CEO Guidelines for Randomized Control Trial (RCT) Designs (Applicable to Impact Estimates for Experimental Studies)

Study Title:

Report type:

Contractor:

I. Study Characteristics	**Addressed on page #**
Intervention	
Does the report describe the intervention (program, practice, or policy) in sufficient detail for readers to know what is being tested?	
Does the report describe the actual implementation of the intervention studied, such as:	
• adaptations of content?	
• level and variation in duration and intensity?	
• technical assistance to program implementers/managers?	
Does the report describe similarities or differences between the intervention studied and other interventions commonly used for similar purposes, including qualities such as duration and intensity, content and delivery, and required and available technical assistance to program implementers/managers?	
Does the report describe the fidelity of implementation of the intervention?	
Does the report present information on the cost of the intervention (if applicable)?	
Comparison Group Conditions	
Does the report describe the comparison condition (counterfactual)? If it includes an intervention, does it describe the comparison intervention and provide details on the actual implementation experience?	
Study Setting	
Does the report include a description of the time period and location of the study, including characteristics of the setting such as region, urbanity, or the size of the project?	
Participants	
Does the report describe the characteristics of the study participants, such as their age, race-ethnicity, gender, and socioeconomic status?	
If the study participants include members of special populations (such as persons with disabilities or dislocated workers), does it describe the process and criteria used to identify those participants, along with their proportion in the study sample?	
II. Study Design & Analysis	
Sample Formation/Recruitment	
Is there a clear description of the sample recruitment procedures (including eligibility criteria) and numbers recruited?	
Is information about the number contacted, number recruited, and characteristics of each group provided for the unit of randomization (e.g. firms, sites, participants)?	
Random Assignment	
Does the report describe the random assignment process, including:	
• The unit of random assignment?	
• Any stratification and blocking procedures used (if applicable)?	
• Who generated the random allocation sequence, and the extent to which that person had a vested interest in the study outcome?	
• Who implemented the process to enroll participants/sites in the treatment or control condition?	

- Any anomalies or exceptions?

Does the report provide evidence for the integrity of random assignment, including:

- Evidence of any breakdowns in random assignment?
- Documentation of any violations of randomization, e.g. the number of 'no shows' and 'crossovers'?

II. Study Design & Analysis (continued) — **Addressed on page #**

Sample Attrition/Nonresponse

For each key outcome measure, does it include a diagram (e.g. Consort diagram) or table that shows a clear pathway to the final analytic study sample for that outcome, including:

- Numbers of sites or individuals randomly assigned to intervention and control groups?
- Numbers for whom outcome data was collected?
- Numbers of individuals or sites that attrited from sample, and reasons for attrition (moved away, absent, refused, site closed)?

Does discussion of attrition and response rates include the extent to which the rates of and reasons for attrition and nonresponse differ for the treatment and control groups?

If there is differential attrition after random assignment, does the report mention that as a potential threat to internal validity?

Tests for Pre-Intervention Treatment and Control Group Equivalence

Does the report provide documentation of sample equivalence (1) at baseline for all randomized sample units (i.e. the initial sample), and (2) for the treatment-control analysis (final) sample?

Does the documentation include sample sizes, means, and standard deviations for key background characteristics and for baseline (pre-intervention) measures of the key outcomes (or closely associated variables)?

Analytic Approach

Does the report adequately describe the approach to estimating intent-to-treat (ITT) impact estimates including models used to estimate effects (e.g. regression, ANCOVA or HLM model) and their appropriateness for the data structure? Do they appropriately account for stratification and clustering?

If the treatment and control groups were not equivalent at baseline, are the characteristics that differed between the treatment and control groups included as covariates in the multivariate analysis?

Does the report provide any rationale for examining subgroups studied, and if so, any approach to estimating effects for sample subgroups?

Does the report clearly describe any sensitivity analyses conducted?

If appropriate, does the report provide a clear rationale for, and approaches to, any non-experimental analyses conducted? Are appropriate caveats included about the appropriateness of interpreting as causal estimates?

If the report includes estimates of 'impacts on the treated', are these analyses properly motivated and described, and appropriate methodology used? Are caveats included about the appropriateness of interpreting TOT (or non-experimental) results as causal estimates? (Note that while some causal inferences may be made, the evidence for the TOT estimator is not strong, as it does not account for selection bias.)

Missing Data

Does the report use appropriate methods for addressing missing data issues, such as case deletion, nonresponse weights, or imputations?

