PROTOCOL TITLE:

Evaluation of a mentorship program for individuals with autism spectrum disorder (ASD)

PRINCIPAL INVESTIGATOR or FACULTY ADVISOR:

Rebekah L. Hudock, PhD
Pediatrics
612-626-3538
kale0040@umn.edu

Lindsey Weiler, PhD
Family Social Science
612-301-9345
lmweiler@umn.edu

STUDENT INVESTIGATOR:

Amy Gunty, MA
Family Social Science
612-460-1782
gunty004@umn.edu

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REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
1	08/08/2018	Detail added to section 5	yes
2	12/17/2018	Additional detail in section 5, information about translation and interpretation	yes
3	1/2/19	Added information about incentives	no
4	8/1/19	Update to recruitment strategy, data collection location, study length, and number of participants. Correction of incentive information (correct on consent form).	no
5	9/13/19	Update to data collection, number of participants, study team, and consent forms	yes
6	5/3/2020	Update to data collection procedures, addition of secondary outcomes, and study team	no
7	9/9/2020	Extension of the study to include Phase 3 (virtual program trial), update to Phase 3 data collection procedures, addition of Phase 3 consent, update to study team - All study activities for Phase 3 will be done via telephone or on-line (secondary to COVID-19 pandemic)	Yes (update to consent for Phase 3)

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ABBREVIATIONS/DEFINITIONS

Include any abbreviations or definitions for key or technical terms you use in your protocol.

- Autism Spectrum Disorder (ASD)
- Autism Society of Minnesota (AuSM)
- Minnesota Independence College and Community (MICC)
- University of Minnesota (UMN)

STUDY SUMMARY

Study Title	*Evaluation of a mentorship program for individuals with autism spectrum disorder (ASD)*
Study Design	Pre-, mid-, and post-program interviews, focus groups, and questionnaires
Primary Objective	Preliminary evaluation of a pilot mentoring program for individuals with ASD
Secondary Objective(s)	
Primary Study Intervention or Interaction	Participants will participate in interviews and focus groups and will complete questionnaires before, during and after participating in a pilot mentoring program.
Study Population	Adolescents and adults with ASD, parents of individuals with ASD, mentoring program staff
Sample Size (number of participants)	50-90 individuals
Study Duration for Individual Participants	Approximately 6-14 hours across 12-18 months For Phase 3 participants, an additional 6 hours over 9 months

1.0 Objectives

1.1 Purpose: *Describe the purpose, specific aims, or objectives.*

The purpose of this project is to evaluate the implementation of a pilot mentorship program for individuals with ASD implemented by a community group. Specific aims include conducting interviews and focus groups with and collecting survey information from individuals with ASD, family members, and mentorship program staff. Information from these interviews and questionnaires will be used to inform further development of the mentoring program for individuals with ASD.

2.0 Background

2.1 Significance of Research Question/Purpose: *Describe the relevant prior research and gaps in current knowledge for your research question.*

2.2 Preliminary Data: *Describe any relevant preliminary data.*

No preliminary data currently exists

2.3 Existing Literature: *Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge.*

Relationships with caring, non-parental adults (i.e., mentors) are critical to healthy child development (DuBois et al., 2011). Mentoring programs can positively influence a range of outcomes for youth, including peer and parental relationships, academic achievement, self-concept, and prevention of problem behaviors, including substance use (DuBois et al., 2011; Rhodes, 2002; Rhodes & Roffman, 2002). Despite the importance of adult youth relationships, mentoring for children with autism spectrum disorder (ASD) has not been described or studied systematically. This is particularly problematic because children who lack quality support networks are vulnerable to behavioral health problems and limited social capital, both of which strongly affect educational achievement, economic success, and quality of life (Hale & Viner, 2012). The promise of youth mentoring for children with ASD is yet to be realized, but theoretical and empirical support for mentoring, in general, suggests such relationships may be a positive youth development intervention worth exploring. The cultural adaptation of evidence-based practices has emerged as a necessary strategy to adequately and appropriately meet the needs of specific populations (Castro, Barrera, & Holleran Steiker, 2010), and will provide a framework for translating and transforming mentoring best practices to fit the unique needs of children with ASD. Because no known research is available, the purpose of this study is to examine the feasibility, acceptability, and limited effectiveness of a pilot mentoring program, which matches children with ASD with adults with ASD in a one-to-one mentoring relationship.

3.0 Study Endpoints/Events/Outcomes

3.1 Primary Endpoint/Event/Outcome: *Describe the primary study endpoint, event, or outcome you will be evaluating or observing.*

The evaluation will focus on identifying elements of the program that worked well as well as elements of the program that were difficult or did not work well. Initial outcomes for the limited exploration of the effectiveness of the program will include quality of life, self-concept, social skills, behavioral challenges, psychological well-being, academic achievement, communication, parent-child relationships, and pride in autistic identity.

3.2 Secondary Endpoint(s)/Event(s)/Outcome(s): *Describe any secondary study endpoints, events, or outcomes you will be evaluating or observing.*

Secondary data will also be collected regarding implementation of the program, including acceptability and feasibility of the intervention and experiences with the modality of the intervention.

4.0 Study Intervention(s)/Interaction(s)

4.1 Description: *Describe the study intervention(s) and/or interaction(s). Interventions may include staging scenarios or manipulating the environment to evaluate behavior. Interactions may include surveys, interviews, or focus groups. If the study does not involve intervention or interactions, describe any observations of public behavior.*

A community group, including the PIs, is overseeing the development and implementation of the mentorship program. The PIs serve on this committee to inform the group of best practice in evaluating such a program. UMN staff will attend training sessions and will continue to engage in steering committee meetings in order to oversee data collection and to educate the community group about participant protections and research procedures. As such, UMN staff will be focused specifically on evaluation of that program. UMN staff will engage participants, parents, and program staff in pre-, mid-, and post-program interviews, focus groups, and surveys. Furthermore, UMN staff will have access to program applications completed by participants and will receive weekly information from program staff regarding attendance and participant ratings of the weekly meetings. While program staff will be collecting application and weekly data, researchers will be overseeing the weekly data collection process. For Phase 3, all study activities will be conducted via telephone or other electronic means.

