The following is an outline of sections of the Manual of Operating Procedures (MOP) which should be considered for a single-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 Single-Site MOP Guidelines.

1. **Introduction**
2. **Brief Overview of the Study Protocol**
3. **Study Staff Responsibilities**
4. **Study Flow Diagram**

# Recruitment and Retention Plan

* 1. Screening and Eligibility Criteria
  2. Screening Log
  3. Eligibility Criteria

# Informed Consent

* 1. HIPAA Authorization

1. **Study Intervention**
2. **Randomization**
3. **Blinding and Unblinding (Masking and Unmasking)**
4. **Safety Reporting**
5. **Study Compliance**

# 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 Documents

# Data Management

* 1. External Data

## Quality Control Procedures

* + 1. Standard Operating Procedures
    2. Data and Form Checks (*as appropriate*)

1. **Concomitant Medications –** *Drug Intervention studies only*

# Data and Safety Monitoring Activities

# Study Completion and Close-Out

* + 1. Participant Notification
    2. Confidentiality Procedures
    3. Publications

1. **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 HIPPA, Standard Operating Procedures, Recruitment Flyers, Letters to Participants, etc.