Improving the outcomes of adolescents with ADHD via a pre-visit question prompt list/video intervention: a randomized controlled feasibility trial

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Short Title: Pre-visit intervention to improve adolescent outcomes with ADHD
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PROTOCOL TITLE: Improving the outcomes of adolescents with ADHD via a pre-visit question prompt list/video intervention: a randomized controlled feasibility trial
Short Title: Pre-visit intervention to improve adolescent outcomes with ADHD

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Version Date: February 12, 2026

I confirm that I have read this protocol and understand it.

Principal Investigator Name: Betsy Sleath

Principal Investigator Signature: 

Date: February 12, 2026

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ABBREVIATIONS AND DEFINITIONS OF TERMS

Abbreviation	Definition
ADHD	Attention-Deficit/Hyperactivity Disorder
HIPAA	Health Insurance Portability and Accountability Act

Study Title	Improving the outcomes of adolescents with ADHD via a pre-visit question prompt list/video intervention: a randomized controlled feasibility trial
Funder	**National Institutes of Health**
Clinical Phase	Phase 3
Study Rationale	• Adolescents and their caregivers asked few questions during ADHD visits despite indicating that they have many. • A pre-visit question prompt list/video intervention can improve communication and clinical outcomes for adolescents with different chronic conditions. • No one has examined whether a pre-visit video only, question prompt list alone, or both improve adolescent and caregiver question-asking and the outcomes of adolescents with ADHD the most compared to usual care.
Study Objective(s)	• To examine whether the ADHD question prompt lists and/or pre-visit video significantly impact the **proposed mechanisms of the intervention**. We will investigate whether adolescents and parents in each of the intervention groups: (a) ask more questions and receive more provider education about ADHD during their baseline and 3 month visits and (b) have higher self-efficacy at 3 and 6 months than adolescents and parents in the usual care group. • To investigate the effectiveness of the ADHD question prompt lists and/or the pre-visit video by examining whether adolescents in each of the intervention groups have improved ADHD symptoms, school and social performance, and quality-of-life at 6 months compared to those in the usual care group. • To assess adolescent and parent feedback on the acceptability, feasibility, tolerability, and safety of using the ADHD question prompt lists and/or the pre-visit video. The results from this pilot trial will be used to inform a larger trial by: (a) identifying the intervention arm with the greatest potential impact, acceptability, feasibility, and tolerability, and (b) determine the best mechanisms and outcome variables to assess in a larger trial.
Test Article(s)	Question prompt list only, video only, question prompt list and video, or usual care
Study Design	This is a randomized controlled feasibility trial design where adolescents with ADHD are assigned to one of four groups: ADHD question prompt list only, pre-visit ADHD video only, pre-visit ADHD video and question prompt list, usual care

Subject Population **key criteria for Inclusion and Exclusion:**	Data will be collected at pediatric clinics in North Carolina. **Inclusion Criteria** 1. Ages 11 to 17 2. Speak and read English 3. Have an ADHD diagnosis 4. Are present at the clinic for an ADHD visit 5. Screen as having predominantly inattentive subtype, hyperactive/impulsive subtype, or combined inattention/hyperactivity on the Vanderbilt parent assessment scale **Exclusion Criteria** 1. There are no exclusion criteria.
Number Of Subjects	Up to 140
Study Duration	**Each subject's participation will last 6 months.** The entire study is expected to last 2 years and 6 months.
Study Phases **Screening** **Study Treatment** **Follow-Up**	Screening: Interested families will be referred to a research assistant based at the clinic to learn more about the study. If the family is interested, the research assistant will obtain parent informed consent, parent permission, and youth assent. Parents will be asked to complete HIPAA forms. Then the research assistant will administer the eligibility screener. Intervention: Youth will be randomized to either the question prompt list only group, the pre-visit video only group, the combined question prompt list/video intervention group, or the control group, stratified by provider. Using a random number generator, the biostatistician will prepar opaque, sealed envelopes containing group assignments. The research assistant will open the envelope when a youth enrolls into the study. Follow-up: The research assistant will interview all youth and have the parent complete a questionnaire after the 3 and 6 month visits. The youth's medical records will be reviewed for the 6-month period before enrollment into the study and the 6-month period after.
Efficacy Evaluations	**Primary Outcomes:** **Vanderbilt Assessment Total Symptom Score (parent informant):** The Vanderbilt parent informant ADHD rating scales are DSM-IV-based scales. The parent Total Symptom Scores (TSS) will be calculated by summing a **Total Symptom Score** the scores on each item; summary scores can range from 0 to 54. Higher scores indicate worse symptoms. We will examine changes over time, using the summary score. **Youth functioning using the Vanderbilt Assessment (parent informant) Average Performance Score**: The Vanderbilt average performance score (parent informant) has 8 functional impairment items (overall school performance, reading, writing, math, relationship with parents, relationship with siblings, relationship with peers, and participation in

