VIRGINIA COMMONWEALTH UNIVERSITY
VCU
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Certification of IND/IDE VCU Sponsor

The Chairperson of the academic department or director of the institute to which the Sponsor of the IND or IDE application administratively reports must review the application, complete the checklist below and sign/date the checklist prior to the Sponsor's submission of the protocol to FDA and the Clinical Research Compliance Officer. This form must be submitted to the Clinical Research Compliance Officer.

(If the Sponsor is the chairperson of an academic department or director of an institute, the Certification of IND/IDE Suitability shall be completed by the dean of the school to which the Sponsor administratively reports.)

VCU/VCUHS Faculty Sponsor Name:

IND/IDE Title:

Please affirm (with initials) that:

Initial to confirm	Criteria
	The clinical protocol(s) incorporated into the IND or IDE application has been reviewed and approved for scientific merit and quality.
	The designated study site Investigator(s) for the conduct of the clinical protocol(s) incorporated into the IND or IDE application are aware of and possess the appropriate qualifications and experience so as to be able to comply with the regulatory responsibilities of an IND or IDE investigator.
	The IND or IDE Sponsor has adequately assessed feasibility of the protocol submitted with this IND/IDE.
	The IND or IDE Sponsor has sufficient resources (e.g., facilities, equipment, staff) and an adequate budget to conduct the clinical protocol incorporated into the IND or IDE application and to comply with applicable FDA regulations and institutional requirements.
	The IND or IDE Sponsor is fully aware of the regulatory responsibilities of the Sponsor of an IND or IDE application;

_____ _____

Signature and Title **Date**