individual enrolled per family. For Phase 2, only one autistic individual may enroll.*

Check all categories that apply to your participant population:	
☒	Adults
☒	Children (< 18 years of age)

☒	Adults with Limited Decision-Making Capacity
☒	Non-English Speaking
☐	Prisoners
☐	BU Employees
☐	BU Students
☐	Wards of the state
☐	Other (please describe):

If a population other than 'Adults' has been checked, describe the additional safeguards that have or will be put in place to protect those individuals, and provide the rationale for including this population in the research study. For information on additional protections, please see the 'Supplemental Guidance' section of the CRC IRB webpage.

Program development phase (Phase 1): Transition-aged youth on the autism spectrum (ages 14-21) will be asked to participate in individual data collection appointments in which we will ascertain the acceptability of the proposed program and collect data on these individuals' preferences regarding program goals and formats. In order to participate, the individuals on the autism spectrum must be able to share their perspective in either verbal or written format and be able to provide consent or assent (if they are not their own legal guardian) for participation. Data collection will be conducted in English, Spanish, Cantonese, and Mandarin.

Proof-of-concept testing phase (Phase 2): Transition-aged youth on the autism spectrum (ages 14-21) may participate in 2 telehealth sessions and provide written feedback about the program (via post-session feedback forms) if it is appropriate. The participating parents/caregivers will inform the researchers of whether they think their child is able and willing to participate both in the session and/or in completing the feedback form. If necessary, these feedback forms can be completed with the support of a research team member, family member, service provider, or other support person. Youth who participate in the program sessions will be considered research participants, regardless of whether or not they complete the session feedback forms. We will attempt to collect session feedback forms from all autistic youth participants and will track data collection completion as a measure of feasibility. Data will be collected in English.

For both phases of this research, we have chosen to include cognitively-impaired individuals to increase participation of youth across the autism spectrum, including those with accompanying intellectual disability. This decision is consistent with person-centered approaches in autism and disability-related service provision whereby the affected individual

is included in all discussions and decisions about his/her/their care. This inclusive approach is expected to improve the program that is being developed.

In Phase 1, we will enroll linguistically-diverse individuals. Our research group has experience conducting multi-lingual studies, and the PI will closely oversee the work of bilingual research team members who will interact with families in Spanish, Cantonese, Mandarin, and English.

Eligibility Criteria

Members of the research team will conduct a phone screen to ensure eligibility.

Inclusion Criteria:

Phase 1

1. Parents or primary caregivers of transition-aged youth on the autism spectrum:
    a. Have one or more child(ren) on the autism spectrum who is/are ages 14-21 years old
    b. Identify as the parent, legal guardian, and/or primary caregiver of the youth
    c. Speak English, Spanish, Cantonese, or Mandarin fluently
2. Youth on the autism spectrum:
    a. Have an autism diagnosis OR identify as autistic
    b. Age 14-21
    c. Have ability to communicate verbally or in written format
    d. Speak English, Spanish, Cantonese, or Mandarin fluently
3. Service providers:
    a. Have professional experiences in serving individuals on the autism spectrum and/or their families.
    b. Age 18+
    c. Speak English, Spanish, Cantonese, or Mandarin fluently

Phase 2

1. Parents or primary caregivers of transition-aged youth on the autism spectrum:
    a. Have one or more child(ren) on the autism spectrum who is/are ages 14-21 years old
    b. Identify as the parent, legal guardian, and/or primary caregiver of the youth
    c. Speak English fluently
    d. Reside in Massachusetts
2. Youth on the autism spectrum:
    a. Have an autism diagnosis OR identify as autistic
    b. Age 14-21
    c. Have ability to communicate verbally or in written format
    d. Speak English fluently
    e. Reside in Massachusetts*
3. Service providers:
    a. Have professional experiences in serving individuals on the autism spectrum and/or their families.
    b. Age 18+

c. Speak English fluently

**Note: Lehigh University staff will NOT be conducting Phase 2 of the study.*

Exclusion Criteria (exclusion criteria are the specific criteria which would disqualify an individual from participating in the study not simply the opposite of the inclusion criteria):

Phases 1 & 2

1. Parents/caregivers: none
2. Youth on the autism spectrum: Youth will be excluded if their abilities would preclude them from sharing their perspective either in written or verbal format (e.g., due to significant cognitive or language challenges)
3. Service providers: none

SECTION J: RECRUITMENT

Provide a summary of the recruitment process, including who will recruit, when and where recruitment will occur, and how subjects will be identified

Submit all recruitment materials (e.g. advertisements, brochures, flyers, letters/e-mails, scripts, etc.) as separate documents in either Word or PDF format.

Parents and youth (Phases 1 and 2) will be recruited through community partners including but not limited to local Arc chapters, the Arc of Massachusetts, the Massachusetts Sibling Support Network (MSSN), Autism/Asperger Network (AANE), and Boston Medical Center. These community partners may distribute a recruitment flier via in-office postings, postal mail, and email, or they may include information about the study on their social media pages. Participants also may be recruited via our Community Advisory Board or word of mouth. Finally, families may be recruited by re-contacting families that either (a) participated in our previous autism-focused studies and provided permission to learn about future studies or (b) who expressed interest in previous studies but were not eligible and asked to learn of future research opportunities.

When recruiting parents and youth for Phase 1, participant characteristics will be reviewed periodically to ensure breadth in the sample based on family race and ethnicity as well as youth age. Continued recruitment will target families with characteristics not as well represented in the sample.

When recruiting families for Phase 2, we will enroll a stratified sample to ensure that families of different races and ethnicities are included, as follows: Black (n = 4-5), Asian (n = 4-5), Latinx of any race (n = 4-5), non-Latinx white (n = 4-5). We will ask about family race/ethnicity during the telephone screen.

Community providers. For Phase 1, community providers will be identified through local and state-wide Arc chapters; recruitment fliers will be posted in the local offices and distributed via email. Additionally, we will use IRB-approved recruitment materials to recruit through social media (e.g., Facebook page). For Phase 2, we will hire 2-4 community-based

providers to serve as program facilitators. These providers also will serve as research participants when providing feedback on the program via session feedback forms and exit interviews.

For both families and community providers, individuals who are interested in participating, but prefer that the research team makes initial contact with them, can do so by entering their contact information into a consent-to-contact portion of our lab's website (see "Consent-to-Contact Write-Up" document), after which a member of the research team will contact them to provide more details about the study. Alternately, if professionals or community partners obtain verbal consent for a potential adult participant (e.g., parent/caregiver or service provider) to be contacted by the researcher, the professional or community partner will communicate this information to the research team, and a member of the research team will reach out directly to the potential participant.

Note about roles: The majority of recruitment activities will be carried out by members of the BU research team. However, Lehigh staff also may contribute to disseminating recruitment materials for Phase 1. This may include sharing fliers with community groups in PA or elsewhere.
Only research-trained staff of Boston University and Lehigh University will be involved in the consent process and the collection of research data; community advisory board members and Arc-based program facilitators may help disseminate fliers about the study, but they will NOT be involved in any research procedures (consent, data collection, etc.). Lehigh University will be involved in Phase 1 of the study, but not Phase 2.

Please Note: *Phase 2 recruitment materials (flier, letter, etc.) will be developed after Phase 1 is complete and will be submitted to the IRB for approval at a later date. This will ensure that the Phase 2 recruitment materials accurately reflect the final format and content of the program being developed.*
Spanish and Chinese versions of Phase 1 recruitment materials will be submitted to the IRB upon approval of the English versions.

SECTION K: CONSENT AND ASSENT

Please refer to the consent and assent form templates on the IRB website when creating your consent/assent documents. The templates include the required elements of consent and will help to ensure that your consent/assent form meets the requirements of the federal regulations and the BU CRC IRB.

STUDENT RESEARCHERS must: 1) indicate in the consent form/information sheet/script that he/she is a student and 2) list the Faculty Advisor as a contact in the form/sheet/script.

Provide a summary of the consent process, including who will consent participants, when and where consent will occur. The summary should include, as appropriate, any waiting period between informing the prospective participant about the research and obtaining consent, such that the prospective participant or the legally authorized representative has sufficient opportunity to consider whether to participate, and steps taken to minimize coercion or undue influence.

Submit copies of all consent forms and scripts; materials should be submitted as separate documents in Word format.

Adult individuals (parents/primary caregivers, service providers, or young adults on the autism spectrum who are their own guardians) who are interested in hearing more about the study will contact the researchers to express their interest, complete a consent-to-contact form on our study website, or provide verbal consent to professionals or community partners that the research team can reach out to them to provide information about the study.

All informed consent procedures will be carried out by members of the research team who are based at BU or Lehigh University; the Arc partners and Community Advisory Board members will not be involved in obtaining informed consent.

Phase 1 interviews:
Verbal consent will be obtained from parents/primary caregivers, service providers, and 18- to 21-year-old individuals on the autism spectrum who are their own legal guardian. If the individual on the autism spectrum has a legal guardian (ages 18-21) or is under 18 years old, verbal consent will be obtained from the guardian. The research team will learn of guardianship status of the individual on the autism spectrum during the phone screen. A research team member will describe the goals of the study, answer questions, and obtain verbal consent or assent from the participants. Potential participants will have the option of thinking about whether they want to participate. Participants will be provided with a copy of the consent or assent document, and the original will be kept in the confidential research file.

For individuals who are not their own legal guardians, there may be situations in which the legal authorized representative provides consent for the individual on the autism spectrum to participate in the study, but the individual on the autism spectrum does not wish to participate. If this occurs, we will first reach out to the individual on the autism spectrum to address any specific concerns about the study. If they still do not wish to participate, the individual on the autism spectrum will not be enrolled, and the legal authorized representative will be informed that the individual on the autism will not be enrolled.

