

PROJECT TITLE:

A Peer-Delivered High School Preparatory Intervention for Students with ADHD.

PRINCIPAL INVESTIGATOR:

Margaret H. Sibley

Center for Child Health Behavior and Development

(206) 884-1424

Margaret.sibley@seattlechildrens.org

Contents

1.	Objectives	3
2.	Background	3
3.	Study Endpoints	8
4.	Drugs, Devices and Biologics	9
5.	Procedures Involved	9
6.	Data and Biospecimen Banking	12
7.	Sharing of Results	13
8.	Study Timelines	14
9.	Study Population	14
10.	Number of Subjects	15
11.	Withdrawal of Subjects	16
12.	Risks to Subjects	16
13.	Potential Benefits to Subjects	18
14.	Data Analysis/Management	18
15.	Confidentiality	19
16.	Provisions to Monitor Data to Ensure the Safety of Subjects	20
17.	Use of Social Media	21
18.	Research Related Injury	21
19.	Recruitment Methods	21
20.	Consent/Assent Process	22
21.	Process to Document Consent in Writing	27
22.	HIPAA Authorization and RCW Criteria	27
23.	Payments/Costs to Subjects	28
24.	Setting	28
25.	Resources Available	28
26.	Coordinating Center Procedures	29
27.	International Center for Harmonization of Good Clinical Practice (ICH-GCP)	29

1. Objectives

1.1. Purpose, specific aims, or objectives:

To test the effect of summer STRIPES (compared to school services plus) on key outcomes and mechanisms. We will also test mediational paths between mechanisms and outcomes.

To assess indices of engagement and school fit (i.e., parent, student, and peer interventionist engagement in the intervention; fidelity, perceived intervention utility and burden).

1.2. Hypotheses to be tested:

Students who receive summer STRIPES will demonstrate greater improvements in ninth grade functional outcomes and proposed mechanisms than participants in SSU plus. Change in mechanisms will mediate the relationship between treatment group and outcome

Students, parents, and peers will demonstrate strong attendance (i.e., at least 80% of sessions attended). Peer interventionists and school staff sponsors will display scores of at least 80% on fidelity checklists and will display positive attitudes toward the treatment delivery experience. Satisfaction, perceived intervention utility, and bond with interventionists will be strong.

2. Background

2.1. Relevant prior experience and gaps in current knowledge:

High school aged adolescents with ADHD experience substantial impairments, particularly in the school setting (Kent et al., 2011). However, very few high school students with ADHD receive evidence-based interventions (medication or psychosocial treatment) for their difficulties. Primary barriers include distaste for stimulant medication (Brinkman et al., 2017), parent-teen conflict that curbs family-based service utilization (Barkley et al., 2001), and resource barriers that hamper high school intervention delivery (Sibley et al., 2016). In this proposal, we seek to improve access to care by adapting evidence-based psychosocial intervention components to a low-resource and novel school-based intervention model (a brief peer-delivered summer orientation to high school with continued peer-delivered sessions during ninth grade). The project will be conducted in real-world high school contexts.

Our previous work in real-world settings (Sibley et al., 2018; Sibley et al., under review) identifies two promising school-based intervention models to promote healthy transitions to ninth grade: (1) an intensive skill-based summer preparatory program (Summer Treatment Program-Adolescent; STP-A) and (2) a weekly peer-delivered organization skill and motivational intervention (Students Taking Responsibility and Initiative through Peer Enhances Support; STRIPES). Yet despite their promise, each of these models possesses significant limitations: (1) the costly STP-A (over \$4000 per student) is not affordable to school districts and (2) though highly effective when attended, ninth grader engagement in STRIPES has been suboptimal (only 50% attendance at best). In this project, we propose that the limitations of each model may be solved by the strengths of the other—the low-cost STRIPES interventionists can reduce

the STP-A's tremendous expense; the highly engaging STP-A model might boost STRIPES' attendance problems. Meanwhile, the STP-A's intensive practice and contingency management components might go beyond simply preventing decline (Sibley et al., under review) to fully increasing performance (Sibley et al., 2018).

2.2. Relevant preliminary data:¹

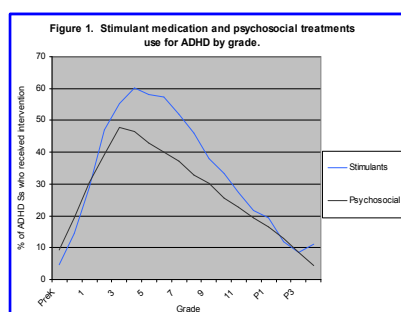
This research is the next phase of the "STRIPES" IRB protocol that recently finished. A brief summary of the findings of that study are below.

In 2015, we started developing a peer-delivered intervention for high school students with ADHD (STRIPES: Students Taking Responsibility and Initiative through Peer Enhanced Support; Sibley et al., under review). STRIPES targets core EF skills and academic motivation. Results of our pilot work indicated that intervention credibility, fidelity, satisfaction, and student-peer bond were positive (see Table 2). Despite these positive results, 9th grade students often failed to attend STRIPES. Thus, the current study seeks to solve the engagement problems of STRIPES by offering a one week enjoyable orientation based on the Summer Treatment Program Adolescent prior to ninth grade, paired with a parenting strategies group. Despite these difficulties, eight sessions of STRIPES delivered as a pullout model led to large statistically significant between group differences (versus enhanced school services) in bookbag organization ($d=1.11$), extrinsic school motivational indices ($d=.85$ to 2.05), and class attendance ($d=1.47$) over time. Most notably, STRIPES delivered as pull-out prevented steep declines in functioning across ninth grade (see Figure 5a-5c).

Despite its promise, STRIPES did not produce effects on planner use, intrinsic motivation, or GPA. We concluded that STRIPES requires additional components to enhance engagement and promote regular practice of EF skills. We believe that the additional STP-A skills training modules may increase effectiveness of STRIPES on underperforming outcomes.

2.3. Scientific or scholarly background:

For adolescents with ADHD, academics are regarded as the most critically impaired domain (Barkley, 2006; Robin, 1998). Compared to non-ADHD peers, high school students with ADHD perform more poorly on standardized tests (Barkley et al., 1991; Fischer et al., 1990), complete fewer assignments (Barkley et al., 1991; Kent et al., 2011; Weiss et al., 1993), and receive poorer course grades (Barkley et al., 2006; Kent et al., 2011). By some estimates, up to a third of students with ADHD fail to complete high school (Barkley et al., 2002). These academic problems are particularly concerning because they predict severe dysfunction in adulthood (Masten et al., 2005; Rindfuss et al., 1999). For example, Molina et al., (2012)



reported that the relationship between ADHD and substance abuse by age 18 was mediated by academic, social, and disciplinary problems during high school. Adolescents who do not finish high school risk further escalating problems, such as criminal behavior (Thornberry et al., 1985), drug and alcohol addiction (Townsend et al., 2007), unemployment (Stanard, 2003), and dependence on government assistance programs (Martin et al., 2002). Therefore, it is not surprising that young

adults with ADHD are at elevated risk for each of these difficulties (Barkley et al., 2010; Hechtman et al., 2017).

Treatment Access. Despite these impairments, a majority of high school students with ADHD do not receive any treatment. Bussing et al., (2011) reported that a majority of adolescents with ADHD (58%) had not received mental health services in the past year. Although medication is considered the first line treatment for ADHD in adolescence (American Academy of Pediatrics, 2011), the Multimodal Treatment of ADHD Study reveals that a majority of teens with ADHD find medication unpalatable, desisting use (Brinkman et al., 2017). The Pittsburgh ADHD Longitudinal Study also reveals a steep decline (see Figure 1) in utilization of medication and psychosocial interventions in high school.

Because a majority of ADHD-related impairment occurs at school, high schools are a logical deployment setting for interventions. However, school-based interventions for ADHD (which are widespread in elementary schools; Pelham & Fabiano, 2008) are rarely available to high school students. A number of systemic barriers limit access. For one, most high school students with ADHD (55%) do not receive special education services and are placed in regular education (Barkley et al., 2006). In elementary school, regular education classroom teachers often oversee behavior modification programs for students with ADHD (Hart et al., 2017); however, their high school counterparts typically teach over 100 students and may have little time to devote to individual students (Benner & Graham, 2009). High school counselors are historically mental health service providers but have seen a shift to administrative duties that include graduation planning, parent liaising, and managing student schedules (American School Counselor Association, 2013). Thus, ancillary intervention staff, rather than academic teachers or counselors, are often tasked with providing services to struggling high school students with ADHD (National Center for Response to Intervention, 2010). Unfortunately, funding for these educational support services—particularly for students without special education entitlement—has slowly declined over the last decade (American Association of School Administrators, 2012). Thus, most high school students with ADHD have no access to interventions in their schools. Regular education students with ADHD are particularly unlikely to access services because they are not a priority for earmarked intervention funds.

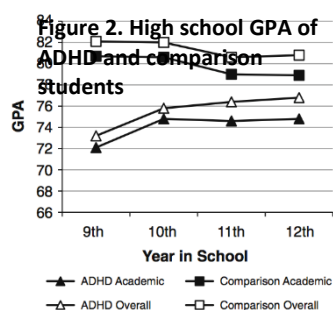
Implementation of Extant Interventions. In high resource settings, designated interventionists might provide a range of services using models that are successful in elementary or middle schools (Evans et al., 2018; Pelham & Fabiano, 2008). The most promising approach may be skills training interventions that were developed for middle school students (Evans et al., 2016) and have been adapted for high school students in clinical (Sibley et al., 2019), school (Evans et al., 2014), and summer treatment settings (Sibley et al., 2018). These interventions target two core ADHD-related cognitive deficits: executive functioning (EF) and motivation (Sonuga-Barke, 2002; Toplak et al., 2005). They do so by teaching compensatory strategies in organization, time management, and planning (OTP) and including motivational components such as goal-setting, contingency management, and strength-based feedback (Sibley, 2017).

Despite the promise of these approaches, transfer of intervention delivery to high school staff has been largely unsuccessful—particularly in regular education settings (Kern et al., under review; Sibley, Olson, et al., 2016). Our team illustrated this challenge in a recent publication (Sibley, Olson, et al., 2016). Using a secondary school consultation model (Evans et al., 2007), outside behavioral consultants identified an in-school interventionist for 218 adolescents with ADHD at 114 different schools. Interventionists were 27.4% teachers, 57.2% counselors, 3.4%

administrators, and 12.0% special education staff. Success rate for the intervention was low. Monthly contact between consultants and interventionists was challenging (38.5% success rate) and only 40.0% of interventionists completed in-person meetings with consultants. Analyses suggested that lower success rates were associated with high school (vs. middle school) and regular education (vs. special education) settings. When surveyed about engagement barriers, staff highlighted resource problems (see Table 1). Thus, an ongoing challenge for high schools is identifying qualified and available interventionists who are willing to deliver evidence-based interventions to regular education students with ADHD.

