UVM Local Context Document

UVM Site Information	
Name of Primary Site	University of Vermont and State Agricultural College (UVM) Burlington, VT, 05405
Federalwide Assurances	Number FWA00000723
Institutional Official	Kirk Dombrowski, PhD Vice President for Research Institutional Official for UVM Kirk.Dombrowski@uvm.edu
Point of Contact	Donna Silver, CIP, Director University of Vermont Research Protections Office 802-656-8804 Donna.Silver@uvm.edu
State and Local Law	1. There are no research specific state or local laws that pertain to clinical research with human subjects. 2. The age of majority in Vermont is 18 years of age. (1 V.S.A. § 173) 3. State law (18 V.S.A. § 9361(d)) does not allow telemedicine consultations to be recorded, therefore, recordings are not allowed in research. 4. No state law specifically addresses legally authorized representatives in research. IRB has developed site policy based on federal regulations and associated hospital policy.
Reliance Agreements	Preference to use SMART IRB but will accept other agreements.
Consent	UVM has a consent template that includes the required local sections. HIPAA is included with the consent form. UVM IRB will allow HIPAA language to be separate from consent form. UVM PIs have access to this template.
Documenting Research Personnel Qualifications	1. The curriculum vitae for research personnel are included in the grant application. 2. FDA form 1572 for drug studies or an Investigator Agreement (21 CFR 812.43) for device studies. 3. There is a process to ensure that all members of the research team have completed the applicable institutional human subjects in research training.

	4. Additionally, the UVM Medical Center Medical Staff Credentialing process requires renewal of medical practice privileges every 2 years; UVM faculty credentials are reviewed through the medical school and allied health & nursing faculty hiring processes (faculty handbook); and there is a process for credentialing non-medical center employees conducting research at the hospital.	
Subject Complaints Process	1. Direct subject complaints received by the Research Protections Office by any means, go directly to the Director of the RPO or designee. 2. Additionally, there is an Ethics and Compliance Reporting Help Line that is noted throughout the Research Protections Office website and on the Research Participant section of our website. 3. For research that is conducted at the University of Vermont Medical Center, concerns may be reported through the Office of Patient and Family Advocacy or through the Integrity and Compliance Hotline. All of these mechanisms feedback research related concerns to the Research Protections Office.	
Financial Conflicts of Interest	1. The IRB Policy Regarding Investigator Financial Interest in projects involving human subjects requires disclosure of financial interests when protocols are submitted for committee review. As part of its review, the IRB considers and evaluates whether such interests have the potential to adversely affect the rights or welfare of human research participants. 2. UVM has a Financial Conflict of Interest in Sponsored Research Policy. This policy requires that all investigators disclose if they have a significant financial interest related to their University responsibilities when submitting a proposal. Positive disclosures are reviewed to determine if they constitute financial conflicts of interest related to University sponsored research that require certain actions to manage, reduce or eliminate potential conflicts. On-line training is required prior to disclosure and every four years thereafter. 3. All investigators complete a financial disclosure/conflict of interest statement for the NCI annually and each study group as requested. UVM collects a Written Disclosure Statement annually from our physicians per policies and standards of the State of Vermont and the Accreditation Council for Continuing Medical Education. 4. Both UVM and UVMMC have Code of Conduct and Financial Conflict of Interest Policies.	
Community Descriptors	VERMONT COUNTIES: Grand Isle County Franklin County Lamoille County Rutland County Orleans County	NEW YORK COUNTIES: St. Lawrence County Warren County Clinton County Washington County

	Washington County Chittenden County Addison County	Franklin County Essex County
Other Context Information	- Our communities have a positive attitude toward the conduct of research. - Much of the anticipated study participant population is coming from rural areas; therefore transportation can be difficult and expensive. - There are diverse immigrant and resettlement populations clustered in the larger urban areas. - There is a transient nature of our population due to the college students and a segment of the population that move to warmer climates during the harsh winters. This can be a challenge for study follow-up. - There is a relatively high literacy rate. - Agriculture comprises a large portion of occupations, which can be strenuous and dangerous. This could impact the ability of patients with weakness and fatigue to be able to work. - There is a very large portion of households with women working outside of the home. This could impact a family's financial status, mobility for treatment, and ability to care for the ill.	
Ancillary Reviews	There can be multiple institutional reviews that need to occur prior to protocol approval. (coverage analysis, biosafety)	

Donna Silver *03/05/21*

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Institutional Official or designee