5.0 Procedures Involved

5.1 Study Design: *Describe and explain the study design.*

5.2 Study Procedures: *Provide a description of all research procedures being performed and when they are performed, including procedures being performed to monitor participants for safety or to minimize risks.*

Describe:

- *Procedures to be performed for research purposes and, if relevant, which procedures would be performed regardless of whether the*

research was conducted, e.g., procedures performed for diagnostic or treatment purposes.

- *The data to be collected about participants and the source records that will be used to collect those data. (Attach all surveys, scripts, and participant-facing data collection forms in ETHOS.)*

5.3 Follow-Up: *The data to be collected, including long-term follow-up data.*

The study will include evaluation activities to inform the further development of a mentorship program for individuals with ASD.

The study will include distributing and collecting surveys from and conducting interviews and focus groups with mentorship program participants from Kennedy High School, Minnesota Independence College and Community (MICC), and the Autism Society of MN, along with parents of participants (where appropriate) and program staff. For Phase 3, all study activities will be conducted via telephone or electronic means. For Phase 3 only, data (naturalistic observations) will also be collected via video recordings of mentoring sessions via Zoom.

Participants will include high school students with ASD, young adults with ASD, parents of individuals with ASD (note: for parents who speak Spanish, consent forms will be professionally translated and a professional interpreter will be present for each data collection meeting), and mentoring program staff (including staff from MICC, Bloomington Public Schools, and AMP-specific staff). The community group is responsible for the recruitment and selection of participants in the program. A member of the research team will assist with the recruitment process by contacting families who indicate to the community group that they are interested in learning more about the AMP program. This team member will call or email interested families who provide their contact information to answer questions about the program, screen for eligibility, and to connect them to the program coordinator for application materials if they would like to apply for the program.

Individual interviews and focus groups will take place at AuSM headquarters, MICC, Kennedy High School, another Bloomington Public Schools building, or a local venue close to the participant's home that can provide adequate privacy for study activities, whichever location is preferred by the participant. Surveys will be completed as a part of those data collection visits in which interviews are conducted. Interviews and select survey tools (NMRC Academic Achievement and School Engagement Scales, Future Orientation Scale, Loneliness Questionnaire, Rosenberg Self-Esteem Scale, Mentoring Relationship Quality Scale) will be administered via Qualtrics with permission from the developers and publishers. Online surveys will be completed by participants within their homes or at the location of their choice on personal electronic devices. Interviews and focus groups will be audio recorded and transcribed for analysis. Qualitative data (i.e., formative evaluation data) will be gathered and analyzed from the interviews and focus groups and will be used to inform the continued development of the mentorship program.

Due to changes in the implementation of the mentoring program on the part of the community partners (who are responsible for the implementation), the length of the program will vary. A shorter program (Phase 1) will run from January until May 2019, during which we will evaluate acceptability and feasibility. A full pilot program (Phase 2) will then run for the next school year, from August 2019 to June 2020, during which we will continue to evaluate acceptability and feasibility while also collecting data to evaluate preliminary outcomes associated with the program. Due to changes in programming resulting from the COVID-19 pandemic, AMP is unable to be implemented in-person as intended; therefore, AMP will be implemented in a virtual format for the 2020-2021 school year (Phase 3), and the program evaluation will be extended to evaluate the initial outcomes of a virtual AMP program.

For Phase 3, all efforts described here will be conducted electronically so as to facilitate appropriate no-person-contact measures that are indicated vis-à-vis current COVID-19 pandemic. Participants will be encouraged to situate themselves in a context where their privacy is ensured / facilitated (e.g., a private room in their apartment or house with the door shut). Researchers will do the same, and communicate as such during consent processes and before study activities begin. To better describe participants, Phase 3 participants will complete a brief assessment of cognitive skills, language skills, and symptoms related to autism. To better understand the content of mentoring sessions and the quality of mentoring interactions and relationships, virtual mentoring sessions will also be video recorded via videoconferencing applications (e.g., Zoom) and analyzed at a later date by the research team for naturalistic observation of the sessions. The consent form will be updated to reflect the addition of Phase 3 and changes in data collection procedures. Consent will be obtained electronically for participants participating in Phase 3.

In sum, researchers will use the following data in the evaluation of the pilot program:

- Pre-program
    - Information from applications to the program
    - Brief baseline skills assessment (Phase 3)
        - Ravens Progressive Matrices (mentees, mentors)
        - Peabody Picture Vocabulary Test- 5th Edition (PPVT-5) (mentees, mentors)
        - Social Responsiveness Scale – 2nd Edition (SRS-2) (mentors, parents)
    - Interviews/Online Surveys (30-60 minutes)
        - Open-ended and Likert-scale questions about demographics (gender, race, ethnicity, household income, diagnosis, education level), quality of life, autistic identity, personal goals, social activities and relationships, independent living skills, social and emotional well-being, experience with the mentorship program, and impact of COVID-19 (COVID-related questions only in Phase 3).
    - Questionnaires (60-90 minutes)

