PROTOCOL FOR TA CALLS (EARLY IMPLEMENTATION)

These questions are guidelines, not exact wording and firm in ordering. You should adjust with the flow of the call and skip questions that are not relevant/have been firmly established recently.

If, at the time of the approval memo, additional issues were identified for immediate follow-up with the grantee, please also include those issues as part of the monthly discussions.

Two days before the call, email a reminder with an agenda to all participants and ask for a submission of any major issues or questions that they would like to discuss (see final bullet in Intro below).

A. INTRO

* *Begin by leading introductions and taking record of everyone participating on the call.*
* *Explain that the purpose of the call is to get an update on where things stand with their evaluation and to answer questions or help address any challenges that have arisen. [Our protocol serves two purposes. We want to track progress through aspects of the evaluation, and we want to monitor the implementation of these aspects.]The call is structured to understand the following elements:*
  + *The current status of their program development and readiness for implementation (Section B)*
  + *Their plans for evaluation and their implementation of aspects of that evaluation (Section C).*
  + *Plans for their implementation evaluation (Section D)*
  + *Issues in program implementation (Section E)*
  + *Progress in follow-up data collection (Section F)*
  + *Information on baseline equivalence assessment (Section G)*
  + *Their upcoming plans for evaluation implementation in the next month (Next steps).*
* [*Does the grantee or local evaluator have any major issues or questions they’d like to discuss?**If so, start with those first.**If not, then continue with discussion questions listed below.*]

B. PROGRAM DEVELOPMENT FINALIZATION

### B.1 Program finalization

* Have you finalized the [Name of program model] content and materials? If not, what program components (e.g., curriculum, identification of core components, fidelity monitoring tools) need to be completed and when do you expect this to happen?
* Have all intervention materials (including supplemental materials) been submitted to OAH for the final medical accuracy review? If so, have all required revisions been made?

Has the program been piloted with a small number of youth from the target population?

### B.2 Training

* Have you finalized the content and materials for the [facilitator/teacher/etc.] training for [Name of program model]?

Is a training plan in place?

### B.3 Piloting program

Can you please describe your piloting process for the program and evaluation materials? When do you expect this to be completed?

C. PLAN FOR IMPLEMENTING PROGRAM MODEL

### C.1 Contrast between treatment and counterfactual

* Have there been any changes to your plans to implement [Name of program model] and (if applicable) [comparison condition]?
  + Select key characteristics of the implementation plans in the communities/schools/clinics and ask some specific confirmatory questions (timing of implementation, model of program administration)
  + Did the implementation of the pilot affect your plans at all?
* As we understand it, the key differences between the treatment and control conditions in your study are:
  + List key differences in the intended experiences of the treatment and control condition, as described in approval memo.

### C.2 Pre-intervention preparation (sites)

* Have you secured MOUs from all of the [#] sites you planned to work with for the evaluation?
  + If not, when do you expect to have these in place?
* Have you had any trouble with sites dropping out or refusing to participate?
  + What was the cause?
  + Do you anticipate this requiring any changes to your plan?

### C.3 Pre-intervention preparation (staffing)

* Can you describe your process for identifying, hiring (if necessary), and training the staff who will deliver the program?
  + What is the status of these efforts?

Are you on pace to begin the implementation of your program on [insert start date]?

D. IMPACT EVALUATION

### D.1 Impact Evaluation design

* Have there been any changes to your research design since receiving your approval memo?
  + Select key characteristics of the evaluation and ask some specific confirmatory questions (see examples below)
    - How many cohorts of participants are planned?
    - How many schools/classrooms/youth will be assigned to each condition?
* Have you received IRB approval?
  + Did IRB require any changes to your study design or instruments?

### D.2 Youth enrollment and consent process

* How are you recruiting (or planning to recruit) individual youth into your sample?
* Please describe your procedures for gathering evaluation consent and program consent.
* Have you finalized your study consent/assent and program consent documents? If so, can you describe them?
  + Are you using the same documents for both the T and C groups?
    - If no, or consent forms sound as if they will be questionable: Can you send us a copy of your finalized consent/assent documents?

### D.3 Youth Enrollment and Consent Implementation

* When did you begin recruitment of individual youth into your program?
  + Have you encountered any problems in recruiting individual youth?
* Have you started the evaluation consent process?
  + Have you encountered any problems?
  + What are your current consent rates overall? By treatment and control/comparison youth?
  + Are you on pace to meet your first year sample size targets?
  + When do you expect to complete sample enrollment (for this cohort)?
  + Have challenges in sample recruitment or lack of consent led to any changes in your study design, intended population, or program implementation?
  + Will youth with evaluation consent who don’t provide program consent/assent still be followed as part of the evaluation sample?