Table 1. % of School Staff Endorsing Barrier	
Insufficient time	75.0
Forgot	21.4
Too tired	10.7
Unable to coordinate with other teachers	7.1

Ninth Grade as a Critical Intervention Period. When resources are low, it becomes important to intervene wisely—conserving services for windows that promote maximal impact (Cohen et al., 2017). Failure to access ADHD treatment may be particularly detrimental to 9th grade students. Typical adolescents display a decline in GPA (Isakson et al., 1999), self-esteem (Barber et al., 2004), and psychological adjustment at the transition to high school (Barone et al., 1991). This deterioration is especially marked in students with ADHD, whose 9th grade year marks the low point of their academic performance (Figure 2; Kent et al., 2011). Performance during ninth grade is implicated as one of the strongest predictors of eventual high school dropout (Neild et al., 2008). Thus, 9th grade is a strategic intervention period to prevent escalating school disengagement among students with ADHD.



Peers as Interventionists. One group of interventionists who are available, qualified, and willing may be academically excellent 11/12th grade peers. Peers are numerous and free interventionists who may possess more time than school staff for intervention delivery. High schoolers have ample opportunities to interact with peers throughout the school day and unlike school staff, peer interventionists may be highly motivated to deliver interventions. Such an experience can enhance college applications, provide community service hours that are required for graduation, and serve as an enriching service learning leadership experience. This low-resource model may be particularly fitting for regular education students with ADHD, who may have mild to moderate impairments that do not require intensive intervention. There is abundant evidence that high school students can deliver a range of interventions to peers with fidelity (Stenhoff et al., 2007; Fuchs et al., 2000; Mastropieri et al., 2003; Stephenson et al., 2004). In fact, a meta-analysis (Wilson, Lipsey, et al., 2003) suggests that peer-delivered interventions for disruptive behavior produce effect sizes that are equal to adult-delivered interventions. Peers play a central role in the lives of high school students, as adolescents spend decreasing amounts of time with adults (Steinberg & Morris, 2001). Thus, adolescents with ADHD may be highly *interested* in engaging with peer interventionists. There is also evidence that peers can serve as salient reinforcers in behavior therapy (Kalfus, 1984), which may be particularly true in high school. Peers also are ecologically valid members of the adolescent context who may serve as promising facilitators of generalization. Since high school students with ADHD are at risk for peer rejection and often possess few or deviant friends (Bagwell et al., 2001), a peer-delivered intervention may provide additional social and mental health benefits to students with ADHD.

Summer before 9th Grade as a Window. A pre-9th grade orientation model (delivered immediately prior to start of 9th grade) may be a strategic option for boosting the EF skills and motivation necessary for high school success. Summer provides available time to participate in focused skill-building before academic demands begin. Orientations prior to high school are common and parents are accustomed to participating in these programs—which often provide important information about the upcoming high school experience. As a result, a high school orientation model may also promote parent engagement and allow for age-appropriate parent training. Finally, including social activities may also engage adolescents in an enjoyable intervention that promotes attendance and introduces students with ADHD to a culture of prosocial peers. One solution to school intervention engagement problems is to consider natural contexts in which students and parents may be naturally present and engaged (Owens et al., 2014). Creating an engaging summer orientation for students with appealing peers may also generate interest in continuing school-year intervention.

Treatment Mechanisms. Compared to elementary and middle school, high school is less structured and offers limited prompts, assistance, and immediate reinforcements from teachers. High school academic work is assigned in large parcels with expectations for independent work completion (Barber & Olsen, 2004). Thus, the transition to high school presents increased expectations for self-regulated learning—independent management of academic work that requires one to regulate both their motivational state and behavior (Zimmerman, 2002). Compared to peers, adolescents with ADHD show marked high school academic problems culminating in an increased risk for dropout (Barkley et al., 1991; Kent et al., 2011). Hallmarks of this impairment are poor work completion and inadequate test preparation (Kent et al., 2011)—tasks that draw heavily on self-regulated learning (Zimmerman, 2002).

Self-regulated learning is bolstered by: (1) intrinsic motivation (i.e., interest in and enjoyment of academic activities), (2) extrinsic motivation (i.e., valuing the outcomes associated with academic success), and (3) EFs (i.e., organization and time management, planning, task-initiation, maintaining on-task behavior, and task shifting; Kim, 2013; Zimmerman, 2002). Due to cognitive control and rewards processing deficits, students with ADHD show impairments in all of these processes (Modesto-Lowe et al., 2013; Sonuga-Barke, 2003). Higher ADHD-related impairments in self-regulated learning are documented as academic demands increase in secondary school (Lee et al., 2017). Therefore, we propose three mechanisms for the proposed intervention: (1) intrinsic motivation, (2) extrinsic motivation, and (3) EFs. Effective ADHD interventions that address these mechanisms have been developed in controlled settings (see Chan et al., 2016; Sibley, Kuriyan et al., 2014 for review); however, their implementation has been stifled in high school contexts.

Intrinsic Motivation. With respect to intrinsic motivation, students with ADHD report lower levels of academic task interest and perceive lengthy assignments to be highly aversive (Carlson et al., 2002; Morsink et al., 2017). Intrinsic motivation deficits appear tied to abnormal anticipatory dopamine response (Oudeyer, et al., 2007)—which is implicated as a core neurocognitive deficit in ADHD (Volkow et al., 2011). Thus, typical academic tasks may feel less intrinsically rewarding to individuals with ADHD (i.e., lower experiences of novelty, curiosity, enjoyment). In the high school context, these deficits may be prominent due to the repetitive and complex nature of many academic tasks (Barber & Olsen, 2004). Intrinsic motivation deficits also may be compounded by ADHD-related delay aversion (Sonuga-Barke et al., 2008)—mental discomfort when tasks contain particularly delayed rewards (i.e., long-term projects, final exams). To escape this aversive mental state, high school students with ADHD may gravitate to

immediately rewarding activities, such as video games or social media (Mazurek et al., 2013; Yen et al., 2007). It is also likely that intrinsic motivation is hampered by ADHD-related learning problems that increase the aversive properties of schoolwork (Loe & Feldman, 2007).

Extrinsic Motivation. With respect to extrinsic, value-driven motivation, students with ADHD report valuing academic achievement and mastery less than peers (Barron et al., 2006; Colomer et al., 2017; Gut, et al., 2012; Olivier & Steenkamp, 2004; Zentall et al., 2012). Extrinsic motivation reflects the perceived utility of a task (i.e., both its reward value and the expected probability of achieving it; Wigfield & Eccles, 2000). For students with ADHD, a built-in preference for immediate rewards (i.e., deficits in delay discounting; Scheres et al., 2006) may prevent high valuation of grades, which are a long-term and symbolic reinforcer. Students with ADHD also show insensitivity to future negative consequences (Toplak et al., 2005), which may reduce extrinsic motivation to avoid negative outcomes (e.g., course failure, expulsion). Thus, high school students with ADHD may be less extrinsically motivated than peers to pursue high grades and avoid problematic consequences. Furthermore, high school students with ADHD may exert lower academic effort because they perceive a reduced probability of achieving high grades, due to years of school failure and negative feedback from adults (i.e., reduced self-efficacy; Newark et al., 2016).

EFs. Even with adequate motivation, deficits in EF—particularly organization skills and goal-directed behavior (Gollwitzer et al., 1997; Zimmerman, 2002) may prevent academic success. This aspect of self-regulated learning involves using top-down executive functions to implement actions in support of one's goals and suppress counterproductive motivational states (Kim, 2013). These functions include working memory (i.e., ability to sustain mental representation of a desired outcome), response inhibition (i.e., ability to suppress urges to engage in problematic behaviors), and cognitive flexibility (i.e., ability to shift from one strategy to another according to the demands of a new situation). Together, these functions promote organization skills and goal-directed behaviors such as planning, task-initiation, inhibiting unproductive behaviors, and task disengagement. The executive functions that are associated with organization skills and goal-directed behavior are notably impaired in individuals with ADHD (Castellanos et al., 2006; Sonuga-Barke, 2003). Thus, it is not surprising that individuals with ADHD show difficulties with organization skills (Kofler et al., 2018) and goal pursuit (Hoza et al., 2001; Nyman et al., 2010). Both of these impairments are linked to academic performance in individuals with ADHD (Gropper & Tannock, 2009; Langberg et al., 2013).

2.4. Prior approvals:

Garfield High School and Roosevelt High School (Seattle Public Schools) have agreed to serve as site; school and district level approval of the research project were obtained.

3. Study Endpoints²

3.1. Primary and secondary endpoints:

We will assess three ecological school outcomes: GPA, class attendance, and ADHD symptom severity over time. Report cards and attendance records will be obtained directly from schools. GPA for each quarter will be calculated by converting academic grades (e.g., English, Math, Science, Social Studies) to a 5-point scale (i.e., 4.0=A to 0.0=F). Grades will not be weighted for the difficulty of the class. Number of class absences will be calculated for each quarter. ADHD symptoms will be measured at each assessment (BL, FU1, FU2, FU3) via parent and teacher reports on a DSM-5

ADHD checklist (Sibley & Kuriyan, 2016) that has strong psychometric properties and is sensitive to intervention response for adolescents with ADHD (Sibley et al., 2019). These rating scales will be administered electronically through redcap.

- 3.2.** Primary or secondary safety endpoints:
Not applicable—testing an academic intervention.

4. Drugs, Devices and Biologics³

- 4.1.** Manufacturer and name of all drugs, devices and biologics:
Not applicable

- 4.2.** Description and purpose of all drugs, devices and biologics:
Not applicable.

- 4.3.** Regulatory status of all drugs, devices and biologics:⁴
Not applicable

- 4.3.1.** Drugs or Biologics:
☐ IND Exempt. Explain:⁵ [Click here to enter text.](#)
☐ IND.

- 4.3.2.** Devices:
☐ IDE Exempt. Explain:⁶ [Click here to enter text.](#)
☐ Abbreviated IDE / Non-Significant Risk. Explain:⁷ [Click here to enter text.](#)
☐ IDE / Significant Risk.

- 4.4.** Plans to store, handle, and administer any study drugs, devices and biologics so they will be used only on subjects and be used only by authorized investigators:
Not applicable

5. Procedures Involved

5.1. Study design:⁸

A randomized trial ($N=72$) that will assign rising ninth grade students with ADHD at two high schools to (1) summer STRIPES or (2) enhanced school services as usual (SSU plus). Students will be randomized within school and cohort using a permuted block randomization strategy. In each of the two annual cohorts, 18 rising ninth grade students will be recruited for each school (nine randomly assigned to each condition), resulting in a total N of 72. . Four assessments will occur at baseline (BL; end of eighth grade), start of ninth grade (FU1), mid-ninth grade (FU2), and end-of-ninth grade (FU3). All assessments and treatments will be delivered in the school setting. Fidelity and intervention attendance measurements will be ongoing during treatment delivery.

5.2. Research procedures:⁹

Intervention

Full intervention procedures will be finalized in Y01 of the trial and will be based on the STP-A and STRIPES manuals. The finalized intervention will be submitted via Modification prior to use.