	organized activities such as team sports) measured on a 5-point Likert scale (ranging from 1 to 5). A summary score will be calculated by summing the scores and dividing by the 8 items to calculate an average performance score. Higher scores indicate worse performance. We will examine changes in the score over time. **Secondary Outcome:** **Pediatric Quality of Life Inventory (PedsQL):** The 23-item PedsQL has strong reliability and validity when used with youth with ADHD. It measures four dimensions of the child's quality-of-life: (a) physical functioning, (b) emotional functioning, (c) social functioning, and (d) school functioning. The items are reverse scored and are transformed to a 0 to 100 scale with higher scores indicating better quality-of-life.
Statistical And Analytic Plan	We will use ANCOVA to investigate which intervention arm (ADHD question prompt lists, pre-visit video, or pre-visit video and ADHD question prompt lists) results in the greatest change (compared to the usual care group) in ADHD symptoms, school and social performance, and quality-of-life at 6 months.
Data And Safety Monitoring Plan	The project manager will travel to the clinics at least once every two months to review data quality. The study has a Data Safety and Monitoring Board who will review study data twice a year.

BACKGROUND AND RATIONALE

Attention-deficit/hyperactivity (ADHD) disorder is one of the most prevalent mental health conditions among youth and the majority of youth with ADHD are cared for in primary care settings.[1-5] Prior work indicates that youth with ADHD have poorer quality-of-life and functioning than youth without ADHD.[6-15] Because better youth-parent-provider communication has been linked with better youth outcomes longitudinally, increasing family involvement during ADHD primary care visits could improve the quality-of-life and functioning of youth.[16, 17]

Few studies have examined youth and parent engagement during ADHD visits.[18-20] Specifically, Brinkman et al.[21] found low levels of shared decision-making during pediatric ADHD visits. In our own study of 67 youth with ADHD (ages 8-17) from five pediatric clinics, we found that less than 5% of parents and 2% of youth asked their providers questions about ADHD.[22] In a separate study of 70 youth with ADHD, we found that youth had an average of 8 questions about ADHD and parents an average of 8.9 questions that they wanted to ask providers.[23] Thus, even though youth and parents have questions about ADHD, they are not asking those questions during office visits. We also found that the primary place where youth want to learn about ADHD is the provider's office.[23]

Simple interventions, such as novel pre-visit videos and prompt lists, which are easy to implement and disseminate, are needed to engage youth and parents more during ADHD pediatric primary care visits. We were one of the first research teams to use question prompt lists with youth.[24] In our prior work, we found that a youth asthma video and question prompt list intervention significantly increased youth question-asking and provider education about asthma.[24, 25] We also found that youth who received the intervention and asked their providers questions were significantly more likely to have improved quality-of-life and asthma control at 12 months.[26]

Using Social Cognitive Theory as a guide, **we hypothesize** that an ADHD video/question prompt list intervention will increase youth and parent question-asking which, in turn, will increase provider education during the medical visit, which ultimately will improve youth and parent ADHD self-efficacy. Youth and parent question asking, provider education, and self-efficacy are the proposed mechanisms of the intervention. By improving youth and parent self-efficacy to manage ADHD, **we also hypothesize** that youth ADHD symptoms, school and social performance, and quality-of-life will improve.

