

## Protocol Template for Methods Section

This template is provided as a guide for developing the protocol to submit to the C2 – Education Coordinating Group (ECG). The bulleted items are keywords for the topics that typically are included in each section; each bullet does NOT need to be a complete section or paragraph the topics just need to be addressed under each heading.

### I. Background

### II. Objective(s)

### III. Method

#### A. Study Inclusion Criteria

- Design
- Participants
- Interventions
- Outcomes
- Measures

#### B. Information Retrieval

- Electronic Search Strategy
- Grey Literature
- Hand Search activities (e.g., ancestry search)

#### C. Coding Procedures & Categories

- Citation & Abstract Level
  - How many coders participate
    - Reliability Level
  - How to handle disagreement
- Full-Text Level
  - How many coders participate
    - Reliability Level
  - How to handle disagreement

#### D. Assessment of Methodological Quality

- design type
- unit of assignment
- unit of analysis
- attrition
- fidelity of intervention

## **E. Calculating Effect Size**

- **calculation of effect size using**
  - 1. Standardized Mean Difference Statistic (d-index)**
    - means & standard deviations (Cohen's d)
    - F test, t test, p value, proportions
    - Inverse mean variance for weighting
    - correction for small sample size (Hedges g)
  - 2. Confidence Interval**
  - 3. Odds Ratio Family** (including risk difference and risk ratio if you think this might be in data for your review)

## **F. Synthesis of Effect Sizes**

- 1. Within Study Synthesis**
  - overall study effect size
  - individual study effect size
  - aggregate across studies using single study effect size
  - multiple effect sizes from a single study
  - aggregating same outcome effect size across studies
- 2. Across Study Synthesis**
  - Aggregation of conceptually similar outcomes
  - No aggregation of two different outcome effect sizes from same study
- 3. Heterogeneity Analysis**
  - Choice, use, and rationale of fixed effects or random effects model
- 4. Sensitivity Analysis**
  - assessment of the impact of a single study on the magnitude of an overall effect size
  - impact moderating variables (e.g., attrition, type of treatment, missing data, sample size, study design)
- 5. Publication Bias**
  - Impact of published vs unpublished included studies
- 6. Incomplete Reporting of Study Data**
  - Method of imputation
    1. Average of post-treatment mean of included studies
    2. Set to zero of included studies
    3. Average of pre-treatment mean of included studies

## **7. Post Hoc Subgroup and Moderator Analyses**

- Analyze impact of specific subsets or study moderators such as
  1. Types of Treatment
  2. Severity Level
  3. Efficacy vs. Effectiveness studies
  4. Intention to Treat vs. Active Treatment only
  5. Age of Participant
  6. Length of Treatment