### D.4 (Random) assignment strategy

* How many schools/teachers/classrooms/youth will be assigned to each condition?
  + If applicable, how many participants within each school (or applicable cluster) will participate in the evaluation? How will they be identified?
  + When will (random) assignment be conducted? By whom?
  + (For clustered RA)What procedures do you have in place to ensure that the sites are still interested in being a part of the study up until the point of RA?
* [*If applicable*] What are your plans for conducting random assignment? For example, —simple random assignment, stratified, matched pairs, etc.?

What procedures do you have in place to monitor compliance with random assignment results?

### D.5 (Random) assignment implementation

* When did you conduct (random) assignment?
  + Did you encounter any problems with your (random) assignment strategy?
  + How many total sites (if applicable, teachers (if applicable) and youth have been randomly assigned to Treatment? To Control?

### D.6 Tracking consented sample over time

* What data are you planning to collect on the consented sample to be able to track study participants?
* What procedures are you planning on using to track youth with evaluation consent over time?
* Will you be able to link surveys completed at baseline and at follow-up to each other (via a name or ID link)? Can these data be linked to the information in the tracking file?

### D.7 Baseline data instrumentation

* Have you finalized your baseline survey instruments?
  + What demographic information will you collect on the baseline survey and/or at intake that will allow you to describe your sample characteristics, and by treatment and control/comparison groups.
  + Does your survey instrument include at least one behavioral outcome measure? [*Measures meeting the OAH requirements include sexual activity (initiation, frequency, number of partners), contraceptive use, sexually transmitted infections (STIs), pregnancies or births.*]

### D.8 Baseline data collection process

* When will baseline data collection be conducted? Is the timing of baseline data collection the same for both treatment and control arms?
  + Will this occur after or before consent and (random) assignment?
  + Who will administer the surveys? How will they be administered? Is the baseline data collection administration different across treatment and control arms?
  + Have you encountered any challenges in planning for the collection of baseline data?

### D.9 Baseline data collection

* When did you begin collecting baseline data for program youth?
  + Have you encountered any problems with baseline data collection?
* What were the response rates on the baseline survey or the treatment and control groups?

E. IMPLEMENTATION EVALUATION PLANNING

### E.1 Plan for measuring program participation/attendance

* What are your plans to measure attendance of youth who have evaluation consent (may be better framed as “participation of youth” for some interventions, such as one-on-one counseling sessions or videos).
  + How will youth attendance/participation be recorded?
  + For whom will it be recorded (i.e. – will they record it for all youth with evaluation consent, whether or not/even if parents did not provide consent to participate in the program?
    - Will they also record any control youth participation/attendance in order to document cross-overs?
  + Who will be collecting these measures? If program staff (likely), how will this information be shared with the evaluator?

### E.2 Plan to assess the degree to which program model is being delivered as intended

* What are your plans to assess whether the program model is being delivered as intended by the program developer?
  + What information will you collect to understand whether the intended number of sessions is being offered? In other words, whether the intended **dosage** is made available to youth?
    - Who will collect this? How?
    - Will information be collected on unexpected occurrences (such as school closings due to weather)?
    - Will you collect this information across all program sites/classrooms? If not, how are you creating subsamples from which the information will be gathered?
  + What information will you collect to understand whether the intended **content** of the sessions is being offered? In other words, whether the intended material is being covered?
    - Who will collect this? How?
    - Will you collect this information across all program sites/classrooms? If not, how are you creating subsamples from which the information will be gathered?
  + What information will you collect to understand the **means/mechanisms** through which the program is delivered to participants?
    - The data collected should reflect the program and its logic model for changing youth outcomes. Examples of the collected data could include staff qualifications, staff training, expected pedagogical techniques, development of relationships/interpersonal communication, working hardware/software, etc.
  + Will observations be part of the data collection effort (presumably, yes, given performance measures)?
    - What units will be observed? How will those units be selected? Who will conduct these observations?

### E.3 Plan to measure the contrast in services received

* What are your plans to measure other related(i.e. – teenage pregnancy prevention/youth development) services received by the treatment and control group members?
  + Are they using interviews/discussions with local program administrator to understand what other activities/services may be available in the local schools and communities?

