**UVM Local Context Document to Provide to a Single IRBs – 11/28/17**

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| **UVM Sites** |
| **Name of Primary Site** | University of Vermont and State Agricultural College (UVM)Burlington, VT, 05405The University of Vermont Medical Center, Inc.(UVMMC) Burlington, VT 05405 |
| **Federalwide Assurances** | * University of Vermont's FWA Number FWA00000723
* UVM Medical Center's FWA Number FWA00000727
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| **Registrations** | The IRBs that serve the two institutions are registered to the University of Vermont and State Agricultural College (IORG 0000289) with the Department of Health & Human Services. Registration numbers for the IRBs are:* IRB00000485 (IRB #1 - Biomedical I IRB - OHRP/FDA)
* IRB00000486 (IRB #2 - Behavioral IRB - OHRP)
* IRB00000487 (IRB #3 - Biomedical II IRB - OHRP/FDA)
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| **Affiliates** | * Central Vermont Medical Center
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| **State and Local Law** | 1. Vermont state law does not have specific law, therefore, we follow the institution’s policy that addresses legally authorized representatives.
2. The age of majority in Vermont is 18 years of age.
3. There are no state or local laws that pertain to clinical research with human subjects apart from the common law of informed consent.
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| **Research Oversight** |
| **Institutional Officials** | Richard A. Galbraith, MD, PhDVice President for ResearchInstitutional Official for UVMRichard.Galbraith@uvm.eduClaude Deschamps, MDPresident & CEO, UVM Medical GroupInstitutional Official for UVMMCClaude.Deschamps@uvmhealth.org |
| **Research Oversight Delegate** | Donna Silver, CIPDirector, Research Protections Office802-656-5040Donna.Silver@uvm.edu |
| **Checking and 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. Principal Investigators for all protocols provide an assurance that all members of the research team have completed the applicable institutional human subjects and GCP training as well as any specific protocol 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. |
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| **Overseeing Conduct of Research** | Research Manual and Operating Procedures  |
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| **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. |
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| **Person Responsible for UAPs or Serious/Continuing Noncompliance** | Donna Silver, CIP802-656-5040Donna.silver@uvm.edu |
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| **How does person identify and manage UAPs and/or serious or continuing noncompliance** | Noncompliance Policies and Procedures  |
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| **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 whether or not 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. |
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| **Consent** | UVM has a consent template that includes the required local sections.  |
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| **Community Descriptors** | VERMONT COUNTIES:Grand Isle CountyFranklin CountyLamoille CountyRutland CountyOrleans CountyWashington CountyChittenden CountyAddison County | NEW YORK COUNTIES:St. Lawrence CountyWarren CountyClinton CountyWashington CountyFranklin CountyEssex County |
|  | - 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.**Additional Information**1. The outpatient clinics at UVM Medical Center are not staffed during evenings and weekends.2. There are multiple institutional reviews that need to occur prior to protocol approval. (pharmacy, radiology, billing, PRMC if not CIRB) |