        - Achenbach scales (Phases 1 &2)
            - Child Behavior Checklist (CBC; parent-report, mentees)
            - Youth Self-Report (YSR; mentees)
            - Adult Self-Report (ASR; mentors)
        - Social Skills Improvement System (SSIS; parent report and student-report, mentors and mentees) (Phases 1-3)
        - Piers-Harris Self-Concept Scale-(Phase 1)/Rosenberg Self-Esteem Scale-full pilot (Phases 2 &3) (mentors and mentees)
        - Mentoring Relationship Quality Scales (Phases 1-3)
        - Child Communication Checklist – 2nd Edition (CCC-2, parents) – (Phases 2 &3)
        - Stress Index for Parents of Adolescents (SIPA, parents) – (Phase 2)
        - NMRC Academic Performance & School Engagement – (Phases 2&3)
        - Future Orientation Scale (mentors and mentees) (Phase 3)
        - Loneliness Questionnaire (mentors and mentees) (Phase 3)
        - Beck Depression Inventory – 2nd Edition (BDI-2) (mentors and mentees) (Phase 3)
        - Beck Anxiety Inventory (BAI) (mentors and mentees) (Phase 3)
- Beginning of Program (90 minutes) – (Phase 1 only)
    - Focus groups regarding goals and program implementation (goals for the program, what is working and what is not working)
- Weekly (5 minutes)
    - Exit slip including information about how that week's particular meeting went, from:
        - mentors
        - mentees
        - staff members
    - Video recordings of virtual mentoring sessions
- Mid-program (60-90 minutes)
    - Interviews/Online Surveys (modified version of pre- and post-interviews/surveys)
        - Mentoring Relationship Quality Scale
        - NMRC Academic Performance & School Engagement Scales – (Phases 2&3)
- Post program
    - Interviews/Online Surveys (30-60 minutes)
    - Questionnaires (60-90 minutes)
        - Achenbach scales (Phases 1&2)
            - Child Behavior Checklist (CBC; parent-report, mentees)
            - Youth Self-Report (YSR; mentees)
            - Adult Self-Report (ASR; mentors)
        - Social Skills Improvement System (SSIS; parent report and student-report, mentors and mentees) (Phases 1-3)
        - Piers-Harris Self-Concept Scale- (Phase 1)/Rosenberg Self-Esteem Scale-full pilot (mentors and mentees) (Phases 2&3)

        - Mentoring Relationship Quality Scale (Phases 1-3)
        - Child Communication Checklist – 2nd Edition (CCC-2, parents) – (Phases 2&3)
        - Stress Index for Parents of Adolescents (SIPA, parents) – (Phase 2)
        - NMRC Academic Performance & School Engagement Scales – (Phases 2&3)
        - Future Orientation Scale (mentors and mentees) (Phase 3)
        - Loneliness Questionnaire (mentors and mentees) (Phase 3)
        - Beck Depression Inventory – 2nd Edition (BDI-2) (mentors and mentees) (Phase 3)
        - Beck Anxiety Inventory (BAI) (mentors and mentees) (Phase 3)
        - Project-developed questionnaire regarding implementation of the program (AMP founder and program manager) – (Phases 2&3)
        - Project-developed questionnaire regarding implementation of the program within a school setting (AMP educational staff from MICC and Bloomington Public Schools) – (Phases 2&3)
        - Project-developed questionnaire regarding planning, acceptability, and feasibility of the program (AMP steering committee, AMP staff) – (Phases 2&3)
    - Focus Groups (mentees, mentors, parents) (Phases 1&3)

Incentives. Participants will receive the following incentives:

- Phase 1 (December 2018 through June 2019): $10 for each completed data collection activity (i.e., pre-program, post-program)
- Phase 2 (August 2019 through June 2020):
    - Baseline data: $10
    - Mid-program interviews: $20
    - Post-program data: $25
- Phase 3 (September 2020-June 2021)
    - Baseline assessment: $20
    - Pre-intervention data collection: $50
    - Mid-program data collection: $30
    - Post-program data collection: $50
    - Post-program focus group: $50

6.0 Data Banking

If this study does not involve data banking for future use, type "N/A" and delete the sub-headings below. Otherwise, complete all items below.

6.1 Storage and Access: *If data will be banked for future use, describe where the data will be stored, how long they will be stored, how the data will be accessed, and who will have access to the data.*

Data from this pilot study will be stored within a secure Box account sponsored by UMN. The PIs will manage this database and will provide access to the data to identified key study personnel who will be responsible for managing and analyzing study data. Data

will not be accessible to individuals outside of the research team. Data will be stored for up to 7 years in order to inform future studies expanding on this work and to be used for preparation of publications.

6.2 Data: *List all of the data elements to be collected and banked for future use.*

Data will be collected regarding interviews, interview responses, focus group discussions, questionnaire/survey responses, educational information (school, grade, classroom, special education services), video recordings of mentoring sessions, brief assessment of cognitive/language functioning and ASD symptoms, clinical and/or educational evaluations to include diagnoses and classifications, and participant demographic information (age, gender, race, ethnicity, city of residence, household income, employment status, educational status) via self- and/or parent-report. Data collected include information mentioned above (protocols included in appendices).

6.3 Release/Sharing: *Describe the procedures to release data, including: the process to request a release, approvals required for release, who can obtain data, and the data elements to be provided.*

Data will not be released to individuals other than those identified by the PIs as key personnel who are responsible for managing or analyzing the data. The PI will grant access to the secure Box database on an individual basis after assessing the need for an individual's access. Otherwise, the PIs will be responsible for sharing relevant information with the advisory team who will develop the mentoring program. Upon request from the community partners, the research team may also produce summaries of study results to be shared with community stakeholders.

7.0 Sharing of Results with Participants

7.1 Describe whether results (study results or individual participant results, such as survey results) will be shared with participants or others (e.g., participants' parent or school administrators) and, if so, describe how the results will be shared.

Please see the Investigator Manual (HRP-103) for additional information about language that should be included in the consent form related to sharing of results.

Results of the interviews and questionnaires will not be shared directly with participants; however, results will be shared with the community group in order to inform the further development of the mentoring program. Upon request from the community partners, the research team may also produce summaries of study results to be shared with community stakeholders, which may be accessible to study participants.