Statistical Adjustments

If appropriate, did the report account for multiple comparisons by adjusting the critical statistical value to account for the analysis of multiple outcomes within the same domain or use of the same intervention or comparison groups in multiple analyses of the same outcomes? _____

Does the report provide any rationale for examining subgroups studied, and approach to estimating effects for sample subgroups? _____

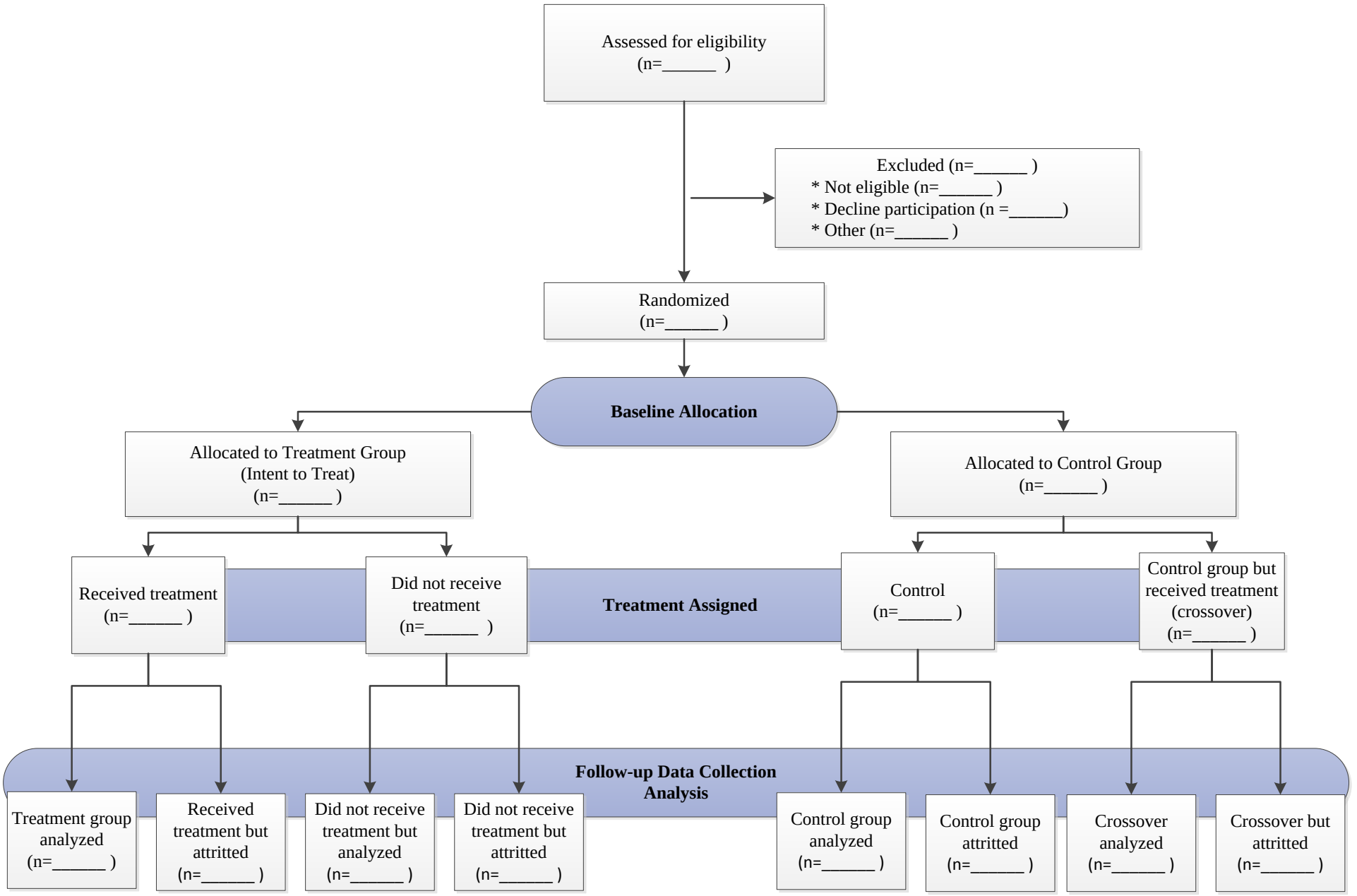
Analytic Approach

Are the results for all outcome measures reported (not just those with significant or positive effects)? _____

Is the reporting of results of outcome measures complete (reporting of sample sizes, means, SDs, confidence intervals, significance test results)? _____

Are the strengths and limitations of the analyses presented clearly? In particular, does the report address any implications arising from methodological shortcomings such as breakdowns in randomization, sample attrition, and challenges to intervention fidelity? _____

Flow Diagram for Randomized Control Trial Study



Key References Cited

Bloom, H. (2006), "The Core Analytics of Randomized Experiments", MDRC Working Paper on Research Methodology

Schulz, K.F., Altman D.G., Moher D. (2010), "CONSORT 2010 Statement: updated guidelines for reporting parallel group randomized trials", *BMJ*, 340:c332.