Note: for individuals on the autism spectrum who may prefer or require written communication, there will be an option for them to ask questions and confirm their assent/consent using a written format (e.g., in email exchanges or via a "chat" function on zoom or other platforms).

Phase 2 proof-of-concept testing:
Parents/primary caregivers will provide consent for participation in the proof-of-concept testing before they complete pre- program measures or participate in program sessions. Measures will be administered through a web-based survey (Qualtrics), which will include the consent form. We will not require written consent from the parents / primary caregivers; rather, they will indicate their consent through continuing to the questionnaires after reading the consent document and answering the questions posed within the consent form. Thus, we are requesting a waiver of documentation of written consent. Because each participant is accessing Qualtrics via a unique personal link, the answers to the questions on the consent

form will be linked to each participant's data on the surveys. In a separate document on the secure site, trained research staff will have access to the key to match up personal Qualtrics links and identifiable participant information (including names). Parents / primary caregivers may also complete the consent and surveys over the phone or zoom, in which a member of the research team reads the questions aloud and records the participant's responses using the participant's personal link in Qualtrics.

We also will request, but not require, **individuals on the autism spectrum** to provide consent or assent for their family's participation in the proof-of-concept trial. There are many situations that may preclude obtaining consent/assent from the individual on the autism spectrum or legal guardian; therefore, we will reach out to these individuals to request their consent/assent, but if we are not able to obtain it, we will still enroll the parent / primary caregiver (but the individual on the autism spectrum will only be enrolled if they provide consent/assent). Individuals on the autism spectrum who participate in any program sessions and/or provide session feedback will be asked to provide consent or assent in order to participate.

We will determine whether the individual on the autism spectrum can provide consent or whether he/she/they have a guardian by asking parents and/or service providers during the study screening procedures. Because youth on the autism spectrum will not be completing measures via Qualtrics, we will request verbal consent/assent for their participation in the study. If verbal/nonverbal behaviors indicate the individual on the autism spectrum is unable to provide consent/assent, we will verbally share study information, and ask for verbal assent, with a yes/no response documented by research staff. If no verbal response is provided, we will document this as well, and carefully monitor the individual on the autism spectrum's willingness to participate, and we will continue unless nonverbal behaviors show unwillingness to participate. If the individual on the autism spectrum shows signs of being unwilling to participate, we will move forward with research activities with only the parent / primary caregiver.

For individuals who are not their own legal guardians, there may be situations in which the legal authorized representative provides consent for the individual on the autism spectrum to participate in the study, but the individual on the autism spectrum does not wish to participate. If this occurs, we will first reach out to the individual on the autism spectrum to address any specific concerns about the study. If they still do not wish to participate, the individual on the autism spectrum will not be enrolled, and the legal authorized representative will be informed that the individual on the autism will not be enrolled. In these cases, the parent/primary caregiver can still be enrolled in the proof-of-concept trial.

Note: for individuals on the autism spectrum who may prefer or require written communication, there will be an option for them to ask questions and confirm their assent/consent using a written format (e.g., in email exchanges or via a "chat" function on zoom or other platforms).

Finally, we will request verbal consent from **service providers** who will be providing feedback on the program.

General note: When families (individuals on the autism spectrum and their parents / primary caregivers) are recruited into either Phase 1 or Phase 2 of this research study, they will be informed that their decision on whether or not to enroll will not impact the eligibility or quality of services for the individual on the autism spectrum. When service providers are recruited into the interview portion of the study, they will be informed that their decision on whether or not to enroll is completely voluntary and will not impact any aspect of their employment.

Indicate the consent and/or assent process and document(s) to be used in this study. Check all that apply

Consent: Adults (≥18 years old); One of the following MUST apply	**N/A ☐**
☒	Consent Form/Information Sheet
☒	Verbal Consent (Script) **Note:** If written consent will not be obtained, complete the 'Waiver of Written Documentation Consent' box (Box 1) located further down in this section
☐	Consent will not be obtained **Note**: If consent will not be obtained, complete the 'Waiver or Alteration of Consent' box (Box 2) located further down in this section

Assent of Children (≤ 18 years old); One of the following MUST apply	**N/A ☐**
☒	Assent Form **OR** Parent Consent Form/Information Sheet (older children may sign the parent consent form along with their parents as long as the consent form is written at the grade level of the subjects) **This will be used for parents/caregivers enrolled in Phase 2 of the project (proof-of-concept testing)**
☒	Verbal Assent (Script) **This will be used for (1) parents/caregivers, youth, and service providers enrolled in Phase 1 of the project and (2) youth and service providers enrolled in Phase 2 of the project**
☐	Assent will not be obtained; one of the following conditions must exist: 1. ☐ The capability of some or all of the children is so limited that they cannot reasonably be consulted; 2. ☐ The children are too young to provide assent;

	3. ☐ The intervention or procedure involved in the research holds out the prospect of direct benefit to the health or well-being of the children and is available only in the context of the research 4. ☐ The research meets the same conditions as those for waiver or alteration of informed consent in research involving adults, as specified in the regulations at 45 CFR 46.116(d)*. **(Complete the 'Waiver or Alteration of Consent' box (Box 2) located further down in this section)**
Guidance on age requirements for obtaining assent: • **Parental Permission for minors under 6 years old** • **Verbal assent for minors 6-11 years old** • **Written assent from minors ages 12-17 (unless verbal consent is approved for the parents/adult subjects**	
Parental Permission; One of the following MUST apply	**N/A ☐**
☐	Parental Consent Form
☒	Parental Verbal Consent (Script) **Note:** If written consent will not be obtained, complete the 'Waiver of Written Documentation of Consent' box (Box 1) located further down in this section
☐	Parental permission will not be obtained; **one of the following conditions must exist:** 1. ☐ The research protocol is designed to study conditions in children or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children). 2. ☐ The research meets the same conditions as those for waiver or alteration of informed consent in research involving adults, as specified in the regulations at 45 CFR 46.116(d)*. **(Complete the 'Waiver or Alteration of Consent' box (Box 2) located further down in this section).**

Consent: Adults with Limited Decisional Capacity to Consent (≥18 years old) N/A ☐ **Describe the consent and/or assent process for enrolling adults with limited decisional capacity to consent to research. Including how decisional capacity will determined, and who will serve as Legally Authorized Representative.**
For the proof-of-concept trial, we will request – but not require – consent from individuals on the autism spectrum or their legal guardian. The research team will learn of guardianship status of the individuals on the autism spectrum by asking parents and/or service providers during the study screening procedures. We will attempt to obtain assent from the individual on the autism spectrum if possible. If verbal/nonverbal behaviors indicate the individual on the autism spectrum is unable to provide assent, we will verbally share study information, and ask for verbal assent, with a yes/no response documented by research staff.

There may be situations in which the legal authorized representative provides consent for the individual on the autism spectrum to participate in the study, but the individual on the autism spectrum does not wish to participate. If this occurs, we will first reach out to the individual on the autism spectrum to address any specific concerns about the study. If they still do not wish to participate, the individual on the autism spectrum will not be enrolled, and the legal authorized representative will be informed that the individual on the autism will not be enrolled.

Assent will be obtained from:
☐ All Subjects
☒ Some Subjects, specify: Individuals on the autism spectrum who show signs of being unable to provide consent will be asked to provide verbal assent. Other individuals on the autism spectrum who are their own guardians will be asked to provide consent.
☐ No Subjects

☒	Consent will be obtained from the subject's Legally Authorized Representative (LAR) **(REQUIRED).** **Who will serve as LAR:** The individual's legal guardian will serve as the LAR.

CONSENT OF NON-ENGLISH SPEAKING SUBJECTS N/A ☐
Describe the process for obtaining consent from non-English speaking subjects. List the individual who will serve as the interpreter and his/her qualifications.

NOTE: A copy of the translated consent along with the Attestation Form for Translation of Consent must be submitted. The Attestation Form can be located on the IRB website.

The procedures for obtaining consent for Spanish-, Cantonese-, and Mandarin-speaking participants will be the same as those for consenting English-speaking participants. For example, two graduate student researchers from BU, Monica Gordillo and Oksana Litardo, are bicultural, bilingual Spanish speakers and have been extensively trained in research methodology. Similarly, a research staff member from Lehigh University (Wenyan Feng) is a bicultural, bilingual Mandarin- and Cantonese-speaker who has been trained in this research methodology. They all have experience conducting research with individuals with autism and their families and will be closely supervised by the PI.

BOX 1—WAIVER OF WRITTEN DOCUMENTATION OF CONSENT

WAIVER OF WRITTEN DOCUMENTATION OF CONSENT N/A ☐ **Either Criteria 1 or 2 must be met in order to qualify**	**Yes**	**No**
☐ **Criteria 1**		
The research is **NOT** FDA Regulated	☐	☐
The only record linking the subject and the research would be the consent document	☐	☐

The principal risk would be potential harm resulting from a breach of confidentiality	☐	☐
Each subject will be asked whether the subject wants documentation linking the subject to the research and the subject's wishes will govern	☐	☐
A written statement/information sheet will be provided to subjects. **If NO**, provide rationale for not providing this information:	☐	☐
☒ **Criteria 2**		
The research is **NOT** FDA Regulated	☒	☐
The research presents no more than minimal risk of harm to subjects	☒	☐
The research involves no procedures for which written consent is normally required outside of the research context	☒	☐
A written statement/information sheet will be provided to subjects. If **NO**, provide rationale for not providing this information:	☒	☐
☐ **Criteria 3**		
The research is **NOT** FDA Regulated	☐	☐
The research presents no more than minimal risk of harm to subjects	☐	☐
The subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm	☐	☐
There is an appropriate mechanism for documenting that informed consent was obtained	☐	☐
A written statement/information sheet will be provided to subjects. If **NO**, provide rationale for not providing this information:	☐	☐