The intervention will be a one week (i.e., five days, four hours per day) intervention immediately

prior to the start of ninth grade, delivered by peer interventionists (2:1 ratio + extra interventionist in case of absences) and a school staff sponsor (e.g., teacher, school psychologist). The intervention will be group-based, however within the group, ninth grade students are assigned to a specific peer mentor who will be their primary counselor in the group and will hold “break” out conversations with the teen within the group context during the intervention session. The activities that will be included in the orientation are listed in Table 3 below:

Table 3. Core summer STRIPES components (all group-based)	
Summer Teen (1 wk/ 5 days a week)	School Year (16 wks/ 1 day a week)
Note-taking (30 mins)	Goal setting (10 mins)
Materials manag. (15 mins)	Organization check (5 mins)
Tracking homework (15 mins)	Homework tracking (5 mins)
Time management (15 mins)	Reviewing progress through online gradebook (10 mins)
Study skills (30 mins)	
Rec period (1 hour)	
Goal Setting (15 mins)	
Summer Parent	School Year Parent (16 wks)
Motivational Strategies I (90 mins)	Monthly Prob. Solving Session (60 mins—4 months)
Motivational Strategies II (90 mins)	
Daily Coaching (5 mins)	Weekly Coaching (5 mins- 16 weeks)

The orientation will be held at the student’s school and will contain the classroom-style modules listed in Table 3. In the note-taking intervention, students will receive a 15 minute lecture delivered by the school staff member and will be asked to take notes. For the second 15 minutes, the peer mentor will give feedback on the student’s note-taking performance. During the materials management module, the students will be given school supplies and taught a bookbag and binder organization system. They will go through a bookbag organization checklist each day to practice monitoring and maintaining organization of school materials. The peer will conduct this organization check. Homework tracking module will include teaching the student how to use a daily planner to record assignments and how to log on to the school’s electronic gradebook to monitor missing assignments. In the time management module students will learn prioritization, time budgeting, and procrastination reduction strategies and will be taught to plan out daily work plans to complete homework and other assignments. Peers will provide feedback on the student’s use of these strategies. Study skills will teach age appropriate test preparation strategies such as using flashcards, taking notes while reading, and mnemonic memorization strategies. A one hour recreation period is included in the program to allow for social bonding and to increase program engagement. These recreational activities will be selected by the stakeholders and will include outdoor group-based activities such as soccer, ultimate Frisbee, softball, or indoor activities such as board games, collaborative art projects, and drama games. Finally, a goal setting meeting will close each day and is a 15 minute discussion between the student and the peer to discuss daily performance on goals and set new goals for the upcoming day (and school year).

A classroom behavior management system will be employed to promote prosocial behavior during the summer orientation. This includes setting clear written expectations for behavior (e.g., no electronics use during program, be respectful to others, stay on task) that the intervention stakeholders will determine. Peers will help each student set personalized goals (e.g., less than three rule violations per day, get at least a 90% on all note-taking tasks, remember to write down all homework assignments) at the start of the intervention.

Parents will receive a 90 minute class on motivational strategies for teenagers before the first day of the summer orientation. During this class they will learn a variety of motivational strategies that parents can use to increase academic engagement in high school students. Among these will be learning how to use contingency management, or linking daily performance to privilege access at home. During this first class, parents will be instructed that adolescents will work with school staff and peers to set personally meaningful daily goals each day in the program. Parents will be coached how to build a contract with their student that builds in rewards at home (e.g., video game time, electronics use) for meeting daily goals. The school staff sponsor will run this meeting and also will provide brief daily coaching (up to five minute phone call) on contingency management implementation to the parent after each orientation day. On this phone call, the school staff member will share the student's performance on their goals and ask the parent about their intentions for using the contract to offer or restrict privileges based on student performance. The school staff member will offer individualized feedback on the parent's response (i.e., clarifying what the student has earned at home based on their performance, problem-solving roadblocks to providing or restricting the privilege). At the end of the orientation, a second 90 minute parenting class will be delivered on how to use the new motivational strategies during the school year. Parents will be encouraged to discuss their experiences with the contract during the orientation and to envision how this plan may be adapted to monitor and reinforce school performance.

During the school year, ninth grade students will continue to meet weekly with their peer interventionists in a group setting under the supervision of the school staff sponsor. This school year follow-up component of summer STRIPES will occur for 16 weeks and occur according to the original STRIPES manual (see Table 3). During STRIPES the student will be pulled out of elective for 30 minutes each week by the peer who will conduct a standardized checklist with the student (see attachment). This meeting includes checking performance on the previous week's academic goal, setting a new academic goal for the week, monitoring organization of the book bag, discussing daily planner use (i.e., recording homework), checking the online gradebook and discussing missing assignments and how to complete them. The intervention is delivered in a group setting with a school staff member in the room, but the peer holding an individualized meeting with the student. At the end of the 30 minute meeting, peers receive 30 minutes of supervision from the school staff member. A standardized agenda for supervision includes discussing whether each student met their weekly goal, discussing overall progress for the student, problem-solving difficulties with intervention engagement, and checking to make sure the peer completed paperwork. All paperwork for the intervention (i.e., student workbooks) are kept by the school staff member in their classroom until the next meeting.

Parent components during the school year will include optional monthly group problem solving sessions with the school staff sponsor and a weekly phone call (up to five minutes) from the school staff sponsor to discuss student progress and providing additional coaching on the privilege contract.

Training

Peer interventionists/mentors: will receive a treatment manual and two full days of training (16 hours) prior to delivering the intervention. They will receive 30 minutes of supervision per day during the summer orientation and 30 minutes per week for 16 weeks during the school year. Supervision will be received from the school staff sponsor.

School Staff Sponsor: Supervision of the peer interventionists will be co-led by the school staff sponsor and the SCH school mental health liaison. The school staff sponsor will receive two days

of training from SCH staff (16 hours) prior to the peer training and 30-minutes of weekly consultation from the SCH school mental health liaison during the intervention period.

Comparison Condition

An enhanced school services as usual (SSU plus) comparison condition was selected to test whether summer STRIPES improves upon optimal school services as usual. Students who are assigned to the SSU plus group will be referred to their identified school counselor for referral to services available in the school setting. The counselor will be provided with a report from the student's intake assessment that summarizes the student's symptoms and presenting problems. The student will also receive new school supplies at the beginning of ninth grade. There are no other activities associated with enhanced school services. In our past trials, SSU plus students typically received subject-specific tutoring or after-school homework help (Sibley et al., 2013). These activities are not a part of the research, but are naturalistic services the students in the control group receive from their school. We will systematically track services received by students in the SSU plus condition. The research study will have no impact on eligibility for other services already being received by the youth or for future services. They will continue all other interventions as usual.

Assessment Procedures

At each assessment, peer interventionist, student, parent, and teacher measures will be obtained as detailed below. Students will be monitored at BL, a FU1 assessment completed during the first quarter of the school year (i.e., October), FU2 at the school year's midpoint (i.e., January), and an end of year FU3 assessment (i.e., May). Student assessments take 90 minutes and will occur at the school with a trained research team member. We will work with the schools to choose an appropriate time during the school day to complete the assessments. Rating scales will be completed electronically on a tablet via RedCap, a scalable, secure, enterprise-level application for data collection. Direct observation of skills and cognitive and analogue academic tasks will be complete in a private room at the school with a trained research staff member.

All students will be required to refrain from taking stimulant medication on the day of their assessment (i.e., 24-hour washout period). Medication use during the study will be monitored via a parent and student medication use survey that our team has used for over a decade to track naturalistic medication use for adolescents with ADHD in psychosocial treatment studies. Medication use will be examined as a covariate in analyses.

Parents, peers, and teachers will complete ratings electronically via RedCap using a link that is sent to their email address. All assessors are masked to group.

Students: At each assessment, ninth grade students will complete three brief academic motivation questionnaires (see attached measures), one youth behavior checklist (youth self-report; YSR), and five computer tasks that measure aspects of cognition and rewards processing. These tasks take three to twenty minutes each and are administered on computers or tablets. Below is a description of each task to be completed:

Hungry Donkey: A computerized Iowa gambling task (Hungry Donkey Task; Crone & van der Molen, 2004) will be administered as a measure of risky decision making (i.e., sensitivity to future negative consequences). Participants were told to assist the hungry donkey to collect as many apples as possible by pressing one of four keys corresponding to four separate doors. The future

yield of each door varied, with higher wins at the high paying doors (A and B), and lower wins at low paying doors (C and D). Selecting door A or B resulted in a gain of four apples, whereas door C or D resulted in a gain of two apples. Number of low-risk doors selected minus number of high-risk doors selected was computed as an index of risky decision making (Crone et al., 2004). The task shows good convergent validity in adolescents (Crone & van der Molen, 2007).

Choice Delay: Delay discounting will be measured using a computerized Choice-Delay Task (Scheres et al., 2006) in which participants are instructed to make repeated choices between a small variable reward (0, 2, 4, 6, 8, or 10 cents) that would be delivered immediately (i.e., after 0 seconds) and a large constant (10 cents) reward that would be delivered after a variable delay of 0, 5, 10, 20, or 30 seconds. After completion of the task, participants receive the total earnings from the examiner. The total amount of money earned serves as an index of delay discounting. This task shows developmental sensitivity (Scheres et al., 2006) and correlates with symptoms of ADHD (Scheres, Lee, & Sumiya, 2008). The Choice Delay Task is unique in that it is a monetary incentive task to measure response to rewards and involves earning real money (i.e., quarters: maximum earnings is \$4.00) for performance in the game.

Go-no-Go Task: Response inhibition will be measured using a go/no-go task that uses both positively and negatively valenced emotional stimuli (Hare, Tottenham, Davidson, Glover, & Casey, 2005). Happy and sad facial expressions are alternated as go and no-go cues across the four blocks in an HSSH order, which results in equal numbers of happy and sad faces serving as go and no-go cues. The number of commission errors on no-go trials across the whole task will be utilized as a measure of response inhibition. The task shows good convergent validity (Schultz et al., 2007) and has been validated with adolescents (Hare et al., 2008).

NIH Toolbox Tasks: Working memory will be measured using the National Institute of Health (NIH) Toolbox List Sorting Working Memory Test. In this task, a series of stimuli is presented visually and orally. Participants are instructed to recall the stimuli in order of size, from smallest to largest. The List Sorting task takes approximately 7 minutes to administer and test scores consist of total items correct across all trials. This task shows excellent test-retest reliability and convergent and discriminant validity. Cognitive flexibility will be measured using the NIH Toolbox Dimensional Change Card Sort Test. In this task, a target visual stimulus must be matched to 1 of 2 choice stimuli according to shape or color. The relevant sorting criterion word, "color" or "shape," appears on the screen. An algorithm weights accuracy and reaction time. A total of 40 trials require 4 minutes. The task shows excellent developmental sensitivity and convergent validity. Response inhibition will be measured using the NIH Toolbox Flanker Task. On this task, participants indicate the left-right orientation of a stimulus presented in the center of the screen while inhibiting their attention to incongruent stimuli on either side. Psychometrics for the flanker task are excellent. The NIH Toolbox Pattern Comparison task will be used as a measure of processing speed. This timed task requires participants to compare two pictures and determine if they are the same or different, completing as many items as possible during a 90-second period. This task shows good convergent and discriminant validity.

Note-taking analogue task. Adolescents watch a lecture on video and are asked to take notes like they would in class. This lecture is approximately 8 minutes long.

Matrix reasoning: A series of puzzles in which the student will have to guess which shape goes next in a pattern.

Vocabulary: A list of increasingly difficult vocabulary words that students must define to the examiner. The tests are scored based on age norms and the number of questions the student gets

correct.