8.0 Study Duration

8.1 Describe:

- *The duration anticipated for an individual participant's participation in the study.*
- *The duration anticipated to enroll all study participants.*
- *The duration anticipated to complete all study procedures and data analysis.*

The study is anticipated to last approximately 12-18 months, depending upon whether participants participate in Phases 1 and 2 of the program, or only Phase 2 of the program. Participants who wish to participate in Phase 3 of the study will participate for an additional 9 months. Researchers will conduct interviews and focus groups and collect questionnaires at the beginning and end of the pilot year of the mentoring program (August-September 2018 and May-June 2019 for Phase 1; in September/October 2019, January/February 2020, and May/June 202 for Phase 2; in October 2020, January 2021, and May/June 2021 for Phase 3) to gather data to be used for formative evaluation of the program. Data analysis will occur in the months following the completion of the program each year. The community group developing and implementing the mentorship program is primarily responsible for the recruitment of participants and decisions regarding the inclusion of participants. We will approach participants during the mentorship program time itself and/or via email or phone call at the beginning of the school year to facilitate evaluation activities. Depending upon which years of the study participants choose to participate in, participation is expected to take approximately 6 hours of the participant's time over the course of 12 months, or 14 hours over the course of 18 months. Phase 3 will require approximately 6 hours of the participants' time over 9 months.

Following the completion of interviews and questionnaires, the research team will meet to analyze the data, share results with the advisory team, and make recommendations regarding further development of the mentoring program.

9.0 Study Population

9.1 Inclusion Criteria: *Describe the criteria that define who will be included in your final study sample.*

Please reference Section: Vulnerable Populations. Please note that you may not include vulnerable populations as participants in your research unless you indicate this in your inclusion criteria.

The mentoring program will include high school students with ASD (ages 14-21) and young adults with ASD (ages 18-35). Evaluation data will also be collected from parents of participants (where appropriate), professionals who work with individuals with ASD who are involved in the implementation of the pilot mentoring program (special educators and school administrator, MICC staff), and community members overseeing the development and implementation of the mentoring program. Inclusion criteria will be that individuals are participants, participants' parents, or staff in the mentoring program.

Participants must have fluent language and will speak and understand English and/or Spanish fluently. Participants must be able to commit to providing evaluation data. Participants will not have an intellectual disability (IQ under 70) as documented in the baseline assessment or in the clinical or educational evaluation provided at the beginning of the program. Participants will have a diagnosis/classification of ASD as documented via medical/psychological documentation or educational records.

9.2 Exclusion Criteria: *Describe the criteria that define who will be excluded in your final study sample.*

Participants will be excluded from the interviews and questionnaires if they are not participants in the mentoring program, parents of participants in the mentoring program, or mentoring program staff. They will also be excluded if they do not have fluent language, and if they do not speak and understand English and/or Spanish. Participants will be excluded if they have an intellectual disability (IQ under 70; note that this is also exclusion criteria for participation in the mentoring program at this time) and if they do not have a diagnosis/classification of ASD. Participants who are unable to commit to the time needed for the interview and questionnaires will not be included.

9.3 Screening: *Describe how individuals will be screened or assessed for eligibility.*

Participants will be personally invited by community group staff at the mentoring program. A brief speech sample will be taken at the beginning of the interview. Participants will also be asked to provide documentation of their ASD diagnosis and IQ either via medical/psychological records or educational evaluation/records.

10.0 Vulnerable Populations

10.1 Vulnerable Populations: *Identify which of the following populations will be involved in this study. (You may not include members of the populations below as participants in your research unless you indicate this in your inclusion criteria above.)*

x Children
☐Pregnant women/Fetuses/Neonates
☐Prisoners
☒Adults lacking capacity to consent and/or adults with diminished capacity to consent, including, but not limited to, those with acute medical conditions, psychiatric disorders, neurologic disorders, developmental disorders, and behavioral disorders
☒ Non-English speakers
☐Those unable to read (illiterate)
☐Employees of the researcher
☐Students of the researcher
☐None of the above

10.2 Adults lacking capacity to consent and/or adults with diminished capacity to consent:

- *If the research involves cognitively impaired adults, or adults with fluctuating, diminished, or lacking capacity to consent, review "CHECKLIST: Cognitively Impaired Adults (HRP-417)" to ensure that you have provided sufficient information.*
- *Provide justification for the inclusion of this population and describe the importance of the knowledge to be gained.*
- *Explain how including this population represents the least degree of impairment compatible with the aims of this study.*
- *Specify how risks are minimized and/or whether the risks or discomforts are greater for this population.*

Participants will not have intellectual/cognitive disability; therefore, they are assumed to have the capacity to consent/assent. However, individuals with ASD may have some difficulty processing information and tend to have higher rates of anxiety, which may make the consent process stressful for some participants. Therefore, we will administer the UBACC to all adults with ASD consenting to participate in this study to ensure that they fully understand their participation and the purpose of the study. Minors and individuals who have a legal guardian will also have their parent/legal guardian consent. This program is being specifically designed for individuals with ASD; therefore, they must be included in the study. Risks will be minimized by reviewing consent and study materials on more than one occasion and by providing visual supports to assist in understanding the information. Adults with ASD are welcome to have their parents/teachers present during the consent process if they wish.

While all mentors and mentees in the program will be fluent in English, some parents of mentees may speak Spanish. Consent forms have been translated into Spanish, and when possible Spanish versions of questionnaires will be provided. A Spanish-speaking interpreter will be present for all portions of the study that parents participate in. Because we are evaluating a community-based program, it is necessary to provide access to the program for a representative sample of the population.

The research team participates in and regularly consults with an advisory board who will be responsible for developing and implementing the mentoring program. The advisory board consists of individuals with ASD, parents of children/young adults with ASD, and individuals who specialize in working with individuals with ASD. Our research team has expertise in working with and creating materials and programming specifically for this population and will work to identify and minimize risks and discomfort to the participants.