BOX 2—WAIVER OR ALTERATION OF CONSENT

NON-FDA REGULATED STUDIES

WAIVER OR ALTERATION OF CONSENT N/A ☒ **45 CFR 46.116 Waiver or alteration of consent. The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents ALL of the criteria listed below:**	**Yes**	**No**
The research involves no more than minimal risk to the subjects;	☐	☐
The waiver or alteration will not adversely affect the rights and welfare of the subjects;	☐	☐
The research could not practicably be carried out without the waiver or alteration;	☐	☐

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;	☐	☐
Whenever appropriate, the subjects will be provided with additional pertinent information after participation. **If NO**, provide rationale for not providing this information:	☐	☐
Provide the justification/rationale for why this study meets the above criteria for waiving or altering consent (REQUIRED):		

FDA-REGULATED STUDIES

Per FDA guidance issued in July 2017, the IRB may waive or alter informed consent requirements for certain minimal risk clinical investigations when the IRB finds and documents ALL of the criteria listed below:	**Yes**	**No**
The clinical investigation involves no more than minimal risk (as defined in 21 CFR 50.3(k) or 56.102(i)) to the subjects;	☐	☐
The waiver or alteration will not adversely affect the rights and welfare of the subjects;	☐	☐
The clinical investigation could not practicably be carried out without the waiver or alteration	☐	☐
Whenever appropriate, the subjects will be provided with additional pertinent information after participation. **If NO**, provide rationale for not providing this information:	☐	☐
Additional Comments:		

SECTION L: STUDY PROCEDURES

In the box below provide a detailed description of the study procedures to be performed (preferably in sequential order). Be sure to specify which procedures are for research purposes and which procedures are part of standard of care, if applicable. Be sure to include the following information:

- **Methods of data collection**
- **Details regarding research activities/procedures/interventions**
- **Number, frequency, duration and types of subject contacts (visits, phone calls, internet surveys, mailings, etc.)**
- **Time required from each subject**
- **Use of equipment (eye-tracker, treadmill, sensors, etc.). Provide a brief description of equipment that will be used in the study.***

***Note: The IRB may request more information about the equipment (including equipment manuals) and/or request that you submit Appendix C: Device Form.**

Submit copies of all surveys, interview questions, assessments, screening scripts, etc. that will be used during the conduct of this study; materials should be submitted as separate documents in either Word or PDF format.

Methods of Data Collection

Phase 1: Individual Interviews.

The first phase of data collection involves qualitative interviews (carried out in either verbal or written format) with transition-aged youth on the autism spectrum, parents/primary caregivers, and service providers. Qualitative data will be collected in English, Spanish, Mandarin, and Cantonese. The interviews will aim to understand current experiences of transition to adulthood and associated planning, including: (1) family involvement in transition planning, (2) services and supports related to transition planning, and (3) cultural considerations related to autism, transition, and adulthood. Interviews also will probe families' and providers' perceptions of Families FORWARD, including: (1) their enthusiasm for a program to engage parents in transition planning, (2) preferences for program components, format, and timing, (3) ideas on how to maximize flexibility so that the program has the broadest possible reach and benefit, and (4) ideas on how to incorporate the preferences of the individual on the autism spectrum. Participants will be presented with an overview of the program and will be asked to provide feedback on the content, format, and materials. Finally, they will be asked to provide high-level feedback on other potential interventions for families of transition-aged youth, such as a parental problem-solving intervention.

Participants will be provided with a variety of options to complete qualitative interviews. **Parents/guardian and service providers** will be asked to participate in traditional verbal interviews. They may choose to interview in-person at a setting of their choice or remotely via telephone or teleconferencing (e.g., Zoom). As long as covid-related precautions remain in place, there will be preference for remote forms of data collection. We will continue to recruit participants until saturation is reached in the primary research questions (i.e., when more interviews do not generate additional information). Some **individuals on the autism spectrum** may be more comfortable providing data in written format (e.g., in a series of email exchanges or in a real-time written chat with a researcher); this alternate mode of interviewing will be offered to individuals on the autism spectrum who are interested in being interviewed but who are unable to or uncomfortable with completing the verbal interview.

In addition to the qualitative interview, parents/caregivers will complete a background questionnaire to provide information about their demographics and educational activities (see Phase 1 & 2 Family Background Form). We expect that the research visit, including the consent process, qualitative interview, and survey measure, will last approximately 1.5 - 2 hours. Participants will be compensated $50 for completion of the study interview and background form.

Participant characteristics will be reviewed periodically to ensure breadth in the sample based on race, ethnicity, and youth age. Continued recruitment will target families with characteristics not as well represented in the sample.

Interviews will be audio recorded using BU-approved version of Zoom and/or handheld audio recorders, transcribed verbatim, and checked for accuracy. Interviews will be transcribed in one of two ways: 1) using a password protected account on Amazon Transcribe or 2) by undergraduate or graduate student researchers with training in research ethics. Only approved study staff will have access to the Amazon Transcribe account. Audio recordings will be temporarily uploaded to the account for transcription (a process that takes approximately an hour) and then deleted from the account immediately following transcription. All transcripts (whether transcribed by an approved study staff member or Amazon Transcribe) will be reviewed a second time by a study staff member to check for accuracy and ensure that all potentially identifying information has been removed. All transcripts will be labeled with unique participant ID numbers. Audio recordings will be moved to a limited-access lab folder after transcription is complete in case it is necessary to reference the original recording to clarify information during analysis. If a participant does not consent to be audio recorded, the interview will be conducted without audio recording and the interviewer's notes will be coded. De-identified transcripts will be entered into a qualitative software program, NVivo12, to facilitate coding and analysis.

Phase 1 data will be collected by BU- and Lehigh-based researchers.

Finally, Phase 1 participants who (1) speak English or Spanish and (2) provide consent to be re-contacted for future research opportunities may be contacted about participation in another study. The research team from Protocol #5790E may reach out to ascertain these participants' interest in completing two standardized measures of the skills and abilities of the adolescent/young adult on the autism spectrum. During the consent process for Protocol #5790E, participants will be informed that their questionnaire data will be linked with the qualitative interviews completed as part of this study. For those families who consent to participate in questionnaires as part of Protocol #5790E, their qualitative data from this study will be shared with the Protocol #5790E research team.

Phase 2: Proof-of-Concept Testing.
Once the program is finalized, 20 families will participate in proof-of-concept testing to assess program acceptability and feasibility. This step is crucial due to the plan to utilize community providers to deliver the program in a telehealth format. Given the small scope of the current project, participating families will need to be fluent in English (not necessarily as a first language) to participate in the trial. The sample will be stratified by race/ethnicity, including approximately equal numbers of families who identify as Black, Latinx of any race, Asian, and non-Latinx white. Parent race/ethnicity will be ascertained during the telephone eligibility screener.

Each service provider will receive in-depth training on the principles and components of the program prior to implementation and will participate in weekly meetings to monitor progress, troubleshoot concerns, and receive intensive consultation on the program. Parents will

participate in the six- to seven-session program and will complete questionnaires pre- and post-participation. Sessions are designed to be delivered once every 2 weeks, though there will be flexibility with scheduling if families need to hold sessions outside of this window. After each session, program facilitators and family participant(s) will complete a brief open-ended session feedback form, and service providers will upload session recordings to the secure BU site. Family participants (parents/caregivers and youth on the autism spectrum) and service providers will participate in exit interviews to collect overall perceptions of the program, assess program satisfaction, and identify areas for improvement. Individuals on the autism spectrum may provide their feedback in either verbal or written format. Phase 2 measures are expected to take approximately 20 minutes at Time 1 (parents/caregivers) and Time 2 (parents/caregivers, youth on the autism spectrum, and providers). Participating parents also will be asked to participate in six or seven 60-minute program sessions.

Phase 2 data will be collected by BU-based researchers. However, facilitators are also listed as staff because they will be engaged in delivering a research-based program. Please note that facilitators will be considered both staff and participants in this project, and they will be compensated for their time learning and delivering the program.

Families FORWARD Program Description

This is a preliminary description, which will be updated once Phase 1 data collection is complete.

The Families FORWARD program will engage families in planning for adulthood. Empirically-informed treatment targets include parent self-efficacy and higher expectations for adult outcomes, which will be bolstered by skill-building in communication and problem-solving; guided practice in setting realistic goals, breaking down goals into incremental action steps, and problem-solving barriers to goal attainment; repeated engagement in future-oriented discussions; and instruction on navigating transition and adult services. To improve implementation, the program will be delivered via community organizations (i.e., local Arc chapters) that support transition-age youth on the autism spectrum. Parents/caregivers will participate in six or seven telehealth sessions (60-75 minutes) and will create individualized transition goals. The individual on the autism spectrum will be invited to participate in one session, but they are not required to do so. The program is designed to enable flexible delivery for families of youth who are diverse across autism severity, co-occurring conditions, service needs, values, and readiness to engage in planning.

