Protocol Implementation Checklist

PI/LIP_____ IRB#_____

Study Title_____

Completed By_____ Date_____

Signature_____

YES	NO	NA	Prior to IRB and ACCTS Approvals	DATE COMPLETED	NOTES
			Training		
			Consenting Tutorial – Part 1 (class)		
			REDCap/other database set-up		
			IATA Training		
			Study specific education/training in preparation for start-up (new procedures and competencies) i.e. skin biopsy, bone marrow aspirations, etc. _____		
			Investigator Responsibilities Training (include IND/IDE associated responsibilities)		
			Team Science Preparation		
			Training for electronic data capture and eCRFs		
			iRIS Training (submissions, study and subject management)		
			Review the guide "Explaining Next Generation Sequencing (NGS) Studies to Research Volunteers in Plain Language"		
			Hospital Orientation (if participants will be seen at RUH)		
			Financial		
			Identify and negotiate CRO with legal counsel		
			All contracts finalized and signed by all parties		

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			Material Transfer Agreement (MTA) finalized		
			Identify existing Lab Account for participant compensation, assays, etc.		
			Check request process established		
			Creation of Participant reimbursement receipt form		
			Complete University on-line RAS COI		
			Recruitment		
			Develop prescreening script with recruitment staff		
			Introduction to Clinical Conductor		
			Finalize recruitment details (based on anticipated study approval date, forecast date and venue of first advertisement)		
			Development of Research Documentation		
			Enrollment Note		
			Inclusion/Exclusion Checklist		
			Study Visit Notes		
			Creation and KSP sign-off on Signature Log		
			Creation of screening/enrollment log		
			Creation of sample storage sharing log		
			Creation of future contact log		
			Creation of compensation log		
			Creation of Regulatory Binder		
			Review research documents with monitor as prep/expectations for monitoring visits		

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			Interdisciplinary Coordination		
			Review Pharmacy Packaging and Dispensing Procedures		
			Review Bionutrition Procedures		
			Review Study visit planning with Nursing		
			Set up access to MSKCC labs		
			Begin the Certificate of Confidentiality application		
			Attain Occupational Health Clearance (OHS) if participants will be seen at RUH		
			Identify vendor to provide on-site language translations		
			Secure refrigerator/freezer space to store research samples		
			Equipment/Device		
			- inspected and approved by WCMC Bioengineering Department		
			- inspected and approved by Infection Control		
			- calibration log created		
			After IRB and ACCTS Approvals		
			Submit IND/IDE application to FDA		
			Assure IND has been assigned or a FDA response has not been received within 30 days of submission		
			When IND/IDE has been approved by FDA, amend the protocol to notify the IRB		
			Arrange delivery of Lab materials from CLIA approved Labs and study documents/equipment from CROs (for industry sponsored studies or studies contracted with a CRO)		
			Confirm shipment of study drug/study device from sponsor to Pharmacy/Research team		

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			Prepare checklist of required documents needed for study visits (assure documents are IRB stamped)		
			Establish grant financial account		
			Petty Cash bank Set-up		
			Complete the Certificate of Confidentiality application and receive the certificate		
			Complete the Consent Tutorial, Part 2 (observational experience)		
			Complete registration and provide study start date on clinicaltrials.gov		
			Learn how to conduct internal monitoring		
			Arrange for translation of consent/assent forms from Pacific Interpreters		
			Ensure that contracts are signed by all parties		
			Establish grant account (if IRB approval is required)		
			Finalize prescreening script with recruitment staff		
			Finalize recruitment details (forecast date and venue of first advertisement)		
			Use of secure email		
			REDCap/other database completion		
			Initiation Meeting		
			Study conduct commences		