



COMMITTEES ON HUMAN RESEARCH NEWSLETTER

Change in Research Activity Notice – June 1, 2021



The University of Vermont

Notice from VP Research Administration

UVM Researchers,

Following changes in CDC guidelines and Vermont State COVID-19 restrictions, UVM is suspending the COVID-19 Research Activity matrix put in place in the Summer of 2020.

Lab, field work and research activities may return to pre-COVID-19 levels with the following exceptions:

- Unvaccinated individuals must continue to mask and social distance while indoors in any UVM research setting. Fully vaccinated individuals are not required to wear face coverings or maintain 6-foot distances.
- Unvaccinated individuals must continue to mask outdoors only when in close contact with others. See face coverings information at <https://www.uvm.edu/uvmforward/face-coverings>.
- Unvaccinated students (both graduate and undergraduate) must continue weekly testing protocols. See testing information page at <https://www.uvm.edu/uvmforward/summer-covid-19-testing>.
- Clinical research that takes place in medical settings including UVM LCOM, UVM Medical Center/Network and clinic facilities will continue to follow the safety and prevention guidelines of those settings. Specific guidance for these settings will be communicated. See notice from Dr. Jensen attached.
- International travel remains suspended. Requests for exceptions can be made via the Office of the Provost.
- Common spaces, equipment, and touch surfaces need to be cleaned regularly.
- Individuals must not come to UVM facilities if exhibiting signs of COVID-19. At present the daily health check requirements remain for UVM employees, see <https://www.uvm.edu/uvmforward/daily-health-screening-tool>.

With these exceptions in mind, individual COVID-19 lab safety plan approvals are no longer necessary. However, attention to lab safety remains a paramount responsibility of the Lab Director and PI. This includes ongoing attention to COVID-19 prevention and ensuring that all staff feel safe from infection risk in their research spaces.

Please note that current restrictions and procedures for lab visitors, study monitors and vendors will remain in place. Information for academic visitors can be found at: https://www.uvm.edu/sites/default/files/UVM-Faculty-Affairs/Academic_Visitor_Exception_Agreement_Form_Rev_Jan21.pdf

Vendor restrictions and approval information can be found here: <https://www.uvm.edu/finance/covid-compliance-essential-suppliers-and-contractors>

Over the summer we will be revisiting and updating the lab activity matrix that guided our activities over the last year to better reflect vaccination status. Should we face a resurgence of COVID-19 disease, our goal is to be able to quickly and easily respond to that situation with a reinstatement of the activity level matrix.

We would like to thank all of the UVM research community for your help and dedication over the last year. We were able to quickly respond to the pandemic, reopen labs safely last summer, and complete our most productive year of research in the history of the University—all without a single known case of lab/research activity-related COVID-19 transmission. That is an amazing feat, and one that we should be very proud of as a community.

As we move to the next phase of our reopening, please continue to use good judgement and to reach out to OVPR, EHS, or your research associate dean with any questions you may have.

Sincerely,
Kirk Dombrowski
Gordon Jensen
Beth Kirkpatrick
Francis Churchill
Dan Harvey

Notice from Senior Associate Dean for Research

Dear Colleagues:

Following changes in CDC guidelines and Vermont State COVID-19 restrictions, UVM is suspending the COVID-19 Research Activity matrix put in place in the Summer of 2020. UVM has also made significant changes in masking and other restrictions as they were applied to vaccinated personnel. In view of these rapidly evolving changes, we are now communicating appropriate adjustments to restrictions on clinical research as conducted in facilities of UVM LCOM and UVM Medical Center/Health Network, associated clinics, and the Clinical Research Center. **Please note that some of the changes that are occurring on the UVM campus are not applicable to these clinical settings.** We must carefully align with Medical Center/Health Network guidance and the clinical environment in which we conduct research. **Until we receive further guidance, masking and distancing, irrespective of vaccination status, will still be required at all times in our clinical research facilities.**

If you are involved in clinical research activities, please review the additional information found in the attached document.

Thank you for your consideration.

Gordon L. Jensen, M.D., Ph.D.
Senior Associate Dean for Research
Professor of Medicine and Nutrition
The Larner College of Medicine
University of Vermont
Office of the Dean, E-126 Given Building
89 Beaumont Ave., Burlington, VT 05405

Director of Research
University of Vermont Health Network

T (802) 656-2156 F (802) 656-8577
Gordon.jensen@med.uvm.edu

Kim Luebbbers, MSHS, RN, BSN, OCN
Assistant Dean for Clinical Research Administrative Director, Clinical
Research Center Director, Office of Clinical Trials Research
kimberly.luebbbers@med.uvm.edu

Claude Deschamps, M.D. President and CEO
UVM Health Network Medical Group

Attachment

Research Activity Level Change effective June 1, 2021 for clinical research conducted at the UVM LCOM and UVM Medical Center/Health Network, associated clinics, and the Clinical Research Center