10.3 Additional Safeguards: *If the research involves individuals Checked in Section 10.1 above, provide justification for their inclusion and describe additional safeguards included to protect their rights and welfare.*

- *If the research involves pregnant women, review "CHECKLIST: Pregnant Women (HRP-412)" to ensure that you have provided sufficient information.*
- *If the research involves neonates of uncertain viability or non-viable neonates, review "CHECKLIST: Non-Viable Neonates (HRP-413)" or "CHECKLIST: Neonates of Uncertain Viability (HRP-414)" to ensure that you have provided sufficient information.*
- *If the research involves prisoners, review "CHECKLIST: Prisoners (HRP-415)" to ensure that you have provided sufficient information.*
- *If the research involves persons who have not attained the legal age for consent to treatments or procedures involves in the research, review "CHECKLIST: Children (HRP-416)" to ensure that you have provided sufficient information.*

See section 10.2

11.0 Number of Participants

11.1 Number of Participants to be Consented: *State the approximate number of participants you plan to enroll. Give the lowest number that will allow data analysis and the maximum that might agree to participate. If the research involves secondary analysis of existing data, give the estimated number of records that will be used.*

We anticipate enrolling 50-90 participants for evaluation of the mentoring program. This includes 10-25 mentors, 10-25 mentees, up to 30 parents of participants, and up to 10 mentoring program staff.

12.0 Recruitment Methods

12.1 Recruitment Process: *Describe when, where, and how potential participants will be recruited.*

The community group implementing the program is primarily responsible for the recruitment and selection of participants in the pilot mentoring program. A member of the research team will assist with the recruitment process by contacting families who indicate to the community group that they are interested in learning more about the AMP program. This team member will call or email interested potential participants who provide their contact information to answer questions about the program, screen for eligibility, and to connect them to the program coordinator for application materials if they would like to apply for the program.

12.2 Source of Participants: *Describe the source of potential participants, e.g., Research Experience Program.*

The community group developing and implementing the pilot program is responsible for the identification of program participants, and they are also responsible for final decisions regarding inclusion or exclusion of those potential participants. This group is hand-selecting participants for the program. Given the pilot nature of the mentoring program, the community group will communicate to potential participants that formative evaluation is an important part of the pilot program.

12.3 Identification of Potential Participants: *Describe the methods that will be used to identify potential participants. Describe whether participants will self-identify in response to posters, mailings, emails, etc., or whether they will be recruited based on information contained in private/protected records (e.g., medical records, student records; note that this also includes participants who will be recruited from the PI's or Co-PI's patient or student population.)*

- *For information contained in private/protected records, explain how the researcher has legitimate access to these records.*
- *Identify who will make initial contact with potential participants.*
- *Identify whether the private/protected records will include **MEDICAL** records and the mechanism the PI will use to confirm that patients have agreed to release their PHI contained in their medical records for research purposes; for example, a particular patient has documented consent to research on their treatment, intake, or hospital admitting form. (MN Statute 144.334 Subd. 3; Access to Medical Records for Research), e.g., Academic Health Center Information Exchange (AHC-IE).*

The community group will send letters and emails advertising the program. Their recruitment materials will allow for potential participants to indicate whether they are interested and would like to learn more about AMP. Potential participants who indicate interest and provide their contact information will then be contacted by a member of the research team to screen for eligibility, answer questions about the program, and refer to the AMP program coordinator if they are interested in applying. See 12.2 for additional information.

12.4 Recruitment Materials: *Describe materials that will be used to recruit participants. (Attach copies of these materials in ETHOS. For advertisements, attach the final copy of printed advertisements. When advertisements are recorded for broadcast, attach the final audio/video recording in ETHOS. You may instead submit the wording or script for any recorded advertisements in ETHOS prior to recording them. This will preclude re-recording because of inappropriate wording, provided the IRB reviews the final audio/video recording after approving the initial wording or script. You would likely include any recording with a modification in ETHOS.)*

The community group implementing the pilot program is responsible for the recruitment and selection of participants in the program.

12.5 Payment: *Describe the amount, timing, and type of any payments to participants.*

- *Indicate whether gifts, payments, compensation, reimbursement, services without charge, or extra credit will be provided to the participants for participating in the research.*
- *Describe the type of compensation and the maximum value participants may receive during the course of participation.*
- *Describe when compensation will be provided, including a schedule, and whether payments will be prorated for multiple visits/sessions.*
- *Describe who will receive payments, if not the participants themselves.*
- *Describe whether Research Experience Points will be awarded.*

Incentives. Participants will receive the following incentives:

- Phase 1 (December 2018 through June 2019): $10 for each completed data collection activity (i.e., pre-program, post-program)
- Phase 2 (August 2019 through June 2020):
    - Baseline data: $10
    - Mid-program interviews: $20
    - Post-program data: $25
- Phase 3 (September 2020-June 2021)
    - Baseline assessment: $20
    - Pre-intervention data collection: $50
    - Mid-program data collection: $30
    - Post-program data collection: $50
    - Post-program focus group: $50

13.0 Withdrawal of Participants

13.1 Withdrawal Circumstances: *Describe anticipated circumstances under which participants will be withdrawn from the research without their consent.*

13.2 Withdrawal Procedures: *Describe procedures that will be followed when participants withdraw from procedures with continued data collection (e.g., participants withdraw, but you wish to continue collecting data from a private/protected record).*

13.3 Termination Procedures: *Describe any procedures for orderly termination and describe whether data will be used after termination.*

Any participants who withdraw from the program will be offered a voluntary final interview at the time of their withdrawal.

14.0 Risks to Participants

For each risk or set of risks below, include the procedures to be performed to lessen the probability, magnitude, duration, or reversibility of those risks.