Families FORWARD Sessions (P = Parent, Y = Youth on the Autism Spectrum)	
Pre-Session (Optional): Autism Info. (P)	- Education about autism characteristics, common needs, and service systems - Autism as a life course condition - Relevance of supporting individuals on the autism spectrum into adulthood
Session 1: Introduction, Assessment,	- Rapport-building - Psychoeducation about autism during the transition to adulthood - Rationale and introduction to Families FORWARD

& Motivation (P)	- Assessment of transition planning to date (within or outside of schools) and relevant goals, family roles, and cultural values - Overview of domains of transition planning (housing, education, guardianship, etc.) - Identification of a high-level transition planning program goal - Motivational enhancement to actively engage in transition planning
Session 2: Communic-ation & Goal-Setting (P)	- Guidance regarding breaking down larger goals into action steps - Rationale for strong communication with family members, community-based providers, school personnel, & other community members - Principles of effective communication, including conveying cultural values - Discussion of youth's communication style - Practice of effective communication via role-playing transition planning scenarios with youth, community-based providers, and/or school personnel - Specific communication goal-setting for between-session practice
Session 3: Family Collaboration (P & Y)	- Introduction of Families FORWARD to youth on the autism spectrum - Identification of youth's post-transition goals or preferences - Discussion of alignment between youth's and parent's goals - Clarification or redefinition of parent and youth roles moving forward - Revision of program goal to incorporate youth's preferences *Alternate version of Session 3 for families of youth who are not willing/able to participate directly (parent only):* - Articulation of youth's communication style and parent's experience communicating with youth - Assessment of parent's awareness of youth's post-transition goals and preferences - Development of strategies to encourage greater consideration of youth's preferences - Revision of program goal to incorporate youth's preferences
Session 4: Systems Navigation & Participation (P)	- Overview of autism-related systems and services for transition-aged youth and adults (community, residential, medical, mental health, occupational, educational) - Identification of service system(s) that are most relevant for the family's individual transition goals - Development of strategies for learning about and/or navigating through these systems - Identification of specific next steps for systems navigation and participation
Session 5: Problem-Solving (P)	- Guidance regarding effective problem-solving skills - Normalization of barriers to working toward transition planning goals within or outside schools - Anticipation of potential barriers specific to the family's planning goals (e.g., autism stigma, discrimination, language barriers, immigration considerations) - Practice of problem-solving strategies to address these specific barriers - Revision of program goal to incorporate learning to date
Session 6: Moving Forward (P)	- Review of skills and progress made during the program - Creation of a specific action plan for continued work toward planning goals after the program ends that includes long-term goals, proximal goals, and concrete next steps - Proactive identification and problem-solving of any remaining barriers

Telehealth Technology. During the proof-of-concept trial, the Families FORWARD program will be delivered via synchronous videoteleconferencing (VTC) technology. VTC technology enables the secure delivery of interactive meetings that incorporate audio and video streams of data across multiple sites. Based on a review of existing VTC providers and the requirements of

the proposed research, we plan to use Zoom software, a high quality and user-friendly videoconferencing format. Zoom has a HIPAA-compliant version that was developed for use in healthcare settings; this version of Zoom features complete end-to-end 256-bit AES encryption and compliance with HIPAA regulations. The host sends participants a secure link through which to access the meeting/session, and can require a password (provided by the host) to join the meeting; thus, families do not need to register for their own Zoom account. Zoom software clearly identifies the user to the host, after which the host must manually admit the participant to the meeting room. The HIPAA-compliant version of Zoom does not store or retain any session content on a network, which allows providers to comply with HIPAA regulatory guidelines relating to use, disclosure, and storage of confidential information. The HIPAA-compliant version of Zoom allows for local recording by the host (but not by participants), which will allow the research team to review sessions to assess fidelity.

Measures

Phase 1 (Qualitative Interviews) Measures

1. Demographics Questionnaire. A background form will include questions that assess family composition & income; family members' age, gender, race/ethnicity, native language, immigration, education, & employment; youth's school type & presence of co-occurring medical, mental health, or developmental conditions; & current autism services. Time to complete: <5 minutes.

Phase 2 (Proof-of-Concept Testing) Measures

Measures at Time 1 – PARENTS (~20 minutes total):

2. Demographics Questionnaire. A background form will include questions that assess family composition & income; family members' age, gender, race/ethnicity, native language, immigration, education, & employment; youth's school type & presence of co-occurring medical, mental health, or developmental conditions; & current autism services. Time to complete: <5 minutes.
3. Autism Symptom Severity. Parents will rate their child's autism symptoms using the Current form of the Social Communication Questionnaire (SCQ; Rutter, Bailey, & Lord, 2003). The SCQ is a 40-item proxy-report measure used to assess the presence of specific autistic behaviors. The items represent three areas of functioning: reciprocal social interaction, language and communication, and repetitive and stereotypical behaviors, where higher scores indicate more severe behaviors. The SCQ has established psychometric properties in children and adults and has good reliability and convergent validity Chandler et al., 2007). The SCQ manual provides additional information on factor analyses, item validity, and ROC analyses that support its validity. Psychometric properties are good, with alpha reliabilities ranging from .84 to .93 in older age groups. Time to complete: <10 minutes
4. Functional Independence. Parents will rate their child's functional independence using the Waisman Activities of Daily Living Scale (W-ADL; Smith et al., 2012). The 17 items cover the domains of personal care, housekeeping, and mealtime activities. Each item is rated on a 3-point scale (0=does not perform the task at all; 1=performs the task

with help; 2=performs the task independently). Items will be summed for a total score. Good reliability (alpha > .90) has been reported. Time to complete: <5 minutes.

5. Family Communication about Future Planning. Parents will rate the frequency with which they have had family discussions about planning for the future of their child on autism spectrum. Parents will respond to a 1-item measure previously used in a study evaluating a peer-support program for aging caregivers of adults with intellectual and developmental disabilities (Heller & Caldwell, 2006). The item is scored on a 3-point scale (not discussed at all, discussed somewhat, discussed a great deal). Time to complete: <1 minute.

Measures at Time 2 – PARENTS/YOUTH/PROVIDERS (~20 minutes total):

6. Exit Interview (20 minutes). Parents, providers, and individuals on the autism spectrum who participate in the program will be invited to share their feedback about their overall satisfaction with the program and will be asked to reflect on aspects of the program that were most and least helpful. They will be asked to discuss the extent to which the program met the needs of participants and to identify ways in which the program can be improved. Time to complete: 20 minutes.
7. Family Communication (see above) – parents only. Time to complete: <1 minute.

All questionnaire data will be collected by the Boston University study team via Qualtrics (or in person/over the phone if necessary) in order to separate data collection from the Arc providers. We will track this data collection method to inform future data collection logistics.

Please Note: *Much of the content for Phase 2 will be determined using Phase 1 data. Therefore, we will submit an amendment with additional recruitment materials and measures prior to starting Phase 2.*
Spanish and Chinese versions of Phase 1 research materials will be submitted to the IRB upon approval of the English versions.

SECTION M: RISKS

Describe any expected risks to subjects. Consider physical, psychological, social, political, legal, economic, or other risks that are related to the study.

The risks in this study are considered minimal. The specific assessment instruments and general qualitative interview methodology have been routinely employed in minimal-risk research studies. Participants may experience some emotional discomfort in discussing or completing questionnaires about their family life or psychosocial functioning. We will attempt to minimize any distress by assuring participants that they can refuse to answer any questions they do not feel comfortable answering. All research staff and Arc service providers will be trained and supervised to help participants manage any discomfort they encounter during the project. There is also a possibility that participants will disclose mental health risks or safety concerns to the research staff during the course of research participation. If this occurs, Dr. Long (PI and licensed clinical psychologist) will be on-call in the event of a clinical emergency during data collection appointments. Direct referral to providers for evaluation will be provided with participants' written authorization. There is also a small risk of breach of confidentiality.

Describe the plan to minimize risks. Include in the description the availability of any medical or psychological resources.

We will attempt to minimize any distress associated with discussing sensitive topics by assuring participants that they can refuse to answer any questions they do not feel comfortable answering.

There is a possibility that participants will disclose mental health risks to the research team during the course of data collection. Dr. Long (PI) is a licensed clinical psychologist experienced in the management of mental health risks. She will be on-call at all times and available for research team members or service providers to call to obtain guidance if imminent risk is uncovered during any research-related activities. We will provide families with appropriate community resources, as necessary. If the participant provides explicit written consent, an appropriate mental health referral will be made. There are some exceptions to confidentiality protection: if in the course of conducting research-related procedures information is revealed that requires mandatory reporting of child or elder abuse or imminent harm by self or others, such information may be provided to the appropriate authorities without participants' written consent. Dr. Long will serve as the contact person for any mental health concerns that arise during research procedures carried out by either the BU team (Phases 1 and 2) or the Lehigh team (Phase 1 only).

Some aspects of the proposed study will use a virtual / telehealth format, so alternative safeguards have been taken to ensure protection of confidentiality throughout these portions of the study, such as use of the HIPAA-compliant version of Zoom software. Zoom has a HIPAA-compliant version that was developed for use in healthcare settings; this version of Zoom features complete end-to-end 256-bit AES encryption and compliance with HIPAA regulations. The host sends participants a secure link through which to access the meeting/session, and can require a password (provided by the host) to join the meeting; thus, families do not need to register for their own Zoom account. Zoom software clearly identifies the user to the host. The HIPAA-compliant version of Zoom does not store or retain any session content on a network. The HIPAA-compliant version of Zoom allows for local recording by the host, which will allow the research team to review sessions to assess fidelity. Phase 1 interviews will be conducted and recorded using either HIPAA-Zoom or Zoom pro, both of which have been vetted by BU's IT department and are considered to have acceptable levels of security for research involvement. Phase 2 program sessions will be conducted and recording using HIPAA-Zoom, given the community-based design.

Video and audio recordings collected by BU or Lehigh investigators and/or Arc-based program facilitators will be transferred to a password-protected secure network drive at BU and secure cloud storage (when interviews are conducted remotely by BU or Lehigh investigators or Arc providers), and will be deleted from the local laptops. The secure Sharepoint site is maintained by the BU-based research team.

During Zoom sessions, first names only will be used and all family members will be asked to announce themselves at the beginning of the interview to verify that there is no else in the room. All Zoom sessions will be recorded to the BU encrypted, password-protected network drive or a secure SharePoint site for adherence purposes and will be labeled with the unique particpant ID number; only researchers specific to the study will be given access to the folder where these

videos are stored, and this access must be provided on an individual case by case basis by the Desktop Services Specialist in BU IT for the Psychology Department. Data collected by both the BU- and Lehigh-based study staff – as well as session recordings being recorded by the Arc-based program facilitators – will be uploaded to a Sharepoint site that is being created and maintained by the BU-based research team.