In focus groups with a total of 14 providers, 12 adolescents, and 13 parents, 100% of participants were strongly supportive of an ADHD question prompt list/video intervention to motivate families to ask more questions during primary care visits. The focus groups provided valuable feedback on the adolescent and parent ADHD question prompt lists and on the key topics the pre-visit video should cover to encourage question-asking: (a) talking to your doctor about ADHD, (b) controlling ADHD without medicine, (c) ADHD medications, (d) ADHD and school, (e) ADHD and your relationships, and (f) helping your parents understand your ADHD. The novel video was then produced in partnership with adolescents. There is a need to conduct a pilot randomized controlled feasibility trial to evaluate the feasibility and effectiveness of the intervention.

1. STUDY OBJECTIVES

The overall objective of this pilot randomized controlled feasibility trial is to investigate the effectiveness of the ADHD question prompt lists and/or the pre-visit video by examining whether adolescents in each of the intervention groups have improved ADHD symptoms, school and social performance, and quality-of-life at 6 months compared to those in the usual care group. We have three specific aims:

1.1 Aim 1: To examine whether the ADHD question prompt lists and/or pre-visit video significantly impact the **proposed mechanisms of the intervention**. We will investigate whether adolescents and parents in each of the intervention groups: (a) ask more questions and receive more provider education about ADHD during their baseline and 3 month visits and (b) have higher self-efficacy at 3 and 6 months than adolescents and parents in the usual care group.

1.2 Aim 2: To investigate the effectiveness of the ADHD question prompt lists and/or the pre-visit video by examining whether adolescents in each of the intervention groups have improved ADHD symptoms, school and social performance, and quality-of-life at 6 months compared to those in the usual care group.

1.3 Aim 3: To assess adolescent and parent feedback on the acceptability, feasibility, tolerability, and safety of using the ADHD question prompt lists and/or the pre-visit video.

The results from this pilot trial will be used to inform a larger trial by: (a) identifying the intervention arm with the greatest potential impact, acceptability, feasibility, and tolerability, and (b) determine the best mechanisms and outcome variables to assess in a larger trial.

2. INVESTIGATIONAL PLAN (brief overview)

2.1 Study Design

The study is a pilot randomized controlled feasibility trial of the video/prompt list intervention that will inform the design of a future larger trial.

Screening: Interested families will be referred to a research assistant based at the clinic to learn more about the study. If the family is interested, the research assistant will obtain parent informed consent, parent permission, and youth assent. Parents will be asked to complete HIPAA forms. Then the research assistant will administer the eligibility screener.

Intervention: Youth will be randomized to either the question prompt list only group, the pre-visit video only group, the combined question prompt list/video intervention group, or the control group, stratified by provider. Using a random number generator, the biostatistician prepared opaque, sealed envelopes containing group assignments. The research assistant will open the envelope when a youth enrolls into the study.

Follow-up: The research assistant will interview all youth and have the parent complete a questionnaire after the 3 and 6 month visits. The youth's medical records will be reviewed for the 6-month period before enrollment into the study and the 6-month period after.

2.2 Study Duration, Enrollment and Number of Subjects

The study includes up to 140 adolescents. The study duration is 6 months for each participant. The overall study duration will be 2 years and 6 months.

2.3 Study Population

Participants will be enrolled from North Carolina pediatric practices. Youth eligibility criteria are: age 11 to 17 years, speak and read English, have an ADHD diagnosis, are present for an ADHD visit, and screen as having predominantly inattentive subtype, hyperactive/impulsive subtype, or combined inattention/hyperactivity on the Vanderbilt parent assessment scale. Youth's parents will be eligible if they are at least 18 years of age, speak and read English, and are the legal guardian of the child.

3. STUDY PROCEDURES

The study team will recruit pediatric clinics to participate. They will then obtain informed consent from health care providers who want to participate. Clinic staff will refer families interested in learning about the study to a research assistant to learn more about the study. We will enroll up to 140 youth. The UNC research staff will explain the study. The research assistant will take the family to a private area within the clinic to learn more about the study. The research assistant will obtain parent informed consent, parent permission, and youth assent will be obtained. Parents will be asked to complete HIPAA forms. Then the research assistant will administer the eligibility screener. We will record why families refuse to participate and why they were ineligible.

