

Instructions

The information collected will be used for internal purposes to 1) assess the sample build-up and compare it to the target sample sizes on which power calculations were based, and 2) assess the likelihood that the final analytic sample for key follow-up time periods might have rates of overall or differential attrition that exceed the HHS evidence standard threshold.

All CONSORT diagrams require a “time stamp” for the CONSORT diagram. The CONSORT should provide information about the number of clusters (or individuals) randomized and the number of clusters (or individuals) participating (i.e., that have not dropped out) as of this particular point in time. Because participants may be at different stages of the study at any point in time due to rolling enrollment or multiple cohorts of implementation, all participants may not have an opportunity to contribute data to all data collection points.

CONSORT diagrams that track clusters as the unit of assignment

For cluster random assignment designs (e.g., random assignment of clinics, community-based organizations, teachers, or schools) and quasi-experimental designs, the following pieces of information are also necessary as documentation of the pooled sample flow in cluster-level CONSORT diagrams:

1. A brief paragraph (3-4 sentences) describing what makes a cluster eligible for the evaluation; the number of clusters screened and the screening criteria used; the number of clusters determined to be eligible and the counts and reasons for those screened out; and the whether and how any clusters were prioritized for inclusion in the study sample.
2. The number of clusters (randomly) assigned in total, to each condition (i.e., treatment and comparison), and the start and end dates of cluster random assignment.
3. The number of clusters still participating (i.e. retained), by study condition, at each data collection time point. A cluster is defined as “participating” if at least one individual in the cluster completed the data collection effort.
 - a. Grantees should also note any reasons for clusters dropping out, and the number of clusters the reason applies to.
4. In addition to tracking cluster flow, it is necessary to complete a CONSORT diagram for the youth in participating clusters.

CONSORT diagrams that track individuals

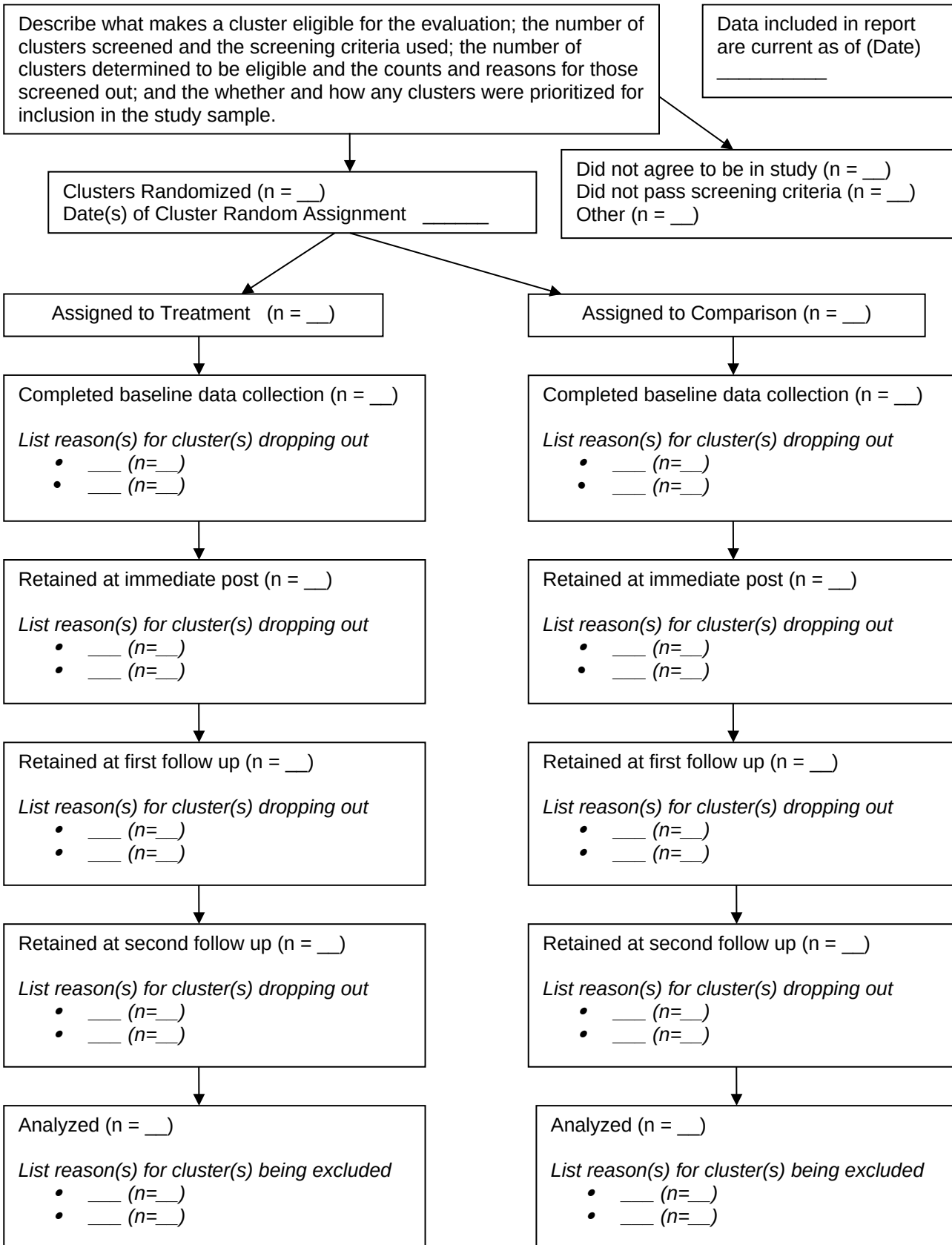
For both individual-level and cluster-level designs, the following pieces of information are also necessary as documentation of sample flow in individual-level CONSORT diagrams:

1. A brief paragraph (3-4 sentences) describing what makes a youth eligible for the evaluation; the number of youth screened and determined to be eligible and the counts and reasons for those screened out; and the process for selecting the pool to be evaluated among those eligible.
2. The number of youth (randomly) assigned in total, the number assigned to each condition, and the start and end dates of assignment.
3. The number of youth that have provided data, by study condition, at each data collection time point (baseline and subsequent follow-ups).
 - a. If the evaluation uses a cluster design, then the number of youth in each condition at any time point should reflect the number of youth only in participating clusters at that time point. Youth in clusters that have dropped entirely from the study should be excluded from these counts.
 - b. At a given time point, a subset of individuals may not have had the opportunity to contribute data for a particular data collection event. For example, individuals that have not completed the program would not have had the opportunity to contribute follow-up data. Therefore, it will be important to document the number of youth that are eligible (i.e. the number of youth that could have contributed data) at a given time point, in addition to providing the number of youth that actually did provide data.
 - c. Grantees should also note any reasons for individual non-response dropping out, and the number of youth the reason applies to.
4. The program start and end dates for the study period.

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this collection is 0970-XXXX; this number is valid through XX/XX/XXXX. Public reporting burden for this collection of information is estimated to average 60 minutes, including the time for reviewing instructions, gathering and maintaining the data needed, and reviewing the collection of information. This collection of information is voluntary for individuals, but the information is required from Grantees.

CONSORT Diagram for Clusters

*Complete based on pooled sample to date. Also complete diagram for youth, using only retained clusters as starting point.



CONSORT Diagram for Youth

*Complete based on pooled sample to date.

