Instructions for the Sample Progress Reporting Tool for Cluster Assignment

The information collected in the tool will be used for internal purposes to (1) assess sample enrollment and compare actual sample sizes to the target sample sizes on which power calculations were based, and (2) for randomized controlled trials (RCTs), assess the likelihood that the final analytic sample for key follow-up time periods might exceed the thresholds for overall or differential attrition specified by the Standards of Rigor and the Teen Pregnancy Prevention Evidence Review. This tool will also help the LES team to identify any specific areas where we can provide additional evaluation support to ensure you have an adequate sample size and minimal attrition to meet the Standards of Rigor.

The tool is for CLUSTER ASSIGNMENT and contains two tabs:

1. Enrolled Clusters
2. Enrolled Youth

This document includes instructions on completing both of these tabs.

A note on follow-up periods:

The PREIS Notice of Funding Opportunity defines short-term follow-up as up to 6 months post intervention and long-term follow-up as 9 months or more post intervention. If you have more than one follow-up period during one of these timeframes, please work with your LES liaison to select the follow-up period that is most meaningful for your evaluation to include in this tool.

Instructions for the Sample Progress Reporting Tool for Cluster Assignment – **Enrolled Clusters**

To complete the **Enrolled Clusters** tab, enter information into the YELLOW cells. For instructions on what to enter, click on a yellow cell and instructions will pop up. GREEN cells will automatically populate based on the information you enter in the yellow cells. (Note: for multi-arm studies, this form should be completed separately for each treatment/control pairing.) For additional support, please contact your LES liaison or PREPLES@abtglobal.com.

Instructions for each data entry box

Box 1

Sample enrollment and data collection through this date

- Please indicate the date through which sample enrollment and data collection are reflected in this form.

Box 2

 # Clusters enrolled in study to date

- Please indicate the number of clusters that have been enrolled in the study, meaning the cluster was assigned to the treatment or control/comparison group.

Box 3a

 # Clusters assigned to treatment

- Please indicate the number of clusters assigned to the treatment group.

Box 3b

 # Clusters assigned to control/comparison

- Please indicate the number of clusters assigned to the control/comparison group.

Box 4a

 # Clusters for which short-term follow up has closed

- Please indicate the number of treatment clusters for which the short-term follow up survey window has closed as of the date of this form.

 # Clusters retained at short-term follow up

- Please indicate the number of treatment clusters in which at least one youth has completed the short-term follow up survey (in all short-term follow up windows that have closed as of the date of this form).

Retention rate (automatically calculated)

- This percentage is (# Clusters retained at short-term follow up) divided by (# Clusters for which short-term follow up has closed) multiplied by 100.

Box 4b

 # Clusters for which short-term follow up has closed

- Please indicate the number of control/comparison clusters for which the short-term follow up survey window has closed as of the date of this form.

 # Clusters retained at short-term follow up

- Please indicate the number of control/comparison clusters in which at least one youth has completed the short-term follow up survey (in all short-term follow up windows that have closed as of the date of this form).

Retention rate (automatically calculated)

- This percentage is (# Clusters retained at short-term follow up) divided by (# Clusters for which short-term follow up has closed) multiplied by 100.

Box 5a

 # Clusters for which long-term follow up has closed

- Please indicate the number of treatment clusters for which the long-term follow up survey window has closed as of the date of this form.

 # Clusters retained at long-term follow up

- Please indicate the number of treatment clusters in which at least one youth has completed the long-term follow up survey (in all long-term follow up windows that have closed as of the date of this form).

Retention rate (automatically calculated)

- This percentage is (# Clusters retained at long-term follow up) divided by (# Clusters for which long-term follow up has closed) multiplied by 100.

Box 5b

 # Clusters for which long-term follow up has closed

- Please indicate the number of control/comparison clusters for which the long-term follow up survey window has closed as of the date of this form.

 # Clusters retained at long-term follow up

- Please indicate the number of control/comparison clusters in which at least one youth has completed the long-term follow up survey (in all long-term follow up windows that have closed as of the date of this form).

Retention rate (automatically calculated)

- This percentage is (# Clusters retained at long-term follow up) divided by (# Clusters for which long-term follow up has closed) multiplied by 100.

Progress Towards Cluster Recruitment Goal - Box 6

Target # clusters from evaluation plan

- Please indicate the target number of clusters needed for the evaluation (from your approved evaluation plan).

 # Clusters enrolled in study to date (from above)

- This is the same number you entered in Box 2.

 # Clusters recruited but not yet enrolled

- Please indicate the number of clusters you have recruited but have not yet been enrolled (i.e., assigned to treatment or control).

 # Clusters needed to recruit (automatically calculated)

- This number is (Target # clusters from evaluation plan) minus (# Clusters enrolled in study to date and # Clusters recruited but not yet enrolled), or zero if the target has been surpassed.

Instructions for the Sample Progress Reporting Tool for Cluster Assignment – **Enrolled Youth**

To complete the Enrolled Youth tab, enter information into the YELLOW cells. For instructions on what to enter, click on a yellow cell and instructions will pop up. GREEN cells will automatically populate based on the information you enter in the yellow cells. (Note: for multi-arm studies, this form should be completed separately for each treatment/control pairing.) For additional support, please contact your LES liaison or PREPLES@abtglobal.com.

Instructions for each data entry box

Box 1

Sample enrollment and data collection through this date

- This date is automatically populated to match the date entered in the "Enrolled Clusters" worksheet.