Youth will be randomized to either the question prompt list only group, the pre-visit video only group, the combined question prompt list/video intervention group, or the control group, stratified by provider. This will ensure group balance. We are including a usual care control group because we need to control for the many factors that might influence communication (such as youth age, parent educational level, etc.). By randomizing families to the four groups, these factors should be evenly distributed across the groups.

Using a random number generator, the biostatistician will prepare opaque, sealed envelopes containing group assignments. The research assistant will open the envelope when a youth enrolls into the study. Youth and parents in question prompt list group will be handed the prompt lists and will be told, "Your provider wants you to ask any questions that you have about ADHD. Here are lists of questions that you may want to ask. Please spend some time reading through this and marking any questions you want to ask your provider during the visit. You can also write other questions you want to ask on the bottom." Parents and youth in the pre-visit video only group will watch a short educational video with six themes on an iPad encouraging families to ask questions and to be engaged during ADHD visits. Youth and parents in the combined pre-visit video/question prompt list group will watch the video and will then be handed the question prompt lists and given the instructions above. The control group will receive usual care.

Next, all participating families (both the intervention and control group families) will have their medical visits audio-tape recorded. After the medical visit, the research assistant will conduct a 15- to 20-minute interview with all participating youth while parents complete a questionnaire. For those in the question prompt list or combined video/question prompt list intervention groups, we will collect the youth's and parent's question prompt lists so that we can compare what questions the youth and parent wanted to ask to what they asked during the visit.

If the team has any concerns about youth harm to self or others, they will refer the family to the primary care provider and Rob Christian, MD (co-investigator) for assistance. The team will report concerns to the state to the extent required by North Carolina law. If the patient states any concerns about adverse events from ADHD medications, the team will advise the family to alert the primary care provider immediately. Of note, no adverse events occurred in the pilot study with 20 families.

Youth typically come back for ADHD follow-up visits every 3 months. Families in the intervention groups will receive the intervention to which they were randomly assigned to use at each follow-up visit. The research assistant will interview all youth and have the parent complete a questionnaire after the 3 and 6 month visits. The research assistant will audio-tape the 3 month visit since we will be examining how baseline and 3 month communication is associated with 6 month outcomes. The youth's medical records will be reviewed for ADHD diagnosis date, co-morbidities, number of ADHD

visits, and ADHD treatment use (medications and other strategies) for the 6-month period before enrollment into the study and the 6-month period after.

4. STUDY EVALUATIONS AND MEASUREMENTS

4.1 Primary Outcomes

Vanderbilt Assessment Total Symptom Score (parent informant): The Vanderbilt parent informant ADHD rating scales is a DSM-IV-based scale, which gives a **Total Symptom Score**.[10-12] The Vanderbilt ADHD Rating Scale has been shown to have valid psychometric properties consistent with the Diagnostic and Statistical Manual for Mental Disorders; the Vanderbilt includes all the DSM-IV symptoms for ADHD.[10, 14, 27] The Vanderbilt has demonstrated acceptable internal consistency, adequate factor structure, and good reliability and validity as a measure of youth behavior and school functioning.[10] The Vanderbilt includes 18 DSM-IV symptoms that are rated on a 4-point Likert scale ranging from 0 to 3. Both the parent Total Symptom Scores (TSS) will be calculated by summing the scores on each item; summary scores can range from 0 to 54. Higher scores indicate worse symptoms. We will examine changes over time, using the summary score.

Youth functioning using the Vanderbilt Assessment (parent informant) Average Performance Score:[10-12] The Vanderbilt average performance score (parent informant) has 8 functional impairment items (overall school performance, reading, writing, math, relationship with parents, relationship with siblings, relationship with peers, and participation in organized activities such as team sports) measured on a 5-point Likert scale (ranging from 1 to 5). A summary score will be calculated by summing the scores and dividing by the 8 items to calculate an average performance score. Higher scores indicate worse performance. We will examine changes in the score over time.

