Icahn School of Medicine at Mount Sinai

Conduits
The Institutes for Translational Sciences

SITE INITIATION Checklist

The purpose of this document is to provide the Lead Site with a system for performing study initiation visits.

Instructions:

The following items should be addressed when initiating a participating site into a multi-center trial.

- Fill in the participating site information, and the names of the attendees. Attach a roster if necessary.
- Some items may need to be discussed in detail, while others only need verification.
- Mark the appropriated box, "YES", "NO" or "N/A", after each item.
- Add any necessary comments or action items.
- Many items can be verified before the actual site initiation. These items are marked with asterisks (**).
- Sign and date the checklist. File with other participating site documents.

Site Information

Name of Participating Site:	Initiation Visit Method:
DF/HCC Protocol Number:	❑ On-Site
Date:	❑ Teleconference
Conducted by:	❑ Other (specify)_____

Lead Site Personnel in attendance

NAME	TITLE

Participating Site Personnel in attendance - See attached attendance sheet

Items Discussed/Verified	Yes	No	N/A	Actions / Comments
Staffing Allocations				
**Clinical staff				
**Study staff				
**Pharmacy staff				
**Research Laboratory staff				
List equipment needed for the study. Check the availability of each item.				
**				

Items Discussed / Verified	Yes	No	N/A	Actions / Comments
Background and Purpose of Study				
Study objectives and design				
Study Procedures				
Drug administration procedures				
Clinical evaluations for each visit				
Specimens to be obtained and frequency				
Special specimens-timing (PK, or other)				
Specimen logs (PK, or other)				
Procedure for recording and reporting Protocol Deviations				
Informed Consent and Enrollment				
Informed Consent Procedures				
Eligibility criteria				**(Eligibility waivers not permitted.)**
Central registration and randomization				
Adverse Event Reporting				
AE/SAE Reporting Procedures				**(All IRB reporting requirements must be met.)**
Notification process				
Toxicity parameters				
Treatment Discontinuation				
Required Evaluations				
Early stopping rules, DLT levels				
Data Collection and Submission				
Format and timelines				
Case report form completion guidelines				
Queries and corrections				
eDC training				
Source Documentation				
Acceptable documentation				
Case Report Forms as Source				
Document Retention				
Communications				
Format and frequency				
Site contact(s)				
Monitoring				
Site monitoring visits				
DSMC/DSMB requirements				

Items Discussed / Verified	Yes	No	N/A	Actions / Comments
Regulatory and Record Keeping				
**Inter-institutional Agreement/Contract				
**IRB Assurance Number				
**Site Specific FDA Form 1572				
**CVs				
**IRB-Approvals (initial and all amendments)				
**IRB-Approved Informed Consent				
**IRB-Approved Advertisements				
**AE/SAE Reports				
**IND Safety Reports				
**Case Report Forms				
Continuing Review Reports				
Final/Closure Reports				
**Site Delegation of Authority Log				
Signed Informed Consents				
Study-related Correspondence				
Additional Comments				
_____ **Signature of Person Completing Form / Date**				