Matrix for IRB Review and Reliance

* If a project includes a line item for IRB fees, VCU expects the funding source to pay the IRB fees, whenever possible. For information on IRB fees, please refer to the June 16, 2021 <u>Full Cost Recovery Guidelines for Clinical Research Initiated and Sponsored by Industry Compliance Notice</u>.

** The RAMS-IRB Reliance application is an abbreviated version of the standard application.

Study type	IRB Fee Payer*	IRB OF Record	Process
Research where a VCU investigator holds the IND/IDE	None	VCU IRB	 Submit standard application via RAMS-IRB
Student-Led Human Subjects Research for credit or scholarship, with faculty member acting as PI	None	VCU IRB	 Submit standard application via RAMS-IRB
Investigator-initiated single-site Human Subjects Research supported by internal VCU departmental or miscellaneous funds (considered "unfunded")	None	VCU IRB	 Submit a standard application via RAMS-IRB
Exempt Studies, regardless of funding source	None	VCU IRB	 Submit a standard application via RAMS-IRB
"Not Human Subjects Research (NHSR)" studies, regardless of funding source	None	VCU IRB	 Submit a standard application via RAMS-IRB
Studies supported by the National Cancer Institute	None	NCI CIRB	 Submit an IRB Reliance Application** in RAMS-IRB; AND Submit an application to the external IRB.
Emergency Use, Expanded Access, Compassionate Use, HUD, and Single-Patient IND/IDE studies	None	VCU IRB	 Submit a standard application via RAMS-IRB
Emergency Use, Expanded Access, Compassionate Use, HUD, and Single-Patient IND/IDE studies <u>where the external sponsor</u> <u>requires use of a specific external IRB</u>	Sponsor	External IRB, as required by the Sponsor	 Submit an IRB Reliance Application** in RAMS-IRB; AND Submit an application to the external IRB.
Industry sponsored studies where the sponsor does <u>not</u> require the use of a specific IRB	Sponsor	External Commercial IRB (e.g., Advarra IRB or WCG)	 Submit an IRB Reliance Application** in RAMS-IRB; AND Submit an application to the external IRB.
Industry sponsored studies where the external sponsor <u>does</u> require use of a specific external IRB	Sponsor	Specified External IRB (commercial or academic)	 Submit an IRB Reliance Application** in RAMS-IRB; AND Submit an application to the external IRB.
Externally funded investigator-initiated Human Subjects Research	External funding source or TBD (depending on the contract)	Advarra IRB	 Submit an IRB Reliance Application in RAMS-IRB; AND Submit an application to Advarra IRB (CIRBI.net).
Other externally funded Human Subjects Research (e.g., foundations, consortiums)	External funding source or TBD (depending on the contract)	Advarra IRB Or, IRB required by the Sponsor	 Submit an IRB Reliance Application in RAMS-IRB; AND Submit an application to Advarra IRB (CIRBI.net).
Federally funded Human Subjects Research	VCU HRPP or TBD (depending on the contract)	Advarra IRB for VCU primed grants Or, IRB as required by prime site	 Submit an IRB Reliance Application in RAMS-IRB; AND Submit an application to Advarra IRB (CIRBI.net).