Students will also participate in a five minute observation of strategy use—the trained assessor will record the number of times the student wrote in their daily planner during the last five school days. They will also conduct a standardized checklist (attached) of how organized the student's bookbag is. Finally, they will ask the student to log on to their online grade book through their phone and show the rater their grades on recent assignments. The rater will count the number of Fs and missing assignments during the assessment period. Proper permission to collect this information will be obtained from the parent and student during the intake process. At the intake assessment they will complete a brief IQ screener (WASI) to determine study eligibility (Matrix reasoning and vocabulary subtests only). This test will be reviewed by two psychologists following the assessment to ensure eligibility. If the student is ineligible based on the IQ score, the participant will be withdrawn from the study and their information will be destroyed.

At the end of treatment, the treatment group will complete three brief rating scales about their satisfaction with the program. They will also complete focus groups and surveys which will be designed at a later date and submitted to the IRB at that time.

Parents: Parents will complete three ratings of student behavior and one rating of parent strategy use at each assessment. Post-treatment, they will also complete three satisfaction scales and participate in to-be-determined surveys and focus groups at the end of the study.

Peers: Peers will complete three questionnaires about their satisfaction with the intervention and will complete the assessments, as listed in the table in Section 5.3. They will also participate in to be determined surveys and focus groups at the end of the study.

Teachers: Teachers are informants who will complete a brief rating scale on the student's behavior in the classroom.

Fidelity observations: Sample fidelity checklists are attached. They will be modified based on the development of the intervention in year 1 of the grant. The final fidelity checklists will be submitted to the IRB prior to their use. Observers who are members of the research team will observe the intervention occurring and will check off whether each item on the checklist occurs.

5.3. Data sources that will be used to collect data about subjects:¹⁰

Table 4. Summer STRIPES Battery	Rater
Preliminary Outcome Measures (All time points)	
GPA	O
Class Attendance	O
ADHD Symptom Severity	PAR,T
Mechanisms (All time points)	
Expectancy-Value Motivation Measure (Wigfield et al., 2000)	S
Quick Delay Questionnaire (Clare et al., 2010)	S
Change Ruler (LaBrie et al., 2005)	S
Daily strategy use (organization checklist, planner use)	R
Hungry Donkey Task (Crone et al., 2004)	S
Choice Delay Task (Scheres et al. 2008)	S
Goal Setting & Planning (Zimmerman & Pons)	PAR
NIH Toolbox Tasks (Zelazo et al., 2013)	S
Go/No-Go Task (Hare et al., 2005)	S
Behavior Rating Index of EF (BRIEF; Gioia et al 2000)	PAR
Note-taking Analogue Task	S
Youth Self Report (Achenbach 1998)	S

Engagement & Fit Measures (During & Post-Treatment)	
Fidelity checklists (ongoing-to be adapted as needed)	R
Intervention Attendance (Parent, Peers, Teens)	R
Parent Academic Management Scale (Sibley et al., 2016)	PAR
Client Credibility Questionnaire (Borkovich et al., 1972)	S, PI, PAR
STRIPES Satisfaction Questionnaire (Sibley et al., in prep)	S, PI, PAR
Therapy-Bond and Engagement Scales (Shirk et al., 1992)	S, PI
Follow-up Focus Groups and Surveys to Guide Next Steps	S, PI, PAR
S=Student; PI=Peer Interventionist; T=Teacher; R=Research Assistant; O=Official School Records; PAR=Parent	

5.4. Data to be collected, including long-term follow-up data:¹¹

See adjacent table and attached documents. We also may contact the participants for long-term follow-up. If we determined that follow-up is necessary, a Modification will be submitted to the IRB to update the Protocol.

6. Data and Biospecimen Banking¹²

6.1. Complete list of the data and/or biospecimens to be included in the bank:¹³

In order to conduct long-term follow-up, we will keep all of the data collected in this study indefinitely.

De-identified data will be banked in the NIMH National Data Archive (NDA).

6.2. Location of data and/or biospecimen storage:¹⁴

We will work with the NIMH to place a fully de-identified version of this dataset in their National Data Archive.

Data kept locally will be stored in Redcap. Physical data (i.e., IQ tests) will be stored in a locked file cabinet in CHBD.

6.3. List of those with direct access to data and/or biospecimens in the bank:

The investigators of this trial will have direct access to the data. NIMH staff managing the NDA will have access to de-identified data. The researchers will also maintain the dataset locally for long-term use after the end of the study.

6.4. Length of time data and/or biospecimens will be stored in the bank:

Indefinitely.

6.5. Procedures for protecting the confidentiality and privacy of the subjects from whom the data and/or biospecimens were collected:¹⁵

The data that is shared with the NDA will be fully de-identified and will not include codes that will allow the data to be linked back to a key. Only the PI will retain a key with the subject identities, which is kept to facilitate follow-up. This key will be stored on a secure SCRI research server.

6.6. How the data and/or biospecimens will be made available for future use:

The NIMH has specific procedures through the National Data Archive that include signing a data use agreement, submitting an application to use the data that specifies the purpose and substantiates the credentials of the applicant, and affirmation of compliance with a long set of policies around the appropriate use of the data.

6.6.1. Who can request data and/or biospecimens from the bank:

The NIMH will determine who has permission to obtain the data.

Data stored locally will be available to study team members for long-term follow – up.

6.6.2. Format in which data and/or biospecimens will be provided:

We will provide the NDA with data entered into excel templates that they provide based on each measure that we collected.

Only study team members who have access to the data as part of the study will have access to the data retained for long-term follow-up.

6.6.3. Process for investigators to request data and/or biospecimens:¹⁶

The investigators who wish to use the data must fill out a Data Use Agreement and Data Use Certificate from the NIMH's National Data Archive.

Data stored locally for long-term follow-up will only be available to study team members.

6.6.4. Restrictions on future use:¹⁷

No restrictions.

6.6.5. Plan for providing data results from banked data/biospecimens:

The NIMH NDA has a policy that all publications stemming from NDA data must be made public access.

7. Sharing of Results

7.1. Plan to share results with subjects/others:¹⁸

Results will be posted in group form on a publicly available lab website for participants to access. We will only share results that are already published in a peer-review journal. The IRB will review this content before it is posted.

8. Study Timelines

8.1. Duration of an individual subject's participation in the study:

The student and parent participants will enroll in the spring of 8th grade and will continue to participate until all follow-up points are complete or attempted (through the end of ninth grade). We may also conduct annual follow-up through the remainder of high school. Participants will be informed of this possibility during the consent/assent. The peers will participate for a single school year.

8.2. Duration anticipated to enroll all study subjects:

18 months.

8.3. Estimated date for the investigators to complete this study:

We will complete the entire study (including possible follow-up through high school) by 2026.

9. Study Population¹⁹**9.1. Inclusion criteria for each subject population (e.g., patients, parents, providers):**

Students: Students will be eligible for participation if they display at least six symptoms of either inattention (IN) or hyperactivity/impulsivity (HI) as reported on the parent and teacher DSM-5 ADHD checklists and significant academic impairment, defined as meeting two of the following four criteria: (1) at least one D or F in a core academic class, (2) at least 20% of assignments missing in one class, (3) at least a “3” on the academic impairment item of the 0-6 teacher Impairment Rating Scale (Fabiano et al, 2006) or (4) elevated academic problems on the teacher Adolescent Academic Problems Checklist (AAPC; 4 items endorsed as “pretty much” or “very much;” Sibley et al., 2014)..

Eligible participants will complete a BL assessment at their middle school. Participants will be required to demonstrate an IQ > 70 on the Wechsler Abbreviated Scale of Intelligence, 2nd edition (WASI-II; Wechsler, 2011). Although DSM-5 symptom and impairment criteria must be met based on parent, teacher, and self rating scales, formal DSM-5 ADHD diagnoses will not be a requirement as it is not ecologically valid for schools to conduct full diagnostic assessments when determining intervention eligibility. Instead, this study will take an ecologically-grounded impairment-based approach to measuring and treating ADHD symptoms in the school setting. Provisional ADHD diagnoses will be assessed by two licensed psychologists (Sibley and Sasser) using combined parent, teacher, and self symptom and impairment ratings (using an item-level “or” rule that specifies that either rater may endorse a symptom; Sibley et al., 2012). Due to the school-based context of this study, we will not assess age of onset (DSM-5 “B-criterion”) or rule out other disorders (DSM-5 “E-criterion”), which would require a comprehensive parent diagnostic interview.

Parents: No inclusion criteria other than being the parent of an enrolled student.

Peer Interventionists: Peer interventionists will be nominated by their teachers. Peers will be required to have at least a 3.0 GPA and good behavior at school (defined as no in- or out-of-school suspensions during the past twelve months). Peer interventionists will participate in an in-person interview. Each school will follow their own internal peer interventionist selection process, so the study team will not facilitate or control the content of the in-person interviews. At each school, the summer STRIPES school staff sponsor will work with the SCH team to select six peer interventionists per year among the pool of applicants.

School Staff Sponsor: The School staff sponsor must be an employee in the appropriate school district.

9.2. Exclusion criteria for each subject population:

Participants will be excluded if they are placed in special education classes, as the purpose of this study is to test a low-cost intervention for use in regular education settings

9.3. Populations with special considerations, involved in the study:²⁰

☒ Children/Teenagers²¹

Risk assessment specific to this vulnerable population and additional safeguards:²²

We are evaluating an intervention for ninth grade students to improve the transition to high school. Thus, in order to conduct the study, minors must be participants. The risks to participation are minimal (described below).

- ☐ Children who are Wards of the State²³

Risk assessment specific to this vulnerable population and additional safeguards:

[Click here to enter text.](#)

- ☐ Adults Unable to Consent ²⁴

Risk assessment specific to this vulnerable population and additional safeguards:

[Click here to enter text.](#)

- ☐ Neonates of Uncertain Viability or Non-Viable Neonates²⁵

Risk assessment specific to this vulnerable population and additional safeguards:

[Click here to enter text.](#)

- ☐ Pregnant Women²⁶

Additional safeguards:

[Click here to enter text.](#)

- ☐ Prisoners²⁷

Additional safeguards:

[Click here to enter text.](#)

- ☐ Economically or educationally disadvantaged persons²⁸

Additional safeguards:

[Click here to enter text.](#)

10. Number of Subjects

- 10.1. Total number of subjects to be enrolled locally:²⁹

72 students, 72 parents, 22 peer interventionists, 2 school staff sponsors

- 10.2. Total number of subjects to be enrolled across all participating sites:³⁰

72 students, 72 parents, 22 peer interventionists, 2 school staff sponsors

- 10.3. Number of screened subjects versus the actual number enrolled in the research:³¹

We anticipate, based on previous research, that we will screen 100 students and their parents, and 60 peer interventionists.