4.2 Secondary Outcome

Pediatric Quality of Life Inventory (PedsQL): The 23-item PedsQL has strong reliability and validity when used with youth with ADHD. [13-15, 28, 29] It measures four dimensions of the child's quality-of-life: (a) physical functioning, (b) emotional functioning, (c) social functioning, and (d) school functioning. The items are reverse scored and are transformed to a 0 to 100 scale with higher scores indicating better quality-of-life.

5. STATISTICAL CONSIDERATIONS

5.1 Statistical Methods

Baseline comparisons

Characteristics of youth, their parents, and their providers will be presented by treatment group and clinic. Unadjusted statistical comparisons, using ANCOVA and the chi-square test or Fischer's exact test will be made between the treatment groups and usual care.

Analysis by Aim

Aim 1: To examine whether the ADHD question prompt lists and/or pre-visit video significantly impacts the proposed mechanisms of the intervention, we will use ANCOVA to investigate which intervention arm (ADHD question prompt lists, pre-visit video, or pre-visit video and ADHD question prompt lists) results in the greatest change (compared to the usual care group) in adolescents and parents: (a) asking more questions and receiving more provider education about ADHD during their baseline and 3 month visits and (b) having higher self-efficacy at 3 and 6 months.

We will examine how trial arms impact family question-asking and provider education directly after the baseline visit. We will examine how trial arms impact family question-asking, provider education and parent and adolescent self-efficacy at 3 months. Additionally, we will examine how trial arms impact the number of questions families ask at

baseline and 3 months combined and the number of areas providers educate about at baseline and 3 months combined. Our models will account for clustering by provider, and in addition to main effects of the intervention, will include several covariates including demographic characteristics such as adolescent race, ethnicity, length of time with ADHD, and parental education attainment. To help us determine whether we should use the combined pre-visit video and question prompt list or just the pre-video or just the question prompt list in the larger trial, we will perform multiple comparisons and use Hochberg's[30] false discovery rate to control overall study-wide type I error at α=0.05.

We expect less than 10% attrition over the 6 months based on our recent pilot with 20 families. We will explore reasons for and mechanisms of missing data to support Aim 1 and 2 analyses. We will use descriptive statistics to summarize the rates and patterns of missing data. We will compare proportions of missing outcome measures (mechanisms of action and our primary and secondary outcomes), at 3- and 6-month follow-ups by the four treatment groups using chi-square tests (or Fisher's exact tests as appropriate). We will test for differences in mean values and proportions of baseline measures between participants with and without missing outcome measures at 3- and 6-month follow-up using t-tests and chi-square tests. We will summarize patterns of missingness of the follow-up measures to assess if they monotone or arbitrary. To test whether outcome measures are missing completely at random (MCAR) we will use Little's $\chi 2$ test.[31] In sensitivity analyses, we will use multiple imputations (MI).[32] This approach accounts for the uncertainty that arises when imputing missing values and requires the less restrictive missing at random (MAR) assumption. Our imputation model will include all variables included in the analyses of mechanisms of action, primary outcomes as well secondary outcomes.

Aim 2: To investigate the effectiveness of the ADHD question prompt lists and/or pre-visit video by examining whether adolescents in each of the intervention groups have improved ADHD symptoms, school and social performance, and quality-of-life at 6 months compared to those in the usual care group. As in Aim 1, we will use ANCOVA to investigate which intervention arm (ADHD question prompt lists, pre-visit video, or pre-visit video and ADHD question prompt lists) results in the greatest change (compared to the usual care group) in ADHD symptoms, school and social performance, and quality-of-life at 6 months. As in Aim 1, we will apply the same analytic approaches to handle missing data and conduct all of the analyses to explore the heterogeneity of treatment effects. If the interventions have significant effect on our outcomes, we will also examine how the mechanisms examined in Aim 1 (question-asking, provider education, adolescent, and parent self-efficacy) impact ADHD symptoms, performance, and quality-of-life at 6 months. This will help us determine which mechanisms have the greatest impact on outcomes as we plan for the future trial.