SECTION N: BENEFITS

Describe the potential benefits to subjects related to the study. State if there are no direct benefits. NOTE: Compensation and/or course credit are not considered benefits.
There are no known direct benefits to participating in this research. Families participating in this research may benefit from individualized support in planning for the transition to adulthood and adult services, which may improve the extent and helpfulness of services obtained into adulthood. Families and service providers may perceive a benefit by knowing that the information provided will assist in the eventual development of better services for culturally-diverse transition-aged youth with autism, for whom there has historically been few evidence-based services.
Describe the potential benefits to society and/or others related to the study
In the next decade, over one half million youths with ASD will enter adulthood (Roux, Shattuck, Rast, Rava, & Anderson, 2015). The responsibility of navigating complex systems of care, coordinating care across systems, advocating for services, and collaboratively setting treatment goals frequently falls on family members. Parents generally assume these responsibilities but report inadequate support over the transition to adulthood. Furthermore, the existing research base and service system have largely neglected cultural differences in transition-related preferences and goals for adulthood. The proposed research aims to develop an innovative program to engage families in the process of creating and implementing a plan to support their child over the transition to adulthood. Individualized and culturally-responsive family engagement in transition planning during adolescence is expected to result in more sustained engagement with the autism service system into adulthood, which in turn may set up more positive trajectories of functional, behavioral, and health outcomes across the life course and decrease race/ethnicity-based service use disparities into adulthood.

SECTION O: COSTS/PAYMENTS

YES*	NO	
☐	☒	Are there any costs to subjects as a result of participating in this study? **If YES**, provide a description of the costs:
☒	☐	Will subjects be compensated for participating in the study? Compensation may include cash, checks, gift cards, lotteries, course credit, etc. Payments should be prorated to compensate subjects for time and procedures completed **If YES**, provide a description of the compensation:

		Phase 1: Parents / primary caregivers, individuals on the autism (when they participate), and service providers will each receive a gift card worth $50 when they complete the qualitative interview. If an adolescent/young adult and caregiver both participate in separate interviews, they will each be compensated $50 (i.e., $100 total for the family). If only the caregiver participates, this individual will receive $50 (i.e., $50 total for the family). This compensation will be provided as gift cards to be distributed in-person, via mail, or electronically. Phase 2: Parents / primary caregivers will receive a gift card worth $30 for completing Time 1 measures. Parents / primary caregivers will receive a gift card worth $50 when they complete post-program data collection. Individuals on the autism will receive $30 for completing post-program exit interviews. (If an adolescent/young adult and caregiver both contribute post-program data, they will each be compensated (i.e., $80 total for the family). If only the parent/caregiver participates, this individual will receive $50 (i.e., $50 total for the family). This compensation will be provided as gift cards to be distributed in-person, via mail, or electronically. Service providers will not be compensated for participating in the exit interview. Families will not be compensated for participating in treatment sessions; rather, compensation will be given for providing research data.
☐	☒	Will identifiable information be sent to Central University departments (e.g. Accounts Payable, Post Award Financial Operations, etc.) for payment purposes? **If YES**, this information must be disclosed in the consent form.

SECTION P: CONFIDENTIALITY OF DATA

Describe how data will be stored (e.g. paper, electronic database, etc.)
Electronic data, written transcripts, and audio recordings of interviews will be maintained in secured project files in the research office at Boston University (900 Commonwealth Ave, 2nd Floor, Boston, MA 02215). Files with identifying information will be maintained in a password protected electronic file separate from completed questionnaires or interview data, which will contain only identification codes. Electronic data will be kept on a secure server that can be accessed only by the PI and any authorized research staff. Hard copies of research-related materials (e.g., handwritten notes taken during the interviews) will be kept in a locked file cabinet in the research office. Audio recordings collected by BU investigators will be transferred to a password-protected secure network drive at BU and secure cloud storage (when interviews are conducted remotely by BU investigators), and will be deleted from the local laptops. Identifying information will be kept in a separate, locked cabinet in the research office. Identifying information about families who decline participation will be destroyed. Maintaining

all records in a locked file that is available only to research personnel will protect confidentiality. Only identification codes (i.e., no protected health information) will be used in presenting data in lectures, seminars, and papers. Participants will be given access to summaries of the study data if requested, after completion of the study.

Interviews may be conducted using video conferencing, so alternative safeguards have been taken to ensure protection of confidentiality throughout these portions of the study. The host sends participants a secure link through which to access the meeting/session, and can require a password (provided by the host) to join the meeting; thus, families do not need to register for their own Zoom account. Zoom software clearly identifies the user to the host. Audio recordings collected by BU investigators will be transferred to a password-protected secure network drive at BU and secure cloud storage (when interviews are conducted remotely by BU investigators), and will be deleted from the local laptops.

YES*	NO	
☒	☐	Will you collect identifiable information? (e.g. names, social security numbers, addresses, telephone numbers, etc.). **If YES**, complete the box below.

Describe the coding system that will be used to protect the information including who will have access to the code. Coding systems are used to: 1) protect the confidentiality of the research data and 2) allow the investigator to link subjects to their responses. Each subject is assigned a unique study ID at the beginning of the study. A separate document (key) should be maintained that links the names of the subjects to the study ID numbers.

The identified data will only be accessed and analyzed by the researchers in the study. PI will use pseudonym to represent each participant. The file documenting the association between the pseudonym and real identity will only be stored in PI's lab.

YES*	NO	
☐	☒	Will you share data with others outside of the study? **If YES**, complete the box below.

Describe how data will be transferred and how confidentiality will be maintained (e.g. identifying information will not be sent outside, etc.):

Describe how you will maintain the confidentiality of the data (e.g. locked cabinet, password-protected files, encryption, etc.). Note: Confidentiality refers to the researcher's agreement with the participant about how the subject's identifiable private information will be handled, managed, and disseminated. For further assistance and/or access to resources regarding information security, please refer to the BU Information Security website**.**

Electronic files with identifying information will be maintained in a password protected electronic file separate from completed questionnaires or interview data, which will contain only identification codes. Electronic data will be kept on a secure server that can be accessed only by the PI and any authorized research staff. Hard copies of completed questionnaires will contain

only identification codes (no identifying information) and will be kept in a locked cabinet. Hard copies of telephone screens will be kept in a separate locked cabinet. Electronic data collection will be entered directly into Qualtrics. Data entered into Qualtrics will only be accessible to research staff who have a username and password. Qualtrics uses secure socket layering (SSL) encryption technology and stores data on a secure, password protected server. No identifying information will be used when presenting findings.

Per Boston University (BU) Record Retention Policy, records concerning human subjects must be retained for 7 years. As the investigator, you must also adhere to all applicable requirements as defined by regulatory agencies (e.g. FDA, etc.) or Sponsors.

SECTION Q: CERTIFICATE OF CONFIDENTIALITY

In 2017 the NIH updated its policy for issuing **Certificates of Confidentiality**. Under the policy, all **eligible** research studies funded by the NIH are automatically issued a certificate of confidentiality. Investigators whose research is not funded or supported by the NIH may request and obtain from the NIH a Certificate of Confidentiality. Investigators who request and receive Certificates must follow the NIH and PHS policies governing such certifications.

YES	NO	
☐	☒	Is your research funded by the NIH and eligible for a Certificate of Confidentiality?
☐	☒	If your research is not funded by the NIH, will you be applying for a Certificate of Confidentiality?

SECTION R: PRIVACY

Describe how you will protect the privacy of subjects (e.g. where will consent procedures take place, if interviews or other interventions, where will these procedures take place)

1. The location of data storage is PIs' research lab at Boston University. Specifically, the research team has set up a secure Sharepoint site that can be accessed by both the BU and Lehigh research staff, and which serves as the repository for all study data.
2. Only the research staff mentioned in this document will be allowed to access to study information.
3. For Phase 1 (interviews), we expect that the majority of interviews will be held online via Zoom. However, participants may also choose to complete qualitative interviews via phone.
4. For Phase 2, all data will be collected by the Boston University study team online via Qualtrics or via zoom/phone in order to separate data collection from the Arc providers.

SECTION S: MONITORING STUDY DATA

How will data be monitored?
Note: The Data and Safety Monitoring Plan should be tailored to the nature, size, and complexity of the research protocol, the expected risks of the research, and the type of subject population being studied.

☒	Principal Investigator
☐	Monitor/Monitoring Group
☐	Data and Safety Monitoring Board (DSMB) Note: The DSMB Charter must be submitted with this Application. For more information regarding a DSMB, please refer to the NIH website.

Describe the plan for monitoring study data. This should include a description of how data will be collected and analyzed as the project progresses to assure the appropriateness of the research, its design, and subject protections.
Data monitoring will be conducted throughout the project period. As part of our weekly research meetings, Drs. Long and Orsmond will evaluate the progress of the study and review data quality, recruitment, and adverse events to identify any changes in participant risk. Dr. Long will assume primary responsibility for ensuring that protocols to ensure participant confidentiality are closely followed. In accordance with the IRB procedures, Dr. Long will monitor all research procedures to ensure that they conform to the approved IRB protocol. Any adverse events will be immediately reported to the Boston University IRB.

SECTION T: HIPAA

Health Insurance Portability and Accountability Act

YES*	NO	

☐	☒	Is this research being conducted in a covered entity?
		The following BU CRC Departments are considered covered entities:
		• Sargent College Rehabilitation Services
		  ○ Physical Therapy Center at the Ryan Center for Sports Medicine and Rehabilitation
		  ○ Sargent Choice Nutrition Center
		• The Danielsen Institute
		• Boston University Health Plan
		*If YES, contact the IRB office for assistance.

SECTION U: FAMILY EDUCATIONAL RIGHTS AND PRIVACY ACT (FERPA)

: FERPA is the federal law that protects the privacy of student education records. Research funded by the Department of Education or research conducted in educational institutions that receive funds from the Department of Education (for research or other purposes) must comply with FERPA.

