**PRS Efficacy Criteria for Best-Evidence Risk Reduction (RR) Individual-level, Group-level, and Couple-level Interventions (ILIs/GLIs/CPLs)**

**Intervention Description**
- Clear description of key aspects of the intervention

**Quality of Study Design**
- Prospective study design
- Appropriate and concurrent comparison arm
- Random or minimally biased assignment of subjects to study arms

**Quality of Study Implementation and Analysis**
- Follow-up assessment ≥ 3-months post completion of intervention for each study arm with recall not referring to pre-intervention period
- At least a 70% retention rate at a single follow-up assessment for each study arm
- Comparison between intervention arm and an appropriate comparison arm
- Analysis of participants subjects in study arms as originally allocated regardless of contamination or logistic/implementation issues
- Analysis of participants regardless of the level of intervention exposure
- Use of appropriate cluster-level analyses if assigned to study arms by cluster or group
- Analysis must be based on post-intervention levels or on pre-post changes in measures
  - For pre-post changes used in analysis, measures must be identical, including identical recall period
- Analysis based on an $\alpha = .05$ (or more stringent) and a 2-sided test
- With nonrandomized assignment, either no statistical differences in baseline levels of the outcome exist or baseline differences are controlled for in the analysis
- Analytic sample ≥ 50 participants per study arm

**Strength of Evidence**

**Demonstrated Significant Positive Intervention Effects**
- Positive and statistically significant ($p < .05$) intervention effect for ≥1 relevant outcome measure
- A positive intervention effect is defined as a greater reduction in HIV/STD incidence or risk behaviors or a greater increase in HIV protective behaviors in the intervention arm relative to the comparison arm
- A relevant outcome is defined as a behavior (e.g., abstinence, mutual monogamy, number of sex partners, consistent condom use with anal/vaginal sex, unprotected anal/vaginal sex, proportion of anal/vaginal sex acts protected, injection drug use, sharing or borrowing needles/works) - that directly impacts HIV risk or a biologic measure indicating HIV or STD infection (i.e., HIV or STD incidence)
• Effect at the follow-up and based on the analyses that meet study implementation and analysis criteria

**No Demonstrated Significant Negative Intervention Effects**

• No negative and statistically significant (p < .05) intervention effect for any relevant outcome
  o A negative intervention effect is defined as a greater increase in HIV/STD incidence or risk behaviors or a greater decrease in HIV protective behaviors in the intervention arm relative to the comparison arm.
• No other statistically significant harmful intervention effect
• For an intervention with a replication evaluation, no significant negative intervention effects in the replication study

**Additional Limitations to Evaluate**

• No evidence that additional limitations resulted in a fatal flaw:
  o A fatal flaw has occurred when the overall evaluation of limitations indicates they resulted in considerable bias, thus substantially reducing the confidence of the findings.
  o Examples of item limitations to check for possible fatal flaw:
    ▪ Effects only found within potentially biased subset analyses;
    ▪ Substantial missing data. Missing data plus loss to attrition exceeds acceptable limits for retention alone (≥ 40%)
    ▪ Study arm non-equivalence: statistically significant differences between arms in important baseline demographics or risk factors
    ▪ Differential retention: (1) significant difference between study arms in characteristics among retained or attrited participants; OR (2) more than minimal rate of differential retention (>10%)
    ▪ Intervention activities did not match with the intervention concepts or guiding theories intended to produce the desired outcomes
    ▪ Did not clearly describe issues related to generalizability
    ▪ Too many post hoc analyses (even with Bonferroni corrections)
    ▪ Inconsistent findings

All criteria must be satisfied for an intervention to be considered as a best-evidence individual-level, group-level, or couple-level intervention.