Montefiore | EINSTEIN Albert Einstein College of Medicine

Site Initiation Checklist

Purpose: To orient and train staff on the protocol and study related processes; to confirm readiness for study implementation; and to identify additional requirements that must be satisfied prior to site activation and subject recruitment.

Instructions:

- Be sure to fill in all information and attach related documents for completeness, if needed.
- This is intended to serve as a guide- Be sure to use your study-specific *Site Initiation Checklist* if one is provided by the Sponsor.
- Indicate whether an item was discussed only, verified, or an outstanding action item to ensure all are addressed.
- Time estimates for completion for each section below are estimates, actual time may vary.
- All verified documents should be retained and stored in the Essential Documents binder
- Sign and date the checklist. File with other participating site documents in your study-specific Essential Documents binder.

Study Information	
Principal Investigator:	
IRB of Oversight & IRB Number:	
Sponsor-designated Site Number *(if applicable):*	
Date of Visit:	
Conducted by:	

Initiation Visit Method
☐ On-site ☐ Remote ☐Teleconference ☐ Other (please specify): _____

Lead Site (or Sponsor) Personnel in Attendance	
Name	**Title**

Participating Site Personnel in Attendance
Enter below, or see attached for an expanded attendance sheet

Name	**Title or Study Role**	**Initials**

STAFFING ALLOCATIONS **Duration: .5/.75 hrs.**

Items Discussed/Verified		Actions / Comments
Study Staff	☐ Yes ☐ No ☐ N/A	
Clinical Staff	☐ Yes ☐ No ☐ N/A	
Research Laboratory Staff	☐ Yes ☐ No ☐ N/A	
Pharmacy Staff	☐ Yes ☐ No ☐ N/A	
Other Ancillary Staff, if applicable Please specify type: _____	☐ Yes ☐ No ☐ N/A	
Other Ancillary Staff, if applicable Please specify type: _____	☐ Yes ☐ No ☐ N/A	

EQUIPMENT REQUIREMENTS **Duration: .5 hrs.**

Enter below and check availability; Obtain approval from Bioengineering, if applicable

Items Discussed/Verified		Actions/Comments
	☐ Yes ☐ No ☐ N/A	
	☐ Yes ☐ No ☐ N/A	
	☐ Yes ☐ No ☐ N/A	
	☐ Yes ☐ No ☐ N/A	

PROTOCOL OVERVIEW **Duration: 1.0-2.25 hrs.**

Items Discussed/Verified		Actions/Comments
Background and Purpose of Study		
Study Objectives & Design	☐ Yes ☐ No ☐ N/A	
Study Procedures		
Manual of Procedures	☐ Yes ☐ No ☐ N/A	
Drug administration procedures & review of Investigator Brochure (IB) or Package Insert	☐ Yes ☐ No ☐ N/A	
Drug storage, dosing, dispensation, & documentation (accountability)	☐ Yes ☐ No ☐ N/A	
Study visits/ Schedule of events	☐ Yes ☐ No ☐ N/A	
Type and frequency of specimen collection	☐ Yes ☐ No ☐ N/A	
Specimen storage & logs	☐ Yes ☐ No ☐ N/A	
Procedure for recording and reporting Protocol Deviations	☐ Yes ☐ No ☐ N/A	

INFORMED CONSENT AND ENROLLMENT **Duration: .5-1.0 hrs.**

Items Discussed/Verified		Actions/Comments
Informed consent procedures	☐ Yes ☐ No ☐ N/A	
Eligibility criteria	☐ Yes ☐ No ☐ N/A	
Recruitment plans & enrollment goals	☐ Yes ☐ No ☐ N/A	
Central registration & randomization	☐ Yes ☐ No ☐ N/A	

SAFETY: DEFINITIONS, COLLECTION, AND REPORTING **Duration: .5-4 hrs.**

Items Discussed/Verified		Actions/Comments
AE/SAE reporting procedures	☐ Yes ☐ No ☐ N/A	
Unanticipated problems	☐ Yes ☐ No ☐ N/A	
Notification process	☐ Yes ☐ No ☐ N/A	
Treatment Discontinuation		
Required evaluations	☐ Yes ☐ No ☐ N/A	
Early stopping rules	☐ Yes ☐ No ☐ N/A	
Unblinding procedures	☐ Yes ☐ No ☐ N/A	

DATA COLLECTION & SOURCE DOCUMENTATION **Duration: 1.5-5 hrs.**

Items Discussed/Verified		Actions/Comments
Data Collection & Submission		
Format and timelines	☐ Yes ☐ No ☐ N/A	
Case report form completion guidelines	☐ Yes ☐ No ☐ N/A	
Queries and corrections	☐ Yes ☐ No ☐ N/A	
eDC training	☐ Yes ☐ No ☐ N/A	
Source Documentation		
Acceptable documentation	☐ Yes ☐ No ☐ N/A	
Case Report Forms as Source	☐ Yes ☐ No ☐ N/A	
Document retention	☐ Yes ☐ No ☐ N/A	

COMMUNICATIONS & MONITORING **Duration: 1-3 hrs.**

Items Discussed/Verified		Actions/Comments
Communications		
Format and frequency	☐ Yes ☐ No ☐ N/A	
Sponsor and Site contact(s)	☐ Yes ☐ No ☐ N/A	
Monitoring		
Site monitoring visits (method, frequency and expectations)	☐ Yes ☐ No ☐ N/A	
DSMC/DSMB requirements	☐ Yes ☐ No ☐ N/A	

REGULATORY & RECORD KEEPING **Duration .5-7 hrs.**

Items Discussed/Verified		Actions/Comments
Regulatory and Record Keeping		
Research Agreement/Contract	☐ Yes ☐ No ☐ N/A	
IRB Assurance Number	☐ Yes ☐ No ☐ N/A	
IRB Roster	☐ Yes ☐ No ☐ N/A	
Site Specific FDA Form 1572	☐ Yes ☐ No ☐ N/A	
Curriculum Vitae (CVs)	☐ Yes ☐ No ☐ N/A	
Good Clinical Practice Training	☐ Yes ☐ No ☐ N/A	
IRB-approvals (initial and all amendments)	☐ Yes ☐ No ☐ N/A	
IRB-approved Informed Consent	☐ Yes ☐ No ☐ N/A	
IRB-approved Advertisements	☐ Yes ☐ No ☐ N/A	
AE/SAE Reports	☐ Yes ☐ No ☐ N/A	
IND Safety Reports	☐ Yes ☐ No ☐ N/A	
Case Report Forms	☐ Yes ☐ No ☐ N/A	
Continuing Review Reports	☐ Yes ☐ No ☐ N/A	
Final/Closure Reports	☐ Yes ☐ No ☐ N/A	
Site Delegation of Authority Log	☐ Yes ☐ No ☐ N/A	
Signed Informed Consent Forms	☐ Yes ☐ No ☐ N/A	
Study-related Correspondence	☐ Yes ☐ No ☐ N/A	

ADDITIONAL REQUIREMENTS OR COMMENTS

See attached action item template

Items Discussed/Verified		Actions/Comments
Tour of facility	☐ Yes ☐ No ☐ N/A	
	☐ Yes ☐ No ☐ N/A	
	☐ Yes ☐ No ☐ N/A	
	☐ Yes ☐ No ☐ N/A	
	☐ Yes ☐ No ☐ N/A	
	☐ Yes ☐ No ☐ N/A	

Signature of Person Completing Form: _____

Printed Name: _____ **Date:** _____

Participating Site Personnel Attendance List

Name	Title or Study Role	Initials

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Action Items

Item Discussed	Required Action	Delegated Staff Member to Address	Outcome