YES*	NO	
☐	☒	Does this study involve collection of information from student school/university records? *If YES, refer to the following websites for guidance on FERPA: • http://www.bu.edu/researchsupport/compliance/human-subjects/ • http://www.bu.edu/reg/general-information/ferpa/ • http://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html

		If FERPA applies, you must complete the box below:
In accordance with FERPA, written consent must be obtained to access student records. The consent must: • Specify the records that may be disclosed • State the purpose of the disclosure • Identify the person or class of parties to whom the disclosure can be made		
☐ YES **(REQUIRED)**		I confirm that I will comply with the FERPA policy that is in place at the educational institution where I am conducting my research. This includes, if applicable, the requirements for written agreement when requesting a waiver of consent for personally identifiable information. **If an agreement is required, this agreement must be submitted to the IRB.**

SECTION V: PROTECTION OF PUPIL RIGHTS AMENDMENT (PPRA):

PPRA is a federal law that affords certain rights to parents of minor students with regard to surveys that ask questions of a personal nature. Research funded by the Department of Education or research conducted in educational institutions that receive funds (for research or other purposes) from the Department of Education must comply with the PPRA.

YES*	NO	
☐	☒	Does PPRA apply to this study? If YES, refer to the following websites for guidance: • http://www2.ed.gov/policy/gen/guid/fpco/ppra/index.html • http://www.bu.edu/researchsupport/compliance/human-subjects/ **If PPRA applies, you must complete the box below:**
In accordance with PPRA, written parental consent must be obtained prior to subject's participation in the study.		
☐ YES **(REQUIRED)**		I confirm that I will comply with the PPRA policy that is in place at the educational institution where I am conducting my research.

SECTION W: CLINICAL TRIALS REGISTRATION:

The Food Drug and Administration Amendments Act (known as FDAAA 801) requires that "applicable clinical trials" be registered and have results reported on clinicaltrials.gov. In addition, the International Committee of Medical Journal Editors (ICJME) and the National Institutes of Health (NIH) also have requirements for registration. Please see box below to determine if your study requires registration in accordance with either FDAAA 801, ICJME, or NIH.

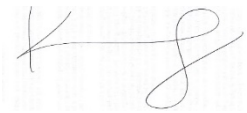
YES	NO	FDAAA 801 Requirements
☐	☒	Does your study meet the definition of an applicable clinical trial (ACT) and require registration **AND** results submission in accordance with FDAAA 801? ACTs include: • Trials of drugs and biologics: Controlled clinical investigations, other than phase 1 clinical investigations, of drugs or biological products subject to Food and Drug Administration (FDA) regulation • Trials of devices (see note): 1) Controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and 2) pediatric post-market surveillance required by FDA

		Note: If your study meets the requirement for registration and reporting, you must submit the National Clinical Trial (NCT) Identifier # to the IRB prior to IRB approval**.** NCT #:
YES	**NO**	**ICMJE Requirements**
☐	☒	Does your study meet the definition of a clinical trial and require registration in accordance with ICMJE? **Note:** If your study meets the requirement for registration, you must submit the National Clinical Trial (NCT) Identifier # to the IRB prior to IRB approval. NCT #:
YES	**NO**	**NIH Requirements**
☐	☒	Does your study meet the definition of an applicable clinical trial and require registration **AND** results submission in accordance with NIH? For more information on this policy please refer to: • NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information • Checklist **Note:** If your study meets the requirement for registration and reporting, you must submit the National Clinical Trial (NCT) Identifier # to the IRB prior to IRB approval. NCT #:

Certification / Signatures

- By submitting this protocol I attest to the fact that all research activities to be implemented related to human subjects have been completely and accurately described herein.
- I agree to conduct the describe research in an ethical manner.
- I agree to comply with all institutional policies and procedures related to human subjects research and will not begin any human subjects research activities until I have obtained full approval from the IRB.
- I agree to conduct the research as described in this protocol and not to make any changes (except to eliminate immediate harm to subjects) without first obtaining approval for the changes from the IRB.
- I agree to immediately report any unanticipated problems involving risks to subjects or others, any subject complaints, and any incidents of non-compliance with the requirements of this protocol as soon as I become aware of them.
- I agree to comply with any relevant HIPAA and FERPA regulations if applicable.
- I verify that all those responsible for the design, conduct, or reporting of the proposed program, including at minimum, all Senior/key personnel in the grant application, have completed the financial interest disclosure forms and completed training as dictated at http://www.bu.edu/orc/coi/forms/, and returned the forms to the Office for Research Compliance COI Unit. **NOTE: If anyone checked "yes" to any of the questions on either the FIND1 or NONFIND1 form, the IRB Director will contact the COI office to obtain the disclosure information.**

PI Printed Name: Kristin Long

PI Signature:  **Date:** 02/08/2022

Submission: This form can be completed, signed, scanned and submitted to the IRB at irb@bu.edu. Faxed documents and handwritten materials are not accepted. Be sure to include all relevant attachments.

FACULTY Research:

The Department Chair signature is required: This application must be signed by the Department Chair for all faculty researchers. If the PI is the Department Chair, then signature by the appropriate Dean is required. Department Chair signature is not required for student research.

By signing this form you are indicating that you have reviewed the application, the faculty/staff person listed as PI on this protocol is a member of your department, hat he/she is qualified to serve as the PI for this study, he/she has the adequate resources, and the research utilizes acceptable practice for the discipline.

Department Chair (print name): David Somers

Department/School: Psychological & Brain Sciences / CAS

Signature: 

Date: Feb 8, 2022

STUDENT Research

Student research: Student research must be signed by the faculty advisor AND the designated School IRB pre-reviewer (if applicable) PRIOR TO submission to the IRB. Students should check with their School to determine if School IRB pre-review is required. Students must submit a copy of their dissertation with the IRB Application

By signing this form, you are indicating that you have reviewed the application, that you agree to serve as the Co-PI for this study with the student and that you will be responsible for the ethical conduct of this student's human subjects research.

Faculty Advisor (print name): _____

Signature: _____

Date: _____

IRB School Reviewer, if applicable (print name): _____

Signature: _____

Date: _____

Statistical Analysis Plan

To assess clinically-significant change in treatment targets and outcomes, we will use both anchor-based and distribution-based approaches. Regarding anchor-based approaches, we will assess changes on proposed treatment targets (parent self-efficacy and expectations for adult outcomes) and program outcomes (transition planning activities and attainment of personalized program goals) in relation to self-reported global assessment of change. Global assessments are considered to be sensitive to change and are obtained by asking participants to think back over a specific period of time (i.e., since before participation in Families FORWARD) and indicate the presence and direction of change in their functioning from that time to the present (i.e., improvement, decline, no change).We will use Pearson correlations to assess associations between global assessment ratings and pre/post-program change scores on treatment targets and outcomes. Regarding distribution-based approaches, we will compare pre- to post-program changes in treatment targets and program outcomes to measures of variability within the sample. We will complete these analyses using standard errors of measurement (SEM), standard deviations (SD), and effect sizes (ES). SEM of 1.0, SD of 0.50, and/or ES (Cohen's d) of 0.20 will be indicative of clinically-significant change. We will analyze qualitative exit interview data using applied thematic analysis. Although our sample is not large enough to reach saturation within each racial/ ethnic group, a nuanced analysis according to race/ethnicity is important for our research question that addresses feasibility, acceptability, and perceptions of program benefit across diverse participants. The goal of proof-of-concept testing is not to demonstrate thematic saturation, but rather, to inform the promise of an intervention to guide future work. We will conduct all analyses for the entire sample and again separately for each racial/ethnic group (Black, Latinx, Asian, and non-Latinx white), since outcomes may differ across groups.

To assess acceptability, descriptive statistics (mean, median, standard deviation) will be calculated for quantitative acceptability ratings. Exit interview data about program usefulness and value will be evaluated using applied thematic analysis. Analyses will be conducted with the whole sample and separately for each racial/ethnic group. To assess feasibility, we will calculate the number of eligible participants who enrolled in the pilot trial. Retention will be presented descriptively as the average number of sessions completed and follow-up rates within each racial/ethnic group. To assess selective attrition, we will use t-tests and chi squares to evaluate the demographic and autism-related characteristics of families who complete the program vs. those who do not complete the program; these analyses will be conducted for the entire sample. To assess feasibility of the telehealth approach, we will capture technology issues during review of session recordings and will track the number of families who required a tablet to be loaned to them in order to participate in the program.

To assess viability of research procedures and measures, rates of completion for pre- and post-program measures will be described descriptively. We will use t-tests and chi squares to evaluate the demographic and autism characteristics of families who complete the measures vs. those who are lost to follow up; these analyses will be conducted for the entire sample. To assess participant understanding of measures, missing data and inconsistent response patterns will be recorded. Data collection time will be calculated descriptively (mean, standard deviation, range); participant burden regarding completing study measures will be captured qualitatively during exit interviews and will be summarized using applied thematic analysis. Fidelity to the program manual will be assessed by evaluating session recordings against checklists of required components and calculating the percentage of required components present.

All consent forms are stored on REDCap platform

Protocol Title: Development of a new family-focused transition program
Principal Investigator: Kristin Long, Ph.D.
Description of Study Population: Parents of adolescents and young adults on the autism spectrum
Version Date: 6/30/2023

Study Summary

The purpose of this research study is to develop and assess the feasibility of a new program to support families of teens and young adults (youth) on the autism spectrum to plan for the future. Families FORWARD (**F**ocusing on **R**elationships, **W**ell-being, and **R**esponsibility ahea**D**) is a new parent-focused, individual telehealth program. The program includes information about the transition to adult life, skills to help work through this transition, and guidance on working toward your family's individual goals for the future.