14.1 Foreseeable Risks: *List the reasonably foreseeable risks, discomforts, hazards, or inconveniences related to participants' participation in the research. Include, as may be useful for the IRB's consideration, a description of the probability, magnitude, duration, and reversibility of the risks. Depending on the type of research, this description may or may not include statistical information. Categories such as common, rare, etc., may be acceptable. Consider physical, psychological, social, legal, and economic risks.*

14.2 Reproduction Risks: *If applicable, indicate which procedures may have risks to an embryo or fetus should the participants or participants' partners be or become pregnant. (Note that if reproductive risks are a factor, then you are likely conducting procedures that would require use of "MEDICAL PROTOCOL TEMPLATE (HRP-590)." Please review the instruction at the beginning of this protocol template.)*

14.3 Risks to Others: *If applicable, describe risks to others who are not participants.*

There are minimal risks involved in participating in study activities. Potential risks may include discomfort resulting from social situations and discussing potentially upsetting topics (e.g., difficulties with friendships).

15.0 Incomplete Disclosure or Deception

15.1 Incomplete Disclosure or Deception: *If the research will use incomplete disclosure or deception, please provide a rationale. Please also provide a description and documentation of the debriefing process, if appropriate, that will be used to make participants aware of the incomplete disclosure or deception and their right to withdraw any record of their participation.*

N/A

16.0 Potential Benefits to Participants

16.1 Potential Benefits: *Describe the potential benefits that individual participants may experience from taking part in the research. Include, as may be useful for the IRB's consideration, the probability, magnitude, and duration of the potential benefits.*

Indicate if there is no direct benefit to individual participants. Do not include benefits to society or others.

There are no direct benefits to participating in this evaluation, though there are potential benefits to participating in the mentoring program itself. Potential benefits of the study include contributing to the development of programming that can benefit families with ASD.

17.0 Data Management

17.1 Data Analysis Plan: *Describe the data analysis plan, including any statistical procedures.*

17.2 Power Analysis: *Provide a power analysis, if applicable.*

17.3 Data Integrity: *Describe any procedures that will be used for quality control of collected data.*

Data from the focus groups will be analyzed qualitatively by identifying themes in the information provided by participants. Demographic data will also be summarized to provide a description of participants who provided input into the development of the mentoring program. Descriptive statistics and visual analyses will be provided for data from interviews and questionnaires. Video recordings of mentoring sessions in Phase 3 will be analyzed qualitatively to identify core components of mentoring sessions and to describe the quality of interactions between mentors/mentees.

18.0 Confidentiality

18.1 Data Security: *Describe the steps that will be taken to secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) for storage, use, and transmission of data.* ***Include also whether a copy of the consent form or other research study information will be placed in the participants' medical, employment, or educational records, and why that is appropriate (if so, this information must be included in the confidentiality section of the consent form).***

Data from this study will be stored within a secure Box account sponsored by UMN. Participants will be assigned a study ID and participant data will be de-identified within the database. The PIs will manage this database and will provide access to the data to key study personnel who will assist in managing and analyzing study data. Consent forms, assessment protocols, and verification of diagnosis and IQ will be kept within a locked file cabinet and a locked office. No study data or information will be placed within medical, employment, or educational records. Data will not be accessible to individuals outside of the research team. Data will be stored for up to 7 years in order to inform future studies expanding on this work and to be used for preparation of publications. For online study activities, participants will be encouraged to situate themselves in a context where their privacy is ensured / facilitated (e.g., a private room in their apartment or house with the door shut). Researchers will do the same, and communicate as such prior to study activities. When using videoconferencing platforms, security measures will be used including: using University-sponsored Zoom accounts, emailing access links directly to the participant, requiring passwords to enter meetings, enabling waiting room, disabling video recording by participants who are not the host, and locking the meeting once in progress.

19.0 Provisions to Monitor the Data to Ensure the Safety of Participants

This section is required when research involves more than Minimal Risk to participants. If you believe that the study is not greater than Minimal Risk, type "N/A" and delete the sub-headings below. Otherwise, complete all items below. The IRB ultimately determines the risk level of the study.

N/A

This study involves minimal risk to participants; however, participants will be asked to report on their emotional functioning, including symptoms of anxiety and depression. If a participant endorses suicidality, research team members will contact Dr. Hudock or Dr. Weiler (both licensed mental health providers) immediately to conduct a risk assessment. Appropriate mental health referrals (including the local suicide hotline and crisis management numbers: https://www.hennepin.us/residents/emergencies/mental-health-emergencies) will be made at that time if needed. The consent form also alerts participants to the fact that confidentiality will be broken if it is determined that a participant is at risk to themselves or others at any time during the study. If needed, parents/guardians and any other necessary authorities will be notified and appropriate referrals will be made.

20.0 Provisions to Protect the Privacy Interests of Participants

20.1 Protecting Privacy: *Describe the steps that will be taken to protect participants' privacy interest. "Privacy interest" refers to a person's desire to place limits on with whom they interact or to whom they provide personal or sensitive information.*

Describe any privacy concerns and what steps you will take to make the participants feel more comfortable with the research situation in terms of the questions being asked and the procedures being performed. "Comfortable" does not refer to physical discomfort only, but to the sense of intrusiveness a participant might experience in response to questions, procedures, or interactions with researchers or in certain settings.

20.2 Access to Participants: *Explain why the research team is permitted to access medical records, student records, or any other sources of private information about the participants. (Note that you were asked a similar question above about access to information about potential participants. This item refers to information about participants who have consented to participate and about whom you are collecting research data.)*

Interviews, surveys, and focus groups will be held in spaces that are closed to the general public, or that provide reasonable privacy (i.e., conversations and interviews cannot be overheard by others in the space) for conducting study activities. For online study activities, participants will be encouraged to situate themselves in a context where their privacy is ensured / facilitated (e.g., a private room in their apartment or house with the door shut). Researchers will do the same, and communicate as such prior to study

activities. When using videoconferencing platforms, security measures will be used including: using University-sponsored Zoom accounts, emailing access links directly to the participant, requiring passwords to enter meetings, enabling waiting room, disabling video recording by participants who are not the host, and locking the meeting once in progress. Confidentiality of participant responses will be discussed at the beginning of the interviews and focus groups and also included within the consent form.

