**National Institute on Aging (NIA)**

# Outline for Manual of Operating Procedures (MOP) for Single Site Studies

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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. STUDY OVERVIEW
3. STUDY ORGANIZATION AND RESPONSIBILITIES
4. STUDY FLOW
5. INFORMED CONSENT
	1. HIPAA AUTHORIZATION
6. RECRUITMENT AND RETENTION
	1. PARTICIPANT RECRUITMENT
	2. PARTICIPANT RETENTION
7. SCREENING AND ELIGIBILITY CRITERIA
	1. SCREENING AND ELIGIBILITY CRITERIA
	2. SCREENING LOG
	3. ELIGIBILITY CRITERIA
8. STUDY INTERVENTION
9. RANDOMIZATION
	1. INVESTIGATIONAL PRODUCT ACTIVITIES
10. BLINDING AND UNBLINDING (MASKING AND UNMASKING)
11. Study Measurements and Procedures
	1. TIMELINE AND VISIT SCHEDUL*E*
	2. VISIT PROCEDURES
	3. FOLLOW-UP
	4. FINAL STUDY/EARLY DISCONTINUATION EVALUATIONS
12. CONCOMITANT MEDICATIONS
13. SAFETY REPORTING
	1. ADVERSE EVENT REPORTING
	2. UNANTICIPATED PROBLEMS
	3. SERIOUS ADVERSE EVENT REPORTING
14. STUDY COMPLIANCE
15. DATA COLLECTION AND STUDY FORMS
	1. SOURCE DOCUMENTATION
	2. STUDY FORMS
	3. GENERAL INSTRUCTIONS FOR COMPLETING FORMS
	4. DATA FLOW
	5. ADMINISTRATIVE FORMS
	6. RETENTION OF STUDY DOCUMENTATION
16. DATA MANAGEMENT
	1. EXTERNAL DATA
	2. QUALITY CONTROL PROCEDURES
		1. STANDARD OPERATING PROCEDURES
		2. DATA AND FORM CHECKS
		3. SITE MONITORING
17. DATA AND SAFETY MONITORING ACTIVITIES
	1. REPORTS
	2. STUDY COMPLETION AND CLOSE-OUT PROCEDURES
		1. PARTICIPANT NOTIFICATION
		2. CONFIDENTIALITY PROCEDURES
		3. PUBLICATIONS
18. 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 Protocol, Study Forms, Informed Consent and HIPPA, Standard Operating Procedures, Recruitment Flyers, Letters to Participants, etc.