To examine the dose of the intervention and its effect on our outcomes, we will first conduct descriptive analyses and assess whether levels of intervention exposure vary by youth and parent characteristics. For each of our intervention arms, we will use Kendall's coefficient of rank correlation to evaluate the extent of the association between the number of times a family receives the intervention and each our primary and secondary outcomes. We will examine the distributions of the intervention dose and, if appropriate, we will categorize them into groups to allow for nonlinear relationship in the multivariate models. As in Aim 1, we will use ANCOVA to evaluate whether the number of times family receives the intervention significantly affects our primary and secondary outcomes. First, we will run separate models for each the three intervention groups to assess how intervention dose affects outcomes by study arm. Second, we will run a model on the entire sample and include the three types of intervention doses as independent variables. Control arm participants will have values of zero coded for the three intervention dose variables.

Aim 3: Assess adolescent and parent feedback on the acceptability, feasibility, tolerability, and safety of using the ADHD question prompt lists <u>and/or</u> pre-visit video.

We will examine the quantitative data from adolescents and parents about the acceptability, feasibility, and tolerability of intervention arms as well as the qualitative data as to why adolescents, parents, and providers choose their answers to determine which intervention to use in the larger trial (ADHD question prompt lists only, pre-visit video only, pre-visit video and ADHD question prompt lists). We will examine means and standard deviations to see if any intervention scored particularly low on acceptability, feasibility, and tolerability. We will examine safety results (adverse events, drop-outs) and any negative feedback about any of the intervention arms from adolescents, parents, and providers to help us determine which intervention to use in the larger trial (ADHD question prompt lists only, pre-visit video only, or pre-visit video <u>and</u> ADHD question prompt lists).

5.2 Sample Size and Power

We present sample size justifications for our primary outcomes, based on the assumption that the results from this research will inform the design of our future main trial. We follow a confidence interval approach outlined by Cocks et al. 2013 and hypothesize that at least one of our active intervention groups will lead to an improvement in health outcomes.[33] This method identifies sample size requirements for a pilot trial such that if the observed difference between the groups (in the pilot trial) is zero, then the upper limit of the confidence interval will exclude the estimate that is considered clinically meaningful in the planned main trial. In our earlier study of youth with asthma[25] as well as in our small pilot trial of 20 adolescents with ADHD, we found that the question prompt list combined with the video intervention significantly increased youth question-asking. Both studies strongly indicated medium to large effect sizes (range of Cohen's h for difference in proportions: 0.42 – 0.98) for this mechanism of action; therefore, we provide our sample size justification for our main outcomes for which smaller effect sizes still reflect clinically meaningful differences. The providers on our team suggested that a difference of 5 points in the Vanderbilt ADHD Total Symptoms score (parent) and a change of 3 points in the Vanderbilt Youth Performance score (parent) reflect a clinically meaningful reduction in the severity or number of symptoms. For example, we expect the average ADHD symptom score in the control group to be 28 and expect a decrease to 23 or lower for participants in one of our intervention groups. Therefore, we present our justification assuming a small-medium effect size (Cohen's d for difference in means = 0.35), [34] which reflects a 5-point change in ADHD symptoms with a standard deviation of 14. Change of 3 points in the parent Vanderbilt performance score with a standard deviation of 6 translates to a larger standardized effect size of d=0.5. Our estimates of standard deviations come from the published literature.[6-12, 14, 22, 23, 35] Further, to account for the fact that we will be performing multiple comparisons with the control group, we assume a one-sided 90% confidence interval (CI) for our justification, which is more conservative than 80% suggested by the original publication. A one-sided CI is chosen because we will only be interested in proceeding with the larger trial if there is some evidence of effectiveness in this pilot trial. Even though data from our ADHD pilot study with 20 families suggest a maximum attrition of 10%, we conservatively assume an attrition rate of 15%. Based on all of these assumptions, we anticipate enrolling 140 patients or 35 per study arm. This sample of 140 would be sufficient to produce an upper limit of a one-sided 90% CI which would exclude 0.35, assuming the null hypothesis of no difference between control and intervention arms is true for this proposed study (i.e., calculated upper 90% CI =0.3488). Additionally, our estimate of 35 participants per group is in agreement with and more conservative than sample sizes recommended for pilot trials published in the literature.[36, 37] It also aligns with the published recommendations regarding sample size requirements necessary to estimate design parameters for our main trial.[38]