- 10.4. Power analysis:

The mean effect size for adolescent interventions for ADHD compared to no treatment is approximately $d=.4$, as was the mean acute effect for the STP-A compared to LI (Sibley et al., 2014; Sibley et al., 2018). To substantiate summer STRIPES as incrementally superior to SSU plus, we will define a $d=.4$ difference between summer STRIPES and SSU plus as a successful outcome signaling the need for further study in an R01 clinical trial. Power analysis for a mixed effects model with $N = 72$, power = .80 and alpha = .05 were conducted using

GPower 3.1. Because the power for this analysis depends partly on the correlation between baseline and follow-up measures of the outcome, we assessed power for several values of this correlation. The proposed analysis has power to detect effects of $d = 0.42, 0.33$, and 0.21 for BL to FU correlations of .2, .5, and .8, respectively. In addition, there are 36 subjects per group; Maas & Hox (2005) recommend at least 30 clusters (here, subjects) per group to reduce bias in estimation of growth models, so we expect little bias in models.

11. Withdrawal of Subjects

11.1. Anticipated circumstances under which subjects will be withdrawn from the research without their consent:

None.

11.2. Procedures for orderly termination:

NA

11.3. Procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection and withdrawal from data/biospecimen banking:

If a participant withdraws from research we will seek consent to maintain already-collected data. If this consent is not provided, we will destroy all of the participant's data. Once data is sent to the NDA, it cannot be withdrawn.

12. Risks to Subjects

12.1. Reasonably foreseeable risks to subjects (include each study population, each arm, and optional procedures):

Risk: The primary risk to participants from the assessment sessions will be the time commitments of completing the necessary ratings. **Procedure:** By hosting visits at the school, and offering electronic assessments for parents, the time commitment of the study is minimized. There is little extra burden to families beyond what constitutes routine school-based services for ADHD other than attending the assessment sessions. The assessment sessions entail four collections of ratings of ADHD and indices of parent and adolescent functioning. The research team has an established process for timely collection of these data that minimizes the burden on families utilizing RedCap secure data collection tools. Participants will be able to opt out of any assessment that they so choose. We will work with the school to conduct the assessments during times that are least invasive to the student such as elective periods.

Risk: Students who receive stimulant medication (estimated: 25% of student participants) will be asked to refrain from taking their medication on days that they will complete a study assessment because computer tasks are invalid when students complete them while on medication. Students may have difficulty focusing in school on the day of assessments. Removing medication during clinical assessment is standard practice in the field of ADHD to allow for observation of symptoms when unmitigated by medication. Therefore, this risk does not exceed the risks included in standard clinical care. To further minimize this risk, we will work with parents, teens, and school staff to avoid scheduling assessments on days with high stakes activities that benefit from medication such as tests and quizzes.

Risk: Discomfort providing personal information about the student's level of functioning or parenting techniques. **Procedure:** This risk is similar to risk associated with clinical/school treatment (i.e., motivation, organization skills, ADHD symptoms). The same staff member will

meet with the subject and parents each time to minimize subject anxiety and provide continuity of care. Though it will not be directly queried in this trial, students will be informed that information disclosed about risk or rule-breaking behaviors will not be shared with their parents unless it represents a medical emergency.

Risk: Some students or parents may not be interested in attending treatment sessions (i.e., parents may feel the program is for the teen and that they should not need to attend parenting classes). **Procedure:** We recognize that by targeting a low motivation population, there may be cases where desire for the parent or student to engage with the intervention may be low. However, the psychosocial intervention is designed to address motivational deficits and includes engagement-specific activities such as a recreation period. It is expected that the majority of students will be willing to participate in these activities as attendance and engagement in our similar treatment programs is typically strong. Attendance is not required and will be measured as an index of engagement. If a student expresses a desire to discontinue participation, the option of withdrawing from the study will be discussed with the student and the parent and the family will be permitted to remove themselves from the project. Study treatments are also designed to address areas of impairment that the students and parents self-identify. Our team is experienced at training community and school staff to deliver psychosocial interventions for ADHD and will provide adequate training and supervision to interventionists to address these concerns. In addition, students and parents will be permitted to discontinue treatment, but complete study assessments (if they desire)—which maintains trial retention even if intervention attendance is suboptimal. Parents will be permitted to continue the parent skills components without the student's participation (and vice versa) should one member of the dyad refuse to participate.

Risk: Loss of confidentiality. **Procedure:** All information gathered is treated under the Seattle Children's guidelines for confidentiality of subject records. All data will be stored at the main research site and not at the schools (beyond routine school records that will be collected according to study protocol and later obtained by study staff for data collection purposes). No study data will be entered into the participant's permanent school records. All data will be transmitted only in encoded form. Most data will be gathered and stored electronically through RedCap. In few cases, physical data will be collected (i.e., IQ test, diagnostic interview). In these cases, data will be locked in a secure file cabinet behind double locked doors in CHBD. All computers in the laboratory are password protected. All stored data will be linked to a participant ID number, rather than the name of the participant. All the research notes only contain the accession number and no other identifiers such as a participant's name. Confidentiality also may be compromised by intervention activities that occur in school, where peers may observe students participating and ask questions. Peer interventionists will participate in a training on maintaining confidentiality of research participants. In addition, students will be permitted to meet in private spaces throughout the school to minimize risk that other students will become aware of the nature of students' participation in the study. This risk is not stronger than typical school services that may be observed by peers such as tutoring, or tier 2 interventions.

Risk: Sensitive information will be disclosed to the peer during intervention delivery.

Procedure: As a part of their training, peers will receive instruction on how to identify different types of sensitive information (i.e., abuse, self-harm, depression, bullying, intent to harm others, ongoing trauma or deprivation, drug abuse) and what to do if the student participant discloses sensitive information to the peer. We will work with schools to develop a school-specific protocol for disclosure of sensitive information that involves appropriate school-staff members (i.e., counselors, administrators).

Risk: Students may feel uncomfortable disclosing information on the Youth Self report form about whether they have had intrusive thoughts about sex or experimented with substances. The Youth Self Report form is among the most common broadband psychopathology scale scales in use in clinical practice and is routinely administered to youth with ADHD as a part of clinical assessment. Therefore, the risk of administering this questionnaire is no more than would typically be administered in a routine ADHD assessment, where questions like these are commonly asked to screen for possible thought disorders or behavioral health concerns.

Procedure: Students will be permitted to decline answering these questions. We will not force answers to these questions on the YSR and instead will put in an option that says “choose not to answer” as a fourth choice to the response option for the items on these topics.

12.2. Procedures with unforeseeable risks:

NA

12.3. Procedures with risks to an embryo or fetus should the subject be or become pregnant:

NA

12.4. Risks to others who are not subjects:

Teachers will be asked to give their time to assist with research procedures and provide information about the students.

12.5. Procedures performed to lessen the probability or magnitude of risks:

See Section 12.1.

13. Potential Benefits to Subjects

13.1. Potential benefits that individual subjects may experience from taking part in the research:³²

The benefits of this study to the student and his/her parent are several. First, the parent will receive a free assessment of the student's ADHD symptomatology. Second, parent and students in the intervention group will receive specialized psychosocial treatment designed to improve the transition to high school. The information gained from the study may also help participating schools develop effective interventions for their students with ADHD. Peers will receive community service hours for their experience and an enriching service-learning leadership opportunity. Serving as a summer STRIPES peer interventionist will also strengthen their college application.

14. Data Analysis/Management

14.1. Data analysis plan, including statistical procedures:

Analyses will be performed using Mplus 7. We will assess missing data prior to analyses. The proposed analysis methods (i.e., multilevel regression with maximum likelihood estimation) are robust to MAR (missing at random) or MCAR (missing completely at random) mechanisms, which will minimize impact of missingness and attrition. If there is evidence of MNAR (missing not at random) patterns, we will use appropriate methods. We will assess whether data meet all assumptions of analysis (multivariate normality, outliers). We will adjust for any violations using robust methods (such as using bootstrap standard errors). We will evaluate group differences in covariates and include in models as needed. **Aim 2a** is to test the effect of summer STRIPES (compared to SSU plus) on the primary outcome measures. The direct

effect of summer STRIPES on proximal outcomes (ADHD symptoms, GPA, class attendance, disciplinary incidents) at FU3 will be evaluated using latent growth models (Preacher, 2008). BL measure of the outcome, group, and their interaction will be used as predictors to evaluate the *improvement* in the outcome from BL to FU3. In longitudinal analyses, time will be modeled as a person-specific variable representing months since BL. We will explore non-linear and piecemeal models to consider that summer STRIPES orientation and its school year follow-up components may enact unique influences on slope over time. **Aim 2b:** The mechanisms by which summer STRIPES leads to improvement in outcomes will be evaluated through mediation growth models in an SEM framework using full information maximum likelihood (FIML) estimation. Three sets of models will be assessed, according to the three theoretical mechanisms (intrinsic motivation, extrinsic motivation, EFs). The models will assess the effect of summer STRIPES on primary outcomes via indices of intrinsic motivation, extrinsic motivation, and goal-directed EFs. For all models, the effect of STAND-YA on change in the mediator (e.g., extrinsic motivation) *from BL to FU2* will be assessed by controlling for BL values of the mediator; the effect of the mediator on change in the outcome across the three visits will be assessed by examining the relationship between FU2 mediator and the slope of the outcome to FU3. Current recommendations (e.g., MacKinnon, Cox, & Baraldi, 2012) advise evaluating mediators individually before considering combining them into a model with multiple simultaneous mediators. **Aim 3.** The effect of summer STRIPES on measures of engagement and school fit (Table 4) will be evaluated descriptively (e.g., treatment fidelity).

14.2. Quality control procedures for collected data:³³

Research staff will monitor all data for accuracy as they are collected through RedCap, which includes an option to require responses to all items. During assessments, research assistants will screen responses entered into RedCap forms to ensure that participants are completing forms thoroughly. Remote electronic assessments will receive data screening immediately after they are completed (staff receive an electronic notification when a new form has been completed by a participant). For any data that requires manual entry (i.e., student transcripts, IQ test results), research assistants will enter data on a rolling basis as the ratings are collected, and check these entries by comparing raw data ratings with computer printouts of the data sets, checking for and correcting any discrepancies.

15. Confidentiality³⁴

15.1. Procedures to secure the data and/or biospecimens during storage, use, and transmission:

Only the research staff performing the assessments, training, and supervision will have access to subjects' identities (approximately 5 staff). All information gathered is treated under Seattle Children's guidelines for confidentiality of subject records. All data will be coded and entered into a secure database on the center server that is only accessible to study staff. Hard copies of data will be stored in a locked data storage room at CHBD. The sheet linking study code numbers to individuals will be stored in a separate electronic database interface than participant data (RedCap). No data disclosed by the youth in the assessments (including the YSR) will be shared with the parent or anyone outside the research team without the youth's explicit permission. This will only be done in cases where concerns about safety are disclosed. YSR data will be collected through a redcap form that is sent in a private link to the youth and will not be shared with the parent or others outside the research team. The data is also protected by a Certificate of Confidentiality so it cannot be requested by non-research team members.

15.2. Location where the data and/or biospecimens will be stored:

Redcap. Physical data (i.e., IQ tests) will be stored in a locked file cabinet in CHBD.

15.3. Length of time data and/or biospecimens will be stored:

Indefinitely to allow for secondary data analysis.

15.4. Individuals with access to data and/or biospecimens:

Study team members listed in Click.

15.5. Process for the transmission of data and/or biospecimens outside Seattle Children's:

15.5.1. List of data and/or biospecimens that will be transmitted:

Not applicable.