Box 2

 # Youth enrolled in study to date

- Please indicate the number of eligible youth for whom you have received consent/assent and who were in clusters assigned to the study treatment or control/comparison groups.

Box 3a

 # Youth enrolled in clusters assigned to treatment

- Please indicate the number of eligible youth in clusters assigned to the treatment group.

 # Youth with valid baseline data

- Please indicate the number of eligible youth in clusters assigned to the treatment group who have completed all or part of the baseline survey.

Box 3b

 # Youth enrolled in clusters assigned to control/comparison

- Please indicate the number of eligible youth in clusters assigned to the control/comparison group.

 # Youth with valid baseline data

- Please indicate the number of eligible youth in clusters assigned to the control/comparison group who have completed all or part of the baseline survey.

Box 4a

 # Youth enrolled in clusters for which short-term follow up has closed

- Please indicate the number of eligible youth in treatment clusters for which short-term follow up windows have closed as of the date of this form. While the study is in progress, some youth may not have had the opportunity to contribute data for the short-term follow up if their cluster has not yet reached the short-term follow up period. For example, youth in clusters that have not completed the program would not have had the opportunity to contribute any follow up data. Therefore, these youth should not be included in these counts. Also do not include in these counts youth in clusters that have dropped entirely from the study at the time of the short-term follow-up period.

 # Youth completed short-term follow up survey

- Please indicate the number of eligible youth in treatment clusters that provided short-term follow up data in all short-term follow up windows that have closed as of the date of this form.

Retention rate (automatically calculated)

- This percentage is (# Youth completed short-term follow up survey) / (# Youth enrolled in clusters for which short-term follow up has closed) multiplied by 100. (If your study obtained consent after random assignment, please consult your LES liaison about calculating attrition.)

Box 4b

 # Youth enrolled in clusters for which short-term follow up has closed

- Please indicate the number of eligible youth in control/comparison clusters for which short-term follow up windows have closed as of the date of this form. While the study is in progress, some youth may not have had the opportunity to contribute data for the short-term follow up if their cluster has not yet reached the short-term follow up period. For example, youth in clusters that have not completed the program would not have had the opportunity to contribute any follow up data. Therefore, these youth should not be included in these counts. Also do not include in these counts youth in clusters that have dropped entirely from the study at the time of the short-term follow-up period.

 # Youth completed short-term follow up survey

- Please indicate the number of eligible youth in control/comparison clusters that provided short-term follow up data in all short-term follow up windows that have closed as of the date of this form.

Retention rate (automatically calculated)

- This percentage is (# Youth completed short-term follow up survey) / (# Youth enrolled in clusters for which short-term follow up has closed) multiplied by 100. (If your study obtained consent after random assignment, please consult your LES liaison about calculating attrition.)

Box 5a

 # Youth enrolled in clusters for which long-term follow up has closed

- Please indicate the number of eligible youth in treatment clusters for which long-term follow up windows have closed as of the date of this form. While the study is in progress, some youth may not have had the opportunity to contribute data for the long-term follow up if their cluster has not yet reached the long-term follow up period. For example, youth in clusters that have not completed the program would not have had the opportunity to contribute any follow up data. Therefore, these youth should not be included in these counts. Also do not include in these counts youth in clusters that have dropped entirely from the study at the time of the long-term follow-up period.

 # Completed long-term follow up survey

- Please indicate the number of eligible youth in treatment clusters that provided long-term follow up data in all long-term follow up windows that have closed as of the date of this form.

Retention rate (automatically calculated)

- This percentage is (# Youth completed long-term follow up survey) divided by (# Youth enrolled in clusters for which long-term follow up has closed) multiplied by 100. (If your study obtained consent after random assignment, please consult your LES liaison about calculating attrition.)

Box 5b

 # Youth enrolled in clusters for which long-term follow up has closed

- Please indicate the number of eligible youth in control/comparison clusters for which long-term follow up windows have closed as of the date of this form. While the study is in progress, some youth may not have had the opportunity to contribute data for the long-term follow up if their cluster has not yet reached the long-term follow up period. For example, youth in clusters that have not completed the program would not have had the

opportunity to contribute any follow up data. Therefore, these youth should not be included in these counts. Also do not include in these counts youth in clusters that have dropped entirely from the study at the time of the long-term follow-up period.

 # Completed long-term follow up survey

- Please indicate the number of eligible youth in control/comparison clusters that provided long-term follow up data in all long-term follow up windows that have closed as of the date of this form.

Retention rate (automatically calculated)

- This percentage is (# Youth completed long-term follow up survey) divided by (# Youth enrolled in clusters for which long-term follow up has closed) multiplied by 100. (If your study obtained consent after random assignment, please consult your LES liaison about calculating attrition.)

Progress Towards Youth Recruitment Goal - Box 6

Target # youth from evaluation plan

- Please indicate the target number of youth needed for the evaluation (from your approved evaluation plan).

 # Youth enrolled in study to date (from above)

- This is the same number you entered in Box 2.

 # Youth in clusters recruited but not yet enrolled

- Please indicate the number of youth in clusters you have recruited but have not yet been enrolled (i.e., assigned to treatment or control).

 # Youth needed to recruit (automatically calculated)

- This number is (Target # youth from evaluation plan) minus (# Youth enrolled in study to date and # Youth in clusters recruited but not yet enrolled), or zero if the target has been surpassed.