21.0 Compensation for Research-Related Injury

21.1 Compensation for Research-Related Injury: *If the research involves greater than Minimal Risk to participants, describe the available compensation in the event of research-related injury. N/A*

21.2 Contract Language: *Provide a copy of the contract language, if any, relevant to compensation for research-related injury. N/A*

22.0 Consent Process

Note: You must follow "SOP: Informed Consent Process for Research (HRP-090)" and "SOP: Written Documentation of Consent (HRP-091)."

22.1 Consent Process (when consent will be obtained): *Describe the consent process, including:*

- *Where the consent process will take place.*
- *Any waiting period available between informing the prospective participants and obtaining the consent.*
- *Any process to ensure ongoing consent.*
- *If you will document consent in writing, submit a consent document in ETHOS. If you will obtain consent, but not document consent in writing, submit a consent script in ETHOS. Review "CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)" to ensure that you have provided sufficient information.*

For Phases 1 and 2, participants will be e-mailed a copy of the consent form for review upon their acceptance into the program and their expressed interest in participating in the evaluation of the pilot program. Consent will then take place at the site of interview (AuSM, MICC, or Kennedy High School, other venue agreed upon by the research team and family). Consent will be obtained by a research team member familiar with obtaining consent who will review the consent form and study procedures with individual families. Families will have an opportunity to ask questions about the study and consent process prior to the beginning of the interviews. For Phase 3, updated consent will be obtained electronically via REDCap; signed consent form returned via email by participant; or photo of signed consent form sent directly to the researcher from the participant.

22.2 Waiver or Alteration of Consent Process (when consent will not be obtained, required information will not be disclosed, or the research involves deception): *If you are not requesting a consent alteration or waiver, type "N/A" and delete the bullets below. Otherwise, complete all items below: N/A*

22.3 Non-English Speaking Participants: *Indicate what language(s) other than English is/are understood by prospective participants or their representatives.*

- *As identified in Section 10.1, if participants who do not speak English will be enrolled, describe the process to ensure that the oral or written information provided to those participants will be in their own language. Indicate the language that will be used by those obtaining consent.*
- *If you will be using a translator during recruitment, consent, data collection, or data analysis, specify how you will identify an appropriate translator and what the provisions will be for protecting the confidentiality of participants.*
- *Translated short forms are available on the UMN IRB website: https://www.research.umn.edu/irb/guidance/short-forms.html.*

  Spanish-speaking families may also enroll in this study. Consent forms will be translated into Spanish for families who do not speak English. A Spanish-speaking interpreter will be present throughout data collection activities for Spanish-speaking families and will assist in interpreting interviews and surveys.

  A professional Spanish-speaking interpreter will be provided by Bloomington Public Schools in order to assist with consent and data collection for Spanish-speaking families. This interpreter will meet with the research team to review study procedures, including the importance of protecting the confidentiality of participant information and responses.

22.4 Participants Who Are Not Yet Adults (infants, children, teenagers under 18 years of age):

- *Describe the criteria that will be used to determine whether a prospective participant has not attained the legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted. (E.g., in Minnesota, individuals under the age of 18 years.)*
  - *For research conducted in Minnesota, review "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" to be aware of which individuals in the state meet the definition of "children."*
  - *For research conducted outside of Minnesota, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of "children" in "SOP:*

Legally Authorized Representatives, Children, and Guardians (HRP-013)."

- *Describe whether parental permission will be obtained from:*
  - *Both parents, unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.*
  - *One parent, even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.*
- *Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. Describe the process used to determine these individuals' authority to consent to each child's general medical care.*
- *Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent.*
- *When assent of children is obtained describe whether and how it will be documented.*

Individuals 18 and over will sign their own consent. Adults with a legal guardian will also have their legal guardian/parent sign the consent form. Individuals under 18 will sign an assent form and one parent will sign the consent form.

22.5 Cognitively Impaired Adults, or adults with fluctuating or diminished capacity to consent:

- *Describe the process to determine whether an individual is capable of consent. Review "POLICY: Capacity to Consent (HRP-110)" and "POLICY: Research Involving Adults Under Court Jurisdiction (HRP-111)" for additional information. Reference "CHECKLIST: Cognitively Impaired Adults (HRP-417)."*
- *Confirm use of one of the approved validated instruments to assess capacity to consent appropriate for the level of risk associated with the research (i.e., the MacArthur Competence Assessment Tool for Clinical Research for greater than Minimal Risk research or the UCSD Brief Assessment of Capacity to Consent for Minimal Risk research). If you will not be using one of these tools, describe the alternative validated tool(s) you propose to use instead. If available in electronic format, submit the alternative tool(s) for review by the IRB in ETHOS.*
- *Document plans, if any, to avoid seeking consent during periods of greater than normal impairment.*

While participants may have a diagnosis of ASD, they will not have intellectual disability and will be able to participate in the consent process. For individuals who have difficulty

with processing information, attention, or executive functioning, the research team will read the consent aloud and allow for extra opportunity for the individual to ask questions.