How will they measure youth participation in those activities/services? For example (and this would seem to be the preferred and most cost-effective way of measuring this), do they plan to ask about participation in those named activities and services on (at least) follow-up surveys? Do they plan on measuring attendance or participation rates of the counterfactual if the control youth are receiving a separate intervention?

F. IMPLEMENTING THE PROGRAM (AND COMPARISON CONDITION)

### F.1 Implementation issues

* Have you experienced any challenges implementing the program model?
* Have there been any changes to the program during implementation as a result of continuous feedback through fidelity monitoring, or other implementation challenges that you have experienced? Do you plan to implement any changes in the future?

*If changes have been implemented – or are anticipated – remind the evaluator that they need to have a record of the change that was made, when it was made, and why the change was made.*

### F.2 Changes to the comparison condition/context

* Have there been any changes to the experiences of the control group?

Are you aware of how state PREP (Personal Responsibility Education Program formula grant) funds are being used in your state? If so, who will be eligible for services (age/grade, target population, location)? Is it possible that students in the treatment and/or control group will receive services through PREP funded programs?

### F.3 Program Attendance

* For Cluster, RCTs, are all clusters who were randomly assigned still participating?
  + If not, how many clusters were lost? From what conditions? For what reasons? Are you going to attempt to collect follow-up data from the students with evaluation consent in these clusters?
    - *Remind grantee/evaluator that for an ITT analysis, data for these youth should be collected.*
* For RCTs, approximately what percent of students took up the program initially, among those who were randomly assigned?
* For QEDs, approximately what percentage of the group that was expected to participate in the program is doing so?
* What are the approximate attendance rates for the sessions?
* Have you examined patterns in attendance rates? Do participation vary by site (or other key characteristic of the design)?
* [If attendance is low overall or within particular sites] Have you initiated any strategies to boost attendance? If so, what are they?
  + If new strategies have been implemented, remind the evaluator that they should have a record of the strategies and when they were implemented.

G. PLANS FOR FIRST FOLLOW-UP DATA COLLECTION

### G.1 First follow-up data instrumentation

* Have you finalized your first follow-up survey instrument(s)?
  + Does your survey instrument include the same behavioral outcome measures as the baseline survey? [*Measures eligible for review under the OAH evidence standards include sexual activity (initiation, frequency, number of partners), contraceptive use, sexually transmitted infections (STIs), pregnancies or births.*] If no, what is the rationale (e.g., mediators only)?
  + Does your survey include questions about teen pregnancy prevention services or abstinence programs received outside of the program for both treatment and control group students? [*If you are confident that this is covered in their survey because of questions asked during the implementation questions, you can skip.*]

### G.2 First follow-up data collection process

* When will the first follow-up data collection be conducted? [*If this is known, there is no need to ask, you can confirm “The first follow-up data will be collected in X, is that correct?*]
  + (If not known,) will this occur during programming or after program end?
* Who will administer the surveys? What is the mode of data collection?
* Is the timing and mode of data collection the same for both treatment and comparison groups?
* Have your data collection plans been influenced by your experiences from the baseline data collection?
  + If so, how?

### G.3 First follow-up data collection

* Have you started follow-up data collection? *(If so, confirm that it occurred when you expected it to)*
  + Have you encountered any problems with data collection?

What are/were the approximate response rates on the survey or the treatment and comparison groups?

**USE SIMILAR QUESTIONS TO PROBE ON 2ND OR 3RD FOLLOW-UP, AS NECESSARY.**

H. BASELINE DATA ANALYSIS PLANS

### H.1 Data quality

* Have you started checking the quality of the baseline data (e.g., response rates, item non-response, internally inconsistent responses)?
  + If so, what are you finding?

### H.2 Data analysis

* Have you examined baseline equivalence of your analytic sample? If so, on which measures? Are the treatment and comparison groups significantly different on any of those measures?
* What analyses do you have planned for the short-term?
* What are your plans to address missing baseline surveys for youth who complete follow-up surveys?

What are your plans to address item non-response for single items? For items that are part of a scale?

NEXT STEPS

* What are you planning on working on next month, in terms of program implementation?
  + Are you planning on making any programming changes?
  + Is there anything that you would like to discuss about your upcoming program implementation following this call?
* What are you planning on working on next month, in terms of evaluation?
  + Are you foreseeing any changes to your evaluation plans?
  + Is there anything that you would like to discuss about your upcoming evaluation following this call?