The following is an outline of sections of the Manual of Operating Procedures (MOP) which should be considered for a multi-site study. However, given that each study is unique, sections could be omitted and/or added at the investigator’s discretion depending on the nature and complexity of the study. For guidance on the content that should be discussed in each of these sections, please refer to the [Multi-Site MOP Guidelines](http://www.nia.nih.gov/sites/default/files/manualofproceduresmopfinal2_0.doc).

1. Introduction
2. Overview
3. MOP Contents and Organization
4. Study Protocol
5. STUDY ORGANIZATION AND RESPONSIBILITIES
   1. Roster
   2. Coordinating Center
   3. Study Sites
   4. Steering Committees
   5. Other Study Committees
   6. NIA’s Role and Responsibility
6. Training Plan
7. Communications Plan
8. Study Flow
9. RECRUITMENT AND RETENTION
   1. Screening and Eligibility Criteria
   2. Screening Log
   3. Eligibility Criteria
10. INFORMED CONSENT
    1. HIPAA Authorization
11. Study Intervention
12. Randomization
13. Blinding and Unblinding (Masking and Unmasking)
14. STUDY MEASUREMENTS AND PROCEDURES
    1. Timeline and visit schedule
    2. Scope/Schema
    3. Final Study/Early Discontinuation Evaluations
15. CONCOMITANT MEDICATIONS
16. Safety Reporting
17. Study Compliance
18. DATA COLLECTION AND STUDY FORMS
    1. Participant Binder
    2. Study Forms
    3. General Instructions for Completing Forms
    4. Data Flow
    5. Administrative Forms
    6. Retention of Study Documentation
19. DATA MANAGEMENT
    1. External Data
    2. Quality Control Procedures
       1. *Standard Operating Procedures*
       2. *Data and Form Checks*
       3. *Site Monitoring*
20. DATA AND SAFETY MONITORING ACTIVITIES
    1. Reports
    2. Study Completion and Close-Out Procedures
       1. *Participant Notification*
       2. *Site Procedures*
       3. *Confidentiality Procedures*
       4. *Publications*
21. MOP Maintenance

***Note: If the study involves drug intervention, either the Package Insert for an approved drug or the Investigator’s Brochure for an investigational product must be included as an appendix.*** The following documents should also be included in the MOP appendices: Study Forms, Informed Consent and HIPAA, Standard Operating Procedures, Recruitment Flyers, Letters to Participants, etc.