6. STUDY INTERVENTION

Families are assigned to one of three pre-visit intervention groups or usual care. The three intervention groups are:
Question Prompt List Only: Youth and their caregivers receive ADHD question prompt lists before their visits to complete for use during visits.
Video Only: Youth and caregivers watch a short video on the importance of asking questions about ADHD and its treatment during pediatric visits.
Question Prompt List and Video: Youth and caregivers watch a short video on the importance of asking questions about ADHD and its treatment during pediatric visits and youth and parents complete ADHD question prompt lists for use during visits.

7. SAFETY MANAGEMENT

All data that will be used is de-identified. The data will be stored on password protected computers. Informed consent and assent will be obtained from all youth, parents, and providers who participate in the study. All data will be stored in a secured fashion. Additionally, we will obtain parent permission for youth participation. Parents will also sign HIPAA forms. Code numbers will be assigned to youth, parents, and providers and any information that could identify youth, parents, or providers participating in this project will not be included in any data sets. Also, the audio-tapes of visits will

be transcribed into text and then erased. All identifiers will be removed and replaced by blank lines. All data will be reported in aggregate and no individual will be identified.

If any member of the research team has any concerns about adolescent harm to self or others, they will refer the family to the primary care provider and Rob Christian, MD (co-investigator) for assistance.

8. DATA COLLECTION AND MANAGEMENT

8.1 Data collection and confidentiality of the data

The project manager will travel and visit the clinics at least once every 2 months to review data quality. Code numbers will be assigned to youth, parents, and providers and any information that could identify youth, parents, or providers participating in this project will not be included in any data sets. The audio-tapes will be kept on a secure HIPPA compliant server. Also, the audio-tapes of visits will be transcribed into text and then erased. All identifiers will be removed and replaced by blank lines in the transcripts. All data will be reported in aggregate and no individual will be identified. Data will be stored in a locked filing cabinet in a locked office separate from the consent forms. All data will be entered by the project manager under unique identifiers. The statistician will perform all analyses using de-identified datasets.

8.2 Monitoring Plan

As Principal Investigator, Dr. Sleath will have overall responsibility for the study. She will report any problems to the UNC Institutional Review Board. The Institutional Review Board will provide ongoing monitoring for this investigation. This study has minimal risk because the intervention is focused on improving communication during medical visits and subsequent health outcomes. However, an independent and unbiased review of the study's ongoing progress will be provided by the Data and Safety Monitoring Board. The Data and Safety Monitoring Board will meet twice a year to monitor the study. Its primary responsibility will be to review the progress of the study to minimize risk and to decide whether or not the study should continue. To help them with their assessment, Drs. Sleath, Carpenter, and Annis will furnish the board with the appropriate monitoring data before each meeting.

9. CONSENT PROCESS

All study procedures will be explained fully to interested families by a member of our UNC research team staff who will be based at the clinics. The research staff member will be able to answer any questions the patient has about the study. All parents will be asked to review and sign an informed consent, parent permission, and HIPAA form. The consent/assent process will occur in a private area in the clinic. Youth will be asked to review and sign an assent form. Some participants may feel uncomfortable having their physician visits audio-tape recorded when discussing sensitive issues. The research staff member will let them know they can ask the provider to turn off the audio recorder at any time during the medical visit Also, the research staff member will tell participants they do not have to answer any questions in the survey that make them feel uncomfortable. After reviewing each section of the consent with the participating families the research staff will ask both parent/child if they have any questions or concerns regarding their participation. Enough time will be given to answer questions to make sure family understands what it takes to participate in the project. The signed assent, consent, parent permission, and HIPAA forms will be kept in a locked file cabinet, and copies will be given to the patients.

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