VCU
Office of the Vice President
for Research and Innovation

IND/IDE External to VCU (Domestic Facilities) Multisite Certification

Attach a list of all external sites, PI at that site, and IRB for that site. To be completed by IND/IDE Sponsor as an internal resource to ensure the VCU study team has considered all options prior to making the study multisite and to ensure they have the appropriate documents from each site. All documents listed on this list should be available to monitors and auditors at all times.

Initials	
	I have considered alternatives to having multisites and have determined that it is necessary to be the sponsor on this multisite study.
	I have read and agree to abide by the Sponsor and as applicable the Investigator responsibilities for holding an IND or IDE.
	If I am transferring any sponsor responsibilities there is a formal transfer of responsibilities agreement signed and on file.
	I have reviewed all investigators and certified they are qualified by education, training, experience and state licensure to conduct the clinical trial.
	I have on file a 1572 (IND) or Investigators Agreement (IDE) for each site.
	I have signed and dated (within the past 2 years) CV's on file for all investigators.
	I have GCP, HSP or any other applicable certifications for all members of the study team from all sites.
	I have instituted training programs for all study staff at all sites and required documentation of training and delegation of responsibilities.
	I have written plans for independent monitoring of this study at all sites.
	I have a communication plan for all study sites.
	I have on file all financial interests certifications and as needed disclosures for all investigators.
	All sites have the current protocol and investigators brochure or device information. These will be kept up to date at all sites.
	Plans for communication of all serious adverse events and unanticipated problems have been established and communicated to all study sites.
	I have a process for obtaining and documenting IRB approval at each site for the initial protocol and all amendments as well as submissions of safety and DSMB reports.
	I have a process in place to ensure accountability of the investigational drug or device at each site.

	I will maintain the certifications and current normal value ranges for external study site laboratories that will be involved the performance of clinical trial safety and effectiveness evaluations.
Initials	
	I have adequate budget and resources to complete the study locally and at external sites and to assure sponsor responsibilities are met. External Sites may have sub-awards or direct funding.