15.5.2. Individual(s) who will transmit data:

Not applicable.

16. Provisions to Monitor Data to Ensure the Safety of Subjects³⁵

16.1. Plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe:³⁶

Study treatments are variations of established evidence based academic interventions, so it is not expected that serious safety concerns will arise. No study staff will be administering pharmacological treatments; however participants are permitted to continue use of previous pharmacological treatments, and medication use will be tracked and analyzed. Due to the minimal risks involved in this treatment, a formal Data Safety Monitoring Board was not deemed necessary for this protocol. To ensure the safety of all study participants, a Data Safety Monitoring Plan will be enacted. Dr. Sibley, Dr. Stefany Coxé (outside consultant with expertise on statistical design--will not be engaged in research or handle data), and Dr. William French, a board certified Child and Adolescent Psychiatrist, will comprise the Data Monitoring Committee (DMC). Dr. French has previous experience working on NIH clinical trials and will oversee monitoring of psychiatric emergencies during the trial.

Prior to the start of the study, the DMC will meet to review the protocol and will give input on augmentation. They will also determine data fields to be included in quarterly reports. In quarterly reports, the groups will be de-identified and information will be prepared Dr. Sibley's staff and shared with Dr. Coxé and Dr. French in a group level format.

16.2. Data reviewed to ensure safety of subjects:

Examined outcomes will include adverse events, dropouts, enrollment, and attendance at the school-based intervention. The DMC will review these summaries on a quarterly basis and determine if any adjustments need to be made to study protocol or other study methodology as result of these data.

16.3. Safety information collection procedures:

At each assessment, the student self-report form will be given, which includes two items about self-harm behaviors and ideation. Research assistants will be trained to screen these questionnaires for endorsement of either item. If endorsement is present a licensed clinical psychologist (Sibley or Sasser) will be contacted to perform an immediate risk assessment. Other than the possibility of existing self-harm behaviors (unrelated to intervention but possible in our population of teenagers with ADHD), we do not expect any safety concerns to stem

from an academic intervention delivered by members of a school community (rather than the SCH team).

16.4. Frequency of cumulative data review:
Quarterly.

16.5. Conditions that trigger an immediate suspension of the research:
Because this is an academic intervention, we cannot think of any foreseeable conditions that could trigger a need to suspend the research.

17. Use of Social Media

17.1. Types of social media to be used and how:
NA

17.2. Measures in place to protect the privacy or confidentiality of subjects:³⁷
NA

17.3. Types of communications that will be submitted to the IRB for review:³⁸
NA

17.4. If user-generated content will be active, how it will be monitored and what actions will be taken to ensure subject safety and study integrity:
NA

18. Research Related Injury³⁹

18.1. Available compensation in the event of research related injury:
None

19. Recruitment Methods⁴⁰

19.1. When, where, and how potential subjects will be recruited:
During the spring of participants' 8th grade year, study staff will work with high schools to distribute nomination forms and study information to feeder middle school counselors and administrators, inviting the schools to nominate students.

Based on procedures that our team has used in two previous federally funded studies (Sibley et al., 2018; 2020), the following process occurs.

First, an informational meeting about the study will be held for staff at each feeder middle school. The research team will explain the study and ask school staff members to contact parents of students who may be a good candidate for the program, based on their profile of school difficulties. A nomination packet will be distributed at this meeting.

The nomination packet contains the parent written informed consent form for the student's participation, written permission form for the school and SCH to exchange information about the student, a demographic survey to collect basin information about the student and the family, and parent informant rating scales that query the

presence of ADHD symptoms and related impairment. Interested parents may complete the packet and return it to the teacher. Once the teacher has the parent packet (which includes the information exchange form and the written parental consent form), the teacher may complete their portion of the nomination packet (brief surveys about classroom performance) and return the packet to the research team, who will be regularly visiting the schools to collect completed packets from teachers.

As part of the nomination form, the parents of rising ninth grade students who are nominated will be sent a cover letter (see attachments) that describes the study and invites them to schedule a phone call with the research team should they be interested in discussing study details with the researchers prior to completing the consent form.

Assent will be pursued for all rising ninth grade students whose parents consent to their participation in the research study. The student will be approached at school, informed about the study and that their parent has signed a consent form for their participation, should they assent. The study will be described in detail and student's will have the opportunity to assent on the written form that was signed previously by their parents.

Peers will be selected by school staff members. The research team will ensure that they meet study criteria after they have been selected by the school stakeholders (i.e., at least a 3.0 and no suspensions from school in the past year). However, there will be school choice in the process that is used to select the peers—some schools have elected to invite particular students directly, while others have decided to open applications to the program to the entire school. The research team will hold a group information session for peers to describe the opportunity and will deliver to peers a parental consent form (for those under 18) and youth assent form that must be signed prior to being considered for participation.

Parents of ninth grade students will complete a separate consent form for their own participation after it has been determined that the student meets study eligibility. Parents will be emailed a link to a written informed consent form that they can sign using a digital signature pad on a touch screen (i.e., on their smart phone). The consent form will reiterate how the parent can contact the research team to discuss their opportunities to be involved. Parental involvement is not a requirement in this study, it is a measured outcome. Therefore, all activities will be offered to the parent, but none will be required (i.e., parent intervention components). The link will also contain the parent rating scale battery.

The school staff members who will help to deliver the intervention will also be participants in this study because we will be measuring their fidelity to intervention procedures. An information sheet will be used to consent these individuals into the study, as their primary role is as an individual engaged in research, not as a research participant.

Teachers who will complete rating scales of student performance and who will pass along study information to parents are not considered participants in research. They are considered informants. We will collect no personal information from these teachers and will collect no information on the teachers' attitudes or behavior. As students have four to five core academic teachers, there is no pressure for a single teacher to serve as an informant so that the student can participate. Any single core academic teacher can complete a rating scale on the adolescent's performance to evaluate inclusion criteria and performance. We will only collect the teacher's information related to reimbursing them for their time completing the informant rating scale at each assessment. Teachers are not paid for nominating (i.e., recruiting students). They are only reimbursed for their time once the student is already in the study and study measures are being collected at each time point.

There are no differences in recruitment methods for Spanish speaking parents, as the students are referred by the school. We will make parent application packets available to the school in both English and Spanish so the school staff can send home the appropriate packet based on parent needs.

19.2. Steps that will be taken to protect potential subjects' privacy interests:⁴¹

To protect privacy during the recruitment process, all teachers will be given a non-descript envelop to send the nomination packet home to parents, so that others in the school will not know the contents of the envelope. The envelope will be returned to the teacher who will bring it to the counselor once they have added their teacher rating form. The research team will visit the counselor several times a week to pick up completed envelopes. Once all the nomination paperwork is complete, the next step is to hold the assessment.

All assessments will be held in private rooms at the school. Parent and teacher ratings will be conducted electronically through secure links sent to their emails. These links expire after one use and do not contain the participant's name.

Students will meet in private spaces throughout the school to minimize risk that other students will become aware of the nature of students' participation in the study. This risk is not stronger than typical school services that may be observed by peers such as tutoring or tier 2 interventions.

19.3. Sources of subjects:⁴²

High schools

19.4. Methods that will be used to identify potential subjects:

Collecting nomination forms from teachers. We will meet with staff at all feeder middle schools to explain the opportunity to participate in the study and the procedure for selecting students.

Once the nomination forms are obtained, as well as appropriate parental consent and youth assent, we will hold an initial visit with the youth at the school to assess additional eligibility criteria (i.e., IQ test).

19.5. Materials that will be used to recruit subjects:⁴³

See information provided above within this section.

19.6. Recruitment methods not controlled by Seattle Children's:

The study team will not have complete control over Peer Interventionist recruitment. Peers will be nominated by teachers and will participate in an interview facilitated by the school. The study team will confirm eligibility.

20. Consent/Assent Process

Consent process overview:⁴⁴

Once a student is referred, active informed consent will be obtained by sending the consent form home to parents. SCH staff and investigators will be available by phone to discuss the research with parents as part of the consent process. The consent form will contain phone numbers to call to discuss the consent form with investigators. Student assent will also be obtained at the school during an intake meeting with study staff and after the parent has already provided written consent for their participation. The staff member will instruct the parent/student to read the consent/assent and will provide a summary of the most important points listed in the document. The staff member will also answer any questions that the parent and/or student has during the consent process. The risks and benefits of participating in the study will be carefully discussed and all participants will be allowed to decline participation in the study.

Written parental consent and assent will be required prior to peer interventionist participation and will be obtained using the procedures above. Students will receive an in-person assent (as well as peers) that will allow them to answer any questions they may have about the research. It will be emphasized to the students and peers that at any time, if they wish to discontinue their involvement in the research, they may approach a study team member to do so. The students and peers will have regular contact with the study team throughout the study and so they will the opportunity to do so. In addition, parents will have the contact information of the investigators, and so they can telephone the team at any time to express concerns or ask additional questions.

Discussion of the consent form will not occur unless the parent contacts the study team. We do not want to require a consent conference in order for the student/peer to participate in the study because we would end up with a biased sample of only students with actively involved parents—and we are deliberately studying students who are known to have disengaged parents—the purpose of the parenting components of this project are to boost parent motivation. If the parent also agrees to participate in the research, they study team would have regular contact with them to complete study procedures. —

20.1. Where the consent process will take place:

For students and peers it will take place at the school in a private room, individually (students) or group administered (peers). For parents, it will take place over a phone call as requested by parents.

20.2. Steps that will be taken to protect prospective subjects' privacy interests:⁴⁵

Study team members will conduct any consent discussions in a private room. Parents will be able to place the signed parental permission/assent form in manila folder sent home with the student/peer.

20.3. Waiting period available between approaching a prospective subject and obtaining consent:
. There will be between three to six months between recruitment and receipt of intervention. Practically, a potential participant needs to decide if they want to participate before the end of their eighth grade year.

20.4. Process to ensure ongoing consent:

Parents and students will be regularly monitored throughout the study by the research team (at least monthly) through intervention activities and assessments. At each point in time the participant will have an opportunity to express concerns about participation.

20.5. If this box is checked, "SOP: Informed Consent Process for Research (HRP-090)" will be followed: ☐

20.6. If "SOP: Informed Consent Process for Research (HRP-090)" will not be followed, address the following:⁴⁶

20.6.1. Role of the individuals listed in the application as being involved in the consent process:

The to be named study coordinator will be available to conduct consent discussions with the parent by phone. However, because this is a naturalistic school-based intervention study (interventions delivered by school members), with optional parental involvement (measured as a study outcome), we may have limited contact with parents. As we have done in our previous school-based trials, parents will be sent a consent form home by the teacher who wants to nominate the student, must sign a permission to nominate form, an exchange of information form for the school/SCH, and the consent form. They will also be given a cover letter asking them to please call the study coordinator if they have any questions about the information on the consent form. If the parent signs the consent form, but does not request a consent discussion, a consent discussion will not occur.

20.6.2. Time that will be devoted to the consent discussion:

As much time as is requested by the parent.

20.6.3. Steps that will be taken to minimize the possibility of coercion or undue influence:

The student and peer will participant in an assent discussion once parent written consent is obtained. The student and peer will be free to decline participation in the study after he/she learns of the study activities.