22.6 Adults Unable to Consent:

- Permission: *List the individuals from whom permission will be obtained in order of priority (e.g., durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child.)*
  - *For research conducted in Minnesota, review "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" to be aware of which individuals in the state meet the definition of "legally authorized representative." Additionally, be aware of special restrictions regarding recruiting or enrolling persons under a stay of commitment.*
  - *For research conducted outside of Minnesota, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective participant to their participation in the procedure(s) involved in this research. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of "legally authorized representative" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."*
- Assent: *Describe the process for assent of the participants. Indicate whether:*
  - *Assent will be required of all, some, or none of the participants. If some, indicate which participants will be required to assent and which will not.*
  - *If assent will not be obtained from some or all participants, an explanation of why not.*
  - *Describe whether assent of the participants will be documented and the process to document assent.*

Adults with ASD will not have intellectual disabilities and will sign their own consent. Individuals under 18 will sign assent forms and their parent/legal guardian will sign consent. For individuals with a legal guardian, the participant and their legal guardian will sign consent.

23.0 Setting

23.1 International Research: *If the research will take place in more than one international location, include information below for each location.*

- *N/A*

23.2 Community Based Participatory Research: *If the research will be based in or in partnership with more than one community, include information below for each community.*

- *Describe how community partners will participate in various stages of the research.*
- *Describe the plan for educating community partners about human research protections.*
- *Describe the agreement with the community partner organization. If appropriate, provide a letter, memorandum of understanding, or contract in the "Supporting Documents" section in ETHOS.*

This project is highly collaborative. The PIs and research team are working closely with staff and individuals with ASD who from MICC, AuSM, and Kennedy High School to plan and implement the evaluation of the pilot mentoring program. The PIs participate on an advisory board with parents, professionals, community members, mentoring experts, and self-advocates with ASD who are have developed and are implementing the mentoring program for individuals with ASD in the community. The PIs are responsible for educating the advisory board and community partners about human research protections and research and data collection and management procedures. While community partners will participate in facilitating portions of the study, the PIs will remain involved in each step of the research. The research team will remain involved with this advisory board and community partners throughout this evaluation and the eventual development and implementation of the program.

23.3 Research Sites: *Describe the sites or locations where your research team will conduct the research.*

- *Identify where your research team will identify and recruit potential participants.*
- *Identify where research procedures will be performed.*
- *Describe the composition and involvement of any community advisory board, school board, school principals or teachers, etc.*
- *For research conducted outside of your organization and its affiliates, describe:*
  - *Site-specific regulations or customs affecting the research.*
  - *Local scientific and ethical review structure.*

The community group implementing the mentoring program is directly responsible for recruitment and selection of participants. Interviews, surveys, and focus groups will be held in spaces that are closed to the general public, or that provide reasonable privacy (i.e., conversations and interviews cannot be overheard by others in the space) for conducting study activities. Due to current COVID-19 pandemic, all study activities will occur via the videoconferencing platform Zoom using a University-sponsored account and appropriate security settings. Qualtrics surveys will be completed by participants on their personal devices. Participants may complete data collection via telephone if they prefer this method to Zoom

and/or Qualtrics. Data storage and analysis will take place at UMN within the PIs' respective departments and office/research spaces.

The evaluation development is being overseen by a board of researchers and community members, comprised of individuals from UMN, MICC, AuSM, and The Mentoring Partnership of MN. Individuals on the board include UMN ASD clinicians and researchers, mentorship specialists, MICC students and staff, self-advocates, and parents of individuals with ASD. This advisory board meets twice per month at AuSM.

24.0 Multi-Site Research

If this is not a multi-site study where you are the lead investigator, type "N/A" and delete the sub-headings below. Otherwise, complete all items below.

N/A

25.0 Resources Available

25.1 Resources Available: *Describe other resources available to conduct the research. For example, as appropriate:*

- *If the study is being conducted by a student investigator, include a description of how the faculty advisor will support the student.*
- *Justify the feasibility of recruiting the required number of suitable participants with the agreed upon recruitment period. For example, to how many potential participants do you have access? What percentage of those potential participants do you need to recruit?*
- *Describe the time that you will devote to conducting and completing the research.*
- *Describe your facilities.*
- *Describe the availability of medical or psychological resources that participants might need as a result of an anticipated or unanticipated consequences of the research.*
- *Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.*

Since participants in the program will be selected by the community group implementing the mentoring program, researchers will utilize this participant pool.

The duration of the study is expected to last approximately 12-18 months. Interviews, surveys, and focus groups will be held in spaces that are closed to the general public, or that provide reasonable privacy (i.e., conversations and interviews cannot be overheard by others in the space) for conducting study activities.

The PIs have expertise in social science, neuroscience, psychology, and educational psychology. Several research team members are teachers, counselors, and psychologists who can assist in providing

mental health supports as needed, including making appropriate referrals if needed. The research team meets approximately every 2 weeks to discuss the project, protocol, and necessary training. The PIs participate on the advisory board and keep the group informed on research policies and procedures. The team is also in frequent contact via e-mail and a private Slack page.

26.0 References

Include references to any scholarly articles or other materials used to discuss the background for the study or to justify any proposed procedures.

Castro, F. G., Barrera Jr, M., & Holleran Steiker, L. K. (2010). Issues and challenges in the design of culturally adapted evidence-based interventions. Annual Review of Clinical Psychology, 6, 213-239.

DuBois, D. L., Portillo, N., Rhodes, J. E., Silverthorn, N., & Valentine, J. C. (2011). How effective are mentoring programs for youth? A systematic assessment of the evidence. *Psychological Science in the Public Interest*,*12*(2), 57-91.

Hale, D. R. & Viner, R. M. (2012). Policy responses to multiple risk behaviors in adolescents. *Journal of Public Health, 34*(suppl 1), i11-i19. doi: 10.1093/pubmed/fdr112

Rhodes, J. E. (2002). *Stand by me: Risks and rewards in youth mentoring*. Cambridge, MA: Harvard University Press.

Rhodes, J.E. & Roffman, J. G. (2002). Nonparental adults as asset builders in the lives of youth. In R. J. Lerner & P. Benson (Eds.) Developmental assets and asset-building communities. Implications for research, policy, and practice. New York: NY: Kluwer Academic Publishers.