New Study/New Site Checklist

REGULATORY	**[NIH-funded]** Have the sites been added to the facesheet of the protocol	☐
	Has the site obtained local ethical clearance?	☐
	Does the local ethical clearance contain amendment # in acknowledgement memo?	☐
	Has a DTA/MTA been executed with primary site?	☐
	Has protocol been registered on clinicaltrials.gov?	☐

DOCUMENTS	Has the site provided the consent forms for review?	☐
	Do the consent forms list collaborating sites as needed (i.e.-data will be shared with MSK for analysis, ensure site contact information is listed in ICF)	☐
	Has any of the IRB template text been removed? If so, please ask site to edit consent forms accordingly to ensure all required template language is in the consent form	☐
	Has the ECL been created or updated to include new sites	☐
	Has the site provided the CPL list?	☐
	Has the site provided all HSP/GCP training certificates?	☐
	Has the site provided all Biosafety Certifications?	☐
	Has the site provided all Nigerian National Code of Ethics Certifications?	☐
	Has the site provided their FWA number?	☐
	Has a study manual been created for this study?	☐

TRAINING/LOGISTICS	Is equipment needed? (i.e. Laptops for RAs, Freezers for specimen collection) If so, are all equipment needs taken care of?	☐
	Has the SIV occurred?	☐
	Is there documentation of the SIV and attendees that were trained?	☐

DATABASE MANAGEMENT	Does a new REDCap Database need to be created? If so, has a database request been submitted to the REDCap team with required documents?	☐
	Has the REDCap Database been published?	☐
	Have the sites RAs all been granted access to the REDCap	☐
	Have all the required documents been added to the File Repository	☐
	Have all the sites RAs been trained on specimen collection and labeling? (if applicable)	☐

	Have all the sites RAs had REDCap database study specific training?	☐
	Has a plan for regular study meetings been established.	☐