20.6.4. Steps that will be taken to ensure the subject's understanding:

We will ask the student and peer a series of comprehension questions to make sure they fully understand the nature of study activities.

20.7. Non-English Speaking Subjects⁴⁷

20.7.1. Anticipated preferred language(s) for subjects or their representatives:

Because all students will be in regular education classrooms, we do not anticipate any non-English speaking students or peers.

We will also include parents who speak a language other than English. At this point we have only identified Spanish as a language which will need accommodation for

parents. Others may be added through a future modification if additional non-English language needs are identified for parents.

All consent procedures will be identical for non-English speaking parents. Mercedes Ortiz, who is a certified bilingual staff member on our research team, will conduct all consent discussions (and assessments) with parents who speak Spanish instead of English. Spanish translated consent forms are appended to this application.

20.7.2. Presentation of Research Information and Documentation:

- ☐ Appendix A-10 of the Investigator Manual will be followed⁴⁸
 - ☐ Short form procedures may be used per HRP-091. If so, choose applicable box(es):
 - ☐ Per section 5.5.1
 - ☐ Per section 5.5.2
- ☐ Appendix A-10 of the Investigator Manual will not be followed. Explanation of procedures not following Appendix A-10:
[Click here to enter text.](#)

20.7.3. Justification if non-English speaking subjects will be excluded from the research:⁴⁹
See Section 20.7.1.

20.8. Subjects Who Are Not Yet Adults (Infants, Children, Teenagers)

20.8.1. Process used to determine whether an individual has not attained the legal age of consent under the applicable law of the jurisdiction in which the research will be conducted (e.g., individuals under the age of 18 years):⁵⁰

We will only be enrolling rising ninth grade students, who by definition, are minors. Peers may be under or over 18 and so we will ask peers to share their date of birth in order to determine whether parental consent is needed (for those under 18).

20.8.2. Parental permission will be obtained from:⁵¹

- ☐ 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.
- ☐ Neither parent.⁵²

20.8.3. Process used to determine an individual's authority to consent to each child's general medical care if permission will be obtained from someone other than parents:⁵³

There is no general medical care involved in this study. The school has on file the name each student's legal guardian and we will double check with school administrators that the correct adult provided consent.

20.8.4. Assent will be obtained from:⁵⁴

- ☒ All children.
- ☐ Some children. Specify: [Click here to enter text.](#)
- ☐ None of the children. Explain: [Click here to enter text.](#)

20.8.5. Procedures for obtaining and documenting assent:

We will follow the consent procedures above for obtaining assent. This will be individual for the rising ninth grade students in a private location with an assent discussion held to ensure the students understand the research procedures and assent. For the peers, we will hold this discussion in a group format at an information meeting about the opportunity to participate. We will have all peers who are interested take a parental consent form home to their parents. They must return it to the research team prior to engaging in any research activities.

20.8.6. Plan for re-approaching children who have reached the age of majority to obtain consent:⁵⁵

This will only be applicable to peers. We will keep the dates of their 18th birthday on file and will approach them to re-consent (will be regularly interacting with them at the school) upon their 18th birthday.

Re – approach for long-term follow – up will be addressed with the Modification adding long-term follow-up procedures.

20.9. Cognitively Impaired Adults/Adults Unable to Consent⁵⁶**20.9.1. Process used to determine whether an individual is capable of consent:**

Not applicable

20.9.2. Individuals from whom permission will be obtained in order of priority:⁵⁷

Not applicable.

20.9.3. Assent will be obtained from:

- ☐ All of these subjects.
- ☐ Some of these subjects. Specify: [Click here to enter text.](#)
- ☐ None of these subjects. Explain: [Click here to enter text.](#)

20.9.4. Process for obtaining and documenting assent:⁵⁸

[Click here to enter text.](#)

20.10. Waiver or Alteration of Consent Process**20.10.1. Reasons for requesting a waiver or alteration of informed consent:⁵⁹**

n/a

20.10.2. Consent Waiver/Alteration Criteria justifications:⁶⁰

20.10.2.1. The research involves no more than minimal risk to the subjects because:
n/a

20.10.2.2. The waiver or alteration will not adversely affect the rights or welfare of the subjects because:⁶¹
n/a

20.10.2.3. The research could not practicably be carried out without the waiver or alteration because:⁶²

n/a

20.10.2.4. 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 because:
n/a

20.10.2.5. Whenever appropriate, the subjects will be provided with additional pertinent information after participation:
n/a

20.10.3. If the research involves a waiver of the consent process for emergency research, provide sufficient information for the IRB to make its determinations:⁶³
NA

21. Process to Document Consent in Writing

21.1. If consent will be documented in writing (check one):

- ☒ "SOP: Written Documentation of Consent (HRP-091)" will be followed.
☐ "SOP: Written Documentation of Consent (HRP-091)" will not be followed.
Process of documenting consent:⁶⁴

[Click here to enter text.](#)

21.2. If consent will not be documented in writing (check all boxes that apply):⁶⁵

- ☒ A written statement/information sheet describing the research will be provided to subjects.⁶⁶
☐ A written statement/information sheet describing the research will not be provided to subjects. Explain: [Click here to enter text.](#)
☐ A consent script will be used.⁶⁷

22. HIPAA Authorization and RCW Criteria


22.1. HIPAA Authorization (check all boxes that apply):

- ☐ The study does not involve the receipt, creation, use and/or disclosure of protected health information (PHI).⁶⁸
☒ HIPAA authorization will be obtained as part of a signed consent form.
☐ The study will access PHI without prior authorization from subjects (including for recruitment purposes – e.g., reviewing the medical record to determine eligibility). See 21.2 below for required HIPAA waiver/alteration criteria.
☐ Subjects will review a written statement/information sheet with the appropriate HIPAA language but will not provide a written signature. See 21.2 below for required HIPAA alteration criteria.⁶⁹
☐ Other. Explain:⁷⁰
[Click here to enter text.](#)


22.2. HIPAA Waiver/Alteration Criteria: Explain why:

22.2.1. The use or disclosure of PHI involves no more than a minimal risk to privacy of individuals, based on, at least the presence of the following elements:


22.2.1.1. An adequate plan to protect the identifiers from improper use and disclosure:

 Click here to enter text.


22.2.1.2. An adequate plan to destroy identifiers at earliest opportunity consistent with conduct of research:

 Click here to enter text.


22.2.1.3. Assurances that PHI will not be reused or disclosed to any other party or entity, except as required by law or for authorized oversight of the research:

 Click here to enter text.

22.2.2. The research could not practicably be conducted without the waiver or alteration of authorization:

 Click here to enter text.

22.2.3. The research could not practicably be conducted without access to and use of the PHI:⁷¹

 Click here to enter text.

23. Payments/Costs to Subjects⁷²

23.1. Amount, method, and timing of payments to subjects:⁷³

Payment will be made based on the length of their assessment batteries. Parents will receive \$50 for each assessment (approximately 30 minutes to complete), peers will receive \$20 (10 minutes to complete), and ninth graders will receive \$75 (one to two hours to complete). This will be given through Clincards (or a new procedure if that is what is in place by March 2021, when the first participants will be paid).

23.2. Reimbursement provided to subjects:⁷⁴

NA

23.3. Additional costs that subjects may be responsible for because of participation in the research:⁷⁵

NA

24. Setting

24.1. Site(s) or location(s) where the research team will conduct the research:

Garfield and Roosevelt (Seattle Public Schools) High Schools.

24.2. Composition and involvement of any community advisory board:

NA

24.3. For research conducted outside of the organization and its affiliates:⁷⁶

24.3.1. Site-specific regulations or customs affecting the research:

NA

24.3.2. Local scientific and ethical review structure:


NA

25. Resources Available

- 25.1.** Qualifications (e.g., training, education, experience, oversight) of investigator(s) to conduct and supervise the research:⁷⁷

Dr. Sibley is a licensed clinical psychologist who has experience overseeing six clinical trials, including four federally funded ones (R01 MH106587, IES R305A150433, R34 MH092466, IES R324A120169). This includes trials of both the STRIPES and STP-A interventions that will be used to adapt the proposed intervention.

- 25.2.** Other resources available to conduct the research:⁷⁸

 Click here to enter text.

26. Coordinating Center Procedures

- 26.1.** Coordinating center institution:

Seattle Children's

- 26.2.** If Seattle Children's is the coordinating center:

- 26.2.1.** Process to ensure communication among sites:⁷⁹

The Seattle Children's study staff will be in constant contact with staff at the high school sites.

- 26.2.2.** Process to ensure all site investigators conduct the study according to the IRB approved protocol and report all non-compliance:

The Seattle Children's Study team will always be present when the two school staff members are engaged in study activities and will be able to monitor and provide feedback on adherence to procedures. Only the Seattle Children's study team will have access to participant data.

- 26.2.3.** Process to ensure all required approvals are obtained at each site:

Both school districts will approve the study formally. Neither have IRBs (FWA numbers) and so Seattle Children's will be the single IRB and will govern the activities of the school staff members.

- 26.2.4.** Process to ensure all sites are informed of any problems and/or interim results:

We will provide annual reports to the school districts during the study.

27. International Center for Harmonization of Good Clinical Practice (ICH-GCP)

- 27.1.** If you have committed to conducting the described study per ICH-GCP, check this box: ☐ ⁸⁰

- This is generally applicable for contracts with industry-sponsored studies or sponsor protocols. See your contract/agreement or Sponsor Documentation if you are unsure.
- Note that completing GCP training is a separate activity and does not automatically mean that you have committed to conducting the study per ICH-GCP.
- **If you check the box, upload a current curriculum vitae (CV) for the PI to the "Other Attachments" section of the "Local Site Documents" SmartForm.**

¹ Include information if this protocol is associated with other IRB-approved studies (e.g. is this application the next part/phase of a previously approved application).

² In clinical trials, an endpoint is an event or outcome that can be measured objectively to determine whether the intervention being studied is beneficial. Some examples of endpoints are survival, improvements in quality of life, relief of symptoms, and disappearance of the tumor.

³ Include information on a drug or biologic in this section if: (1) the study specifies the use of an approved drug or biologic; (2) the study uses an unapproved drug or biologic; (3) the study uses a food or dietary supplement to diagnose, cure, treat, or mitigate a disease or condition; or (4) data regarding subjects will be submitted to or held for inspection by the Food and Drug Administration (FDA). Only include information on a device in this section if: (1) the study evaluates the safety or effectiveness of a device; (2) the study uses a humanitarian use device (HUD) for research purposes; or (3) data regarding subjects will be submitted to or held for inspection by the FDA. Please note that mobile medical applications may meet the definition of a device – see [FDA Guidance](#).

⁴ See the Investigator Manual HRP-103 for sponsor requirements for FDA-regulated research.

⁵ Explain what IND exemption category applies to the drug and why. Note that a drug is not exempt from an IND unless all criteria for one category are met. See “HRP-306: Drugs” for more information.

⁶ Explain what IDE exemption category applies to the device and why. Note that a device is not exempt from an IDE unless all criteria for one category are met. See “HRP-307: Devices” for more information.

⁷ Explain why the device is NOT a significant risk device. A significant risk device means an investigational device that: (a) is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject; (b) is purported or represented to be for use supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject; (c) is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or (d) otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

⁸ Be sure to indicate if controls will be included and include information about why control arms are ethically acceptable.