Parents will take part in 6 to 7 sessions (60-75 minutes each) led by a program coach to build skills and plan for the future. Youth can choose to participate in portions of 1, 2, or 3 sessions, along with their parent. Parents will take a survey before and after the program, give feedback after each session, and participate in an exit interview at the end of the program. Youth can take a survey and do an exit interview at the end of the program.

Introduction

Please read this form carefully. Our study team wants to provide you with important information about taking part in a research study. If any details about this study or information on this consent form seem unclear, please let us know. We are happy to answer any questions that may arise. If you agree to take part in this study, we will ask you to indicate your willingness to continue on to the survey. You will have the option to download a copy of this consent form at the end. You also may request a copy of the consent form to be emailed to you after you complete it.

The person in charge of this study is **Kristin Long, PhD.** Dr. Long can be reached by telephone at 617-358-4296, or by email at kalong@bu.edu. We will refer to this person as the "researcher" throughout this form.

What should I know about a research study?

Participation in research is voluntary, which means that it is something for which you volunteer. It is your choice to participate in the study, or not to participate. If you choose to participate now,

Study Title: Development of a new family-focused transition program
IRB Protocol Number: 6444E
Consent Form Valid Date: 8/21/2023
Study Expiration Date: 04/18/2024

you may change your mind and stop participating later. If you decide not to participate, that decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

Why is this study being done?

The purpose of this study is to develop a new program that supports families of youth on the autism spectrum to plan for the transition to adult life. Many families describe this transition to adult life as challenging. Parents often express a need for additional support, skills, and information while helping their youth transition to adult life. As a result, we have developed the Families FORWARD (**F**ocusing on **R**elationships, **W**ell-being, and **R**esponsibility ahea**D**) program to help families of youth on the autism spectrum build skills and learn information that will help them plan for the future. This program includes 6 to 7 sessions for the parents. Youth may also choose to participate in portions of 1, 2, or 3 sessions (optional). We are conducting a small trial of this new program and to hear families' feedback about how to improve the program.

We are asking you to take part in this study because you **are parent of a youth (aged 14-21), who lives in the state of Massachusetts and are fluent in English.**

About **20** subjects will take part in this research study at Boston University.

Who is Funding the Study?

The study is funded by **The Deborah Munroe Noonan Memorial Research Fund.**

How long will I take part in this research study?

We expect that you will be in this research study for **approximately 3 months**.

What will happen if I take part in this research study?

If you agree to take part in this study, we will ask you to sign the consent form before we conduct any study procedures. If you choose to be part of this study, you will be asked to complete survey before and after participating in the Families FORWARD program. The survey can be completed on a computer, laptop, or tablet. If you need assistance, a Boston University researcher can help you complete it over the phone. After you complete this first set of survey (Time 1), you will be asked to participate in the Families FORWARD program, which includes 6 to 7 sessions online with a coach. After each session, you will complete a feedback form about the helpful and unhelpful aspects of the session and how we can improve it. At the end of the program, you will complete a second set of survey and participate in an exit interview (Time 2). Youth may participate in portions of sessions 1, 2, or 3 and complete a feedback form for the attended sessions. They can also take a short survey and do an exit interview at the end of the program (Time 2).

Time 1 Survey Details

Completing the survey will take approximately 70 minutes. This survey will ask you to tell us about your family (background information, family communication about planning for the future, and plans for youth's adult life); your youth on the autism spectrum (autism severity); and yourself (your experience with future planning for youth, barriers to future planning, and knowledge of services).

Pre-Session Phone Call

Once you have completed the survey at Time 1, a coach will reach out to you to share more information about the program, learn about your youth's interest in participating, and answer any other questions you may have about the program. In addition, you and the coach will also work together to discuss technology required to participate. In this conversation you will discuss how to set up Zoom on a computer, tablet, or smartphone. This phone call will take 15 minutes or less and can be scheduled at a time that is convenient for you.

Families FORWARD Program (6 to 7 sessions)

Parents will participate in an online program consisting of 6 to 7 sessions, which will take approximately 3 months to complete. Each session is 60-75 minutes long. During the sessions, parents will discuss their future goals and may participate with their youth in three sessions to learn about their desires, they may also communicate with others to refine their goals, learn about adult service systems, and engage in problem-solving. Parents will practice skills and work on their identified goal between sessions. After each session, parents and youth will complete a brief feedback form.

Time 2 Survey and Exit Interview

At the end of the program (approximately three months after you start the study), we will ask you to complete another set of survey and an exit interview. The survey will take about 60 minutes to complete and ask you about your family (family communication about future planning, and plans for your youth's adult life) and yourself (your experience with future planning for youth, barriers to future planning, and knowledge of services). The exit interview will take 20-30 minutes, where you will provide feedback about your experiences participating in the program.

What are the risks of taking part in this research study?

Risks of Completing Tasks

Thinking about the future may be challenging at times. You may be uncomfortable with some of the questions and topics we will ask about. You do not have to answer any questions or participate in any sessions that make you feel uncomfortable.

Study Title: Development of a new family-focused transition program
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Study Expiration Date: 04/18/2024

If you or your youth decide to withdraw from the study, we ask that you let us know. There will be no penalty or loss of benefits to which you are entitled. If you decide to withdraw from the study, the information that you and your child have already provided will be kept confidential.

If you withdraw from the study, you may still receive services for yourself or your family members (including the youth) if you choose not to participate. Your decision will not affect the care you receive now or in the future. Participation in this research is voluntary and you may leave or stop the study at any time without penalty and without affecting your services. If you would like to stop participating in this research, please let us know.

Questionnaire/Survey Risks

You may feel emotional or upset when answering some of the questions. Tell the interviewer at any time if you want to take a break or stop the interview.

You may be uncomfortable with some of the questions and topics we will ask about. You do not have to answer any questions that make you feel uncomfortable.

Loss of Confidentiality

The main risk of allowing us to use and store your information for research is a potential loss of privacy. We will protect your privacy by labeling your information with a code and keeping the key to the code in a password-protected computer.

You will be informed of any significant new findings developed during the course of this research which may affect your willingness to continue participation.

Mandated Reporting

If, during your participation in this study, we have reasonable cause to believe that **individual/child/elder** abuse is occurring, we must report this to authorities as required by law. The researcher will make every reasonable effort to protect the confidentiality of your research information. However, it might be possible that a civil or criminal court might demand the release of identifiable research information.

Reporting Suicidal Risk: If, during your participation of this study, we have reason to believe that you are at risk for being suicidal or otherwise harming yourself, we are required to take the necessary actions. This may include notifying your doctor, your therapist, or other individuals. If this were to occur, we would not be able to assure confidentiality.

Reporting Sexual Misconduct, Sexual Harassment and/or Sexual Assault:

If you are a member of the Boston University community and you report sexual misconduct to study personnel, including as part of study procedures, we are mandated to report the misconduct to the Boston University Title IX Coordinator. Members of the Boston University

community include students, faculty, staff, affiliates, visitors, applicants for admission or employment, and independent contractors. Sexual misconduct includes sexual assault, sexual harassment, dating violence, domestic violence, stalking, and sexual exploitation. If you have questions, please review the BU Title IX policy, contact the Title IX coordinator, the Study Investigator, or the IRB Office.

Are there any benefits from being in this research study?

The family may perceive direct benefits, such as skill development, knowledge, and a greater clarity about their plans for the future. The primary goal of this research is to collect information about the scientific questions asked in this study. Through your participation, you may help the investigators learn about how to support youth on the autism spectrum and/or their families.

Study Participation and Early Withdrawal

Taking part in this study is your choice. You are free not to take part or to withdraw at any time for any reason. No matter what you decide, there will be no penalty or loss of benefit to which you are entitled. If you decide to withdraw from this study, the information that you have already provided will remain in the data set and be kept confidential.

Audio/Video Recording

We would like to video record you during this study. We would like to audio record the exit interviews conducted at the end of the program. If you are video- and audio-recorded, it will be possible to identify you. We will store these recordings on our computer and only approved study staff will have access to the recordings. We will label these recordings with a code instead of your name. The key to the code connects your name to your recording. The researcher will keep the key to the code in a **password-protected computer.** According to Boston University's policies, recordings will be stored for 7 years.

Do you agree to allow us to audio and video- and audio-record you during this study?

_____YES _____NO _____ INITIALS

How Will You Keep My Study Records Confidential?

Storing Study Information for Future Use

We will keep the records of this study confidential by **using a code to identify your study information instead of your name.** We will make every effort to keep your records confidential. However, there are times when federal or state law requires the disclosure of your records. The key to the code that links your name to the information you provide us will be stored in a password-protected on our secure limited access network drive. However, there are times when federal or state law requires the disclosure of your records.

The following people or groups may review your study records for purposes such as quality control or safety:

- The Researcher and any member of their research team
- The Institutional Review Board at Boston University. The Institutional Review Board is a group of people who review human research studies for safety and protection of people who take part in the studies.
- The sponsor or funding agency for this study
- Federal and state agencies that oversee or review research
- Central University Offices

The results of this research study may be published or used for teaching. We will not include identifiable information on data that are used for these purposes.

Future Contact

We may want to contact you in the future either to follow-up to this study or to see if you are interested in other studies taking place at Boston University.

May we contact you in the future?

_____YES _____NO _____ INITIALS

Will I get paid for taking part in this research study?

Parents and their youth can receive gift cards worth up to $110 for completing the survey at the beginning and after the end of the program. Parents will receive a $30 gift card for completing the Time 1 survey, and a $50 gift card for completing the Time 2 survey and exit interview. Youth will receive a $30 gift card for completing the Time 2 survey and exit interview. The gift cards will be sent via email.

What will it cost me to take part in this research study?

There are no costs to you for taking part in this research study.

What alternatives are available?

You may choose not to take part in this research study.

ClinicalTrials.Gov

A description of this clinical trial will be available on https://clinicaltrials.gov/. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Who do I ask if I have questions or concerns about this research study?

