University of Vermont & State Agricultural College

Institutional Profile Document

UVM and UVM Health Network Site Information	
Name of Primary Site	University of Vermont and State Agricultural College (UVM) Burlington, VT, 05405
Affiliated Sites (covered entities)	UVM Health Network affiliate hospitals: UVM Medical Center, Central Vermont Medical Center, Champlain Valley Physicians Hospital
Federalwide Assurance and applicability	Number: FWA00000723 While the UVM FWA is limited in applicability to federally sponsored project, UVM extend the principles of the regulations governing research with human subjects to research that is not federally sponsored.
Institutional Official	Kirk Dombrowski, PhD Vice President for Research Institutional Official for UVM Kirk.Dombrowski@uvm.edu
Reliance Point of Contact	Jen Dulin, DVM, MS IRB Reliance Administrator & Health Network Liaison University of Vermont Research Protections Office jen.dulin@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 of such clinical visits are not allowed in research. 4. State law does not specifically address 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 (Consent/HIPAA Checklist for Required Language) that includes the required local sections. UVM PIs have access to this template. Please see attached. Consent of Minors: In addition to 45 CFR 46 Subpart D regulations, local policy requires minors 11-17 to provide written assent and minors under 11 to provide verbal assent if appropriate based on age, maturity, psychological state of the children involved and complexity/risk level of the study. Only parents or legal guardians (granted formal custody by court order) may provide permission for the minor's participation in research. Children who are wards of the state must have permission from the Department of Children and

	Families; foster parents do not have the authority. According to Vermont Statute, emancipated minors are those who have entered into a valid marriage, are on active duty with any armed forces of USA, or have been ordered by court of law to be emancipated. More can be found in the UVM Policies and Procedures Section 9.1. Local policy about use of Legally Authorized Representatives may be found in Section 9.2 of the UVM Policies and Procedures. UVM Health Network policy on surrogate consent requires that it is obtained by the decision-maker designated by the participant in a Living Will or Durable Power of Attorney for Health Care, a judicially-appointed guardian if the court order explicitly grants the guardian clinical decision making authority pursuant to 14 V.S.A. § 3069 (c) (2), or a spouse, civil union partner, adult child, adult sibling, or other family member/friend if a decision maker is not designated in the Advanced Directive. Local policy about use of impartial witness may be found in Section 9.3 of the Policies and Procedures and Section 9.6 of the Policies and Procedures. The impartial witness should be a patient advocate or someone not affiliated with the research team; it must be someone who cannot be unfairly influenced by people involved with the research, who does not have a coercive relationship with the participant, who attends the informed consent process. Local policy about Informed Consent and HIPAA Authorization for Non-English Speaking Individuals may be found in Section 9.4 of the Policies and Procedures. UVM allows use of both long form and short form consent, but short form should be reserved for situations in which there is not sufficient time to translate the long-form consent (i.e. occasional and unexpected non-English speaking participants who require quick enrollment). UVM allows use of electronic methods to obtain written consent.
HIPAA	Required HIPAA template language is found in the Consent/HIPAA Checklist for Required Language. HIPAA Authorization may be combined with the consent form. UVM IRB will allow HIPAA language to be separate from consent form if required. UVMHN affiliate hospitals are all covered entities, as is the UVM Luse Center.
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 (and good clinical practice if applicable) 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 (RPO) by any means, go directly to the Director of the RPO or designee. Contact information for the Director is in the local consent template language. 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 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 local initiation of research activities. UVM allows for these reviews to be pending during submission to an External IRB. (Examples include investigational drug services, billing coverage analysis, biosafety, radiation, Cancer Center protocol review and monitoring committee, etc.)	
Policies and Procedures	The UVM IRB Policies and Procedures may be found here: https://www.uvm.edu/rpo/irb-policies-and-procedures	