⁹ Describe all of the research procedures being performed. Be sure to make it clear which procedures apply to each subject population. When applicable, describe how research procedures differ from standard of care and/or affect standard of care. Describe any audio/video recording that will be involved.

¹⁰ Attach all surveys, scripts, and data collection forms to the “Supporting Documents” page.

¹¹ Include information about the frequency of data collection.

¹² See HRP-001 - SOP – Definitions for definition of banking. Type N/A if not applicable. If the data is subject to NIH Genomic Data Sharing Policies (e.g. you will submit data to dbGaP, NDAR, FITBIR), indicate here.

¹³ If applicable, include a list of identifiers that will be banked.

¹⁴ Be general (e.g., researchers' lab, clinic, etc.)

¹⁵ Generally, data and/or biospecimens should be released in a coded, non – identifiable manner.

¹⁶ Include a description of the process used to verify and document that any required approvals have been obtained prior to release of data/biospecimens from the bank.

¹⁷ You can allow for use for broad purposes

¹⁸ This includes putting results and/or data in the subject medical records.

¹⁹ If your population will differ from the representative population where the study will take place (e.g., race, ethnic group, or gender), provide a rationale for the differences.

²⁰ If you check a box below, be sure to include the additional safeguards associated with the population.

²¹ Refer to HRP-416 CHECKLIST: Children.

²² If the study is minimal risk, explain why. Must also include, as applicable: (1) why direct benefits are anticipated, (2) why risks are justified by anticipated benefit and/or the relationship between risk and prospective benefit compared to available alternatives, (3) why risk represents only minor increase over minimal risk, (4) how study procedures are reasonably commensurate with those inherent to the child's actual or expected conditions, (5) whether the interventions/procedures are likely to yield generalizable knowledge about the participant's condition and why it is of "vital importance" to understanding or amelioration of the participant's underlying disorder or condition, and (6) an explanation of what alternative methods/approaches were considered to make the above assessments (as applicable).

²³ This population may be wards of the state or any other agency, institution, or entity. Refer to HRP-416 CHECKLIST: Children, Section 6, for additional guidance on required considerations for this population.

²⁴ This refers to both cognitive impairments and adults who are incapacitated for any other reason. As applicable, refer to HRP-417 CHECKLIST: Cognitively Impaired Adults.

²⁵ Refer to HRP-413 CHECKLIST: Neonates and HRP-414 CHECKLIST: Neonates of Uncertain Viability.

²⁶ Refer to HRP-412 CHECKLIST: Pregnant Women.

²⁷ Refer to HRP-415 CHECKLIST: Prisoners

²⁸ Indicate how you will ensure that there is no coercion or undue influence

²⁹ A subject is considered "enrolled" when they consent to be in the study.

³⁰ Only applicable for multisite studies.

³¹ i.e., numbers of subjects excluding screen failures.

³² Payment for participation is not considered a benefit.

³³ For example, data will be double entered, data will be reviewed by another study team member to ensure accuracy, etc.

³⁴ If your study is multisite and there are differences in how confidentiality will be maintained by the coordination center and our local site, this should be explained in this section (e.g. local site will have samples that are linked to a person's name, but the coordination center will only receive coded samples without any links). Confidentiality regarding use of Social Media will be explained in a protocol section below.

³⁵ Applicable for studies that present more than minimal risk.

³⁶ Include information about who (describe in terms of role or group) will review the data.

³⁷ This should be specific to the social media you are using for the research.

³⁸ All communications that are directed towards subjects and specific to a particular study will require prior IRB review and approval. All non-IRB reviewable communications can be described in general terms by category – news stories, relevant publications – and representative examples of each can be provided.

³⁹ Applicable if the research involves more than minimal risk to subjects. If minimal risk, this section is N/A.

⁴⁰ If this is a multicenter study and subjects will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements) those methods should also be described here.

⁴¹ “Privacy interest” refers to a person’s desire to place limits on whom they interact or whom they provide personal information.

⁴² For example: medical records, CIS, clinical databases, other study records. If the study will access PHI for recruitment purposes without prior authorization from subjects, please address this in the HIPAA Authorization section below.

⁴³ Attach copies of these documents to the Recruitment Materials section of the study SmartForm. For printed advertisements, attach the final copy. For online advertisements, attach the final screen shots (including any images). When advertisements are taped for broadcast, send the final audio/video tape to IRB@seattlechildrens.org. You may attach the wording of the advertisement to the SmartForm prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.

⁴⁴ Include how you will ensure that subjects and/or their parent/legally authorized representative have sufficient opportunity to discuss and consider whether or not to participate in the research. .

⁴⁵ “Privacy interest” refers to a person’s desire to place limits on whom they interact or whom they provide personal information.

⁴⁶ This section describes the way(s) in which the processes for this study will not follow Seattle Children’s SOP.

⁴⁷ See HRP-090, HRP-091, and Investigator Manual HRP-103 for more information.

⁴⁸ Note the Short Form Consent may only be used when certain conditions are met. See HRP-091 for requirements for Short Form consent form use.

⁴⁹ Seattle Children’s IRB prohibits the exclusion of non-English speaking populations from research unless there is sufficient justification for the exclusion. See Investigator Manual HRP-103 for more information.

⁵⁰ For research conducted in the state, review “SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)” to be aware of which individuals in the state meet the definition of “children.” The age of majority in Washington is 18; however, sometimes younger children have ability to consent for certain types of care (e.g. sexual reproduction/health; mental health; drug/alcohol treatment). For research conducted outside of the state, 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 the definition of “children” in “SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013).” If the sites in other states in the

study are conducting their own IRB review, you do not need to worry about this--type N/A. If you are conducting research and are actively recruiting participants outside of Washington who are NOT coming to SCH to give consent and who will be covered under SCH IRB approval, this section should be addressed in your protocol.

⁵¹ For minimal risk studies and greater than minimal risk studies that offer a prospect of benefit, the IRB generally requires one parent to provide permission for the child to participate.

⁵² If parental permission will not be obtained, please address this in the Waiver or Alteration of Consent Process below.

⁵³ See HRP-013 for more information.

⁵⁴ The IRB generally follows the following guidelines for written assent: children 7-12 should provide written assent on the "simple" assent form (HRP-502G); children 13-17 should provide written assent by co-signing the parental permission form (HRP-502A). The IRB will consider other assent scenarios (e.g. verbal assent for some or all children; not requiring assent for some or all children; or waiving assent); please provide details about the plan for your study. See HRP-090 and HRP-416 for more information on waiving assent and when assent is not necessary.

⁵⁵ See Appendix A-13 of the Investigator Manual HRP-103 for requirements for re-consent at age 18. If you think you meet the conditions for a waiver at 18, please address this in the Waiver or Alteration of Consent Process below.

⁵⁶ See "HRP-417 Cognitively Impaired Adults" for further information.

⁵⁷ For example: durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child. If you are following HRP-013 in order to make this determination, simply state that in this section. For research conducted in the state, 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." For research conducted outside of the state, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject 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 the definition of "legally authorized representative" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)." If the sites in other states in the study are conducting their own IRB review, you do not need to worry about this--type N/A. If you are conducting research and are actively recruiting participants outside of Washington who are NOT coming to Washington to give consent and who will be covered under SCH IRB approval, this section should be addressed in your protocol.

⁵⁸ The IRB may allow the person obtaining assent to document assent on the consent document.

⁵⁹ For example: consent/parental permission will not be obtained, required information will not be disclosed, the research involves deception, waiver for participants who turn 18, waiver for information collected about a non-present parent, or other waivers as necessary.

⁶⁰ The IRB needs to make all the waiver findings and key to this determination is that the IRB understand why it is not practicable to do the research without a waiver of consent. You need to provide a rationale in order for the IRB to consider whether the waiver criteria are met. See "HRP-410: Waiver or Alteration of the Consent Process" for further information.

⁶¹ Possible reasons might include: a) you are not collecting information that could put subjects or their families at harm, e.g., affect eligibility for insurance, employability, stigmatization; b) you are not collecting information that would alter or affect the subject's care; c) any publication or presentation of research results would be done in a manner that would never reveal an individual's identity either directly or indirectly.

⁶² Possible reasons could be: a) inability to locate families because of the lengthy time period over which the records/samples were created; b) many of the subjects whose records, data, or biospecimens will be used may have died and contacting the families about the research could cause harm and anguish to families; c) all eligible patients must be included in the study for the results to be meaningful.

⁶³ See “HRP 419: Waiver of Consent for Emergency Research” for further information.

⁶⁴ This section describes the ways in which the procedures will not be following Seattle Children's SOP.

⁶⁵ See “HRP-411: Waiver or Written Documentation of Informed Consent” for further information.

⁶⁶ An information sheet template can be found in the Click IRB Library and should be attached to the consent form of the study SmartForm. For internet research, the information sheet can be translated to an on-line format, if desired.

⁶⁷ The IRB sometimes requires a script if you are having the consent conversation over the phone rather than in person. Templates for a consent script are available on the IRB website on the Participant Recruitment page and should be attached to the study SmartForm.

⁶⁸ PHI is health information that is also identifiable because it includes one or more of the 18 HIPAA identifiers. See Investigator Manual HRP-103 for the list of HIPAA identifiers.

⁶⁹ If your study involves using or creating PHI and your only contact with participants is online, you can request an alteration of HIPAA authorization to remove the signature requirement. As an alternative to a waiver of documentation of consent and an alteration of HIPAA authorization, you must demonstrate that the electronic consent signatures are compliant with applicable state/international law (in Washington, see [RCW 19.34.300](#)).

⁷⁰ For example: altering HIPAA elements for international research.

⁷¹ Possible reason could be: the nature of the research is specific to individuals' health and requires access to individuals' health records.

⁷² See “HRP-316: Payments” for further information.

⁷³ Methods of payment include check, ClinCard, gift cards, etc. Provide details on who will be the recipient of the payment (parent or child).

⁷⁴ Reimbursement is used when the subject is paid back for travel expenses such as transportation, food, childcare, or lodging. Reimbursement is generally distributed to person who incurred cost (usually parent) and requires receipts to be submitted.

⁷⁵ This could include things like fuel/transportation costs, parking, and/or childcare.

⁷⁶ Type N/A if this section does not apply.

⁷⁷ Provide enough information to convince the IRB that the principal and/or co-investigator(s) are appropriately qualified to conduct and supervise the proposed research. When applicable, describe their prior clinical experience with the test article or study-related procedures, or describe their knowledge of the local study sites, culture, and society.

⁷⁸ For example, as appropriate: (1) Justify the feasibility of recruiting the required number of suitable subjects within the agreed recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit? (2) Describe the time that you will devote to conducting and

completing the research. (3) Describe the facilities in which the research will be conducted. (4) Describe the availability of medical or psychological resources that subjects might need as a result of anticipated consequences of the human research. (5) 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.

⁷⁹ Including communication between sites of current study document versions and modifications.

⁸⁰ If you check the box, you are required to conduct your study according to the principles outlined at <https://www.ich.org/products/guidelines/efficacy/efficacy-single/article/integrated-addendum-good-clinical-practice.html>.