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- IRB approval of your research is of course required, including any protocol modifications necessary related to COVID-19, e.g. conducting remote activities, changes in testing/assessments to reduce exposure risks, etc.
- Access to appropriate PPE is required as indicated by UVM and UVM Health Network guidance.
- **Masks and physical distancing are still required for clinical research activities.**
- Limit in-person activities to no more than two research personnel and one participant per interaction per room. A waiver must be requested for any greater number of people.
- Continue the required COVID-19 screening of subjects 24-48 hours prior to their visit to campus if conducting in-person research activities. [Available screening tool.](#)
- Self-report of vaccination status should be recorded for all subjects and they must all be made aware that they will need to wear a mask upon entering and while at our facilities.
- UVM undergraduate student engagement in the conduct of research can resume but must have prior approval and student must have completed UVM Researcher Credentialing to be able to conduct work at UVMHC/HN.
 - Requests for review must be submitted by the mentor for each student via both the [UVM](#) and [LCOM](#)-based online applications.
 - [UVM Researcher Credentialing](#) through the Office of Clinical Trials Research (OCTR) is required if the research utilizes UVMHC/HN resources/facilities, patients, or data. This applies to undergraduates engaged at research at both at UVM HN and in labs at UVM.
 - Undergraduates are still not allowed to support research in high-risk areas including ED, ICU, and COVID-19 wards at this time.
- Any UVM student who is fully vaccinated is no longer required to test every seven days. To be exempt from the required testing, they must provide [verification to Student Health Services](#) confirming that they are fully vaccinated. Note that all non-UVM students must be vaccinated to be on campus this summer.
- Any student who is not fully vaccinated is required to test over the summer and must continue to test every seven days. Visit the UVM Forward website for information [about vaccinations and availability.](#)
- Non-UVM undergraduate students who will be conducting research in LCOM labs are required to be fully vaccinated and will not be enrolled in UVM's testing protocol. Faculty sponsors must complete both the on-line [UVM vaccination verification](#) and [LCOM application](#) forms before non-UVM students will be allowed on campus and have access to LCOM facilities.

Vendors, company representatives and contracted service providers:

UVM Medical Center/Health Network, associated clinics, and the Clinical Research Center:

The State of Vermont requires that this group must be fully vaccinated. They will also be screened upon entry for symptoms and required to wear a mask at all times. Fully vaccinated external vendors, company representatives, and contract service providers are now allowed on site in the Medical Center. Research faculty or staff can query vaccination status and if reported, these fully vaccinated individuals can proceed with their visits. They must still be pre-screened for COVID-19 symptoms and exposure prior to their arrival to campus ([screening tool](#)), have them complete the welcoming/screening process upon entering hospital facilities and check in per usual vendor/ visitor hospital policies. Unvaccinated external vendors/representatives are not allowed to conduct their business at UVM Medical Center facilities without prior approval. The request form below must be completed

and emailed to Kimberly Luebbbers, Assistant Dean for Clinical Research Administration, at Kimberly.Luebbbers@med.uvm.edu for review and approval, prior to any external persons arriving at any UVM Medical Center facilities for research purposes.
[Research Related External Vendor-Representatives Request Form.docx](#)

Vendors, company representatives (e.g. monitors) and contracted service providers:

UVM/ UVM LCOM:

Please refer to the University of Vermont's COVID Compliance for Essential Suppliers and Contractors page, link below:

[COVID Compliance for Essential Suppliers and Contractors | Division of Finance & Administration | The University of Vermont \(uvm.edu\)](#)

[Note that this guidance currently applies whether the individual is vaccinated or not.](#)

Please note – We anticipate that further changes in relevant UVM guidance for vendors, company representatives, contracted service providers, and external visitors will be forthcoming, but we were unable to obtain confirmation in time for this communication.

Please also note that UVM LCOM conference rooms are not yet available for scheduling or use at this time.

For researchers and research staff who may be accessing both UVM and UVMHC/HN resources, the more current stringent guidelines of UVM must be applied.

For example:

- A vaccinated research monitor will be traveling to campus and accessing both UVM LCOM and UVMHC/HN facilities, so prior approval from UVM is required.
- All research participants engaged in research activities must be prescreened for COVID -19 symptoms and exposure prior to coming to campus.

Please appreciate that the level of restriction may change again on short notice depending upon the evolution of the pandemic and guidance from the CDC and State of Vermont.

Thank you,

Gordon L. Jensen, M.D., Ph.D. Senior Associate Dean for
Research
Director of Research, UVM Health Network

Kim Luebbbers, MSHS, RN, BSN, OCN Assistant Dean for Clinical Research
Administrative Director, Clinical Research Center Director, Office of Clinical Trials
Research

Claude Deschamps, M.D. President and CEO
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