### Module C: Reporting Standards for Studies Involving Clinical Trials

#### Title and Title Page
- State whether trial was registered prior to implementation.

#### Abstract
- State whether the trial was registered. If the trial was registered, state where and include the registration number.
- Describe public health implications of trial results.

#### Introduction
- State the rationale for evaluating specific intervention(s) for a given clinical problem, disorder, or variable.
- Describe the approach, if any, to assess mediators and moderators of treatment effects.
- Describe potential public health implications of study.
- State how results from current study can advance knowledge in this area.

#### Method

##### Participant Characteristics
- State the method(s) of ascertaining how participants met all inclusion and exclusion criteria, especially if assessing clinical diagnosis(es).

##### Sampling Procedures
- Provide details regarding similarities and differences of data collection locations if multisite study.

##### Measures
- State whether clinical assessors were
  - Involved in providing treatment for studies involving clinical assessments
  - Aware or unaware of assignment to condition at post-treatment and follow-up assessment(s); (if unaware, how was this accomplished?)

##### Experimental Interventions
- Report whether the study protocol was publicly available (e.g., published) prior to enrolling participants; if so, where and when.
- Describe how intervention in this study differed from the "standard" approach in order to tailor it to a new population (e.g., differing age, ethnicity, comorbidity).

#### Research Design
- Provide rationale for length of follow-up assessment.

#### Results
- Describe how treatment fidelity (i.e., therapist adherence and competence ratings) and participant adherence was related to intervention outcome.
- Describe method of assessing clinical significance, including if the threshold for clinical significance was prespecified (e.g., as part of a publicly available protocol).
- Identify possible differences in treatment effects due to intervention deliverer.
- Describe possible differences in treatment effects due to data collection site if multisite study.
- Describe results of analyses of moderation–mediation effects, if tested.
- Explain why study was discontinued, if appropriate.
- Describe frequency and type of adverse effects that occurred (or state that none occurred).

#### Discussion
- Describe how this study advances knowledge about the intervention, clinical problem, and/or population.