Please call us with any concerns or questions about the research, or any research-related problems:

Kristin Long, PhD (Principal Investigator)
Phone (617-358-4296)
Email (kalong@bu.edu)
Availability: Weekdays 9am-5pm

If you have questions about your rights as a research participant, or if you have any complaints or concerns and want to speak with someone independent of the research team, you may contact the Boston University Charles River Campus IRB at 617-358-6115. The IRB Office webpage has information where you can learn more about being a participant in research, and you can also complete a Participant Feedback Survey.

Statement of Consent: I have read this information and have been given the chance to contact the researchers to ask questions. I agree to participate in the study.

☐ (check box to note consent)

Statement of Consent: I have also read this information and have been given the chance to contact the researchers to ask questions about my youth's participate in the study. I am aware that the research team will complete a consent or assent with my child before including them in research. I agree to have my child on the autism spectrum participate in the program.

☐ (check box to note consent for your child)

Study Title: Development of a new family-focused transition program
IRB Protocol Number: 6444E
Consent Form Valid Date: 8/21/2023
Study Expiration Date: 04/18/2024

All consent forms are stored on REDCap platform

Protocol Title: Development of a new family-focused transition program
Principal Investigator: Kristin Long, Ph.D.
Description of Study Population: Parents interested in future planning with their adolescent and young adult on the autism spectrum
Version Date: 6/30/2023

Study Summary

The purpose of this research study is to develop and assess the feasibility of a new program to support families of teens and young adults (youth)on the autism spectrum to plan for the future. Families FORWARD (**F**ocusing on **R**elationships, **W**ell-being, and **R**esponsibility ahea**D**) is a new parent-focused, individual telehealth program. The program includes information about the transition to adult life, skills to help work through this transition, and guidance on working toward your family's individual goals for the future.

Parents will take part in 6 to 7 sessions (60-75 minutes each) led by a program coach to build skills and plan for the future. Youth can choose to participate in portions of 1, 2, or 3 sessions, along with their parent. Parents will take a survey before and after the program, give feedback after each session, and participate in an exit interview at the end of the program. Youth can take a survey and do an exit interview at the end of the program.

Introduction

Our study team wants to provide you with important information about taking part in a research study. If any details about this study or information on this consent form seem unclear, please let us know. We are happy to answer any questions that may arise. If you agree to take part in this study, we will ask you to verbally consent your willingness to participate in the study. We will provide you a copy of this verbal consent form.

The person in charge of this study is **Kristin Long, PhD.** Dr. Long can be reached by telephone at 617-358-4296, or by email at kalong@bu.edu. We will refer to this person as the "researcher" throughout this form.

What should I know about a research study?

Participation in research is voluntary, which means that it is something for which you volunteer. It is your choice to participate in the study, or not to participate. If you choose to participate now, you may change your mind and stop participating later. If you decide not to participate, that decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

Why is this study being done?

The purpose of this study is to develop a new program that supports families of youth on the autism spectrum to plan for the transition to adult life. Many families describe this transition to adult life as challenging. Parents often express a need for additional support, skills, and information while helping their youth transition to adult life. As a result, we have developed the Families FORWARD (**F**ocusing on **R**elationships, **W**ell-being, and **R**esponsibility ahea**D**) program to help families of youth on the autism spectrum build skills and learn information that will help them plan for the future. This program includes 6 to 7 sessions for the parents. Youth may also choose to participate in portions of 1, 2, or 3 sessions (optional). We are conducting a small trial of this new program and to hear families' feedback about how to improve the program.

We are asking you to take part in this study because you are a **youth (aged 14-21), whose parent has agreed to participate in the program.**

About **20** subjects will take part in this research study at Boston University.

Who is Funding the Study?

The study is funded by **The Deborah Munroe Noonan Memorial Research Fund.**

How long will I take part in this research study?

We expect that you will be in this research study for **approximately 3 months**. During this time, if you choose to participate with your parent, we will ask you to attend 1, 2, or 3 online.

What will happen if I take part in this research study?

If you agree to take part in this study, we will ask you for your verbal consent before we conduct any study procedures. If you choose to be part of this study, you will be asked to participate with your parent in the Families FORWARD program for portions of 1, 2, or 3 sessions online with a coach. After each session, you will complete a feedback form about the helpful and unhelpful aspects of the session and how we can improve it. At the end of the program, you will complete a survey and participate in an exit interview.

Families FORWARD Program (6 to 7 sessions)

Your parent will participate in an online program of 6 to 7 sessions over 3 months. You can choose to participate in portions of 1, 2, or 3 sessions, each lasting 30 minutes or less. During these sessions, you and your parent will communicate and plan for the future with a coach's help. In other sessions, your parents will develop skills such as goal-setting, navigating service systems, and problem-solving. For each of the sessions you attend, we will ask you to complete a feedback form.

End of Program Survey and Interview

At the end of the program, which is three months after you started the program, we will ask you to complete a short survey and participate in an exit interview. This will take about 20-30 minutes to complete. In the survey and the exit interview, we will ask you to provide feedback about your experiences participating in the program.

What are the risks of taking part in this research study?

Risks of Completing Tasks

Thinking about the future may be challenging at times. You may be uncomfortable with some of the questions and topics we will ask about. You do not have to answer any questions or participate in any sessions that make you feel uncomfortable.

If you decide to withdraw from the study, we ask that you let us know. There will be no penalty or loss of benefits to which you are entitled. If you decide to withdraw from the study, the information that you have already provided will be kept confidential.

If you withdraw from the study, you may still receive services for yourself or your family members. Your decision will not affect the care you receive now or in the future. Participation in this research is voluntary and you may leave or stop the study at any time without penalty and without affecting your services. If you would like to stop participating in this research, please let us know.

Questionnaire/Survey Risks

You may feel emotional or upset when answering some of the questions. Tell the interviewer at any time if you want to take a break or stop the interview.

You may be uncomfortable with some of the questions and topics we will ask about. You do not have to answer any questions that make you feel uncomfortable.

Loss of Confidentiality

The main risk of allowing us to use and store your information for research is a potential loss of privacy. We will protect your privacy by labeling your information with a code and keeping the key to the code in a password-protected computer.

You will be informed of any significant new findings developed during the course of this research which may affect your willingness to continue participation.

Mandated Reporting

If, during your participation in this study, we have reasonable cause to believe that **individual/child/elder** abuse is occurring, we must report this to authorities as required by law. The researcher will make every reasonable effort to protect the confidentiality of your research information. However, it might be possible that a civil or criminal court might demand the release of identifiable research information.

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Are there any benefits from being in this research study?

The family may perceive direct benefits, such as skill development, knowledge, and a greater clarity about their plans for the future. The primary goal of this research is to collect information about the scientific questions asked in this study. Through your participation, you may help the investigators learn about how to support youth on the autism spectrum and/or their families.

Study Participation and Early Withdrawal

Taking part in this study is your choice. You are free not to take part or to withdraw at any time for any reason. No matter what you decide, there will be no penalty or loss of benefit to which you are entitled. If you decide to withdraw from this study, the information that you have already provided will remain in the data set and be kept confidential.

Audio/Video Recording

We would like to video record you during this study. We would like to audio record the exit interviews conducted at the end of the program. If you are video- and audio-recorded, it will be possible to identify you. We will store these recordings on our computer and only approved study staff will have access to the recordings. We will label these recordings with a code instead of your name. The key to the code connects your name to your recording. The

researcher will keep the key to the code in a **password-protected computer.** According to Boston University's policies, recordings will be stored for 7 years.

Do you agree to allow us to audio and video- and audio-record you during this study?

_____YES _____NO _____ Study Staff Initials (for verbal consent is provided)

How Will You Keep My Study Records Confidential?

Storing Study Information for Future Use

We will keep the records of this study confidential by **using a code to identify your study information instead of your name.** We will make every effort to keep your records confidential. However, there are times when federal or state law requires the disclosure of your records. The key to the code that links your name to the information you provide us will be stored in a password-protected on our secure limited access network drive. However, there are times when federal or state law requires the disclosure of your records.

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- The sponsor or funding agency for this study
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The results of this research study may be published or used for teaching. We will not include identifiable information on data that are used for these purposes.

Future Contact

We may want to contact you in the future either to follow-up to this study or to see if you are interested in other studies taking place at Boston University.

May we contact you in the future?

_____YES _____NO _____ Study Staff Initials (for verbal consent is provided)

Will I get paid for taking part in this research study?

You can receive $30 for completing the survey and exit interview end at the program. The gift cards will be sent via email.

What will it cost me to take part in this research study?
There are no costs to you for taking part in this research study.

What alternatives are available?
You may choose not to take part in this research study.

ClinicalTrials.Gov
A description of this clinical trial will be available on https://clinicaltrials.gov/. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Who do I ask if I have questions or concerns about this research study?
Please call us with any concerns or questions about the research, or any research-related problems:

Kristin Long, PhD (Principal Investigator)
Phone (617-358-4296)
Email (kalong@bu.edu)
Availability: Weekdays 9am-5pm

If you have questions about your rights as a research participant, or if you have any complaints or concerns and want to speak with someone independent of the research team, you may contact the Boston University Charles River Campus IRB at 617-358-6115. The IRB Office webpage has information where you can learn more about being a participant in research, and you can also complete a Participant Feedback Survey.

Statement of Consent
I have heard the information in this consent form including risks and possible benefits. I have been given the chance to ask questions. My questions have been answered to my satisfaction, and I agree to participate in the study.

Signature:

I agree to participate in this study:

____Yes ____No

Study Staff Completing Consent Form (if applicable): _____

Date Consent Form Completed:_____

Study Title: Development of a new family-focused transition program
IRB Protocol Number: 6444E
Consent Form Valid Date: 8/21/2023
Study Expiration Date: 04/18/2024